

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

IN RE DENTSPLY SIRONA, INC.
SECURITIES LITIGATION,

No. 24 Civ. 9083 (NRB)

CLASS ACTION

**AMENDED CONSOLIDATED CLASS
ACTION COMPLAINT FOR
VIOLATIONS OF THE FEDERAL
SECURITIES LAWS**

JURY TRIAL DEMANDED

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Lead Plaintiffs HANSAINVEST Hanseatische Investment-Gesellschaft mit beschränkter Haftung (“HANSAINVEST”) and City of Miami General Employees’ & Sanitation Employees’ Retirement Trust (“Miami Retirement Trust” and, together with HANSAINVEST, “Lead Plaintiffs”), by and through their counsel, bring this action for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (“Exchange Act”), 15 U.S.C. §§78j(b) and 78t(a), and U.S. Securities and Exchange Commission (“SEC”) Rule 10b-5, 17 C.F.R. § 240.10b-5, against Defendants Dentsply Sirona Inc. (“Dentsply” or the “Company”), Donald M. Casey, Jr. (“Casey”), Jorge M. Gomez (“Gomez”), Simon D. Campion (“Campion”), Glenn G. Coleman (“Coleman”), Andreas G. Frank (“Frank”), Neeraj Gunsagar (“Gunsagar”), and Erania Brackett (“Brackett”) (collectively, “Defendants”). Lead Plaintiffs bring these claims on behalf of all persons and entities that purchased Dentsply common stock between January 4, 2021 to February 26, 2025, inclusive (the “Class Period”) and were damaged thereby.

Lead Plaintiffs allege the following upon personal knowledge as to themselves and their own acts and upon information and belief as to all other matters. Lead Plaintiffs’ information and belief is based on, among other things, the investigation of their Counsel, which includes, but is not limited to, a review and analysis of: (a) Dentsply’s public filings with the SEC; (b) transcripts of Dentsply’s management’s conference calls with investors and analysts; (c) press releases disseminated by Dentsply; (d) analyst and press reports about Dentsply; (e) other public information and data regarding the Company; (f) interviews of former Dentsply’s employees and a Byte patient; (g) consultation with relevant experts and consultant; (h) material and information obtained through Freedom of Information Act (“FOIA”) and similar public access requests to relevant government agencies; (i) filings and consultations with attorneys in other litigation involving Defendants including, *San Antonio Fire & Police Pension Fund v. Dentsply Sirona Inc.*,

No. 22-cv-6339 (S.D.N.Y.), *Louisiana Sheriffs' Pension & Relief Fund v. Cardinal Health Inc.*, No. 2:19-CV-3347 (S.D. Ohio), and *Phillips v. Straight Smile LLC*, No. 1:25-cv-21074 (S.D. Fla.); and (j) other sources cited herein. Lead Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. PRELIMINARY STATEMENT

1. This case is about a dental products company that manufactured and sold a clear dental teeth-straightening aligner called “Byte,” which Defendants touted as a safe, “doctor-directed” treatment that was “prescribed and overseen” “every step of the way” by licensed dentists and orthodontists. During the Class Period, Byte represented Dentsply’s fastest growing revenue-driver in a rapidly expanding market that delivered 20% year-over-year revenue gains at a critical time when other product lines had faltered. In reality, as Dentsply CEO Defendant Campion was ultimately forced to admit, Dentsply secretly drove revenues by selling Byte to patients who should never have been prescribed the product, resulting in thousands of patient injuries and dangerous malfunctions that senior management closely tracked by failed to report to the FDA—a decision undertaken specifically in order to avoid further scrutiny from physicians, legislators, and regulators who were questioning Byte’s direct-to-consumer model.

2. Defendants’ representations about Byte’s safety and sales growth were crucial to investors. During the Class Period, as the Company’s sales of traditional dental products faced headwinds from the COVID-19 pandemic and other issues, Defendants told investors that Byte remained a “bright spot” in the Company’s portfolio and would help achieve the Company’s ambitious growth targets and strategic objectives. In doing so, Defendants represented that Byte was different than other direct-to-consumer aligner brands—most notably, SmileDirectClub—which had come under scrutiny for its business practices. Specifically, Dentsply represented that, unlike Byte’s competitors, Byte followed a “doctor-directed” treatment, that Byte was not sold to

contraindicated patients, and that Dentsply complied with FDA regulations for medical devices—including a regulation requiring Dentsply to report serious patient injuries to the FDA within 30 days. In reality, Byte was a dangerous do-it-yourself treatment, and Dentsply was pushing it on contraindicated patients, without the involvement of any qualified dentist or orthodontist, while covering up serious patient injuries.

3. When the truth was finally revealed in a series of corrective disclosures from October 2024 to February 2025, Dentsply was forced to shut down the Byte business altogether, write down hundreds of millions of dollars of Byte goodwill to zero, pay tens of millions of dollars in refunds to patients, and incur other remediation expenses. In response, the Company's stock price plunged by more than one-third, causing massive damages to investors.

4. Dentsply has since admitted the falsity of the core representations alleged in this case. For example, Defendant Campion, Dentsply's CEO, admitted in October 2024 that—contrary to Defendants' public statements during the Class Period—Dentsply had in fact repeatedly sold Byte to “contraindicated” patients who were never supposed to use the product. Defendants have also now conceded, in an avalanche of “retrospective”—i.e., untimely—reports of serious patient injuries filed with the FDA since September 2024, that 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.

A. Background of Defendants' Fraud

5. Clear aligners like Byte were first commercialized by Align Technologies, whose Invisalign product soon became the market leader in the late 1990s, followed by direct-to-consumer clear aligners that were commercialized by SmileDirectClub beginning in 2014. By the start of the Class Period, however, SmileDirectClub and its business model began to come under significant scrutiny by patients, legislators, and the news media as posing risks to patients. By

leveraging Dentsply's century-old reputation as a manufacturer of professional dental products, with an established clinical reputation, Defendants presented Byte as a clear aligner that combined the doctor-directed benefits of Invisalign with a lower price point of direct-to-consumer brands like SmileDirectClub. In doing so, Dentsply repeatedly distinguished Byte as overseen "every step of the way" by "licensed dentists and orthodontists" responsible for "the oversight and control of each customer's clinical treatment."

6. For example, when Dentsply announced the Byte acquisition, one of the first questions it received from investors was how the product was different from SmileDirectClub. Defendant Casey had a ready answer: "Byte was built from the beginning around a direct-to-consumer business with a full network of license professionals involved." That same message was disseminated by Byte's multi-channel advertising, featuring claims such as: "[l]icensed doctors and orthodontists [are] with [patients] every step of the way." In other words, Defendants represented that, even though Byte patients were not seeing dentists for in-person visits, they were still having their treatment supervised by them. That distinction was important to investors. Not only was dentist supervision critical to the safety and efficacy of Byte treatment, but Defendants told investors that Byte was supposed to achieve strategic synergies by driving patients to dental offices.

7. Thereafter and throughout the Class Period, Defendants made repeated positive statements about Byte as other challenges weighed on Dentsply shares. For example, following a decline in dental sales and supply chain difficulties triggered by the COVID-19 pandemic (which drastically reduced the number of in-person dental visits and corresponding use of Dentsply's traditional products), the Company's senior leadership turned to channel-stuffing. In doing so, Defendants Casey and Gomez inflated reported sales by offering Dentsply's distributors outsized

incentives to convince them to take on more inventory—and then failed to properly account for those incentives. The channel-stuffing scheme unraveled in 2022, when Dentsply was forced to disclose the audit committee was investigating Defendants’ improper accounting practices, the Company would have to restate its financial results, and that Defendant Casey was terminated and Gomez had resigned—with the Company’s audit committee concluding that the two had established an improper “tone at the top.”

8. The abrupt end to Dentsply’s channel-stuffing meant that Defendants had to rely even more heavily on the undisclosed practices that had been fueling the growth of Byte sales. In fact, immediately after they were installed as CEO and CFO, Defendants Campion and Coleman turned to Byte as one of the few remaining “bright spots” at the Company—and looked to the product as one of the key drivers of the Company’s financial success.

9. As Defendant Campion made clear on his first earnings call as Dentsply’s CEO, Byte played a “key role in our portfolio” and would help buoy Dentsply’s results at a crucial time. Significantly, Byte was Dentsply’s most significant product line that was not sold through distributors—and thus unaffected by Dentsply’s audit committee’s investigation and remediation into the distributor relationships at issue in the channel-stuffing fraud. Dentsply’s new management repeatedly highlighted Byte on investor calls as producing “strong growth despite slowing consumer spending trends,” touted their familiarity with Byte’s sales practices, and highlighted Byte as the Company’s fastest growing revenue driver, with an annual revenue “run-rate” of over 20% per year, and a key contributor to the Company’s \$3.00 per share EPS target—the only product line specifically called out by name.

10. Given its importance, Defendants Campion and Coleman repeatedly discussed Byte’s performance on investor conference calls in which they described the product’s

performance in detail. For example, Defendants Campion and Coleman repeatedly told investors that increased Byte’s sales had been driven by the Company’s efforts to improve the “conversion rate”—i.e., the rate at which a proposed Byte customer who received an impression kit then purchased a Byte aligner—by superior customer targeting that fed better-qualified patients into Byte’s sales “funnel.”

11. Contrary to Defendants’ representations, in reality, Byte treatment was not “directed” or “oversee[n]” by doctors, let alone by doctors who were there “every step of the way.” In truth, as the consistent accounts of numerous Dentsply former employees and former patients have confirmed, the involvement of dentists or orthodontists in Byte treatment was generally limited to a single point of approval at the outset of a treatment plan. That approval, given after patients had already arranged payment, was based on a cursory review of an inadequate medical history and scans made from an unreliable patient-created impression. As Dentsply knew, this was not enough information to screen patients effectively for contraindications.

12. Once the patient agreed to pay for Byte clear aligners, Byte’s supposed “network” of dentists and orthodontists had no further role in patient’s treatment. Typically, no doctor—whether the approving doctor or another—was ever in direct communication with the patient. Dentsply had no doctors available or trained for that purpose. In fact, Dentsply actively prevented doctor-patient communications from occurring—even when those patients suffered serious injuries.

13. Instead, all further patient monitoring and clinical treatment decisions were made by Dentsply’s customer support employees, who were not dentists or orthodontists. They were grossly unqualified to handle the deluge of incoming patient complaints. For example, when patients complained to Dentsply that their Byte aligners did not fit, Dentsply’s customer support

employees played dentist. They would ask patients diagnostic questions or have them to take pictures of their teeth with smart phones. Then they would suggest do-it-yourself remedies, such as having the patient modify the clear aligners with tools available around the house. When, in the middle of Byte treatment, the next aligner in the sequence did not fit, as was common, Dentsply's lay customer support employees directed patients to "backtrack" their aligners—i.e., to switch to wearing an earlier aligner in the sequence. Backtracking lengthened the treatment time and altered the treatment plan approved by a doctor, significantly increasing the risk of injury.

14. Defendants also falsely reassured investors (and patients) that Dentsply did not sell Byte to contraindicated patients. For example, Defendants stated that Byte would "only accept patients who are great candidates for teledentistry and clear aligners," which it defined as patients with only "mild to moderate spacing and crowding" issues. Defendants told investors that patients with more complex cases would be declined. In reality, as Dentsply and Campion have now admitted, Byte was sold to "contraindicated" patients whose use of Byte aligners predictably led to injuries.

15. Worse, just as Defendant Campion took over as CEO—and as Dentsply was struggling to regain its footing after the revelations of the separate channel-stuffing scandal—Dentsply management secretly and dramatically accelerated its targeting of contraindicated patients. As reported by former employees, in an August 2022 meeting, Tyler Stoker, Head of Sales and Business Development for Byte, ordered the sales force to stop telling prospective patients that they were contraindicated. Almost immediately, sales to contraindicated patients increased in droves, leading to an approximately 20% increase in Byte's "conversion rate."

16. Dentsply's dangerous sales practices led to an extraordinary amount of serious patient injuries that management tracked during the Class Period. In a scheme to deceive investors,

Defendants failed to report at least 6,894 Byte injuries and malfunctions during the Class Period—and only belatedly reported these injuries when Dentsply’s failures came under scrutiny by the FDA. According to Dentsply’s own untimely reports to the FDA, those injuries included lost, fractured, and dead teeth, nerve damage, lacerations, and other disfigurement and deformities. According to one former Dentsply manager, as many as 25% of Byte patients suffered injuries.

17. As a former Dentsply quality executive confirms, Dentsply’s senior executives had real-time access to patient complaints of these injuries through a software system called Trackwise that was specifically designed to inform management of injuries and facilitate Dentsply’s compliance with its FDA reporting obligations. FDA regulations required “management with executive responsibility” (a category including the Executive Defendants) to ensure compliance with those regulations, which were central to Dentsply’s business. That quality executive described how Dentsply determined, before the Class Period, that any injury involving the loss of a tooth was required to be reported to the FDA and documented that requirement in an important policy known as the “Decision Tree.” But according to Dentsply’s own retrospective reports, Dentsply failed to timely report hundreds of injuries involving the complete loss of a tooth, a “fracture” (an at least partial loss of a tooth), or pulp “necrosis” (death of a tooth requiring a root canal or extraction). And other senior executives acknowledged that Dentsply fielded questions from the FDA about Byte injuries during the Class Period, and all the Executive Defendants had access to the Company’s systems that tracked this very data.

18. Despite their direct access to alarming reports of patient injuries incurred as a result of senior management’s directive to sell Byte to contraindicated patients, and the Company’s legal obligation to report them to the FDA within 30 days, Defendants were highly motivated to suppress them. That is because the FDA makes adverse event reports publicly available through an online

database, the Manufacturer and User Facility Device Experience or MAUDE database. For this reason, Dentsply knew that reporting injuries to the FDA would not only immediately trigger scrutiny from the agency, but also from state legislatures, patient advocates, and investors who were focused on the safety of direct-to-consumer aligner products like Byte.

19. In fact, during the Class Period, leading dental and orthodontist organizations and clinicians became increasingly concerned about the direct-to-consumer model that Byte used, prompting a number of state legislative measures that would require in-person treatment or other additional regulatory oversight of aligner products like Byte. These efforts and the threat they posed to Byte's business model were particularly concerning to Dentsply senior management, and prompted aggressive lobbying efforts by Dentsply to kill them. As representatives from those organizations testified at legislative hearings concerning those measures, the MAUDE database was a key datapoint that would allow a comparison between the injuries caused by direct-to-consumer and similar in-person aligner treatments. But if Dentsply reported the Byte injuries it was tracking, those reports would become publicly available online through the FDA's MAUDE database and expose the truth about Byte.

20. However, even as investigative journalists identified an uptick in the number of Byte adverse events and questioned Dentsply about them, Dentsply denied they reflected any problems. For example, in response to questions from journalists from *The Capitol Forum* who identified an increase in Byte MAUDE reports in June 2024, Dentsply told investors that it adhered to FDA reporting requirements, that "all medical device reports are thoroughly investigated in accordance" with those laws, that the recent reports were "strictly related to our efforts to continuously improve our process in alignment with current, global regulatory requirements," and

that the increase in reports did not reflect any issues with the “quality, safety, or effectiveness of our Byte products.”

B. Investors Suffer Damages When The Truth Is Revealed

21. The truth about Byte and Dentsply’s sales practices was revealed in a series of corrective disclosures between October 2024 and February 2025. Specifically, over that period, Dentsply announced that it was ceasing all Byte sales, then shuttering Byte permanently; Dentsply CEO Defendant Campion admitted that the Company sold Byte to contraindicated patients and warned that it would need to file additional untimely reports of serious patient injuries; and, after formally withdrawing the product, wrote down Byte’s hundreds of millions of dollars in goodwill all the way to zero and disclosed that the Company would be forced to incur tens of millions of dollars in remediation, refund and other related expenses. In response to these disclosures, Dentsply stock plummeted, causing investors massive damages.

22. In the wake of these disclosures, virtually every single senior member of Dentsply’s executive management has been terminated or replaced. Defendants Casey (CEO) and Gomez (CFO) were terminated as a result of their channel-stuffing fraud in April 2022, and their replacements and the rest of Byte’s senior leadership (except Campion) departed in connection with the revelations of Dentsply’s Byte misconduct or under similarly suspicious circumstances. Defendant Gunsagar, the CEO of Byte, left in August 2022, having stayed just as long as needed to collect on a \$19.6 million pay-day and capitalize on inflated Byte sales. Then, as the FDA was bearing down and demanding Dentsply address its reporting failures in 2024, Defendants Frank (Chief Business Officer), Coleman (CFO), Brackett (the SVP responsible for Byte), and a quality executive responsible for Byte’s FDA reporting all departed in short succession—just before Dentsply began filing thousands of “retrospective” reports of serious patient injuries to the FDA

23. After the end of the Class Period, Dentsply has continued to file belated reports of Byte injuries, Byte customers have filed a class action lawsuit seeking recovery for deceptive trade practices, and the SEC has initiated an investigation specifically into Byte.

II. JURISDICTION

24. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5.

25. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

26. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa(c). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this District. Many of the acts and omissions charged herein, including the dissemination of materially false and misleading information to the investing public, and the omission of material information, occurred in this District. Dentsply's common stock traded on The Nasdaq Stock Market LLC ("Nasdaq") in this District.

27. In connection with the acts, transactions, and conduct alleged herein, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the U.S. Mail, interstate wire communications, and the facilities of a national securities exchange.

III. PARTIES

A. Lead Plaintiffs

28. Lead Plaintiff HANSAINVEST Hanseatische Investment-GmbH ("HANSAINVEST") is a German investment firm. HANSAINVEST is known as a Kapitalverwaltungsgesellschaft ("KVG") and functions as a "Master KVG" under German investment company law. Under the German Investment Act, a KVG invests the assets of a third party in its own name and makes investments in such name for the benefit of a third party. A

KVG's investment power and legal ownership of the funds carries with it the right to bring legal claims, in its own name, to recover losses incurred by any funds set up by the KVG. As set forth in the certification attached hereto and incorporated by reference herein, HANSAINVEST purchased Dentsply common stock at artificially inflated prices during the Class Period and suffered damages as a result of the federal securities law violations alleged herein.

29. Lead Plaintiff City of Miami General Employees' & Sanitation Employees' Retirement Trust ("Miami Retirement Trust") is pension fund providing retirement benefits to eligible employees of the government of the City of Miami, Florida. As set forth in the certification attached hereto and incorporated by reference herein, Miami Retirement Trust purchased Dentsply common stock at artificially inflated prices during the Class Period and suffered damages as a result of the federal securities law violations alleged herein.

B. Defendants

30. Defendant Dentsply is a manufacturer of dental products. Dentsply is incorporated in Delaware and headquartered in Charlotte, North Carolina. Dentsply's common stock trades on Nasdaq under the symbol "XRAY."

31. Defendant Casey served as Dentsply's CEO and a member of its Board of Directors from February 2018 until his termination on April 19, 2022, when the Board uncovered channel-stuffing misconduct. As Dentsply's CEO, Casey had ultimate responsibility for the Company's performance and strategic objectives. Casey personally led the Byte acquisition from Dentsply's side in 2020 and then, from 2021 until his termination, touted Byte as part of Dentsply's strategy of growth and transformation. Casey was a signatory of Dentsply's 10-Ks and 10-Qs and other SEC filings during his tenure and spoke directly to analysts and investors about Byte on the Company's earnings calls and other events. Before joining Dentsply, Casey was a long-time medical device executive, most recently serving as the CEO of Cardinal Health's Medical division

from April 2012 to February 2018. Before that, Casey held various executive roles at Johnson & Johnson and its subsidiaries for 25 years.

32. Defendant Gomez served as Dentsply's Executive Vice President, Chief Financial Officer ("CFO") from August 2019 until his resignation effective May 6, 2022. As Dentsply's CFO, Gomez shared responsibility with Casey for achieving the company's strategic objectives. Gomez personally participated in the Byte acquisition and then, until his termination, touted Byte's financial performance. Gomez was a signatory of Dentsply's 10-Ks and 10-Qs and other SEC filings during his tenure and spoke directly to analysts and investors about Byte on the Company's earnings calls and other events. Before joining Dentsply, Gomez was the CFO of Cardinal Health from January 2018 to August 2019 and before that the CFO of Cardinal Health's Medical division (the same division of which Casey was the CEO) from July 2015 to December 2017.

33. As senior healthcare company executives, Casey and Gomez have been named as defendants in at least two other securities fraud actions in which federal judges have upheld allegations that Casey and Gomez made misstatements to investors with scienter in *Louisiana Sheriffs' Pension & Relief Fund v. Cardinal Health Inc.*, No. 2:19-CV-3347, 2021 WL 4397946 (S.D. Ohio Sept. 27, 2021), and *San Antonio Fire & Police Pension Fund v. Dentsply Sirona Inc.*, 732 F. Supp. 3d 300 (S.D.N.Y. 2024). Cardinal Health paid \$109 million to settle the first action, and the action against Dentsply is still pending. In the second action, investors allege that Casey and Gomez perpetrated a channel-stuffing fraud that unraveled after the Audit and Finance Committee of Dentsply's Board of Directors started investigating allegations of channel-stuffing in March 2022. One month later, Casey was terminated and Gomez resigned. Dentsply has now admitted that the channel stuffing occurred and has acknowledged that Casey and Gomez violated its Code of Conduct, created a culture where subordinates feared retaliation for raising concerns,

and set a poor tone at the top. Dentsply also admitted that it lacked effective compliance and disclosure controls and suffered from material weaknesses related to financial reporting.¹

34. Defendant Campion—Defendant Casey’s replacement—has served as Dentsply’s President and CEO and a member of its Board of Directors since September 12, 2022. As CEO, Campion assumed ultimate responsibility for the Company’s performance and strategic objectives and for remediating the cultural, tone, compliance, and disclosure failures of Casey and Gomez. Campion was a signatory of Dentsply’s 10-Ks and 10-Qs and other SEC filings during his tenure and spoke directly to analysts and investors about Byte on the Company’s earnings calls and other events. Previously, Campion was the President of Becton Dickinson’s Medical division (from July 1 to September 9, 2022); before that, the President of Becton Dickinson’s Interventional division (September 2018 to June 2022) and President of its Surgery business unit (within Interventional); and before that, an executive at C.R. Bard from 2008 until Becton Dickinson acquired it in 2017. In these roles, Campion had extensive experience with FDA medical device regulations.

35. Defendant Coleman served as Dentsply’s Executive Vice President, CFO from September 26, 2022 until his resignation on November 7, 2024. As CFO, Coleman shared responsibility with Campion for achieving the company’s strategic objectives and for remediating the cultural, tone, compliance, and disclosure failures of Casey and Gomez. Coleman was a signatory of Dentsply’s 10-Ks and 10-Qs and other SEC filings during his tenure and spoke directly to analysts and investors about Byte on the Company’s earnings calls and other events.

¹ Plaintiffs’ claims and damages do not arise from the false statements alleged in that channel-stuffing case, *San Antonio Fire & Police Pension Fund v. Dentsply Sirona Inc.*, No. 22-cv-6339 (S.D.N.Y.) (“*San Antonio*”), which does not concern Byte at all. As alleged herein, Lead Plaintiffs’ claims arise from Defendants’ deceptive conduct and misstatements concerning Byte, and they do not seek to recover any damages alleged to have caused investors’ losses in *San Antonio*.

Coleman was a member of the ESG Steering Committee for 2022 and the Extended ESG Steering Committee for 2023.

36. Before joining Dentsply, Coleman had been Senior Vice President, Chief Operating Officer at Integra Life Sciences Holdings Corporation, a medical technology company, since June 2019 and, before that, Coleman was Integra's Corporate Vice President and Chief Financial Officer from May 2014 to June 2019. In these prior roles, Coleman had extensive experience with the FDA regulations governing post-approval marketing practices, including through interacting with the FDA and speaking frequently and authoritatively with investors about these topics. For example, according to a securities fraud action naming Coleman as a defendant, captioned *In re Integra LifeSciences Holdings Corp. Securities Litigation*, No. 23-cv-20321 (D.N.J.), as Integra's COO, Coleman was intimately involved in responding to and overseeing remediation efforts triggered by FDA inspections and Warning Letters but made repeated misrepresentations to investors about those topics—including that there were “no patient safety issues” identified by the FDA, when in truth the company's regulatory violations were so rampant they triggered a recall of the company's most important product.

37. Defendant Frank served as Dentsply's Executive Vice President, Product Group from April 2022 to April 2023 and then Dentsply's Executive Vice President, Chief Business Officer (“CBO”) from April 2023 until year end 2024. In both roles, the Executive Vice President for the clear aligner business reported to Frank. Frank had specific responsibility to “oversee[]” Byte's “customer conversion rates” and spoke directly to analysts and investors about them on the Company's earnings calls and other events. Frank reported to CEO Campion and was a member of the Extended ESG Steering Committee for 2022.

38. Defendant Gunsagar served as CEO of Sure Smile LLC (d/b/a Byte) from July 2019 to August 2022. As Byte's long-time CEO, both before and after the acquisition, Gunsagar was familiar with its business practices, including the limited involvement of doctors, the targeting of contraindicated patients, and its lack of FDA reporting. Gunsagar spoke directly to analysts and investors about Byte in the Company's investor presentations, conference calls and through other media. Gunsagar reported to Defendant Casey from January 2021 to April 2022, and then to Matthew Coggin, Dentsply's Senior Vice President, Clear Aligners from April 2022 until Gunsagar's departure in August 2022.

39. Defendant Brackett served as Dentsply's Senior Vice President, Orthodontic Aligner Solutions & Customer Experience, and Head of Sustainability from April 2023 to early September 2024. As Senior Vice President, Orthodontic Aligner Solutions & Customer Experience, Brackett succeeded Coggin as the executive responsible for the Byte and SureSmile businesses. She reported to Frank, who reported to the CEO. As Head of Sustainability, Brackett had an additional role with knowledge of quality and regulatory reporting. Brackett also was the Chair of the ESG Steering Committee for 2022, in which role she approved the company's "Sustainability Report" for 2022. Previously, Brackett served as Dentsply's Senior Vice President, Chief Marketing Officer from August 2021 to April 2023.

40. Defendants Casey, Gomez, Campion, Coleman, Frank, Gunsagar, and Brackett are referred to as the "Executive Defendants." Defendants Dentsply and the Executive Defendants are collectively referred to as "Defendants."

IV. DEFENDANTS' SCHEME TO MISLEAD INVESTORS ABOUT BYTE

A. Dentsply's Business Before Clear Aligners

41. Dentsply is the world's largest manufacturer of dental products. Dentsply is the result of a series of corporate acquisitions, including the 2016 merger of Dentsply International

Inc. and Sirona Dental Systems—which elevated Dentsply to become the world’s largest manufacturer of professional dental products and technologies.

42. Following the merger, most of Dentsply’s products were designed for use in brick-and-mortar dental offices by licensed dentists—such as consumables like dental anesthetics, and sealants; dental implants; and technology and equipment like CAD (Computer-Aided Design)/CAM (Computer-Aided Manufacturing) systems. Dentsply sold most of its traditional dental products to distributors (primarily, Patterson Dental and Henry Schein), which in turn sold Dentsply’s products through to dental and orthodontist practices.

43. Defendant Casey was hired as Dentsply’s Chief Executive Officer in February 2018 to clean up a mess. Casey’s predecessor—plus Dentsply’s former Executive Chairman, Chief Operating Officer, General Counsel, and Chief Financial Officer—were all forced to depart the Company in late 2017 in the wake of disastrous sales results and allegations of improper channel-stuffing. Specifically, as the SEC would later conclude, beginning in early 2016, Dentsply and its senior management knew that Dentsply had sold more of its dental technologies equipment to its exclusive U.S. distributor—Patterson—than Patterson could sell to retail purchasers, resulting in excess inventory in its exclusive U.S. distribution channel. Over the first three quarters of 2016, retail demand for Dentsply’s technology products was not keeping pace with the exclusive distributor’s purchases, and Dentsply knew this was reasonably likely to have a material unfavorable impact on net sales or revenues in future periods. In November 2016, Patterson surrendered its exclusivity, and Dentsply’s sales languished for three quarters while Patterson sold off inventory.

44. Casey—and Gomez, who Casey hired as Dentsply’s CFO in July 2019—became familiar with their predecessors’ misconduct and how the Company’s distributor model

constrained Dentsply's business. Under their watch, in December 2020, Dentsply agreed to cease and desist and to pay a \$1 million penalty. *Dentsply Sirona Inc.*, Exchange Act Release No. 90681, 2020 WL 7396438 (Dec. 16, 2020). Until that settlement, the SEC's investigation had been ongoing for Casey and Gomez's entire tenures. Through this experience, Defendant Casey and Gomez became acutely aware of Dentsply's dependence, before Byte, on its distributors to grow sales and to meet Wall Street earnings expectations, as well as how Dentsply had previously exploited and could in the future exploit its distributor relationships to boost reported sales.

B. Dentsply's Cautious Entry Into The Clear Aligner Market

45. Casey appeared to begin to right the ship at Dentsply by announcing a restructuring plan in 2018 which called for exiting non-core and underperforming businesses and significant layoffs. A central part of the 2018 Restructuring Plan was Dentsply's May 2018 acquisition of SureSmile, a brand of orthodontic clear aligners sold through dental and orthodontic offices.

46. SureSmile competed with incumbent Invisalign—a clear aligner developed by Align Technology, approved by the FDA in 1998, and marketed since at least 2000. Clear aligners are transparent plastic shells used for moving teeth. They are popular with patients because of the visual stigma of traditional metal braces, particularly when worn by adults. Clear aligner therapy consists of a sequence of aligners that are each worn by the patient generally for one week or more before being replaced by the next aligner in the sequence.

47. For years, Invisalign maintained a monopoly on clear aligner products through an extensive patent portfolio and, by 2012, over 2 million patients were using Invisalign. Further, despite the expiration of Invisalign's original patent portfolio in late 2017, Invisalign's monopoly remained somewhat entrenched by volume pricing with doctors and exclusive dealing arrangements with dental service organizations ("DSOs"). However, Dentsply's established relationships with doctors and DSOs made SureSmile a plausible competitor to Invisalign.

48. Dentsply's entry into clear aligners with SureSmile was appealing to investors because clear aligners were a profitable, high-growth product with a large potential market. Indeed, by 2019, Align Technologies (Invisalign's parent company) had sold over 1.5 million clear aligners for \$2 billion. By 2020, the global market for clear aligners reached \$3.5 billion, and was expected to increase at a 28.5% growth rate and exceed \$20 billion by 2027. Moreover, because clear aligners were a patient-customized product, sold directly, Dentsply was (as Campion later put it) "in control of our own destiny." That is because there were no distributors to drag down Dentsply's margins, and Dentsply had far more control over pricing, marketing, and sales.

49. In 2020, Dentsply exited the traditional orthodontics business, which manufactured wires and brackets for traditional metal braces. In doing so, Casey told investors on August 6, 2020 that Dentsply would focus "our efforts in the ortho space on the clear aligner area" and that "our bet and belief is that the clear aligner space is going to be a significant contributor to our aggregate growth rate over time." To that end, at a November 19, 2020 investor conference, Defendant Casey predicted that clear aligners "will be a multibillion-dollar category in 5 years" and that, even if Invisalign retained majority market share, "I'll take the 25% to 30%, as second place, in a \$5 billion category." Analysts echoed these sentiments and responded favorably to Dentsply's shift from traditional orthodontics to clear aligners.

50. When Dentsply acquired SureSmile, there were already other brands of direct-to-consumer clear aligners that cut costs by limiting the role of doctors after the initial prescription—including, most prominently, SmileDirectClub, which was then the DTC clear aligner market leader, growing rapidly, and reporting sales approaching a billion dollars per year.

51. However, by the time SmileDirectClub had its IPO in September 2019, the lack of an ongoing, in-person supervision of a licensed dentist or orthodontist—and resulting

consequences for patients—caused some to question the direct-to-consumer model. For example, on February 13, 2020, NBC Nightly News with Lester Holt aired a feature reporting on SmileDirectClub’s business practices, as well as ensuing customer complaints and patient injuries potentially caused by SmileDirectClub aligners. The report highlighted a lack of dentist involvement in prescribing SmileDirectClub aligners, including a report by a patient who was not connected to, nor given contact information for, her assigned dentist from SmileDirectClub—and was forced to see an outside orthodontist, who diagnosed her with misalignment possibly caused by the aligners. The report also highlighted how SmileDirectClub required customers seeking refunds to sign a confidentiality agreement. The widely watched report triggered a 16% decline in SmileDirectClub’s stock the next day, wiping out nearly a billion dollars in market capitalization

52. Recognizing the obvious investor concern over SmileDirectClub’s model, throughout 2019 and 2020, Dentsply told investors that it was very cautious about the DTC aligner business and would remain on the sidelines. For example, Defendant Casey distinguished SureSmile from SmileDirectClub and other alternatives by describing SureSmile as “a complete clinician-controlled clear aligner treatment solution” in a March 2019 conference call. And on January 15, 2020, Casey specifically criticized SmileDirectClub and the “five or six others” offering direct-to-consumer clear aligners, calling that a “tough row to hoe.” Instead, Casey reiterated that Dentsply was a “dentist-focused company” and that “we don’t believe the path to success for us is to try and be the fourth in on ... DTC.”

C. The Onset Of COVID-19 Challenges Prompts The Byte Acquisition

53. Defendant Casey’s publicly voiced concerns about the clear aligner direct-to-consumer model appeared to shift after the onset of the COVID-19 pandemic—which delivered a substantial blow to Dentsply’s core business given the dramatic reduction in in-person dental and orthodontist visits and the resulting decline in product use that followed. The pandemic also

wreaked havoc on Dentsply's supply chains. For example, for second quarter of 2020, *i.e.*, the quarter after the COVID pandemic was declared a national emergency, Casey announced a 50% decline in organic revenue "due to the impact of the coronavirus."

54. Conversely, Byte—then an independent company—was experiencing its highest-ever sales. As *Bloomberg* reported in May 2020, in the first quarter, Byte reported that sales surged **1,000%** and that the startup expected revenue to grow past \$100 million in 2020 as patients sought out online dental treatment. As described in a November 2020 *Forbes* article, Byte capitalized on COVID by undertaking a concerted public relations and marketing campaign. As Byte CEO Defendant Gunsagar explained, Byte had tried to develop "consumer trust" by being "honest with their consumers about supply chain issues, shipping delays, and whether or not a consumer was a good candidate for the Byte system" and that these efforts were a huge success. The article highlighted media posts from Byte customers praising the company's individual sales representatives, a phenomenon that was "completely unprecedented" in the dental services industry and, according to *Forbes*, in "no doubt the result of Byte's trustworthy behavior."

55. Dentsply sought to capitalize on Byte's explosive sales and "trustworthy" reputation by acquiring it for \$1.04 billion in December 2020. On January 4, 2021, the first day of the Class Period, Defendants Casey, Gomez, and Gunsagar—each of whom personally worked on and negotiated the deal—announced the acquisition, which was the Company's largest in years, representing 9.4% of Dentsply's market capitalization and 80% of its cash on hand.

56. In announcing the deal to investors, Defendants highlighted Byte's business model and repeatedly emphasized its supposedly differentiated, and clinically superior, doctor-directed patient treatment and oversight—as well as the key strategic benefits to Dentsply. Specifically, Dentsply highlighted Byte's expected revenue run-rate of \$200 million in sales for 2021, its proven

profitably record to date, and the expectation that Byte would add \$0.05 to Dentsply's earnings-per-share in 2021—providing an immediate boost to the Company's bottom line.

57. In light of increasing public concerns over DTC competitors like SmileDirectClub, Defendants were intently focused on differentiating Byte—and did so by highlighting Byte's supposedly superior clinical dentist and orthodontist-backed treatment in doing so. For example, in the press release announcing the acquisition, Dentsply told investors that Byte was a “**doctor-directed** clear aligner system” backed by a “**nationwide network of licensed dentists and orthodontists [who] prescribe and oversee every customer's treatment plan.**” Defendant Gunsagar highlighted these features on the investor call, describing Byte as “**doctor-directed care**” that was “**overseen by an extensive network of licensed dentists and orthodontists.**”

58. In the context of clear aligners, the phrase “doctor-directed” had an established meaning—treatment that occurs under the ongoing supervision of a patient's dentist. In other words, the dentist would regularly check-in with the patient for the duration of treatment, monitor whether the treatment was progressing as planned, check whether the treatment was causing injury, consider alterations to the treatment plan, and address patient concerns. Doctor-directed did **not** refer to clear aligners that were merely prescribed by a dentist and then supervised by non-dentists. All clear aligners with FDA clearance must be prescribed by a dentist and are required to include a “Rx only” label—and thus, analysts covering the clear aligner industry regularly distinguished between the “doctor-directed” brands (including Invisalign, ClearCorrect, and SureSmile) and “direct-to-consumer” brands (including SmileDirectClub and Candid).

59. In other words, by describing Byte as “doctor-directed,” Defendants were attempting to differentiate Byte from other direct-to-consumer brands like SmileDirectClub. For example, on the conference call announcing the acquisition, Defendant Casey was asked “How

does Byte differentiate versus Smile Direct, Candid, or some of the other direct-to-consumer companies?” He responded that Byte was different because of the “**full network of licensed professionals involved.**”

60. Defendants also detailed the selectiveness of Byte’s patient onboarding process to further distinguish Byte’s model from SmileDirectClub’s. For example, on the call, Casey told analysts that “**we do a good job there targeting people with mild-to-moderate occlusion,**” i.e., teeth that are slightly misaligned. He specifically pointed to the fact that, unlike Dentsply’s SureSmile product, which involved in-person dental care and “can handle Class I, Class II, Class III”—i.e., complex cases involving overbite and underbite—Byte did not target those kinds of patients and was instead “**very focused on mild to moderate occlusion.**”

61. Dentsply repeated these and similar statements about Byte throughout the Class Period, careful to distinguish Byte from competitors like SmileDirectClub that had increasingly attracted customer complaints, lawsuits, and regulatory scrutiny. For example, on January 13, 2021, at the 39th Annual JP Morgan Virtual Healthcare Conference, a JPMorgan analyst asked Defendants “How do you avoid some of the traps that SmileDirect has fallen into around quality and other issues?” In reply, Defendant Casey distinguished Byte from SmileDirectClub based on its “really carefully curated” customer experience and Dentsply’s “expertise” in Quality Assurance and Regulatory Affairs, which would allow Byte to “avoid the traps for rapid growth”:

If you look at Candid and SmileDirect, I’ll let them comment, but they started out kind of as a retail and then direct-to-consumer play. This was built from the ground up to be a DTC play.

And **we believe that the customer experience that had been really carefully curated at Byte was really a sustainable advantage for us.** So that’s kind of how we settled on Byte. And again, we’ve been running the business for a week. But everything we saw in diligence and now that we see even in this early stage excites us even more.

In terms of *how do you avoid the traps for rapid growth*, I mean, one of the things that I believe the reasons that the founders at Byte and the Byte management team is looking at it, they wanted to avoid some of those mistakes. They wanted to be able to *take advantage of the scale and the expertise that we have in* globalizing businesses, things around supply chain, *QA [Quality Assurance], RA [Regulatory Affairs]* and other areas. *We bring immediate credibility and can give them a solid foundation to build out expansion.*

62. Defendant Casey thus asserted that under Dentsply’s control, and with the benefit of Dentsply’s quality assurance and regulatory affairs expertise, Byte was equipped to grow rapidly without suffering from quality and regulatory issues experienced by SmileDirectClub.

63. Defendants continued to distinguish Byte’s purported differences from SmileDirectClub throughout the Class Period, including as the public controversy regarding the standard of care SmileDirectClub provided intensified. For instance, on a webpage titled “How Byte Compares to Smile Direct Club,” under the heading “Professional supervision: what differences can you expect?” Dentsply claimed that Byte offered patients greater access to dentists and orthodontists than SmileDirectClub. Significantly, Dentsply also stated that while both Byte and SmileDirectClub had a “network” of “dentists and orthodontists,” there were “differences in timeframes, guarantees, and service levels.” Specifically, Dentsply claimed that with SmileDirectClub, the patient would “check in with that dentist” “every 90 days,” while with Byte “you can access your team *at any time* by logging on” and they would “*assess every step* of your smile improvement program.”

64. These representations were all the more important in light of the fact that Dentsply purposefully marketed Byte to low-income patients who often had little to no regular dental care. As Defendant Gunsagar told investors when announcing the acquisition, Byte’s lower price point helped to advance its “mission” to increase access and affordability of dental health care, as exemplified by the fact that the “majority” of Byte customers either had not visited the dentist’s office recently or never had any dental procedures before. Naturally, management’s focus on

lower income patients took into account the substantial body of evidence demonstrating significant health disparities due to access and affordability issues. To take one example, according to Center for Disease Control data, periodontal disease—a contraindication for Byte treatment—is twice as common (60%) among adults (aged 30 or older) with low income, compared with adults who had higher income (30%). The Executive Defendants were acutely aware of the fact that the targeted Byte demographic was higher risk, which highlighted the importance of prescribing Byte only to those patients with “mild to moderate occlusion,” as Defendants repeatedly represented they did.

65. Investor and industry analysts credited Defendants’ representations and understood Byte to have successfully avoided many of the quality and safety problems experienced by its competitors and Dentsply’s purported commitment to increasing access to safe dental care for low-income patients. For example, JPMorgan analysts parroted Defendants’ representations about Byte’s business, describing the products as “**doctor-directed** clear aligners for patients with mild to moderate orthodontic needs through a DTC system that **leverages a nationwide network of dentists and orthodontists.**” Similarly, an industry analyst from “Aligners and Things” concluded that of the two brands, Byte was the clear “winner” in “expertise” over SmileDirectClub. As noted in a February 18, 2021 report, that was because SmileDirectClub “doesn’t clarify if it will be an orthodontist or a dentist prescribing and overseeing my treatment plan”—a “[v]ery shady” practice—whereas Byte “guarantees that your treatment plan will be developed by an orthodontist in your state, then you will continue to work with a care team of dental professionals that includes dentists.”

D. Byte Buys Dentsply's Results In The Face Of COVID Headwinds Even As Scrutiny Into The Direct-to-Consumer Aligner Model Intensifies

66. The Byte acquisition occurred at a critical time for the Company, as supply chain problems and a sustained decline in demand due to the COVID pandemic hampered sales throughout 2021.

67. Throughout this time, Dentsply's senior executives highlighted Byte's contributions to the Company's revenues and profitability and made clear that the product was the target of intense focus of Defendants Casey and Gomez. For example, Dentsply's May 6, 2021 first quarter earnings call, Defendant Gomez highlighted its "clear aligners franchise performed very well in the quarter," and that the "Byte teams are excited about the growth trajectory." On that same earnings call, Defendant Casey labeled Byte a "terrific addition" with a "very bright future"—noting that the business was expected to be "accretive to Dentsply's long-term financial targets and non-GAAP EPS in 2021."

68. Defendant Casey also deliberately distinguished Byte from its competitors like SmileDirectClub. For example, Casey attempted to distinguish Byte by conveying that, unlike SmileDirectClub, Byte had strong data backing its claims of overwhelming customer approval—including by telling investors he personally reviewed Byte patient feedback. As Casey explained, the Byte business was "very customer focused and we remain very, very customer focused in terms of those reviews" which was "Literally, something we look at as a team on an hourly and nightly basis." Casey also underscored Dentsply's supposedly rigorous marketing efforts, ensuring the Company was selling only to patients who were appropriate for the product—explaining, Dentsply was focused on, ***"how do we attract those patients, correctly put them in, are they eligible for Class 1? And we want to maintain a really strong relationship with that patient, and we do."***

69. Dentsply continued to report positive results for Byte throughout the year. For example, on Dentsply's August 5, 2021 second quarter earnings call, Defendant Casey agreed with an analyst that Byte was "doing incredibly well," added that it was "performing as we expected it to" and "above expectations." Similarly, at September 15, 2021 investor conference, Defendant Gomez pushed back on the idea that Byte's faced increasing pressures from orthodontist and dentist groups opposed to the treatment, stating that while there may be some dentists who had concerns about the DTC model "in general," their focus was not on Byte in particular—and that this trend was not "been a major headwind for us." To the contrary, Defendant Gomez said, Dentsply was rigorously targeting Byte sales to appropriate patient candidates while "directing traffic of complicated cases that cannot be handled by Byte" elsewhere.

70. Defendants continued to report positive results for Byte and defended the product to analysts who repeatedly questioned management about it. For example, Defendant Casey explained on a December 1, 2021 conference call that Byte was "performing ahead of what the business plan – that we put together to do the acquisition internally." And after Dentsply reported disappointing fourth quarter results—including a small drop-off in Byte sales—on February 28, 2022, Defendant Casey explained that he expected that to change moving forward, and provided guidance showing that Byte sales would increase every quarter over the next year, and margins would see growth in the second half of 2022.

71. In explaining his confidence in these numbers, Defendant Casey said that he personally closely tracked Byte sales—stating that "we get stuff that we look at on a daily and weekly monthly basis"—and told investors he was intimately aware of the factors impacting that business. As Defendant Casey clarified on a March 29, 2022 Piper Sandler analyst call a couple

weeks later, Dentsply’s “confidence” in its Byte guidance was based on Defendants’ close tracking of sales and “conversions” of customers who ordered impression kits and then purchased aligners:

Our confidence in the guide Jason, the nice thing about Byte, *literally at the end of every day I see what they did*. I mean I can tell you, *week-by-week, day-by-day how many aligner trials did we sell, how many what we call S1s, how many people who we sent molds to, how many actually converted into Byte?* ... So our confidence in the guide when we said, look, we felt that we’ll grow each quarter sequentially versus the prior quarter, we’re basing that on a trend line we’re seeing on a week-to-week basis that we’ve been observing for enough time that you feel pretty comfortable that in the new dynamics of the marketplace you understand what’s going on.

E. Dentsply Terminates Defendants Casey and Gomez, Initiates An Audit Committee Investigation, And Turns To Byte To Regain Investor Trust

72. Just after Dentsply reported disappointing fourth quarter 2021 results, Dentsply quickly disclosed a series of additional concerning developments. First, on April 11, 2022, Dentsply disclosed that Defendant Gomez had unexpectedly resigned because he had taken a role as a CFO at another company (later revealed to be biotechnology company Moderna). Second, on April 19, 2022, Dentsply pre-released disappointing preliminary first quarter financial results which again missed analyst estimates, and disclosed that Defendant Casey had been terminated as CEO and as member of the Dentsply Board “effective immediately.”

73. Most concerning, on May 10, 2022, in connection with the Company’s first quarter earnings call, Dentsply disclosed that its audit committee had previously begun an investigation in March 2022—*i.e.*, before Gomez’s resignation—concerning “certain financial reporting matters” and, in particular, the Company’s “use of incentives to sell products to distributors in the third and fourth quarters of 2021.” The Company also reported results in-line with the preliminary results reported on April 19 but reduced its organic revenue and EPS guidance. The next day, in light of the investigation, Gomez departed his new role at Moderna, having just “officially” started the job the day before.

74. The disclosures revealing management’s apparent use of “incentives” and potential channel-stuffing triggered significant declines in the Company’s share price, and immediate analyst and investor concern over Dentsply’s business. For example, in a May 10, 2022 report, Piper Sandler noted the “Audit Committee [investigation] into channel stuffing that may have aided in hitting comp targets, and reinstated guidance showing meaningful near-term profitability pressures,” which it concluded “are incremental concerns and add to the risks that investors are navigating with this name.”

75. Over the next two quarters, while the Audit Committee investigated and Dentsply conducted a search for a new permanent CEO and CFO, Dentsply stopped holding regular quarterly earnings calls and did not file its first and second quarter 10-Qs. Instead, the Company provided investors with very limited disclosures, publishing only “select preliminary” results that provided “topline” net sales and EPS figures that incorporated Byte’s contributions.

76. Throughout this time, however, investors were intently focused on the Byte business and its growth and viability in light of the accounting investigation and the involvement in apparent channel stuffing by Defendants Casey and Gomez. For example, on the Company’s May 10, 2022 first quarter earnings call (when Dentsply disclosed the Audit Committee investigation), Dentsply told investors that Byte remained a bright spot as the Company’s other distributor-sold product lines went through a period of “destocking” of excess inventory that had accumulated as a result of the channel-stuffing misconduct. For example, in response to analyst questions about management’s “confidence level” on the Byte business and the possibility of “getting back to any kind of year-over-year growth,” Dentsply’s Interim CFO Barbara W. Bodem reassured investors that Byte remained a “very positive” business whose sales and margins were expected to grow at double-digit rates. As she explained, “with regards to Byte, we remain very

positive about the transaction as well as the performance,” and for the upcoming year, “we are expecting Byte to be a grower.”

F. Dentsply’s New Leadership Reaffirms Its Commitment To Byte

77. In the aftermath of Dentsply’s channel stuffing scandal and following a months’ long search, on August 22, 2022, the Company appointed Defendant Campion to be Defendant Casey’s successor as Dentsply’s new CEO and a member of the Board and, on September 22, 2022, appointed Defendant Coleman as CFO, replacing Defendant Gomez.

78. At around the same time, the Audit Committee’s investigation was nearing a conclusion, which the Company formally announced on November 1, 2022. Specifically, on that day, Dentsply disclosed that it completed the internal accounting investigation, restated the Company’s third quarter, fourth quarter and full year 2021 results—reporting that it had overstated net sales and net income for the nine-month period ended September 30, 2021 by \$35 million and \$27 million, respectively, overstated net sales and net income for the 2021 fiscal year by \$20 million and \$10 million, respectively, and took a goodwill impairment of \$1 billion to \$1.3 billion. In reporting its findings, the Audit Committee concluded that Defendants 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. The Company further disclosed that it was taken a number of measures to improve its financial-reporting controls and procedures to address the deficiencies that the Committee identified.

79. The Company’s admissions of this accounting misconduct were particularly concerning to investors in light of the fact that Dentsply’s results were still suffering from stagnant sales as the Company’s distributors were selling off excess inventory. For example, despite additional clarity on the investigation, William Blair analysts pointed to the fact that the

Company's third-quarter sales were about 9% below consensus, and that these "weak fundamentals seems to suggest there could be some ongoing commercial disruption associated with the recent leadership changes and recently concluded audit."

80. As soon as they took the helm, Dentsply's new leadership—Defendant CEO Campion and CFO Coleman—reaffirmed management was particularly focused on demonstrating that Dentsply's supply chain and inventory issues were behind it, and there was a clear path to profitability. Defendants did so by highlighting Dentsply's clear aligner business—a product line not subject to the distributor model at issue in the Audit Committee investigation—and told investors that the Byte business remained a "bright spot" in the Company's portfolio given the product's promising double-digit growth.

81. For example, on his first earnings call as CEO on November 14, 2022, Defendant Campion asserted that despite the recent turmoil, "Dentsply Sirona has a strong foundation from which we can accelerate growth" and, in particular, its "unique delivery models like Byte." Campion also stated that "Byte has a key role in our portfolio moving forward," that "there's a future for Byte," and that "[t]he aligner business has delivered double-digit growth for us."

82. On that same earnings call, also Coleman's first as CFO, Coleman touted "double-digit growth in clear aligners" and "strong demand" for Byte, which "returned to growth in the quarter." Coleman stated, "Given the momentum we have in the aligners business, we expect to see double-digit growth in the fourth quarter." In response to an analyst question regarding where the Company was "seeing underinvestment in sales" and whether that underinvestment should be "attribute[d] to the [] general [] turmoil left over that you guys obviously inherited," Coleman stated that despite the "reductions overall in the U.S. business and volumes being down . . . [t]he Ortho business continues to perform quite well, both Byte and SureSmile." As a result, Coleman

concluded that Byte was one of the remaining “bright spots in the U.S. business, which we expect to continue as we move forward.”

83. Dentsply’s new leadership immediately understood and adopted Byte as a strategic priority. On January 11, 2023, Campion announced at the annual JPMorgan Healthcare Conference the “five core tactical and strategic objectives” for Dentsply—highlighting, in particular, the Company’s goal to “*win in the aligner space*” with Byte. At that same conference, Campion announced that, with Byte’s growth—as well as other cost-cutting measures—“we do feel that we have eyes to reestablishing a trajectory to \$3 EPS by the end of 2025, which I think is a Rubicon for this organization.”

G. Byte Pushes Dentsply To \$3.00 EPS With 20% Growth Rates, Improved Patient Conversion Rates, And Investments In Treatment Planners

84. On February 16, 2023, Dentsply’s Board of Directors formally backed the “strategic objectives” Campion described at the JPMorgan Health Conference by approving another restructuring plan. As Dentsply told investors, that restructuring plan included a number of “streamlining” measures which the Company claimed “are key to achieving the Company’s strategic objectives and delivering” the \$3.00 EPS goal.

85. Analysts reacted favorably to the Company’s trajectory, and specifically highlighted Byte’s role in the Company’s recovery. For example, on February 28, 2023, a BoA analyst noted that, “We expect XRAY to continue to benefit from the strong momentum within ortho from both the SureSmile and Byte offerings,” while, on March 1, 2023, Jefferies analysts highlighted the strong results in the Company’s aligner business ending 2022 on a “high note” with where aligners were the “stand out,” growing at over 25%.

86. In fact, Byte was particularly critical to Dentsply’s plan to achieve \$3.00 EPS by 2026. Aside from being part of one of the Company’s five core strategic objectives and one of the

few “bright spots” left after the Company’s previous channel-stuffing scandal, Dentsply set concrete, interim financial targets for Byte to help reach the Company’s \$3.00 EPS goal. For example, at its 2023 Investor Day, Dentsply singled out “Byte conversion and lower financing costs” as one of the key “Building Blocks to \$3.00 Adj. EPS Target”—the only single product line mentioned by name. In doing so, Dentsply stated that Byte would contribute “~\$0.05” to Dentsply’s \$3.00 EPS target.

87. In touting Byte’s impressive 20% annual growth rate, and in direct response to analyst questions about the drivers and sustainability of those growth rates, Defendants attributed the product’s increased sales to Dentsply’s legitimate sales efforts and thoughtful marketing approach. For example, on Dentsply’s May 3, 2023 first quarter 2023 earnings call, Defendant Coleman reported that strong Byte sales and profitability had been driven by **“higher customer conversion rates and lower customer acquisition costs,”** which Dentsply had achieved by **“really looking at the quality of the funnel and how we’re targeting customers”**—i.e., targeting patients who were suitable for Byte. Similarly, in a June 1, 2023 investor conference, Defendants Campion and Coleman attributed Byte’s strong performance to the fact that **“we have a more focused funnel,”** that **“[w]e validate customers as they enter the funnel, so we don’t spend money sending an impression kit to a customer who is not likely to actually purchase,”** and that these were the “building blocks in place for sustained growth in both SureSmile and Byte.” Along the same lines, in a September 2023 investor call, Defendant Campion attributed Byte’s success to targeting the appropriate patients, and that Dentsply had achieved this by **“refin[ing] our questioning on our surveys as they come into the funnel that we move potential customers to the side if we really don’t think that they’re going to end up purchasing,”** which, according to Campion, “meaningfully improved” Byte’s conversion rate over past 12 months.

88. By 2024, Defendants’ prospects seemed better than ever. At that time, Byte was purportedly benefiting from an improved conversion rate and from the bankruptcy of SmileDirectClub in late 2023. In light of these developments, Defendants continued to claim that Byte was growing and profitable and that, to anticipate further growth, Dentsply was increasing its investment in the Byte business, including by hiring more treatment planners. For example, during Dentsply’s on February 29, 2024 fourth quarter 2023 earnings call, Defendant Coleman claimed that Dentsply was “putting more investments into Byte,” including by hiring “*more ... treatment planners*,” which it had “already started in the fourth quarter” of 2023.

89. Similarly, on Dentsply’s May 2, 2024 first quarter 2024 earnings call, Defendant Campion repeated that Dentsply had “invested behind the growth that we’re seeing” with Byte following the SmileDirectClub bankruptcy, including by “increasing the number of treatment planners.” As a result of this investment, Defendants Campion and Coleman told investors during the first quarter earnings call that Dentsply expected “to be north of 20% growth for Byte this year.” Coleman repeated this claim at an investor conference two weeks later, on May 15, 2024, highlighting how Dentsply had “invested in resources to support a ramp in revenue growth” including by hiring “more treatment planners,” and reaffirmed that Dentsply expected Byte to “grow over 20% for the rest of the year.”

V. IN TRUTH, DENTSPLY SOLD BYTE TO CONTRAINDICATED PATIENTS WITHOUT DOCTOR OVERSIGHT, CAUSING THOUSANDS OF INJURIES

90. Unfortunately for investors, Defendants’ statements about Byte were untrue. *First*, contrary to Defendants’ statements that Byte was sold through a “doctor-directed” program overseen by a “nationwide network of licensed dentists” who “prescribe and oversee every customer’s treatment plan,” “assess every step,” and are available for consultation “7 days a week,” in truth, licensed dentists played no meaningful role in Byte patient care, which was instead

handled by unqualified non-doctors. **Second**, contrary to Dentsply’s representations that the Company would “only accept customers who are great candidates for teledentistry” with “mild-to-moderate occlusion,” in truth, Dentsply targeted contraindicated patients who should never have been prescribed Byte, and who were placed at risk of serious injury.

91. **Third**, contrary to Dentsply’s representations that the Company was in “compliance with applicable PMS” (post-market surveillance) rules and “FDA QSR 820” (Quality System Regulation, 21 C.F.R. part 820)—both of which included the FDA’s rules requiring that serious injuries be reported to the FDA within 30 days—in truth, Dentsply flagrantly violated those laws by deliberately and repeatedly failing to timely report thousands of Byte serious patient injuries and dangerous malfunctions to the FDA. **Fourth**, contrary to Defendants’ statements that Byte’s impressive revenue growth driven by Dentsply’s internet marketing efforts or other measures to fine-tune its sales “funnel” and target appropriate Byte candidates, in truth, Byte sales growth had been spurred and sustained due to Defendants’ reckless and sometimes deliberate efforts to sell Byte to contraindicated patients who never should have been prescribed the product.

A. Byte’s Advertising, Sales And Customer Service Practices

92. Dentsply cast a wide net for Byte with multi-channel, direct-to-consumer marketing, including online and television advertising. For example, Byte published a television advertisement on December 14, 2022 touting Byte aligners as “painless, affordable, and they work.” Interested patients who then visited Byte’s website initially provided Dentsply with, at most, minimal information in response to a “30 Second Questionnaire.” The 30 Second Questionnaire included rudimentary questions that appeared designed to elicit some of the most obvious contraindications, such as extreme teeth crowding, extreme teeth spacing, crossbite, underbite, overbite, mixed dentition, existing dental work, and missing teeth. The 30 Second Questionnaire was optional, and not all customers filled it out.

93. Prospective patients then proceeded through two steps to complete a Byte aligner purchase—referred to at Dentsply as the S1 and S2 steps. First, in the “S1” stage, Dentsply offered the prospective patient a Byte impression kit that would be mailed to the patient’s home at a price point just below \$100. Prospective patients would use the impression kit to make a mold of their teeth, which they mailed back to Dentsply. According to Byte’s website, the impression was used to determine whether the patient was a good candidate for treatment with Byte aligners. If a patient’s impressions revealed that they were not a good candidate, Byte’s website consistently stated that the Company would offer the patient a full refund for the price of the impression kit.

94. Second, at the “S2” stage, after the Company had purportedly determined from the patient’s at-home impressions that the patient was a good candidate for treatment, Byte offered the patient a personalized treatment plan with clear aligners, which was approved by a licensed dentist or orthodontist. In general, the treatment plan would involve the use of a series of clear aligners designed to gradually move a patient’s teeth into the desired positioning, often involving (for example) twelve or so progressively sized aligners that would be worn sequentially over the course of a several month period. The full treatment plan was generally sold at a price point just below \$2,000 lump sum (or with a monthly payment plan and financing). As described further below, multiple former employees attest that Byte employed sales representatives to talk through any concerns the prospective patient may have, and to attempt to close the S2 sale. The percentage of S1 customers who became S2 customers was referred to as the “conversion rate.”

B. Byte’s Supposed “Network” Of Dentists Was And Dentists Played Little To No Role In Patient Care

95. Defendants consistently reassured investors (and patients) that, even though Byte was marketed direct-to-consumer, licensed and board-certified dentists and orthodontists exercised “oversight and control of each customer’s clinical treatment” with Byte. For example, Dentsply

represented that “[l]icensed doctors and orthodontists [are] with [patients] every step of the way”; that they would “check in with customers throughout their journey”; and that Dentsply would “*make it easy to get in touch,*” “*7 days a week,*” if patients “*need[ed] to consult the doctor.*” These statements were false. In reality, a dentist or orthodontist would only provide a “rubber stamp” to a treatment plan created by non-licensed “Treatment Planner”—and would thereafter have no ongoing role in monitoring the patient’s treatment or progress or in making necessary changes. As discussed below, numerous former employees and patients recalled that, even as patients suffered serious injuries and called Dentsply begging for help, the Company refused to connect them with any dentist or orthodontist.

96. As an initial matter, Dentsply did not employ any U.S.-licensed dentists or orthodontists to create treatment plans for Byte patients. Instead, Dentsply relied on dental hygienists located in Costa Rica (who were not licensed dentists or orthodontists in either the U.S. or Costa Rica) to design patient treatment plans. Dentsply Former Employee 1 (or “FE-1”) worked remotely in Costa Rica as a Treatment Planner for Byte from 2020 to November 2024.² FE-1 has a background as a dental hygienist, not a dentist. As a licensed dental hygienist, he was in the minority amongst Treatment Planners, as 80% of them did not have any dental-related license, according to FE-1. As a Treatment Planner, FE-1’s job was to create the series of aligner designs for a patient based off the patient’s dental impression and other paperwork, like the questionnaire and medical history. However, according to FE-1, most of the time key pieces of information

² FE-1 reported to Fabian Espinoza Castro, a Treatment Planning Supervisor in Costa Rica, who in turn reported to Joselyn Kladensky, the Director of Operations and Legal Representative in Costa Rica. FE-1 also served as an impression reviewer from May to June 2022. In this role, he would decide whether impressions of patients’ teeth could be used for treatment planning, or whether they had issues that would require the patient to re-do the impression. FE-1 stated that after his first week in this role, he had rejected approximately 100 impressions. He was reprimanded by his managers for rejecting so many impressions.

would either be missing (left blank) or incomplete, and patients' medical history or photos of the patient's teeth were rarely submitted. FE-1 said submitting photos and/or medical history was optional for the customer under Byte's protocol (which was in English), resulting in FE-1 and other Treatment Planners needing to guess or estimate the shape and positioning of teeth when designing the patient's series of aligners. FE-1 stated he received pressure from his managers to come up with treatment plans even when key information was missing. As a result, according to FE-1, the aligners would often not fit the patient's teeth. FE-3 (discussed in more detail below) explained that customers would often complain about ill-fitting aligners causing injuries, such as lacerations to their gums. FE-1 stated approximately 30% of the patient cases he handled on a daily basis were for redesigns for patients who had issues with their previous set of aligners. FE-1 confirmed he never spoke to or coordinated with a dentist in the process of creating and submitting a treatment plan. FE-1 said he believed—and most of his colleagues that he spoke to agreed—that the Byte protocol was unethical because its allowance for incomplete patient submissions resulted in issues for patients.

97. Similar to FE-1, Dentsply Former Employee 2 ("FE-2"), a Senior Software Engineer for Byte from February 2019 to January 2022, was familiar with the Byte treatment process because he designed the software used to track and manage it.³ According to FE-2, dental technicians located in Costa Rica performed the treatment planning work. These technicians were supposed to receive a scan derived from the mold created by the patient, review a questionnaire filled out by the patient, and design a sequence of clear aligners for the patient. FE-2 confirmed

³ FE-2 reported to Byte's Chief Technology Officer, Mark McCrimmon, who in turn reported to Defendant Gunsagar. FE-2's responsibilities included designing Byte's software systems and integrating them with Dentsply's after the acquisition, including the systems used for treatment planning, treatment approval, and customer service.

that, to expedite turnaround times, Dentsply would send cases to treatment planners in Costa Rica with incomplete questionnaire responses and without photos. According to FE-2, even where Dentsply's patient questionnaires identified contraindications for Byte aligners, such patients were not excluded—they could still purchase an impression kit, and their case would still be assigned to a treatment planner in Costa Rica. Further, FE-2 recalled, Dentsply's treatment planners could override the patient's self-identified contraindication and propose a treatment plan anyway; if one treatment planner declined to create a treatment plan on the ground that the patient was contraindicated, Dentsply would ask a different treatment planner to create a treatment plan for that same patient.

98. Second, only *after* the patient accepted Dentsply's treatment plan and made arrangements for payment was the treatment plan presented to a U.S.-licensed dentist or orthodontist for approval—who would approve the treatment plan with *only four clicks* (after logging in) and sometimes do so in *less than two minutes*. Specifically, on click one, the dentist opened the patient's proposed treatment plan; on click two, the dentist would see the patient's medical history, including allergies, generalized medications, and dental history; on click three, the dentist would “approve” (green), “reject” (red), or “modify” (grey) the patient's treatment plan (and, starting in 2021, had the option to approve “with comments”); and, on click four, the dentist would confirm the decision, which had the effect of creating an electronic signature and a time stamp. FE-2 recalled that Dentsply's system did *not* require the dentist to “scroll through” the materials before approving.

99. Senior management specifically encouraged this expedited approval process. Dentsply instituted a dentist-compensation and case-assignment scheme that strongly encouraged rubber-stamp approvals of the treatment plans. FE-2 said that dentists were compensated on a “per

case” basis, that each review was worth approximately \$65 to \$70, and that there were examples of a dentist approving approximately 30 cases per day—including by so-called “**super-approvers**,” who earned that nickname due to their high approval rates in the range of 85% to 95%. FE-2 explained that he built the algorithm at the direction of several of Defendant Gunsagar’s direct reports—including Dr. Jay Khorsandi, Byte’s lead dentist; Amy Carter, the Chief Human Resources Officer and dentist liaison for Byte; and Amber Medsker, the Director of Clinical Support for Byte—that calculated a probabilistic preference for assigning cases to dentists who were entitled to the **lowest fee per case**. FE-2 became concerned after observing examples of extraordinarily fast approvals by dentists with high approval rates and raised those concerns with members of the Byte clinical team, including Medsker.⁴

100. FE-2 said (and FE-3 corroborated) that, beginning in early- to mid-2021 after the acquisition, Byte would “**auto-reassign**” cases rejected by one or two dentists to another dentist, meaning that a patient could be approved for treatment **even if two out of three dentists rejected them**. FE-2 was told to create this feature by his supervisor, Byte’s CTO, who reported to Gunsagar, and who was implementing a business decision made by management.

101. Third, after the dentist’s four-click approval, as a general matter, the approving dentist or orthodontist had **no further role** in the patient’s treatment. While patients would often ask to speak to the dentist or orthodontist who approved their treatment plan, FE-2 stated that Dentsply’s practice was to prevent them from doing so, and that it was rare for Dentsply to connect a concerned customer with any dentist or orthodontist. FE-2 explained that approving dentists and orthodontists did not have customer support training, and that there was not any formal mechanism

⁴ 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 the case was sent to the dentist for review and when the dentist approved—and which showed approvals granted within two minutes.

for them to communicate with patients. Instead, FE-2 said that after the patient started treatment, any incoming patient concerns generally would be directed to Byte customer support employees who were not dentists or orthodontists.

102. Doctors were not involved in patients' Byte treatment following the rubber stamp four-click approval process—instead, Byte patients' remaining treatment would be provided non-dentist customer support employees who routinely provided unqualified medical advice to Byte patients. For example, FE-3, who worked as a Professional Care Specialist for Byte from July 2020 to May 2022, explained that Byte's support staff would answer patient inquiries through email or video chat and provide treatment advice to patients whose progress was not tracking their treatment plan and whose dental alignment was deteriorating week by week without the involvement or consultation with any doctor whatsoever. FE-3 said there were many instances where, after several weeks of treatment, patients' dental alignment would deteriorate to the point where they could not even fit their aligners on their teeth—and that Dentsply would typically just send them a new impression kit to restart the treatment. Oftentimes, FE-3 explained, the new aligners would not fit either, and the process would repeat itself. As FE-3 described, Dentsply management instructed Byte support to tell patients what they wanted to hear, while simultaneously attempting to blame the patients for the failure of the Byte aligners.

103. The Byte support staff were not remotely equipped to provide such treatment advice. As another former Dentsply customer service representative explained to *The Capitol Forum*: “I didn't get any training that I can recall on what we were supposed to do with an injury. What always bothered me was that customer service employees, in essence, were **trying to act like a doctor or someone that has more medical training**, and I was always uncomfortable with that.” The representative explained: “If 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*** and hoping their teeth moved more so they could wear the next set."

104. There was nothing backing Defendants' statements about patients having access to a "nationwide network of independent licensed dentists and orthodontists," as such network was illusory and no licensed professional provided Byte patients with any actual treatment. Instead, FE-3 confirmed the Company's team of "Professional Care Specialists" was unequivocally not permitted to allow patients to speak to any dentist, including their prescribing dentist. As FE-3 explained, he would frequently receive such requests from patients, but per the Company's policy, and much to those patients' chagrin, the answer always had to be "no." FE-3 further explained that he found himself frequently apologizing to these patients, as he lacked sufficient medical training to appropriately handle their complaints.

105. Instead, for those patients who persisted in demanding to speak to a medical professional, Dentsply's dental assistants would respond to those inquiries. Again, these dental assistants were not licensed dentists or orthodontists. For example, FE-4, who worked as a Remote Dental Assistant at Byte from July 2023 to October 2023, described how the lack of doctor involvement throughout the treatment plan put patients at risk. As a Remote Dental Assistant, FE-4 would "check in" with patients after twelve weeks of aligner treatment and review photos taken by the patients of their progress. FE-4 confirmed that patients were otherwise on their own until the twelve-week check-in—even though the photos they submitted at the twelve-week mark often revealed that the patients' aligners had not been tracking the entire time and were thus completely ineffective.

106. In his role as a Remote Dental Assistant, FE-4 was asked to respond to approximately 50 Byte patient emails each day—which included both patient complaints and the

twelve-week check-ins. According to FE-4, it was nearly impossible to accurately respond to this many emails each day, and it took a significant amount of time just to identify what exactly the patient's problem or issue was. In fact, FE-4 stated that he was never able to respond to more than 13 emails in a single day—or about a quarter of the 50 emails he was supposed to handle—and that it was normal for dental assistants to be three days behind on emails. Indeed, according to FE-4, Dentsply's policy was that remote dental assistants would only be offered overtime pay to catch up on their backlog of patient complaints if they were five days or more behind on emails—resulting in a constant backlog of patient complaints awaiting responses. During his tenure, FE-4 was aware of Byte patients who had been emailing back and forth with Dentsply in an attempt to resolve their complaints for three years (*i.e.*, with the initial patient complaint dating back to around the time of the Byte acquisition).

107. Similar to Byte patients and other Dentsply staff involved in patient treatment, dental assistants like FE-4 were likewise not permitted to seek input from a licensed dentist or orthodontist, including the dentist or orthodontist who had approved that patient's treatment plan. In fact, FE-4 stated that dentists were not involved in overseeing their patients' treatment at all following the initial approval of the treatment plan—even though dental assistants like FE-4 provided treatment advice to patients. For example, under Byte policy, dental assistants were instructed to tell patients to “backtrack” their aligner treatment—meaning, to go back and use a previous aligner in the treatment plan's sequence if the desired movement was not achieved. In fact, FE-4 reported, only if such backtracking required the patient to go back more than five aligners in the patient's treatment plan would he even be required to check with this team lead about that advice—even though the team leads were not dentists either, but fellow dental assistants. FE-4 confirmed that at no point would dentists, such as the patients' prescribing dentist, be

consulted prior to Dentsply instructing patients to “backtrack” their treatment. In fact, both FE-4 and FE-3 reported that customer service managers overseeing FE-4 and FE-3’s 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 that were causing discomfort or pain. None of this advice was overseen or approved by any licensed medical professional.

108. Many of Dentsply’s own (belated) reports to the FDA likewise confirm that, during the Class Period, Byte customer service personnel who were not dentists or orthodontists provided medical advice to Byte patients—often instructing them to “backtrack” their treatment or to alter the device:

- “The patient reported: my final aligner step is so old that it’s scratching the inside of my lips and causing pain. **Customer service advised the patient to backtrack** to the most comfortable aligners and provided fit tips to help alleviate discomfort.” (reported by patient to Dentsply May 2024; reported by Dentsply to FDA November 2024)
- “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. The patient indicated they have some sensitivity, and that one tooth is wigglier than the others.” (reported by patient to Dentsply October 2022; reported by Dentsply to FDA November 2024)
- “The patient reported . . . the inner side of the aligner exposes half of my teeth, while the outer part cuts into my gums. **Customer service provided molar alignment education and requested the customer file down the sharp edges** and soak the aligners in warm water.” (reported by patient to Dentsply September 2023; reported by Dentsply to FDA October 2024)
- “A patient reported that she stopped wearing her aligners due to pain and some bleeding. **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. A letter of recommendation was received on behalf of the patient indicating ‘the patient came into the dentist office for an emergency treatment. She had a large cavity on tooth number five, and it turned into a root canal. A root canal procedure was done and needed restorative restoration of a crown in order to

save the tooth from fracturing.’” (reported by patient to Dentsply August 2022; reported by Dentsply to FDA December 2024)

109. The accounts of former Dentsply employees and the FDA’s MAUDE database are also confirmed by former Byte patients who reported that, contrary to Defendants’ representations, Byte treatment was not overseen by dentists or orthodontists. For example, one Byte patient who first initiated treatment in October 2020 and repeatedly interacted with the Byte customer service team reported how the advice he received from Dentsply’s customer service staff caused him severe injuries. After the patient finished the original sequence, his teeth still were not straight—and, after speaking with Byte customer sales staff, the Company sent him a new set of aligners, which again failed to adjust the patient’s teeth to their desired positioning. This process repeated itself until around February 2024, when the patient started experiencing pain in the eye area, and problems with vision, photophobia (light sensitivity), and headaches. After being repeatedly told that the patient could not speak to any dentist at the Company, these issues eventually prompted a visit to an orthodontist who diagnosed the patient with trigeminal neuralgia—an intense facial pain caused by damage to the trigeminal nerve that can occur during orthodontic teeth movement. This Byte patient believed Dentsply’s statements that the treatment would be supervised by a dentist and never would have signed up otherwise—but at no point during the treatment was he allowed to speak to a dentist or orthodontist.

C. Medical Injuries Spiked Following An Explicit Instruction From Dentsply Senior Management To Sell To Contraindicated Patients

110. Throughout the Class Period, Dentsply told investors (and patients) that Dentsply would “*only accept customers who are great candidates for teledentistry*,” which Defendants defined as “Class I” malocclusion with “*mild to moderate spacing and crowding*” only. If a patient had “Class II” or “Class III” malocclusion, a complex case, or was otherwise contraindicated,

Defendants represented that they refunded that patient for the impression kit and would not sell Byte aligners to that patient.

111. These statements were materially false and misleading. In truth, rather than “only accept customers who were great candidates,” Dentsply had no effective process to limit Byte treatment to patients with “mild to moderate spacing and crowding.” In fact, Dentsply senior management *intentionally* targeted contraindicated patients by directing its sales force not to inform prospective patients of contraindications. As a result, throughout the Class Period, Dentsply sold Byte to patients who were terrible candidates for teledentistry and for Byte—facts that were confirmed by numerous former employees and by Dentsply’s own belated reports to the FDA. In truth, Dentsply sold Byte to patients with critical contraindications like gum disease, open bite, overjet, severe cases requiring surgery, mixed dentition, prosthetics and implants, and skeletally narrow jaws that made Byte an unsuitable and dangerous treatment for those patients.

112. Defendants were motivated to sell Byte to contraindicated patients in order to make up for Dentsply’s other struggling business lines. Following the unraveling of the channel-stuffing scheme orchestrated by Defendants Casey and Gomez, Dentsply senior management increasingly relied on sales of Byte to patients that should never have purchased the product—and specifically carried out a strategy to sell to contraindicated patients in order to boost sales and the conversion rate beginning in August 2022.

113. Numerous former Dentsply employees confirmed this management-backed initiative. Specifically, according to FE-5⁵ and FE-6,⁶ Dentsply’s Head of Sales and Business

⁵ FE-5 worked as a Manager of Customer Success at Byte from August 2021 to October 2022. He worked in an S2 sales role, selling aligner treatment plans to potential patients who submitted molds from the impression kits they purchased at S1.

⁶ FE-6 worked as an Account Manager at Byte from August 2019 to October 2023. He started in S1 sales for a little over a year and then moved into the S2 division after the one-year mark.

Development for Byte, Tyler Stoker, held a meeting in 2022 during which sales representatives were instructed to no longer tell prospective patients that had contraindications that they were not suitable for a Byte aligner. As FE-5 explained, this meeting took place in August 2022—four months into Defendant Frank’s tenure as Senior Vice President, Product Group and the same month that Defendant Campion was appointed as CEO. Both FE-5 and FE-6 reported that, at this meeting, Stoker went over sales data and told the sales representatives that those figures would be improved once they ceased mentioning to customers that they were contraindicated. FE-6 explained that, although he expressed that there were customers whom he did not feel comfortable selling aligners to on account of their contraindications, Stoker made it clear that it was not his decision whether to sell to those customers. Rather, FE-6 explained, there was a company-wide policy to sell to patients so long as the treatment plan was approved, despite any contraindications—a fact that Stoker confirmed was a decision made and approved by senior leadership.

114. Similarly, FE-5 explained that, as directed at the August 2022 meeting, Byte’s sales representatives stopped taking prospective patients’ dental histories into account during the sales process. Instead, Byte’s dentists and designers tried to work their way around any issues to make sure the sale could be completed. For instance, FE-5 explained that when he started at the Company, fake teeth, such as dental implants, were a contraindication that needed to be taken into account before a patient could be given a treatment plan. However, at the August 2022 meeting, FE-5 was told not to worry about patients’ fake teeth any longer. FE-6 also confirmed that not only did he personally begin selling aligner treatment plans to customers whom he was not comfortable selling to, but that customers were in fact enrolled in treatment plans who should never have been prescribed Byte.

115. Senior management's instruction to sell to contraindicated patients had its intended effect. As FE-5 reported, 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. FE-5 specified that following the August meeting, Byte's rejection rate decreased from a 35% rejection rate to less than a 10-15% rejection rate. According to FE-5, he was able to confirm this by looking at data from a sales dashboard that was accessible to senior management.

116. In fact, FE-5 explained that Stoker led a second, follow-up meeting in the fall of 2022 to specifically address the "improvements" that followed from the policy instituted at the August 2022 meeting. At this second meeting, FE-5 reported that, rather than discuss whether the change in rejection rate indicated that the Company was violating its promise to only accept patients it could treat safely, Stoker highlighted how Byte's rejection rate declined, praised the sales team, reported that sales were increasing, and told sales representatives that they were expected and encouraged to keep up the good work. As FE-5 explained, at this second meeting, Stoker claimed that because Byte's business model relied on dental work conducted outside the United States, the Company could get away with bypassing certain standards. FE-5 confirmed that the policies conveyed by Stoker were formulated and approved by Dentsply's senior leadership—and were directly tied to Byte's need to improve its numbers, to ensure bonuses would be paid, and to keep the new CEO happy.

117. Dentsply's sales practices with respect to Byte contraindications were not only encouraged by management, but when employees raised concerns about them, management shot them down. For example, FE-3 informed his supervisor Zeinab Kleit, Clinical Operations Manager at Dentsply, that he was concerned that customers with underlying contraindications were being

inappropriately approved—as he saw numerous customers with tooth or gum issues that necessitated braces or other in-person treatment but were nonetheless approved for Byte. According to FE-3, Kleit dismissed these concerns and told FE-3 that he needed to go along with whatever the Dentsply dentists and orthodontists said. FE-3 explained that his colleagues had similar experiences, and that the consensus in his department was that the Company was inappropriately approving customers in order to maximize their short-term profit—conduct that ultimately prompted FE-3 to leave Dentsply.

D. Dentsply’s Routine And Unsupervised Byte Sales To Patients Who Were Contraindicated For Its Use Resulted In Thousands of Medical Injuries

118. Dentsply has now admitted that it repeatedly sold Byte to “contraindicated” patients. Specifically, as Dentsply disclosed at the end of the Class Period, Dentsply sold Byte to contraindicated patients including those who “have known active periodontal disease, severe open bite, severe overjet, tooth malocclusion requiring surgical correction, mixed dentition, have dental prosthetics or dental implants, or are an adolescent with a skeletally narrow jaw.” These conditions comprise nearly all of the contraindications identified on Dentsply’s website for Byte throughout the Class Period.

119. Numerous former employees confirmed sales of Byte to contraindicated patients triggered alarming rates of injuries. For instance, FE-5 estimated that approximately **25% of customers** were injured by Byte’s aligners—a figure that was based on conversations he had with his sales colleagues, each of whom confirmed they were inundated with a deluge of complaints. Similarly, FE-5 reported that the rate of injuries was alarming, given that he personally dealt with complaints from at least nine different customers each week. FE-4 reported that patients in his cue who were experiencing complications from their aligner treatment should have never been

approved in the first place, including many who should have been deemed ineligible on account of either their contraindications or the severity of their dental crowding.

120. Dentsply's belated reports to the FDA conservatively show that at least hundreds of patients prescribed Byte treatment despite clear contraindications led to serious adverse outcomes. These include all of the contraindications that Dentsply has admitted that it failed to exclude—active periodontal disease, severe open bite, severe overjet, tooth malocclusion requiring surgical correction, mixed dentition, dental prosthetics or dental implants, or adolescents with a skeletally narrow jaw—and more.

121. Dentsply's inadequate clinical oversight and its aggressive push to sell Byte to contraindicated patients resulted in patients suffering a range of disturbing and painful dental injuries, many involving irreversible tooth loss and associated complications. Specifically, during the Class Period, Byte patients experienced teeth cracking, chipping, falling out entirely, or requiring emergency extractions. Hundreds of patients lost one or more teeth, often as a result of significant bone loss and infection. Other patients suffered broken crowns and bridges or loosened teeth requiring extensive dental intervention. Many patients also began experiencing jaw misalignment and jaw locking when they used the aligners, and other patients experienced uncontrollable bleeding, exposed nerves, and oral abscesses, often demanding emergency dental procedures or long-term antibiotics. Dentsply's belated reports also show that many other patients avoided these outcomes only because they were advised by unaffiliated dentists to stop treatment due to imminent risk of tooth loss.

122. In fact, the FDA reports show that hundreds of individuals began Byte aligner treatment despite clear contraindications leading to serious adverse outcomes that Dentsply failed to report to the FDA in a timely manner. Again, Dentsply posted these same contraindications—

active periodontal disease, severe open bite, severe overjet, tooth malocclusion requiring surgical correction, mixed dentition, dental prosthetics or dental implants, or adolescents with a skeletally narrow jaw—on its website for Byte throughout the Class Period.

123. For example, one of the contraindications for which Dentsply admitted its onboarding procedures were inadequate was “active periodontal disease,” also called periodontitis or gum disease. Periodontitis is characterized by bleeding, gum recession, loose teeth, and bone loss. Byte aligners are contraindicated for patients with periodontitis because they apply pressure that can exacerbate inflammation and accelerate bone loss and tooth loosening and ultimately cause tooth loss. Towards the end of the Class Period, Dentsply filed at least 65 reports that cite periodontitis and admit that the patient was “contraindicated.” For example, one untimely report filed in January 2025 disclosed that a customer learned from an orthodontist about a contraindication due to periodontal disease. The customer wrote: ***“This is frustrating because I noted this on my Byte intake and asked the sales rep directly about the safety of Byte and Hyperbyte with periodontal disease and her response was it was ‘totally fine.’”*** Another report Dentsply filed with the FDA in March 2025 states: ***“support told [the patient] to just press on despite all the issues. The aligners started chipping their teeth, their gums bleeding, teeth became yellow, and their overall dental alignment failed. At check in patient marked true to excessive bleeding, periodontitis, chipped, and sensitivity. ... This is a contraindicated patient.”***

124. Although they do not use the word “contraindicated,” at least 260 additional untimely reports filed by Dentsply throughout the Class Period report periodontitis or injuries strongly associated with it, such as bone loss. For example, an untimely reported filed by Dentsply in December 2024 stated that “my dentist ... said that due to my periodontal disease, I’m at risk of losing this tooth and others if I continue ... ***Obviously, I disclosed my periodontal disease when***

i applied for byte treatment, the provided pictures show evidence of the disease and I was approved. I was assured that the treatment was safe when I expressed concern.” Another untimely report filed in January 2025 stated: **“On the questionnaire the patient marked true to the following: periodontitis, not fitting, compromised implant and chipped.”**

125. Another contraindication for which Dentsply admitted its onboarding procedures were inadequate was dental prosthetics (such as crowns, bridges, and veneers) or dental implants. Byte aligners were contraindicated for patients with implants or prosthetics because implants and prosthetics cannot be safely moved by clear aligners. Towards the end of the Class Period, Dentsply filed at least 57 reports that cite prosthetics or implants that state the patient was “contraindicated.” Further, although they do not use the word “contraindicated,” at least 236 additional untimely reports filed by Dentsply identify implants or prosthetics. For example, two reports filed by Dentsply with the FDA in December 2024 state: **“Patient reported they had disclosed they have an implant but were still allowed to have aligner treatment, which is contraindicated”**; and “Patient reports the retainers have never sat correctly for over a year This has resulted in issues with the molar crown bleeding, receding gums on the lower front and the bite is misaligned **The molar crown was disclosed at start of treatment.**” Another report—received by Dentsply in May 2024, yet reported by Dentsply to the FDA only in November 2024—states: “one of her crowns fell out, and her implant tooth also became loose due to using the top aligners.”

126. Dentsply also admitted its onboarding procedures were inadequate to screen for the contraindication of “severe open bite,” which is a condition where the upper and lower teeth do not meet when the mouth is closed—and requires surgery to correct. Towards the end of the Class Period, Dentsply filed at least 17 reports that cite an open bite and admit that the patient was

“contraindicated.” Although they do not use the word “contraindicated,” at least 140 additional untimely reports filed by Dentsply throughout the Class Period report open bite. For example, one untimely report filed by Dentsply states: “A patient reported that their anterior open bite is more apparent than it was prior to starting treatment.”

127. Other contraindications for which Dentsply admitted its onboarding procedures were inadequate include “severe overjet,” a dental condition where the upper front teeth protrude further forward than the lower front teeth; “tooth malocclusion requiring surgical correction”; “mixed dentition,” which refers to the presence of both baby and adult teeth, which generally occurs in adolescents aged 9-12 years, among others. For each of these contraindications, Dentsply belatedly filed reports identifying that Byte was sold to patients with these conditions—with the MAUDE database revealing, for example, that 6 reports cite an “overjet” and admit that the patient was “contraindicated” while another 16 additional untimely reports similarly report overjet without specifically saying “contraindication”; that at least 3 reports cite severe malocclusion and admit that the patient was “contraindicated” while another 23 untimely reports cite severe malocclusion; and that several belatedly filed reports indicate Byte was sold to patients with mixed dentition, with one January 2025 report specifically stating “***The patient is contraindicated due to mixed dentition.***”

128. Dentsply also failed to screen patients for the contraindications that were listed on the website for Byte throughout the Class Period, but were not included on the list of contraindications that Dentsply admitted—in the Important Notice to Patients and Urgent Field Safety Notice—that it failed to screen. Towards the end of the Class Period, Dentsply filed reports that cite overbite, cavities, permanent retainer, and allergic reaction and admit that the patients were “contraindicated.” Additionally, although they do not use the word “contraindicated,”

Dentsply filed untimely reports relating to the Class Period for allergic reactions, cavities or tooth decay, and overbite.

129. The above examples confirm Byte's systemic failure, described by numerous former employees, to screen patients with contraindications.

E. Dentsply Management Actively Tracked These Serious Medical Injuries

130. Not only did Dentsply senior management instruct the Byte sales force to sell to contraindicated patients—and thereby obviously increase the risk and occurrence of patient injuries—but the Executive Defendants were directly informed of those injuries, were required by law to monitor them, and had direct access to the patient complaints.

131. First, Defendants Gunsagar and Brackett had knowledge of patient complaints of serious injuries because they were the executives directly overseeing the Byte business, communicated with the FDA about them, had access to a Snowflake database containing patient injury complaints, and discussed them with Dentsply's quality executives. Specifically, during the Class Period, Dentsply's quality executives who had direct responsibility for Dentsply's FDA reporting included Hannah Seevaratnam, who served as Vice President, Corporate Quality Systems from October 2019 to May 2024; Charles Pigott, Dentsply's Corporate Vice President, Quality and Regulatory, from September 2007 to the present; and Emily P. Miner, Dentsply's Chief Quality Officer, from May 2023 to present. In these roles, Seevaratnam reported to Pigott; Pigott reported directly to CEO Casey and then Campion (before Miner's appointment) then Miner; and, as soon as Miner took over as Chief Quality Officer, she reported directly to CEO Campion.

132. As described by FE-7, Seevaratnam's long-time predecessor until 2019, Dentsply's quality executives were responsible for reporting serious injuries to the FDA for all Dentsply-manufactured medical devices. They had access to all patient complaints—including both

“serious” complaints (those involving injury) and “non-serious” complaints—through a sophisticated database called Trackwise. Trackwise is a quality management system created and licensed by Honeywell that is purpose-built for FDA reporting. That database had significant functionality, including the ability to search by product or keyword. During his tenure, FE-7 personally reviewed all customer complaints alleging injury, which numbered approximately 2,500 per month, and could be reviewed in about 8 hours. FE-7 met 3-4 times per quarter with Pigott to discuss injuries, and Pigott then met once per quarter with Dentsply’s senior executives, including the CEO, to discuss injuries.⁷

133. During his tenure, FE-7 created Dentsply’s “Decision Tree,” an approximately 20-page policy defining patient injuries that Dentsply determined were required to be reported to the FDA. According to FE-7, the Decision Tree provided that the loss of a tooth was required to be reported to the FDA as an example of “permanent damage to a body structure.” 21 C.F.R. § 803.3(w). That decision was made in 2014, following a long discussion between FE-7, Pigott, Andrew Lichkus, Dentsply’s Corporate Vice President, New Product Development, and Dentsply’s corporate dentist. All of those executives agreed with the decision, and that policy remained in place through the end of FE-7’s tenure and remained in place after FE-7 left the Company. The policy applied to all devices; regardless of the device at issue, the loss of a tooth was required to be reported to the FDA.

⁷ FE-7 was Dentsply’s Director, Corporate Compliance and Regulatory Affairs from 2003 until his retirement in 2019. FE-7 reported to Pigott from 2007 to 2019. Both FE-7 and Pigott were “management representatives” within the meaning of the FDA’s Quality System Regulation rule. FE-7 was familiar with Seevaratnam, who worked in a different position for FE-7’s final two years and then succeeded to FE-7’s role upon FE-7’s retirement. FE-7’s responsibilities included overseeing quality system compliance worldwide and submitting FDA medical device reports.

F. Dentsply Violated FDA Reporting Laws, Failing To Timely Report More Than 6,000 Serious Patient Injuries

134. In Dentsply’s annual “Sustainability Reports” for 2021, 2022, and 2023 published during the Class Period, Defendants stated that Dentsply complied with the FDA’s medical device regulations, representing that “*we comply with*” “*FDA QSR [Quality System Regulation] 820*” and “*applicable PMS [post-market surveillance] requirements*”—i.e., the rules requiring Dentsply to report adverse events associated with its products to the FDA. In Forms 10-K and 10-Q filed during the Class Period, Defendants further represented that Dentsply believed it was in “*substantial compliance*” with applicable laws and regulations, including FDA regulations requiring “*notification*” and reporting of adverse events to the FDA and “*misbranding*.”

135. These statements were false and misleading. In reality, Dentsply did not “comply with,” nor was Dentsply in “substantial compliance” with, the FDA’s medical device regulations concerning Medical Device Reporting (which is a type of post-market surveillance) or Quality System Regulation. By its own subsequent admission, Byte patients suffered at least 6,894 serious patient injuries during the Class Period that Dentsply failed to timely report to the FDA, including 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. As a result, Byte was misbranded, and Dentsply was committing a crime with each Byte sale (and each time it imported a Byte aligner into the United States from its manufacturing facility in Mexicali, Mexico). The FDA’s Quality System Regulation, with which Defendants represented Dentsply complied, required Dentsply’s management with “executive responsibility” to ensure Medical Device Reporting. In fact, during the Class Period, Dentsply possessed all the technology and personnel necessary to comply with the FDA’s Medical Device Reporting rule.

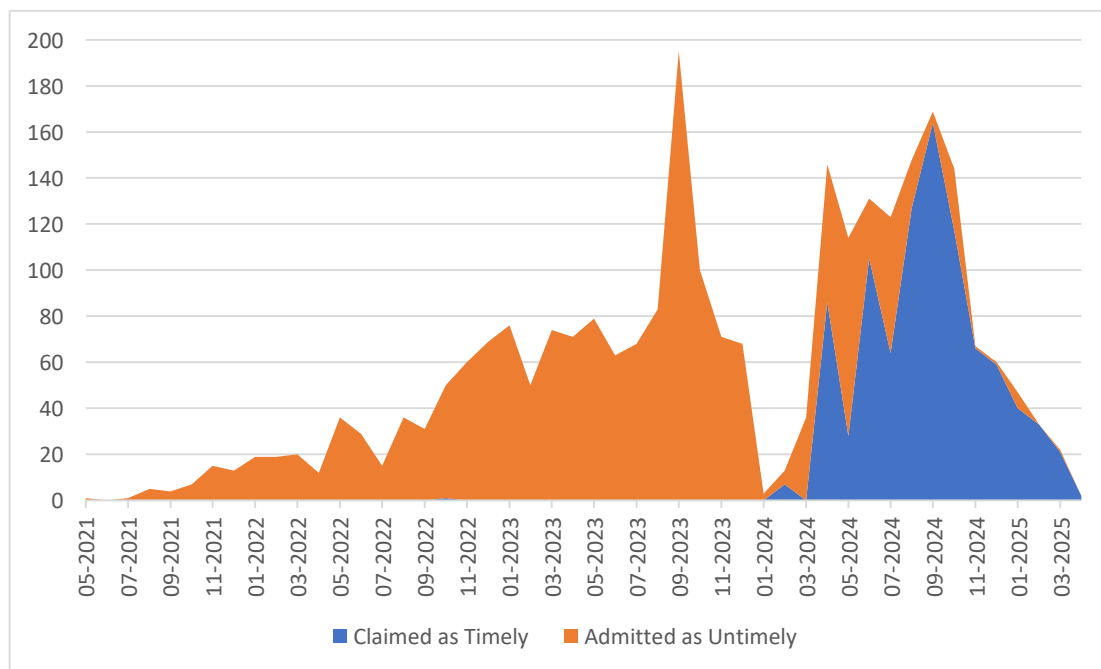
136. As described by the FDA, these regulations are specifically designed to ensure that individuals at the highest levels of a company are actively involved in and accountable for the quality system, which includes the reporting of adverse events to the FDA, a critical public safety compliance function. But, by Dentsply’s own admission in “retrospective” reports filed since September 2024, Dentsply failed to file thousands of reports of serious injuries of which it was contemporaneously aware, all the way back to 2021. These include patient complaints of obviously serious injuries, such as the loss of a tooth, that Dentsply’s own written policies acknowledged were subject to mandatory reporting.

137. These reporting failures persisted throughout each Executive Defendant’s tenure and were particularly egregious during the portion of the Class Period starting in January 2021 after the Byte acquisition and continuing until August 2024, the last month before Dentsply began filing a large number of retrospective reports.

Defendant	Exemplar Period	Number of Injuries Not Timely Reported	Percentage of Injuries Not Timely Reported
Casey (CEO)	January 1, 2021 to April 19, 2022	At least 739	At least 99%
Gomez (CFO)	January 1, 2021 to May 6, 2022	At least 794	At least 99%
Gunsagar (CEO of Byte)	January 1, 2021 to August 31, 2022	At least 1,201	At least 99%
Campion (CEO)	September 12, 2022 to August 31, 2024	At least 5,289	At least 80%
Coleman (CFO)	September 26, 2022 to August 31, 2024	At least 5,247	At least 80%
Frank (CBO)	April 1, 2022 to August 31, 2024	At least 5,849	At least 81%
Brackett (SVP, Clear Aligners and Head of Sustainability)	April 1, 2023 to August 31, 2024	At least 3,959	At least 76%

138. Senior Dentsply executives—including Defendants Gunsagar and Brackett—personally reviewed examples of customer complaints alleging injury and participated in Dentsply’s response to FDA concerns regarding the same. For example, during the Class Period, the FDA identified concerns about lacerations caused by Byte. However, as reflected below, despite knowing the FDA’s concerns regarding lacerations caused by Byte, Dentsply continued to massively under-report customer complaints regarding lacerations to the FDA until at least August 2024—failing to timely report dozens of such incidents per month:

Lacerations reported by Dentsply to the FDA for Byte, sorted by month in which Dentsply admits it became aware of them, and by whether Dentsply claimed the report as timely or admitted that the report was untimely⁸



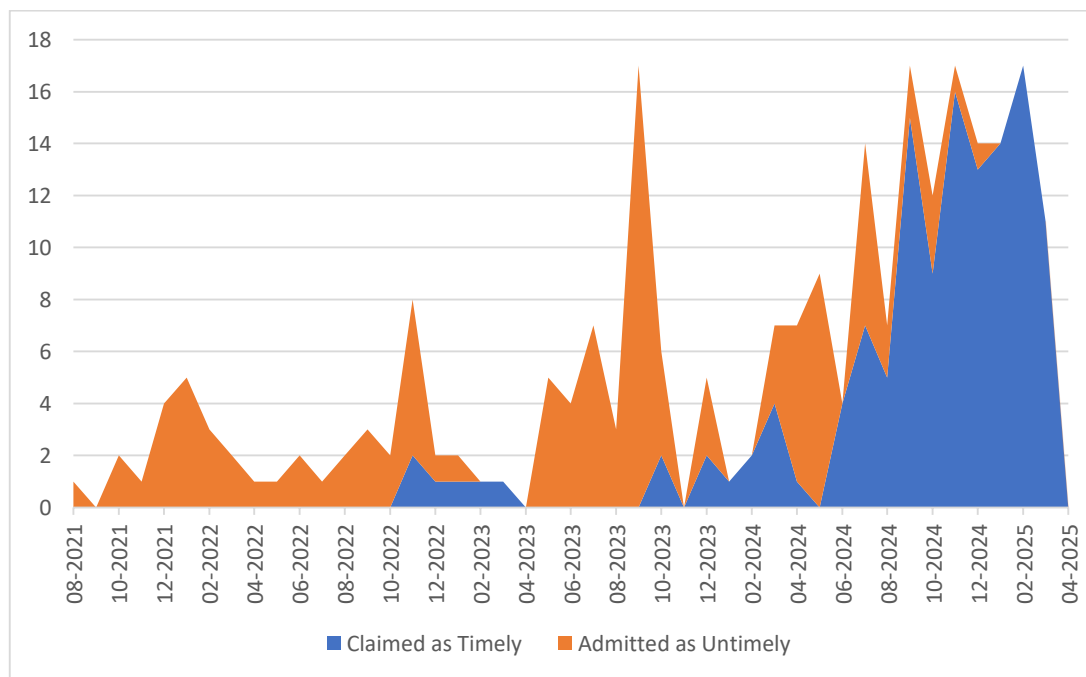
139. FE-7 reported that Dentsply’s “Decision Tree” required the loss of a tooth to be

⁸ Dentsply’s reports to the FDA include data fields for the date when the adverse event was reported to Dentsply and when it was reported by Dentsply to the FDA. If, according to Dentsply’s own report, the adverse event was reported to Dentsply more than 30 days before Dentsply reported it to the FDA, it is classified in the above charts as “Admitted as Untimely.” Otherwise, it is classified as “Claimed as Timely.”

reported to the FDA. That policy was approved in 2014 by Pigott, who served as a Dentsply as a quality executive throughout the Class Period.

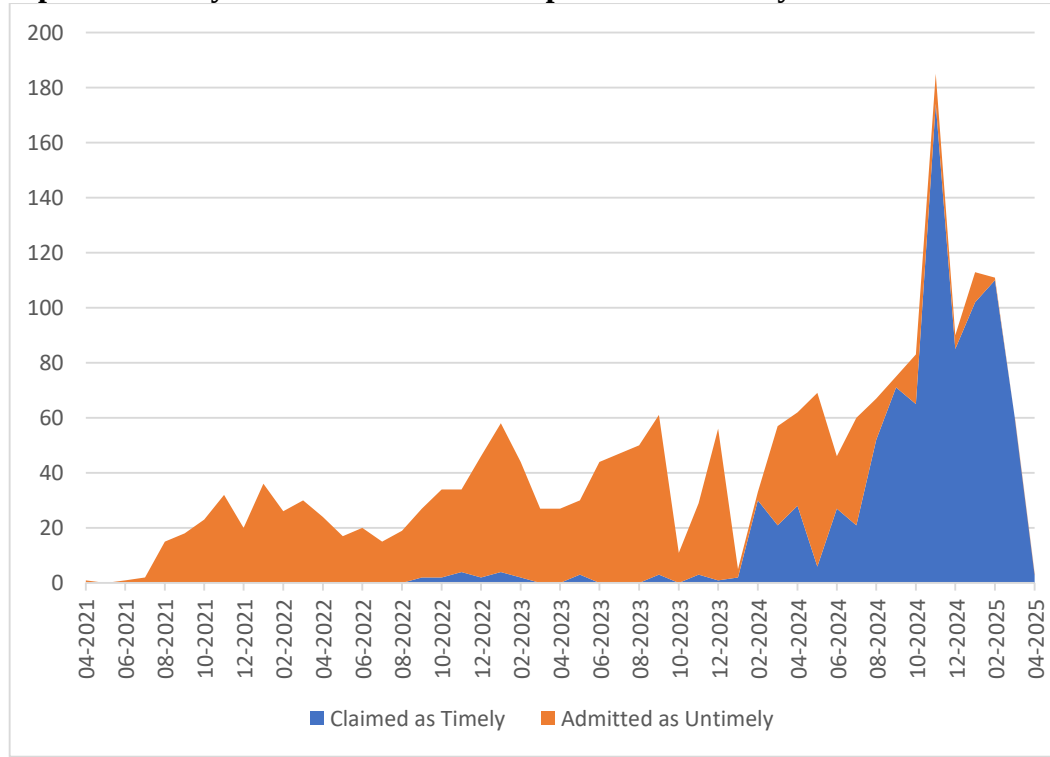
140. Despite knowledge that the loss of a tooth was subject to mandatory reporting, by Dentsply’s own admission in retrospective reports to the FDA, Dentsply failed to timely report **at least 115** incidents of lost teeth; plus at least **110** additional incidents of pulp necrosis, where the soft tissue inside a tooth dies, and at least an additional **1,160** incidents of tooth fracture. Despite the obvious seriousness of these injuries, from the Byte acquisition until July 2024, Dentsply failed to timely report substantially all of the lost, dead, and fractured teeth caused by Byte.⁹

Loss of teeth reported by Dentsply to the FDA for Byte, sorted by month in which Dentsply admits it became aware of them, and by whether Dentsply claimed the report as timely or admitted that the report was untimely

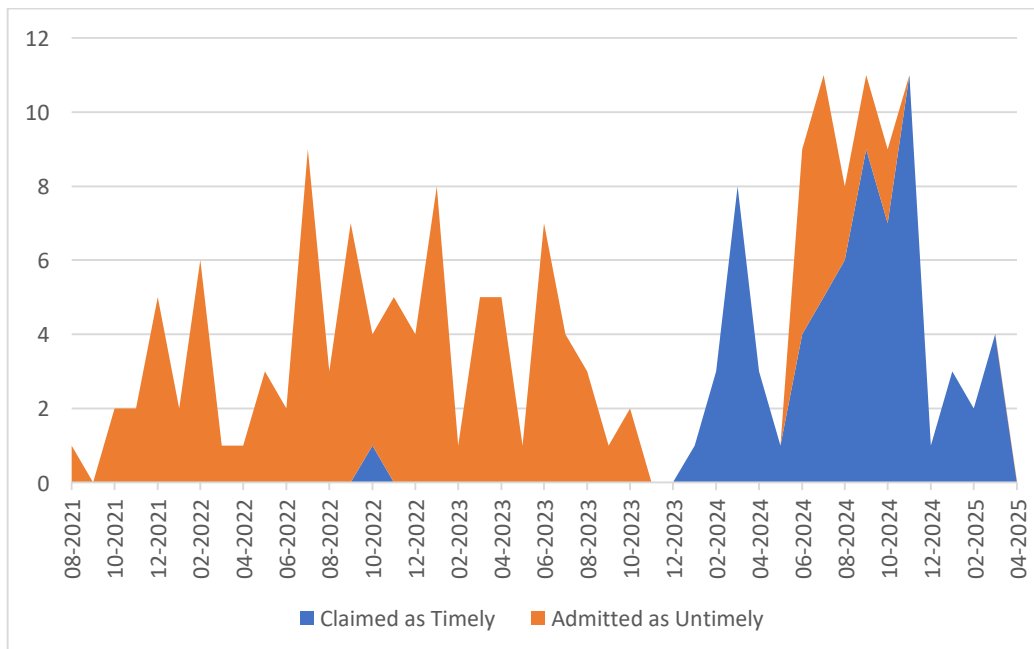


⁹ Reports of tooth loss were identified by analyzing the “Event Description” in Dentsply’s reports. Examples include: “the patient by using night aligner reported tooth #14 was broken and her dentist extracted the tooth”; and “the patient reported that their step 2 aligner caused one of their teeth to crack and their dentist is now needing to remove it.”

Tooth fractures reported by Dentsply to the FDA for Byte, sorted by month in which Dentsply admits it became aware of them, and by whether Dentsply claimed the report as timely or admitted that the report was untimely



Necrosis reported by Dentsply to the FDA for Byte, sorted by month in which Dentsply admits it became aware of them, and by whether Dentsply claimed the report as timely or admitted that the report was untimely



141. Patient reports of lost, dead, and broken teeth were neither subtle nor difficult to interpret. For example, one report reads: “**tooth (#9) fell out** . . . and that their dentist says they might lose the tooth next to it as well **because of the aligners.**” This injury was reported by the patient to Dentsply in October 2021, but only reported by Dentsply to the FDA in September 2024. Another reported that the patient “had to have [a] **broken molar removed and [a] bone graft,**” and that the patient stated: “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.” This injury was reported by the patient to Dentsply in September 2023, but only reported by Dentsply to the FDA in November 2024.

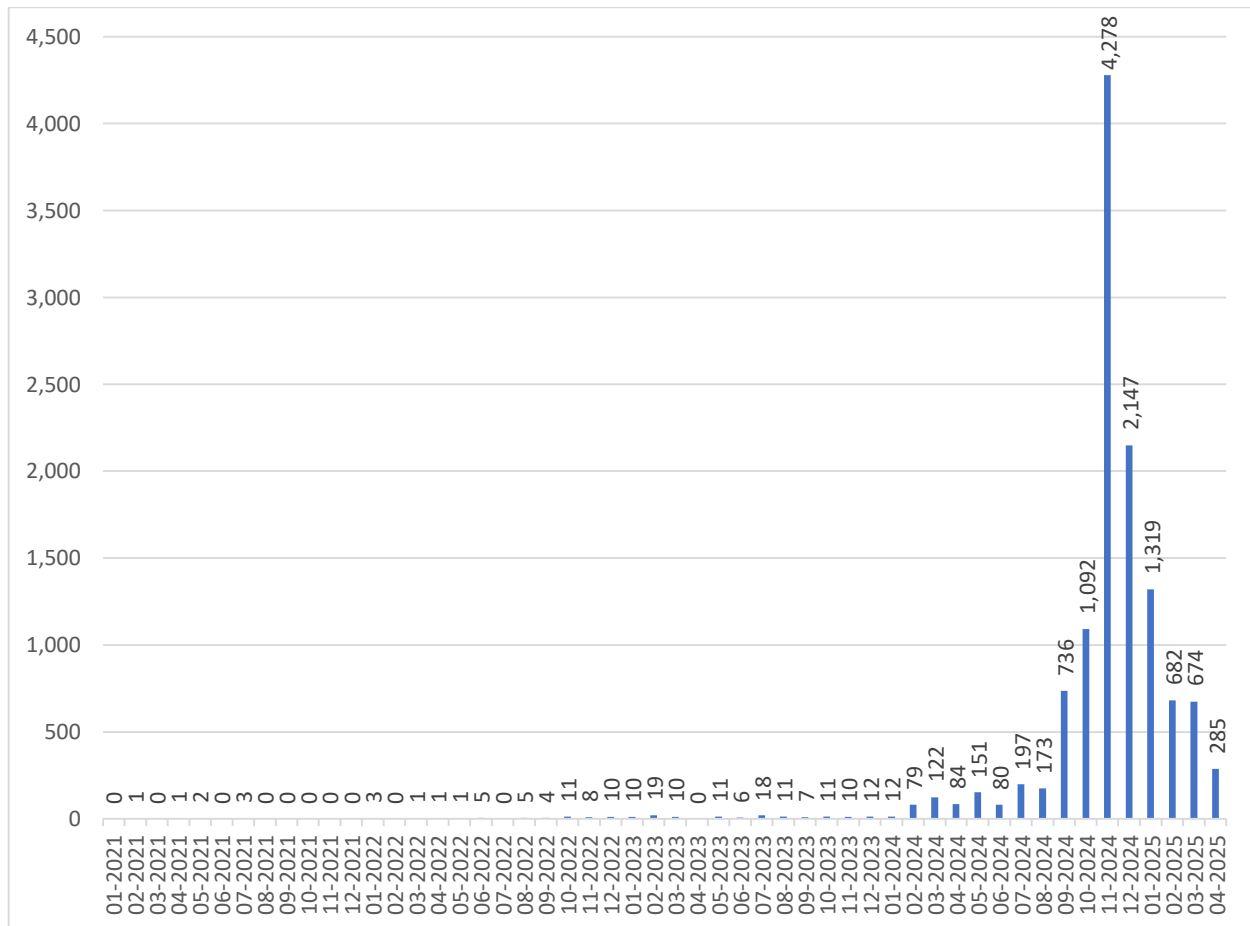
142. Dentsply’s egregious violation of the Medical Device Reporting and Quality System Regulation rules is apparent from Dentsply’s own belated reporting to the FDA since September 2024, which is publicly available (with redactions for individual privacy) on the internet on the MAUDE database. The FDA generally makes new reports available in the public MAUDE database one month at a time, generally releasing new batches of reports in the next month.

143. Following the Byte acquisition through January 2024, Dentsply reported very few serious patient injuries to the FDA regarding Byte. In several months during this period, including from August 2021 to December 2021, Dentsply reported zero patient injuries. And prior to February 2024, the most injuries Dentsply reported in one month was 19, in February 2023. Of the few reports that Dentsply did make during January 2021 to January 2024, most involved relatively minor issues (such as allergies) that did not call into question Byte’s safety and efficacy or its ability to deliver growth and strategic synergies to Dentsply.

144. In fact, Dentsply only began meaningfully reporting the serious injuries Byte patients were experiencing and that management was tracking when it became clear the FDA was taking action. Specifically, Dentsply's reporting of serious injuries increased from February to August 2024, reflecting an uptick to between 79 and 197 injury reports for Byte per month. Then, starting in September 2024 and continuing through April 2025, Dentsply started reporting hundreds to thousands of injury reports for Byte per month—including reports that had occurred months and sometimes years beforehand and which were known and tracked by senior management throughout the Class Period. As confirmed by FE-8,¹⁰ management had already raised awareness of Byte's underreporting at an internal meeting in 2023, during which management informed Byte employees that the Company was not sufficiently reporting injuries to the FDA. FE-8 stated that in approximately June 2024, management called a second meeting warning Byte employees that the influx of injury reports could be capturing the FDA's attention, and instructed employees not to speak to anyone from the FDA without management present. The following graph illustrates the number of FDA reports concerning Byte made by Dentsply, on a monthly basis, sorted by the month in which the report was made. As shown below, Dentsply reported 4,278 injuries in November 2024—the month immediately after Dentsply was forced to disclose that it was suspending the sales and marketing of its Byte aligner kits.

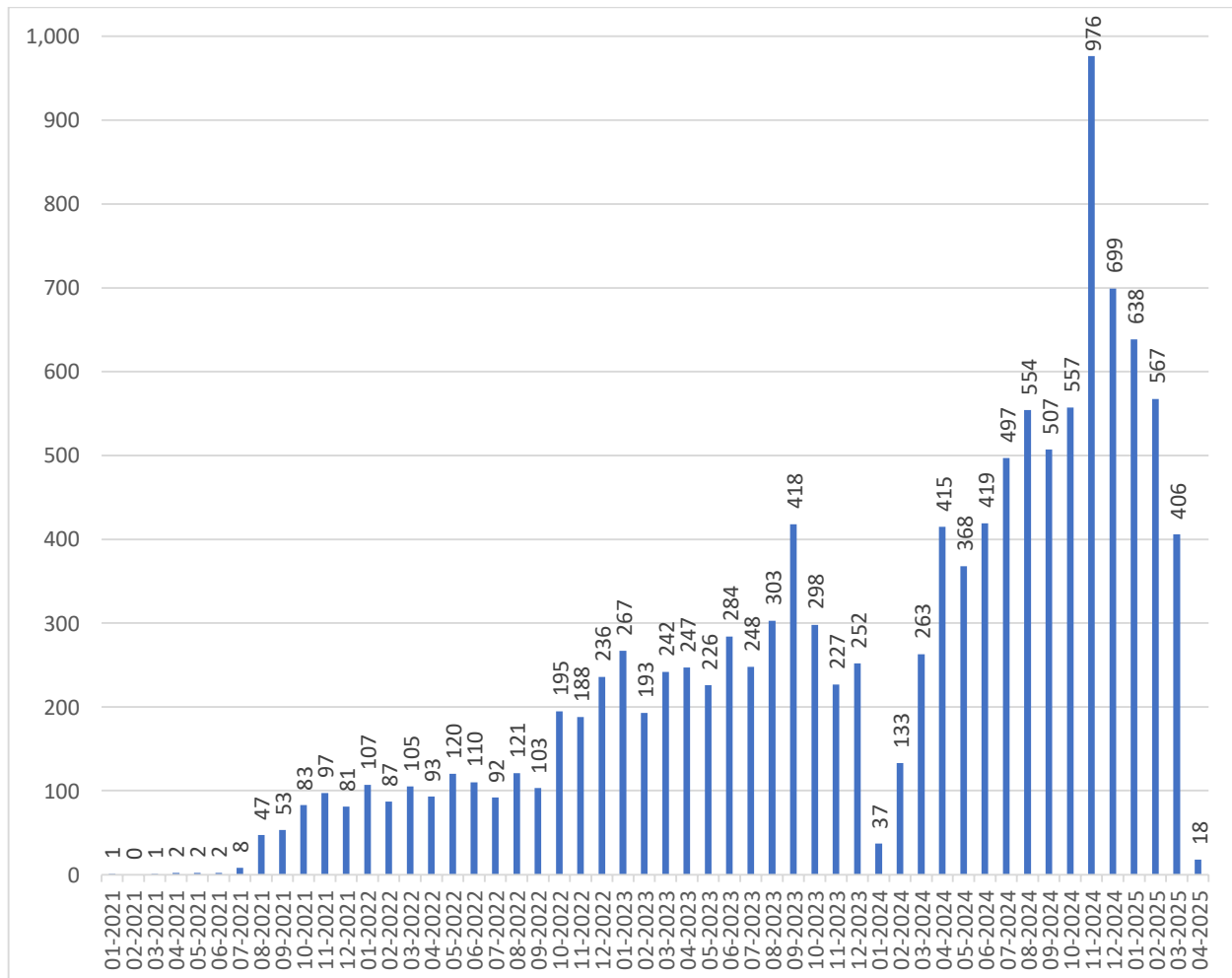
¹⁰ FE-8 worked as an "S1" Sales Specialist and then as a Records Specialist at Byte from March 2021 to January 2025.

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



145. The majority of the spike in reports regarding Byte from September 2024 to April 2025 are **not** timely reports made within 30 days of when Dentsply became aware of the serious patient injury. Rather, the majority of those reports were filed **months or years after** Dentsply became aware of the serious patient injury, including serious patient injuries dating all the way back to 2021. The graph below displays the number of serious patient injuries for Byte, reported by Dentsply to the FDA, sorted by the month in which—according to Dentsply’s own report—Dentsply became aware of the injury.

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



146. In other words, nearly **every month** during the Class Period, Dentsply was aware of **dozens to hundreds** of serious patient injuries and malfunctions that it failed to timely report to the FDA. The vast majority of these suppressed adverse events were not reported to the FDA until September 2024 or later.

147. Dentsply's admission in the retrospective reports that it was aware of serious patient injuries dating back to 2021 is also confirmed by former employees. For example, a former Dentsply customer service employee for Byte, quoted by *The Capitol Forum*, reported that "**the injuries really started pouring in 2021,**" while FE-3 similarly explained that he received numerous

complaints of patient injuries—including lacerations and other problems—throughout his tenure from June 2020 to May 2022.

148. Dentsply has stated (in certain reports available on MAUDE) that its retrospective review was limited to adverse events that occurred during May 17, 2021 to May 31, 2024. Thus, Dentsply’s failure to file retrospective reports prior to the May 17, 2021 does not show that Dentsply complied with FDA reporting requirements prior to that date. Moreover, given Dentsply’s abject failure to file serious injury event reports concerning Byte, the lack of reports of adverse events filed by Dentsply from the beginning of the Class Period to the May 17, 2021 date does not suggest there were few or no injuries during that time period. To the contrary, Dentsply identified serious patient injuries that it was required to report—but did not timely do so—for every month covered by its retrospective review.

149. During the Class Period, Dentsply failed to timely report at least **6,894** serious patient injuries and malfunctions that Dentsply has since reported to the FDA. Those included, among other serious patient injuries, at least 2,466 incidents of deformity/disfigurement, 1,777 incidents of laceration, 1,160 incidents of tooth fracture, 345 incidents of tissue breakdown, 189 incidents of hemorrhage/bleeding, and 110 incidents of necrosis.

150. Prior to January 2024, based on Dentsply’s own reporting, **at most 160 out of 5,139** (or **3%**) serious patient injuries and malfunctions were timely reported. Prior to September 2024, based on Dentsply’s own reporting, **at most 1,305 out of 7,825** (or **16.7%**) serious patient injuries and malfunctions were timely reported.

151. In light of Dentsply’s severe failure to report Byte serious patient injuries to the FDA, if the Executive Defendants had “review[ed] the suitability and effectiveness of the quality system,” as they were required to do by the FDA’s Quality System Regulation and represented

that they did, they could not have concluded that Dentsply had an effective system to comply with the FDA's Medical Device Reporting rule.

152. Despite being legally required to report serious injury caused by Byte to the FDA, Defendants withheld those reports as part of a fraudulent scheme to create a false impression about Byte's safety record. Defendants' scheme was intended not only to deceive the immediate required recipient of the serious injury reports, *i.e.*, the FDA, but also others who Defendants knew would have access to the serious injury reports through the FDA's MAUDE database. For example, during the Class Period, Dentsply was actively lobbying state legislatures and state dental boards not to pass laws or regulations imposing patient-safety requirements on direct-to-consumer clear aligners. In doing so, Dentsply specifically cited a supposed lack of "any clinical or evidentiary support" to justify additional patient protections—despite the fact the Company was at the same time withholding ***hundreds*** of injury reports from Byte patients. Dentsply senior executives were acutely aware that state legislators and dental boards looked to MAUDE reports and believed that any reported injuries would be seized upon by opponents of direct-to-consumer clear aligners—indeed, patient advocates expressly identified the injuries reported in the MAUDE database in testimony advocating for the legislative changes that Dentsply opposed. If Dentsply had timely filed the required injury reports, that also would have undercut Defendants' false statements to investors about Byte's commercial and strategic value.

G. Dentsply Used Non-Disclosure Agreements To Silence Patients With Injuries

153. In addition to failing to report Byte serious patient injuries and malfunctions to the FDA, throughout the Class Period, Dentsply also used non-disclosure and non-disparagement agreements ("NDAs") to prevent patients who were injured by Byte from disclosing those facts to the public. Dentsply would condition its offer of a refund on the patient's signing the NDA.

154. Specifically, as uncovered during Lead Plaintiffs’ investigation into litigation against Dentsply and Byte, and reported by Byte patients, Dentsply used a form NDA in resolving patient injury complaints that prevented those patients from making any public statements regarding their experience with Byte, including by prohibiting them from making public statements about “the facts, claims or circumstances asserted in and/or giving rise to the complaint.” The NDA also contained a non-disparagement clause that barred patients from making “any comments regarding Byte’s business practices or operations,” and specifically identified “comments and statements made on social media, networking and blogging sites” as constituting a material breach of the agreement.

155. Dentsply’s use of NDAs to conceal the true facts about Byte’s safety profile is particularly alarming in light of the fact that, before the Class Period, SmileDirectClub had been criticized for employing NDAs to silence injured customers—including in a January 21, 2020 *The New York Times* article that highlighting the practice. See Erin Griffith, *This Company Says It Will Fix Your Smile. It May Shush You if It Doesn’t*, N.Y. Times (Jan. 21, 2020). In January 2023, SmileDirectClub settled a lawsuit brought by the District of Columbia Attorney General, alleging that the use of NDAs was a deceptive trade practice, and agreed to release customers who asked for refunds from nondisclosure agreements. Despite this, Dentsply continued to insist that injured Byte patients sign NDAs to conceal the true facts about Byte.

H. Defendants Continue To Mislead Investors Concerning Byte As Dental Organizations Raise Alarm Bells And The DTC Market Leader Collapses

156. Through these deceptive measures, Defendants were able to maintain the illusion that Byte was different than the market leader—SmileDirectClub—which, by 2023, had become a posterchild for the dangers posed to patients by the direct-to-consumer aligner model. By the beginning of 2023, SmileDirectClub had become the target of numerous patient and orthodontic

and dental organization lawsuits targeting its core business model, as well as the Attorney General for the District of Columbia, who filed a lawsuit challenging SmileDirectClub's alleged deceptive practices, including its use of NDAs. In September 2023, in the face of this onslaught of litigation and increasing regulatory action, SmileDirectClub filed for bankruptcy, shuttering the market leader of DTC clear aligners.

157. Throughout this time, Dentsply senior management continued to tell investors that Byte was different than SmileDirectClub, that the Byte business was “doctor-directed,” safe, and viable, and that, if anything, SmileDirectClub's demise would benefit Dentsply. In fact, rather than suggest the SmileDirectClub's experience foreshadowed any problems with Byte, Defendants told investors that an “uptick” in sales following SmileDirectClub's closure was **not** a “one-time bump”—but rather, Dentsply had continued to invest in “treatment planners, clinical operations, support people, salespeople, etc. knowing that we're expecting to see a faster growing business” and that “this is a business that should be growing double-digits consistently.”

158. Indeed, between February and May 2024, Defendants Campion and Coleman repeatedly claimed that Dentsply was continuing to invest in Byte by hiring “**more treatment planners**” and “**increasing the number of treatment planners.**” However, as reported by FE-1, at the time Defendants made these statements, Dentsply was actually reducing its treatment planning workforce, having terminated approximately 50 of the 320 treatment planning employees in Costa Rica at the beginning of 2024 and did not at all “increase” the number of treatment planners in 2024.

159. At the same time Defendants made these false statements reassuring investors about Byte's safety and growth, Defendants were secretly violating FDA regulations requiring them to report the serious Byte injuries they knew were occurring. Despite the severe consequences of

failing to report these injuries, Dentsply took this course because senior management knew doing so would expose Byte's true safety profile and quickly bring about the demise of the business.

160. Indeed, over the course of 2023, numerous state legislatures considered measures that would do just that—impose strict restrictions on direct-to-consumer aligner products that, Defendants feared would destroy Byte's business model. In 2023 and 2024, three states (Nevada, Florida, and Illinois) passed legislation that posed a substantial challenge to Byte's business model. Dentsply management was acutely aware of these measures, tracked their progression, and lobbied against them. Most significantly, the legislative focus on Byte's direct-to-consumer business model motivated Dentsply to continue concealing Byte injuries from the FDA.

161. That is because debates over potential legislation turned on arguments concerning the safety profile of DTC aligners—and specifically, whether they posed a greater patient risk than in-person treatments. And by and large, the data for those differences were sourced from the FDA and its MAUDE database. This dynamic was well understood by Dentsply senior management and motivated Dentsply's decision to fail to report the injuries it was tracking throughout the Class Period. As Dentsply's senior executives well knew, serious patient injuries reported to the FDA would become publicly available online through the FDA's MAUDE database, and those reports would prompt state legislatures and state dental boards to curtail aspects of Byte's direct-to-consumer clear aligner business model.

162. In fact, advocates of these new measures cited the injury reports of Byte's competitors, like SmileDirectClub, as evidence of the measures' necessity. For example, Dentsply worked to oppose an Illinois measure proposed in May 2023 that would have required in-person examination for clear-aligner products—including by funding the testimony of Dr. Khorsandi, who

advocated against the measure on behalf of Byte at a March 2024 Illinois Senate Licensed Activities Hearing and through other efforts by Byte’s lobbying firm, McGuireWoods Consulting.

163. In fact, due to their deliberate concealment of Byte injury reports, Dentsply was able to successfully lobby against an earlier attempt by the Illinois Department of Financial and Professional Regulation to enact a similar regulation through the state’s rulemaking process in March 2022 that would have mandated a “review of the patient’s most recent x-rays” and an in-person visit within the previous year prior to the provision of teledentistry services. In an April 25, 2022 letter signed by Byte’s Director of Government Affairs and Community Relations Shirley Kim, Byte argued that the measure was without “any clinical or evidentiary support” and failed to cite “any underlying data”—despite the fact that, at the time, hundreds of Byte injuries had been reported to Dentsply but not to the FDA. In part due to Dentsply’s lobbying efforts, the measure was abandoned as set forth in a February 2023 notice in the Illinois Register.

164. Legislators in Florida introduced similar legislation in late 2023. Those bills would result in the “denial of a license or disciplinary action” if any licensed dentist failed to “perform an in-person examination of the patient or obtain records from an in-person examination within the last 12 months,” including the patients’ x-rays or “equivalent bone imaging,” prior to beginning treatment with an “orthodontic appliance,” such as clear aligners. In other words, just like in Illinois, Byte patients in Florida would be required to either meet with their dentist in-person or submit x-rays prior to receiving clear aligner treatment.

165. Like it did in Illinois, Byte aggressively lobbied against the measures, including by obtaining testimony from a dentist who was purportedly a member of Byte’s network. Specifically, on January 16, 2024, Dr. Angela McMullin testified at the Florida Senate on behalf of Dentsply and Byte in opposition to the measure, stating that as a licensed dentist in Florida she worked with

Dentsply to prescribe Byte clear aligners. In her testimony, Dr. McMullin described how Dentsply and Byte ensured “that each Florida patient receives an individualized treatment plan that is reviewed, prescribed, and ***overseen by a Florida licensed dentist or orthodontist***,” described the “***review process [as] a comprehensive one***,” and stated that the dentist who prescribes the treatment plan can “***advise the patient directly*** through the company’s portal.”

166. Dr. McMullin also testified that “provided the patient is approved for treatment, ***the patient stays with that same Florida licensed dentist***, . . . and ***if there are any issues they run into, the dentist is the one consulted on how to proceed***.” Though Dr. McMullin clarified that Byte was opposed to the measure’s requirement of a “mandated in-office exam or in-office x-ray,” Florida legislators were left with the impression that Byte was already in substantial compliance with its regulations based on her representations about how actual dentists oversaw Byte treatments. Indeed, after hearing Dr. McMullin’s testimony, Florida State Senator Gayle Harrell summarized McMullin’s testimony as follows: “everything that’s in this bill, you’re already doing.”

167. The debate over the Florida measures was particularly focused on whether the current practices of direct-to-consumer clear aligner companies posed a greater risk of injury to patients—and advocates of the bills specifically referenced the MAUDE database to depict the relative threat posed by each type of treatment under the current regulatory regime. At a January 17, 2024 hearing, a leading orthodontist advocate, Trey Lawrence, the Vice President and General Counsel for the AAO, pointed to the MAUDE database for evidence of increased injuries for dental aligners like SmileDirectClub, testifying:

The Food and Drug Administration has a database [i.e., the MAUDE database] for these clear aligners where complaints can be registered by a dentist. The number of complaints against the leading direct to consumer company that has just recently gone out of business [SmileDirectClub] was multiple times—four or five times the

number of complaints—of the leading brand that you would’ve heard of that can only treat through a dentist or orthodontist in person which has millions more patients [Invisalign].

168. After the Nevada and Florida laws were enacted (and while the Illinois law was already under consideration), Defendants continued to assure investors that any resulting headwinds would be of little long-term consequence to Byte. For instance, in the Company’s Form 10-Q filed on July 31, 2024, Dentsply disclosed that:

[E]nacted and pending legislative changes in certain [] states including ***Florida and Illinois are expected to impact sales in the second half of 2024.*** These changes would require certain adjustments to our business model, some of which have been made preemptively and have started to negatively impact sales of direct-to-consumer aligners in those states. . . . Our response to these legislative developments resulted in reduced sales of direct-to-consumer orthodontic aligners by approximately \$6 million during the second quarter of 2024, with a similar estimated impact for each of the remaining quarters of 2024, ***which we expect will be more than offset by organic growth.***

169. Dentsply was able to convince investors that this was true because Dentsply had failed to report the injuries Byte was causing to the FDA. Dentsply only warned that additional harm to the Byte business could result if “other states” adopted legislative or regulatory changes—without disclosing the alarming injuries that Byte was causing, that Dentsply had failed to report them to the FDA, or that legislators were specifically looking to the MAUDE data when considering legislation impacting Byte.

170. For example, on Dentsply’s July 31, 2024 earnings call, Defendant Coleman acknowledged “the evolving legislative and regulatory environment,” but stated that the Company still “expect[ed] Byte to grow approximately 15% for the full year,” albeit down from the Company’s “previous estimate of more than 20% growth.”

171. On that same earnings call, an analyst with Stifel, Nicolaus & Company asked Defendant Campion, with regards to the state legislation, “it’s sort of been drip, drip, drip with some states. . . . [W]here does this go longer term, [] when we think out over the next couple of

years[?] Or do you feel like the states that have moved, have moved and you’ve largely ring-fenced this as we think about things going forward?” Defendant Campion replied:

[T]hat legislation varies state to state, but there are some common themes between them all. ***We’ve done a number of things to mitigate that.*** Number one, we’ve invested in government relations or more investment in government relations to help states understand the process of direct-to-consumer aligners.

And then secondarily, ***we’ve adjusted our internal processes to facilitate these changes that some states are mandating.*** And then I’d say, thirdly, ***the Byte Plus model, which continues to gain some momentum and traction is also going to help us here.*** I think the adjustment that you’ve seen in the growth rates is because of the incremental steps and arguably costs to patients, because they’ve to take some time out of work to go to the dentist, or do a teledentistry visit. So ***it’s not a reflection on the product that we provide.*** It’s a reflection of rather on the internal steps that these regulations are enforcing or placing on potential customers. And it continues to evolve

172. Even after the Illinois law passed in August 2024, Defendants continued to downplay the impact of the regulatory headwinds facing Byte. Specifically, at Baird’s 2024 Global Healthcare Conference on September 10, 2024, in response to an analyst question regarding how to “keep that demand growing over the next couple of years on the DTC side,” Defendant Campion stated that despite any “regulatory challenges . . . the growth profile is still pretty robust in the direct-to-consumer business . . . it’s certainly still double-digit revenue growth in that space.”

I. Management Admits Internally That Dentsply Is Failing To Report Serious Patient Injuries For Byte To The FDA

173. As injuries continued to be reported internally through Dentsply’s Trackwise System at alarming rates, Dentsply slowly began to increase the number of Byte adverse events reported to the FDA. Predictably, these new reports were immediately picked up by journalists and others carefully monitoring the MAUDE database for information about companies like Dentsply and products like Byte. On June 28, 2024, investigative journalists from *The Capitol Forum* reported an uptick in the number of Byte injuries reported through the MAUDE database, noting that there had been a sharp increase in reports over the last few months. The article noted

that Dentsply had historically reported around 10 Byte injuries per month until February 2024, when “that number began to drastically increase, with 146 injuries submitted in May.”

174. Dentsply publicly downplayed the increase in reports and denied that it reflected any issues with the Byte product. In response to questions from *The Capitol Forum*, a Dentsply spokesperson said that the increase in reports was “***strictly related to our efforts to continuously improve our process in alignment with current, global regulatory requirements.***” Critically, the Dentsply spokesperson represented that it strictly adhered to FDA reporting requirements, and said that at Dentsply, “***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.***”

175. The Dentsply spokesperson further reassured investors and the public that Dentsply “will continue to monitor medical device reports and adverse events associated with this device” and took “seriously our role to provide timely and accurate information to the public and will keep health care providers and the public informed if any new safety information becomes available.”

176. Despite Dentsply’s public assurances, internally at the Company, it was clear that coming clean and disclosing Byte injuries to the FDA spelled doom for the business. As was later reported by *The Capitol Forum*, in July 2024, reacting to the increased media and regulatory scrutiny into Byte’s safety, Dentsply held an emergency internal meeting in which senior management acknowledged that Dentsply had been failing to report serious patient injuries related to Byte to the FDA, as it was required to do by the FDA’s Medical Device Reporting and Quality System Regulation rules.

177. That Company insider acknowledged that “***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*** and here’s how you should be doing them.’” As *The Capitol Forum* reported, while Dentsply personnel were not told about the actual injuries at this meeting—“just about the new reporting system”—when the employees saw the rates of injuries that Defendants had been tracking throughout the Class Period, and just how serious those injuries were, it was immediately apparent that Byte would quickly go out of business. As the insider told *The Capitol Forum*, “When people saw those injuries, they were like ‘Oh my God, this is bad.’ People started looking for new jobs.”

178. As made clear by Dentsply’s later admissions, the July meeting occurred at the same time the FDA’s scrutiny was forcing the Company to come clean. As Defendant Campion later explained on the Company’s November 7, 2024 earnings call, Dentsply made the decision to suspend the sale and marketing of Byte “in communication with the FDA and remain in close contact with them.” Further, the FDA-mandated patient communications for the Byte suspension—including the “Important Message for Patients” dated October 25, 2024—similarly acknowledges that the FDA was driving the market withdrawal, and states that the decision was made “[d]uring review and discussion of a subset of medical device reports related to our Byte Aligner product, and through our communication with the FDA.”

179. As the FDA bore down, the number of Byte adverse events that Dentsply reported to the agency spiked correspondingly. As described above, Dentsply made very few reports of serious patient injuries prior to February 2024; an increased number of reports between February and August 2024; and then a massive number of reports starting in September 2024—a clear acknowledgement that Dentsply had failed to file required reports with the FDA, and was only belatedly doing so at the agency’s insistence once it became clear that its fraudulent scheme was

no longer sustainable. As that data showed—and as an investigation by *The Capitol Forum* that included interviews with patients and former employees as well as an analysis of that same MAUDE data concluded—Dentsply “knew its dental aligners were causing severe patient injuries for years but did little to investigate those injuries or notify the FDA.”

VI. THE TRUTH ABOUT BYTE EMERGES IN A SERIES OF DISCLOSURES

180. Investors began to learn the truth when Dentsply announced that it was suspending sales and marketing of Byte aligners following conversations with the FDA regarding the Company’s highly dangerous practice of enrolling contraindicated patients. Investors learned the truth about Dentsply’s Byte marketing practices, the sales to contraindicated patients resulting in injuries, and the Byte suspension—which was ultimately revealed to be permanent—through a series of corrective disclosures over the course of four months.

181. First, on October 24, 2024, after the market closed, Dentsply stunned investors by announcing the “voluntary suspension of sales and marketing of its Byte Aligners and Impression Kits while the Company conducts a review of certain regulatory requirements related to these products,” stating that the decision to suspend sales and marketing was made “in consultation with” the FDA. The October 24 press release further announced: “The Company expects to record non-cash charges for the impairment of goodwill within the range of \$450 - \$550 million, net of tax, pertaining to two of its reporting units, Orthodontic Aligner Solutions and Implants & Prosthetic Solutions, which together comprise the Orthodontic and Implant Solutions segment.”

182. In an attempt to minimize the connection between Defendants’ fraudulent behavior and the necessity of the impairment, the Company characterized the “decline in fair value for the Orthodontic Aligner Solutions reporting unit” as being “driven primarily by adverse impacts from state regulatory trends pertaining to the Company’s Byte Aligner business.” However, the October 24 announcement was **not** preceded by any **new** regulation of clear aligners adopted by **any** U.S.

state. To the contrary, the only thing that changed since Dentsply's July 31, 2024 disclosure (after the Nevada and Florida laws were passed and the Illinois law was under consideration) assuring investors that any impacts from state regulatory trends "will be more than offset by organic growth" was that the FDA had uncovered Dentsply's reporting violations.

183. On a conference call held before the market opened the following day, Defendant Campion elaborated that the suspension of sales and marketing of Byte was due to FDA regulations concerning "post-market surveillance" and "reporting"; admitted that Dentsply was doing "retrospective" (*i.e.*, not timely) reporting of Byte injuries; and admitted that Dentsply had been selling Byte to contraindicated patients:

We disclosed that Dentsply Sirona voluntarily suspended sales and marketing of our Byte Aligners and Impression Kits. We've also suspended shipments and processing of new and recently placed orders for Byte Aligners and Impression Kits. This decision is related to a review we are conducting regarding certain regulatory requirements for these products, and it was made by ***working closely with the US FDA***. ...

[W]e have proactively taken steps to continuously improve our ***post-market surveillance processes***. One way we do this is through the company's operating model, which includes ***retrospective analysis and reporting***. Through this process and in connection with our ***ongoing discussions with FDA***, we have determined ***that our patient onboarding workflow may not provide adequate assurance that certain contraindicated patients do not enter treatment with Byte Aligners....***

184. The FDA regulatory requirements applicable to Byte had remained unchanged in relevant part throughout the Class Period, including the FDA's Medical Device Reporting and Quality System Regulation rules. Up until this point, Defendants had repeatedly and falsely stated that Dentsply complied with those regulations, so the confession that Dentsply needed to conduct a "review" of those regulations or come into "retrospective" compliance with its reporting obligations was shocking, highly material, and highly adverse information.

185. Nonetheless, Defendants attempted to downplay the severity of these disclosures on the October 25, 2024 conference call. In response to an analyst question regarding how the

Company was “supporting those customers” for whom treatment had been “paused,” Defendant Campion stated, “[W]e continue to believe that the potential risk to patients remains low. . . . There have been no changes to the quality, safety and effectiveness of the Byte Aligners and Impression Kits.” Defendant Campion further told investors that “we have not established a causal link between the Aligners and Impression Kits and any reports of serious injuries or adverse results”—without disclosing that senior management had in fact directed Byte sales representatives to sell to contraindicated patients.

186. On October 25, 2024, Byte also published on its website and emailed to its patients an “Important Message for Patients.” That message reiterated the suspension of Byte sales, which it attributed specifically to issues with “medical device reports” and “communications with the FDA,” and admitted that Byte had been sold to “contraindicated” patients, including patients with “known active periodontal disease, severe open bite, severe overjet, tooth malocclusion requiring surgical correction, mixed dentition, [] dental prosthetics or dental implants, [and] adolescents with a skeletally narrow jaw”:

During review and discussion of a subset of medical device reports related to our Byte Aligner product, and through our communication with the FDA, we have determined that our patient onboarding workflow may not provide adequate assurance that certain contraindicated patients do not enter treatment with Byte Aligners. ...

If you are currently in Byte Aligner treatment and have known active periodontal disease, severe open bite, severe overjet, tooth malocclusion requiring surgical correction, mixed dentition, have dental prosthetics or dental implants, or are an adolescent with a skeletally narrow jaw, please stop treatment. We also recommend that you visit a dentist to review your overall oral health. ...

187. Analyst reaction in reports published on October 24 and October 25, 2024 confirms that the disclosures were unexpected, negative, and material. As characterized by a Piper Sandler analyst report, the “DTC Clear Aligner Market on Life Support” posed “‘Material’ Revenue Risk to XRAY.” UBS analysts noted that “XRAY Surprises With Suspension of Byte Sales,” while

BofA Securities analysts noted that Byte's withdrawal "matters" because it "[p]resses" Dentsply's "growth algorithm even more," such that "near-term risks as elevated, with lower visibility into growth heading into FY25."

188. However, analysts also credited Defendants' downplaying of the severity of Byte's issues, with Evercore ISI stating in a report published October 25, 2024 that one of the "Key Takes from the call" is that "[t]here has been no record of serious injury or adverse results."

189. In response to Dentsply's admissions that it was suspending sales and marketing of Byte because of FDA regulatory issues and that it had sold Byte to contraindicated patients, Dentsply's stock price fell \$1.10 per share, or 4.51%, from a close of \$24.41 on October 24, 2025 to a close of \$23.31 on October 25, 2024, on heavy trading volume.

190. Second, on November 7, 2024, Dentsply disclosed further negative news about Byte, revealing troubling new details regarding the scope and duration of the suspension and its financial impact on the Company. Specifically, Dentsply filed a Form 8-K before the market opened that day disclosing (1) Dentsply was lowering full year organic sales outlook and EPS guidance due to "the evolving landscape with Byte," including "the voluntary suspension of sales, marketing, and shipments of Byte Aligners and Impression Kits" and purported "legislative changes affecting the direct-to-consumer aligner business model"; (2) a \$145 million impairment of goodwill for the Orthodontic and Implant Solutions segment due to the Byte withdrawal; and (3) that the Company would incur additional costs, "not include[d]" in its outlook, from "additional Byte remediation measures."

191. On the earnings call held that same day, a Needham & Co. analyst asked, "how long you think the [Byte] suspension might last?" In reply, Defendant Campion revealed that Dentsply had informed the relevant Byte employees that their jobs would cease to exist:

We've taken very fast action on the cost side. We've ceased all marketing activities. For example, ***we informed the – all – shall we say, relevant employees yesterday that their jobs will be ceasing to exist over the next couple of weeks.*** And the redeployment of assets that we think can be redeployed is ongoing, but we already have moved different groups of people, such as software developers over to other areas of our business.

192. In response to Defendant Campion's statement that the Byte employees had been given notice, another analyst commented, "[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." Defendant Campion pushed back, stating, "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."

193. Analyst reaction in reports published on November 7, 2024 confirms that these additional disclosures were highly unexpected, negative, and material. Analysts largely concluded that despite Campion's equivocation, the Byte suspension might be permanent. For example, Evercore ISI stated, "Tough day. Today's update to . . . the 2025 financial implications from the Byte suspension (which we are assuming will be permanent), have complicated the outlook for XRAY." Leerink Partners stated that "our previous view had been that the company has numerous levers to sustain profit growth. With ongoing growth challenges, the Byte suspension (we have removed Byte from our model for now), and what remains a choppy market, we find it hard to remain constructive until we see better data points."

194. In response to the news about Byte, Dentsply's stock price collapsed—***falling over 28%***, or \$6.72 per share, from a close of \$23.98 on November 6, 2024, to a close of \$17.26 on November 7, 2024, on extraordinarily high trading volume.

195. Third, on January 14, 2025, Dentsply confirmed that the suspension of Byte as a direct-to-consumer product was permanent, and that the direct-to-consumer business model was

being abandoned. Specifically, Dentsply published a press release before the market opened stating that “the Company plans to refocus the Byte business model around treatments that include expanded in-person dentist oversight.” The press release also stated that Dentsply “is not reinstating the at-home Byte Aligner Systems and Impression Kits but will continue to provide support for non-contraindicated Byte Aligner patients currently undergoing treatment.”

196. In a report published on January 14, 2025, UBS analysts credited the Company’s representations that Byte would return to the market with expanded in-person dentist oversight. Specifically, in that report, UBS analysts said their assessment of Dentsply shares turned on, among other things: “(1) what timeframe XRAY expects to receive FDA approval and re-launch Byte Plus by (or some other iteration of the system), (2) how revenue and margin per case economics from Byte Plus differed from traditional Byte, (3) what scale in-office treatment will need to operate at in order to achieve EBIT [earnings before interest and taxes] breakeven . . . , and (4) a better understanding of how an in-office focused Byte offering will differ from the company’s existing in-office aligner system (SureSmile).”

197. In response to the January 14, 2025 news that Dentsply would officially not be reinstating at-home treatment with Byte and would instead be refocusing the Byte business model around expanded in-person dental oversight, Dentsply’s stock fell by \$0.60 per share, or 3.5%, from a close of \$18.66 on January 13, 2025, to a close of \$18.06 on January 14, 2025.

198. Last, on February 27, 2025, Dentsply disclosed additional news about Byte, revealing that, contrary to Defendants’ prior representations, the business was being shut down entirely, hundreds of millions of dollars of Byte goodwill was being written down to zero, and that the Company had incurred tens of millions of dollars in remediation, refund and other costs related to the Byte shut-down. Specifically, before the market opened that day, Dentsply disclosed that:

(1) the Byte shut-down reduced full year 2024 net sales by 1.2%, reduced fourth quarter 2024 sales by 6.1%, and reduced the Company's full year 2025 net sales outlook by 2%; (2) the Byte shut-down and remediation resulted in a fourth quarter EPS hit of \$0.24 per share compared to the guidance provided in November; and (2) Dentsply had recorded an additional charge of \$370 million representing a "**full write-off** [of] the Byte trademark based on a determination that the trademark **will not be used in the future** aligners operating model."

199. On the call that same day, Defendant Coleman's replacement, Interim CFO Herman Cueto, explained that the Byte drag on net sales also included "an incremental \$29 million associated with Byte estimated customer refunds recognized in Q4"—and that the "suspension of sales and marketing of Byte Aligners resulted in a charge for customer refunds above what we contemplated on our November call." In response to a question about the full write-off of the Byte trademark, Defendant Campion reiterated "we are exclusively focusing now on SureSmile."

200. Dentsply's new CFO put it more bluntly when responding to an analyst's question about Byte becoming a potential "tailwind" after some restructuring, and whether the brand and business could positively contribute to the Company's results going forward. According to Cueto, that was the wrong way to think about the Byte business, and that investors should instead "think of Byte as a very substantial headwind to Dentsply growth in 2025," as remediation and other costs from Byte "will put pressure on the margins, especially Q1 and Q2,"

201. Analyst reaction in reports published on February 27 and 28, 2025 confirms that the disclosures were unexpected, negative, and material. For example, Jefferies noted that Dentsply badly missed guidance "on both rev and EBITDA as macro pressure and ongoing headwinds from Byte continue to weigh on the business." Barrington Research stated that while Dentsply's "fourth quarter results were generally weak," they were "absolutely driven through the

floor via the impact of the Byte shutdown including \$62 million in lost revenue and refunds,” and that the Byte shut-down was “was the key driver of the awful result[.]” UBS agreed that the results were “much worse than expected,” particularly with regard to the EPS miss resulting from Byte—“a \$0.17 miss vs. the midpoint of the guide that was set in November”—with the analysts questioning how “management underestimated the impact of the stranded and other costs associated with the halt in Byte sales and operations in October.”

202. In response to the news about permanent shut-down of Byte, its impact on sales and EPS, and the “full write-off” of Byte goodwill, Dentsply’s stock price plunged again, by \$1.66 per share, or **8.83%**, from a close of \$18.81 on February 26, 2025, to a close of \$17.15 on February 27, 2025, on heavy trading volume.

VII. POST-CLASS PERIOD DEVELOPMENTS

203. After the end of the Class Period, additional facts have continued to be revealed that further demonstrate the false and misleading nature of Defendants’ prior misstatements. In March 2025, the Company submitted to the FDA an additional 674 reports of injuries caused by Byte, including more cracked and missing teeth, severe jaw pain and bleeding, and gum disease and recession. According to a report published by *The Capitol Forum* on April 17, 2025, “Narratives submitted with those reports reveal that dentists are increasingly finding contraindicated patients.” Indeed, over 100 of those 674 reports contained the word “contraindicated”—further demonstrating the pervasiveness of Byte’s illicit sales practices.

204. Consistent with its prior belated reporting, in April 2025, the Company submitted an additional 285 reports of injuries caused by Byte to the FDA. These belatedly filed reports identified instances of additional fractured and lost teeth, with 60 reports (over 20%) indicating the patient was contraindicated.

205. Dentsply's fraudulent practices related to Byte are also now the subject of lawsuits. On March 7, 2025, Byte patients brought a class action complaint alleging that Dentsply falsely and deceptively marketed Byte Aligner Systems and Impression Kits. *Phillips v. Straight Smile LLC*, No. 1:25-cv-21074 (S.D. Fla.). Among other things, the patients allege that Dentsply "lacked essential feedback loops to timely advise regulators and, by extension the public, of adverse incidents involving their products," and that contrary to the Company's public statements, Byte products "were not sufficiently overseen, reviewed, or directed by a medical professional."

206. In the wake of these disclosures, the SEC has also initiated or otherwise expanded an ongoing investigation to specifically target Dentsply's conduct concerning its Byte Aligner Product line.

207. In fact, Dentsply has admitted that during the Class Period, the Company's processes for reporting injuries to governmental authorities such as the FDA were deficient. Specifically, in Dentsply's Form 10-K for fiscal year 2024, filed on February 27, 2025, Dentsply admitted under "Item 1A. Risk Factors" that the Company is "currently in the process of implementing enhancements to our post-market surveillance processes and reportability criteria, which has resulted in an increase in the number of regulatory reports that we have filed, including retrospective reports, for complaints regarding medical devices."

208. Then, on May 8, 2025, Dentsply filed its Form 10-Q for the first quarter of fiscal year 2025. In that Form 10-Q, Dentsply disclosed that there had "no material changes to the risk" factors listed in its Form 10-K for fiscal year 2024. In other words, Dentsply was *still* "in the process" of "enhancing" their post-market surveillance processes in order to properly apprise governmental authorities of their products' safety profiles and compliance with applicable laws, including through the filling of previously concealed untimely reports.

VIII. ADDITIONAL ALLEGATIONS OF SCIENTER

209. Numerous facts including those detailed above, considered collectively, demonstrate that Defendants knew or recklessly disregarded that they were misrepresenting the involvement of doctors in Byte treatment, the screening of contraindicated patients, and Dentsply's compliance with FDA regulations regarding reporting of serious patient injuries.

210. **First**, Dentsply senior management specifically devised and enforced the directive to sell Byte to contraindicated patients, which had an immediate and dramatic impact on the Company's revenue. As described by FE-5, in an August 2022 meeting with the entire Byte sales team, Tyler Stoker, Head of Sales and Business Development for Byte, commanded Dentsply's sales force to ***stop informing patients of contraindications***. As relayed by Stoker in a follow-up meeting in October 2022 and confirmed by a former Byte employee, that change had an immediate impact, reducing patient rejections from approximately 35% to approximately 10-15%—and led to a corresponding boost in sales and Byte “conversion” rates. Pursuing this aggressive management-initiated directive, and the immediate, dramatic, and obvious boost in sales it prompted, could only have occurred with the knowledge and/or specific approval of the Executive Defendants.

211. As soon as the head of Byte Sales issued this directive, Defendants Campion, Coleman, and Frank publicly touted the corresponding impact on sales to investors—highlighting a purported 20% improvement to Byte's “conversion rate” that was secretly driven by sales to contraindicated patients. In doing so, these Defendants spoke in detail about this phenomenon on investor conference calls, falsely attributing the improvement to, for example, the ***“quality of the funnel and how we’re targeting customers”*** and other legitimate sales practices. The fact that Executive Defendants paid careful attention to the drivers of Byte revenues and spoke about them in detail with investors—and management's instruction to sell to contraindicated patients

immediately impacted those numbers—supports a strong inference that the Executive Defendants knew the actual sales strategy behind them.

212. The inference of scienter is particularly strong here in light of the fact that senior management’s instruction to deliberately sell Byte to contraindicated patients occurred at a critical time for Dentsply. Specifically, Stoker’s instruction to sell to contraindicated patients coincided with Campion’s appointment as CEO in August (and followed Frank’s appointment in April) and occurred at a time when Dentsply was desperately trying to recover from the channel-stuffing scandal that led to Casey and Gomez’s terminations—and which publicly exposed how stagnant sales in the Company’s distributor model channels actually had been. Due to the Audit Committee’s ongoing investigation and focus on the distributor channel, the Byte product line—which was not sold through distributors—thus became a critical lever for management to manipulate performance metrics. Indeed, on their first public conference call with investors as CEO and CFO, Defendants Campion and Coleman highlighted Byte as a “bright spot” at Dentsply and spoke in glowing and detailed terms about the product’s role in the Company’s overall strategy in achieving its \$3.00 EPS goal. Given the intent focus on Byte and its role in the Company’s corporate strategy, the timing of Stoker’s sales directive, and the resulting impact, it would be implausible for these Defendants to claim they were unaware of the true facts when they made their representations.

213. **Second**, the size and scale of Defendants’ fraud—and the thousands of injuries caused by Dentsply’s improper sales practices—provide powerful evidence of scienter. For example, during the Class Period, Dentsply failed to timely report **6,894** serious patient injuries, including **97%** of the serious patient injuries that in fact occurred during the Class Period through end of 2023, and **76%** of the Byte injuries that occurred until October 2024—when Dentsply was

forced to disclose that it was suspending Byte marketing and sales altogether. Moreover, the injuries Defendants failed to report were egregious and included adverse events—such as tooth loss and other injuries requiring surgery—that Dentsply’s senior management previously determined were “serious” and were required to be reported to the FDA under Dentsply’s formal reporting process.

214. **Third**, the Executive Defendants had a legal obligation to make themselves aware of serious patient injuries. Specifically, pursuant to medical device regulations including FDA Quality System Regulation 820 and Post-Market Surveillance requirements, Dentsply was required to report adverse events associated with its products to the FDA—and specifically required to report serious injuries within 30 days of learning of them. Under the FDA’s Quality System Regulation rule, with which Defendants represented that they complied, Dentsply’s quality executives were required to keep senior management informed of quality issues, and senior management was required to ensure compliance with those rules.

215. **Fourth**, the Executive Defendants in fact did track such patient injuries during the Class Period. Dentsply’s quality system, including its Trackwise software, accurately reflected the serious patient injuries from Byte—indeed, patient injuries were one of the most critical and closely tracked quality metrics at Dentsply. As described by FE-7, Dentsply’s quality executives met with senior management, including Dentsply’s CEO—i.e., Defendant Casey and Campion—on patient injuries every quarter. Specifically, Emily Miner, Dentsply’s Chief Quality Officer, and Charles Pigott, Dentsply’s top quality executive before Miner’s appointment, provided quarterly reports to Dentsply’s CEOs (Casey and Campion) about patient injuries and injury trends. Miner, Pigott, and the Executive Defendants were able to track Byte injuries through Dentsply’s quality system, including its Trackwise program, which accurately reflected the serious patient injuries

from Byte. Further, in connection with briefing Defendants Casey and Campion in quarterly injury reviews, Miner and Pigott reviewed Byte injury report data through Trackwise, and obviously saw and appreciated the seriousness and extent of the injuries caused by Byte when they did so, bolstering the inference that the Executive Defendants were informed of the Byte injury rates during the Class Period.

216. ***Fifth***, Defendants were highly motivated to conceal serious patient injuries from the FDA because they knew that disclosure to the FDA would result in public disclosure through the FDA’s online MAUDE database. During the Class Period, Defendants knew that opponents of direct-to-consumer aligners like Byte were scrutinizing MAUDE data and citing it to state legislatures and state dental boards as evidence of their risks to patients. For example, MAUDE data (filed by SmileDirectClub, not Byte) was cited in testimony in favor of a Florida measure that Dentsply actively lobbied against. Defendants thus had every incentive to avoid the public revelation of these patient injuries—especially during a critical time of the Class Period, when such legislation was gaining momentum and threatened to totally derail the Byte business.

217. The inference that the Executive Defendants were aware of and highly motivated to avoid disclosure of the Byte injuries they internally tracked is bolstered by the fact that the Executive Defendants closely monitored the legislative developments impacting Byte. In Dentsply’s “Sustainability Reports” during the Class Period, which were signed by Defendants Casey (in 2020 and 2021) and Campion (in 2022 and 2023), Dentsply highlighted its Byte lobbying activity, underscoring that Dentsply’s “government affairs department team leads preapproved engagements of our Byte division around issues relating to telehealth and/or teledentistry, as we believe this will continue to be a significant topic in medical legislation.” In doing so, the Company acknowledged spending over \$1.3 million in political contributions and lobbying

expenditures in connection with these efforts—expenditures that were, under Company policy, explicitly approved by the Company’s General Counsel (Cherée Johnson and Richard Rosenzweig) and Chief Ethics & Compliance Officer (Michael Pacella). Moreover, the Executive Defendants themselves discussed Dentsply’s Byte lobbying efforts, with Defendant Campion telling investors that the Company had increased investments in “government relations to help states understand the process of direct-to-consumer aligners” and defeat legislation that targeted Byte. The senior-level focus, funding and lobbying efforts, and the personal involvement on the part of the Executive Defendants in them further bolsters the inference that Dentsply’s reporting failures were known and deliberate.

218. **Sixth**, Byte represented a crucial part of Dentsply’s business, as the Executive Defendants spoke about it on every conference call with investors, repeatedly emphasized its importance, and professed a deep understanding about the product and its performance. To start, the Byte acquisition was Dentsply’s largest in recent memory—a billion dollar purchase amounting to one-tenth of Dentsply’s total market capitalization. The deal was personally negotiated by Defendants Casey, Gomez and Gunsagar, and each of these executives actually knew or became intimately familiar with the actual drivers of Byte’s performance and the risks it posed to patients during due diligence and when agreeing to spend a billion dollars of the Company’s capital on this product.

219. Moreover, throughout the Class Period, the Executive Defendants highlighted Byte as one of the critical drivers of profitability and growth—including by calling it out as the only Dentsply product identified by name as contributing to Dentsply’s goal of hitting \$3.00 EPS, the Company’s “Rubicon,” and described its performance and the drivers behind it on every investor conference call during the Class Period. For example, Defendant Casey told investors that he

personally reviewed social media feedback on Byte, calling it something “***we look at as a team on a hourly and nightly basis***” and that he closely followed Byte’s performance, and 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.***” Not only did Defendant Gunsagar know Byte’s business model in detail as its CEO, but he told investors during the Class Period that he personally reviewed Byte’s “***customer feedback channel***” first thing in the morning on Slack every day—which would have revealed the deluge of patient complaints and injuries that were occurring. And Defendant Campion similarly spoke knowledgably when questioned about Byte, telling investors, for example, that the Company had “***refined our questioning on our surveys as they come into the funnel***” and achieved a “***higher quality funnel as a result of the ton of the work that the team in Salt Lake City has done***” when explaining how sales results had improved. As a result, the Executive Defendants were intently focused on Byte’s performance throughout the Class Period, and were intimately familiar with Byte’s actual performance and the reasons for it at the time they made their misstatements.

220. ***Seventh***, the Executive Defendants themselves were intimately involved in approving Byte’s sales strategies and administering the supposed “network” of dentists that Defendants falsely represented oversaw Byte patient treatment care. For example, as reported by FE-2, Byte’s longtime CEO, Defendant Gunsagar, was intimately familiar with Byte’s business model and was a detail-oriented, hands-on manager who worked closely in developing and overseeing the Byte dentist “network”—including with Amy Carter, Byte’s Chief Human Resources Officer (who served as liaison to approving dentists), Dr. Jay Khorsandi, Byte’s corporate dentist, and Amber Medsker, Byte’s Director of Clinical Support. According to FE-2,

Defendant Gunsagar personally oversaw the development of the coding algorithms that probabilistically assigned Byte cases in the most profitable manner—including to the “**super-approver**” dentists who approved almost all cases assigned to them. FE-2 personally participated in meetings with Gunsagar in which the role of doctors in Byte’s patient onboarding and treatment process was discussed. Gunsagar knew how doctors actually interacted with Byte patients because he directed and enforced the policy mandating that limited involvement.

221. Along similar lines, Defendant Brackett, who served as the Senior Vice President Orthodontic Aligner Solutions & Customer Experience in charge of Byte and SureSmile, interacted with the FDA on Byte and knew the risks it posed to patients. Indeed, as Dentsply’s Head of Sustainability and its ESG Committee Chair, Brackett publicly touted Dentsply’s fidelity to following FDA medical device reporting regulations in Dentsply’s Sustainability Report while senior executives including Gunsagar and Brackett personally reviewed patient complaints of serious injury and participated in Dentsply’s response to FDA concerns regarding the same. And Defendant Frank, who served as Dentsply’s Product Group head and then Chief Business Officer and directly supervised the head of Clear Aligners Coggin, then Defendant Brackett, from April 2022 to year end 2024, guided the Byte business. In these roles, Frank participated in all major decisions affecting Byte, including the decision in August 2022 (four months into Frank’s tenure) to stop informing Byte patients of contraindications, and touted Byte’s improved conversion rate to investors and professed to know how those improved conversion rates were achieved.

222. ***Eighth***, the size, scope, and seriousness of the misstatements raise a strong inference of scienter. Byte was one of Dentsply’s most important and fastest-growing products during the Class Period and provided a much-needed contribution to revenue growth during a time when Dentsply’s traditional products and sales channels were facing headwinds. The product was

also sold to lower-income patients, which the Executive Defendants and Dentsply's quality executives knew had a higher incidence of the very contraindications that Byte prescribers were supposed to avoid. The misstatements concerned the core of Byte's business model, which was fundamentally misrepresented to investors. Indeed, the misstatements that Byte was a doctor-directed treatment and sold only to patients with mild to moderate malocclusion directly undercut Byte's purported strategic benefit, emphasized by the Executive Defendants, of driving to brick-and-mortar dental offices contraindicated patients who were screened out of Byte treatment (who would be treated with SureSmile) and satisfied Byte patients. Defendants' scienter is also supported by the fact that Dentsply was racing to develop a replacement for Byte—the next generation device that would actually be administered by licensed dentists—due to the patient risks and adverse events that Dentsply's Byte DTC model invited. That Defendants repeatedly touted Byte's "doctor-directed" DTC model, spent a considerable amount of resources during the Class Period to develop a replacement for it, and announced the discontinuance of Byte so shortly after belatedly and finally reporting an uptick in adverse events, provides strong evidence that Defendants knowingly misled investors concerning Byte during the Class Period.

223. *Ninth*, Defendants' fraudulent sales practices had a direct, obvious and visible economic impact on Byte's revenues and costs, which were a focal point for investors and the Executive Defendants during the Class Period. For example, selling to contraindicated patients, eliminating expenses for licensed doctor care following the initial treatment plan "approval," refusing refunds to injured customers and urging patients to "backtrack" aligner treatments instead, each had a visible impact on Byte margins. Not only did Dentsply avoid refunding the price of impression kits sold to contraindicated patients, but they converted those contraindicated patients and sold aligners to them as well. Given that Byte's financial performance and margins were a

key focus of investors during the Class Period—and Defendants Campion, Coleman, and Frank spoke intelligently and extensively about those topics when asked—bolsters the inference that they knew the true drivers of Byte’s financial performance.

224. ***Tenth***, Defendants repeatedly represented to numerous constituencies—including investors, state legislators, government regulators, and dental and orthodontist organizations—that Byte and the Byte treatment program was safe and effective, affirmatively contrasted Dentsply’s sales practices with those of competitors like SmileDirectClub, and specifically denied violating the FDA reporting laws when specifically questioned about Dentsply’s compliance. During the Class Period, the Executive Defendants held out Byte as different from SmileDirectClub on the premise that, unlike SmileDirectClub, Byte was “doctor-directed” through an engaged and active ***“network of licensed dentists and orthodontists who direct each individual treatment plan”*** and that Dentsply was able to “avoid” some of the “traps” impacting SmileDirectClub by taking advantage of Dentsply’s rigorous and respected quality assurance and regulatory affairs competencies.

225. Then, when Byte’s business model was threatened by legislation, Dentsply responded through aggressive lobbying efforts to project the false impression that a Byte “patient stays with that same [l]icensed dentist” throughout the treatment and “and if there are any issues they run into, the dentist is the one consulted on how to proceed”—leading legislators to incorrectly believe that Byte’s treatment was safe and effective and no additional regulations were needed. Dentsply did so without disclosing that it failed to report thousands of Byte injuries to the FDA as it was legally required to do.

226. Moreover, when responding to investigative journalists’ inquiries about patient complaints and an uptick in FDA adverse event reports, the Company flatly denied they were

related to any safety issues with Byte and, moreover, that Dentsply was in full compliance with its FDA reporting obligations. Specifically, Dentsply represented it strictly followed its FDA reporting obligations and that “all medical device reports are thoroughly investigated in accordance” with those laws when, in truth, Dentsply had for years willfully failed to report thousands of serious injuries in violation of FDA law. These facts further confirm that Defendants either knew their statements were false, or were reckless in making them.

227. ***Eleventh***, Defendants have admitted that, for a substantial portion of the Class Period, the Company’s leadership—and Defendants Casey and Gomez in particular—created an “inappropriate tone at the top,” promoted a “culture where employees did not feel comfortable raising concerns without fear of retaliation,” and that the Company lacked effective disclosure controls and procedures. Dentsply’s admitted culture of retaliation by executives against lower-level employees who raised legitimate concerns, by its an inappropriate “tone at the top” that encouraged and demanded cheating to meet performance goals, and Dentsply’s ineffective compliance and disclosure controls contribute to the inference of scienter. The accounts of FE-3 and FE-4—both of whom left the Company because they believed Dentsply was harming patients and engaging in unethical conduct—demonstrates that Dentsply’s problematic “culture” and inappropriate “tone at the top” persisted throughout the Class Period, and further support a strong inference of scienter.

228. ***Twelfth***, all of the Executive Defendants (except Campion) departed Dentsply under suspicious circumstances. Defendants Casey and Gomez exited Dentsply in April 2022, just one month after the Audit and Finance Committee of Dentsply’s Board of Directors began its internal investigation into the channel stuffing. Casey was fired “effective immediately” due to his participation in the channel-stuffing scheme while Gomez was forced to step down one day into

his new job as CFO of another company for the same reason. Just months later, in August 2022, Gunsagar left the Company—staying just long enough to collect a lucrative \$19.6 million compensation package tied to Byte. Defendants Frank, Coleman, and Brackett (along with Vice President, Corporate Quality Systems Seevaratnam) departed in mid-2024, prior to the large spike in retrospective reports of serious patient injuries to the FDA.

229. The circumstances suggest Defendant Gomez knew that he was culpable in two frauds and attempted to seek other employment before his culpability was discovered. On April 11, 2022, Dentsply announced that Gomez had resigned, effective May 6, 2022, to assume a CFO position at “another public company,” which was Moderna. Moderna has disclosed Gomez’s offer letter, which was dated April 4, 2022, signed by him on April 6, 2022, and provided for a start date of May 9, 2022. The offer letter does not state when Gomez first contacted Moderna, but a typical public-company CFO hiring process takes about three to four months, which would suggest that Gomez was already looking for a new job in early 2022 or late 2021.¹¹

230. Casey was terminated by Dentsply and removed from its Board of Directors, effective immediately, on April 19, 2022. Casey’s termination followed only shortly after the start of the internal investigation into the channel stuffing. His swift termination suggests that his culpability was obvious.

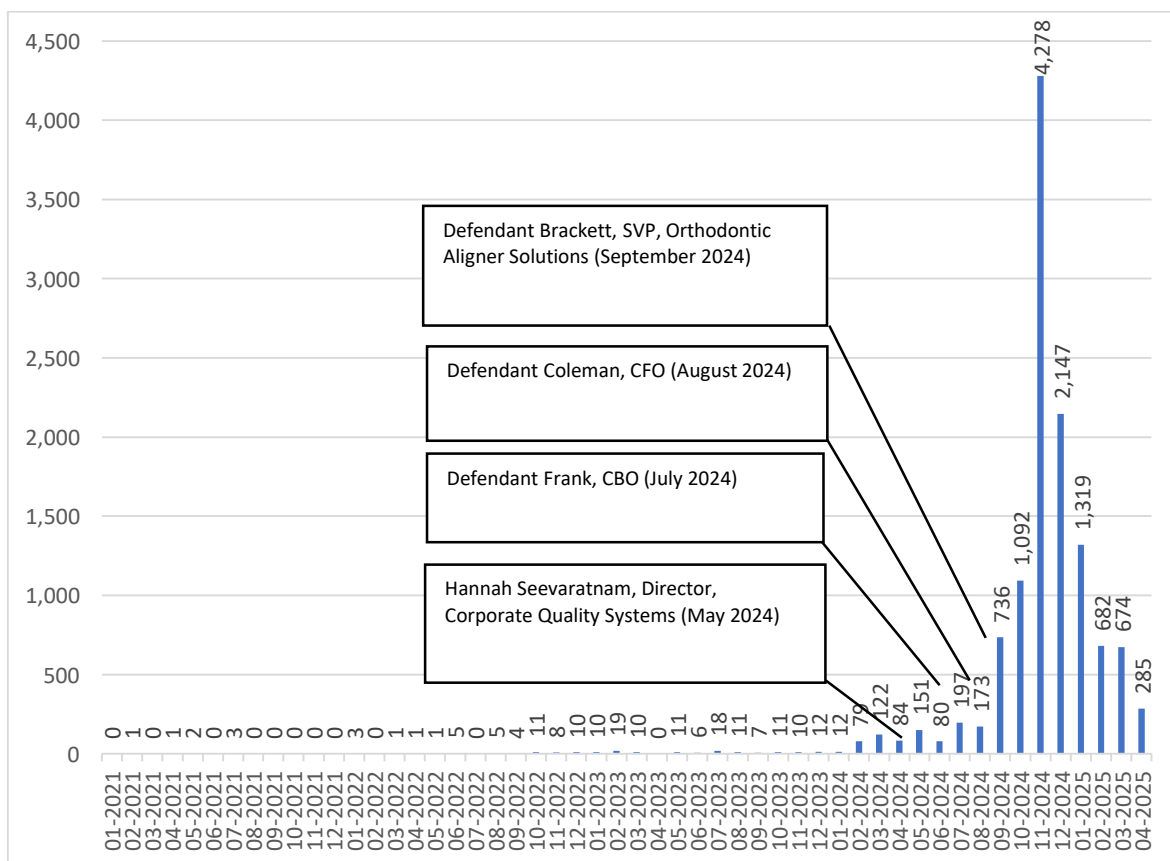
231. Defendant Gunsagar departed Dentsply in August 2022—the same month that Dentsply stopped informing Byte patients of contraindications, and just as long as Gunsagar had to remain to receive approximately \$19.6 million held in escrow since the Byte acquisition. The Equity Purchase Agreement stated that Gunsagar would receive that sum “if he has satisfied the

¹¹ Gomez departed Moderna on May 10, 2022, his second day on the job, after Dentsply announced its internal investigation into the channel stuffing.

terms of Section 2(b)(v) of his Unit Award Agreement dated July 1, 2019.” It is customary for a unit award agreement to condition vesting upon the recipient remaining employed for three years and upon a performance metric (as was the case with Dentsply’s unit award agreements and Gunsagar’s unit award agreement at TrueCar before Byte).

232. Defendants Frank, Coleman, and Brackett were removed from their positions in July, August, and September 2024, respectively—during the window of time when Dentsply was starting to increase its reports of serious patient injuries to the FDA, and prior to the large spike in reports in September 2024 becoming public. In May 2024, Seevaratnam, who was responsible for FDA reporting for Byte for most of the Class Period, also departed. The circumstances suggest these successive departures were a result of their culpability in the Byte fraud.

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



233. Defendant Frank's position as Dentsply's Chief Business Officer was eliminated by Dentsply's Board of Directors on July 29, 2024 (originally effective October 1, 2024, later extended to January 2025). Dentsply claimed that his elimination was part of a "restructuring," but Frank's was the only officer's position eliminated.

234. Defendant Coleman resigned as Dentsply's CFO on August 15, 2024 (effective November 7, 2024, the day Dentsply was due to announce the quarter's results). On Coleman's last day, Dentsply wrote-down goodwill for Byte.

235. Defendant Brackett, Dentsply's Senior Vice President, Orthodontic Aligner Solutions & Customer Experience and Head of Sustainability, exited Dentsply without explanation or announcement no later than September 3, 2024. In an unusual move, sometime between July 24 and September 20, 2024, Dentsply retained the page for Brackett (with her picture, title, and biography) on its website but quietly removed her picture and the link to her page from its "Executive Team" page. Brackett's departure from Dentsply was revealed only indirectly, when she was required to resign as an independent director of Knowles Corporation (which she did on September 3, 2024) due to a "substantial change in her principal position of employment." No public information indicates that Brackett has obtained other employment.

236. ***Thirteenth***, the Executive Defendants had personal financial motives to obtain incentive compensation inflated by the Byte securities fraud. But for that fraud, significant performance metrics (including sales and earnings per share) would have fallen from above to below minimum thresholds, and as a result, lucrative categories of the Executive Defendants' compensation would have been erased entirely. The Executive Defendants' desire to receive this compensation provided a powerful motive to conceal the truth about Byte.

237. **Financial Incentives for Defendants Gomez and Casey.** As a direct result of the Byte fraud, Defendants Casey and Gomez would have received ill-gotten gains of at least **\$1.3 million and over \$650,000**, respectively, for 2021—but for the Board’s unexpected discovery of the channel stuffing fraud.

238. According to Dentsply’s guidance, Byte was expected to contribute five cents of EPS in 2021. Casey and Gomez were highly motivated to deliver each of those five cents. Casey and Gomez’s 2019-2021 performance-based restricted stock units (“PRSUs”) were based on three-year cumulative performance measures, including Dentsply’s cumulative non-GAAP EPS for 2019-2021, which was given a weight of 80%. Dentsply exceeded the minimum EPS threshold, \$7.09, by **just two cents**. If Dentsply’s 2021 EPS had been more than two cents lower, the EPS threshold would have been missed. In other words, Byte’s expected contribution to Dentsply’s non-GAAP EPS was critical. Dentsply’s Byte-inflated 2021 EPS would have triggered the vesting of PRSUs worth **\$1,304,184 for Casey and \$650,393 for Gomez** (based on Dentsply’s closing stock price on December 31, 2021)—if the Board had not revised their compensation downward after uncovering their channel stuffing.¹²

239. In the Dentsply channel stuffing case, Judge Subramanian held that Casey and Gomez’s motive to receive these PRSUs supported a strong inference of scienter. *San Antonio Fire and Policy Fund v. Dentsply Sirona Inc.*, 732 F. Supp. 3d 300, 318 (S.D.N.Y. 2024). The channel stuffing fraud contributed only four cents of EPS in 2021, while Casey and Gomez expected Byte

¹² After the discovery of the channel stuffing fraud, the Human Resources Committee excluded the impact of the 2021 AIP reduction from the EPS calculation, which had the effect of reducing Dentsply’s 2019-2021 EPS to \$7.06, thus depriving Casey and Gomez of the non-GAAP EPS portion of the 2019-2021 PRSUs. This after-the-fact deprivation in no way negates Casey and Gomez’s contemporaneous motives. As Judge Subramanian held: “Casey and Gomez would’ve gotten away with more, too, if it weren’t for the meddling board.” *San Antonio Fire and Policy Fund v. Dentsply Sirona Inc.*, 732 F. Supp. 3d 300, 318 (S.D.N.Y. 2024).

to contribute five cents of EPS. But for either fraud, Dentsply's EPS would have fallen below the minimum threshold that was exceeded by just two cents. The fact that Casey and Gomez perpetrated two frauds to just barely cross that threshold underscores their motive.

240. Casey and Gomez were additionally motivated to inflate Dentsply's 2021 EPS and revenue to increase the vesting of other PRSUs, including the 2021-2023 PRSUs (tied to EPS and revenue for 2021) and the 2020-2022 PRSUs (tied to 2020-2022 EPS). Casey and Gomez expected \$200 million in revenue and five cents in EPS from Byte in 2021, which increased the number of 2021-2023 PRSUs that vested in 2021 and contributed towards the potential vesting of the 2020-2022 PRSUs in 2022 (but for the revelations of the channel-stuffing scheme leading to Casey's termination and Gomez's resignation).¹³

241. Due to Casey's termination and Gomez's resignation, they would have been able to sell all of their vested Dentsply shares (563,675 for Casey and 108,205 for Gomez) at inflated prices—with a market value of approximately **\$23.8 million** for Casey and on his termination day, and **\$4.4 million** for Gomez on his departure day—immediately and without public disclosure on Form 4. Had they held those shares until the end of the Class Period, when the truth regarding Byte was revealed, they would have been worth less than half of those amounts.

242. **Financial Incentives for Defendants Campion, Coleman, Frank.** Similar to Defendants Casey and Gomez, the new Dentsply leadership installed after Casey and Gomez's departures—Defendants current CEO Campion, former CFO Coleman, and former Chief Business Officer Frank—were likewise personally financially motivated to conceal the truth about Byte in

¹³ Specifically, the first of three equal tranches of the 2021-2023 PRSUs was tied to 2021 performance—40% to Dentsply's 2021 EPS and another 40% to 2021 revenue. The minimum thresholds were \$2.45 EPS and \$3.945 billion revenue. Dentsply's as-reported EPS and revenue for 2021 (before restatement) were \$2.87 and \$4.251 billion, respectively—meaning that the loss of Byte revenue and EPS would have reduced the number of PRSUs vesting.

2023 and 2024 because their cash bonuses and the vesting of their PRSUs depended upon it. Specifically, these Defendants reaped millions in compensation by inflating Byte sales.

243. **2023 Compensation Incentives.** For example, under the 2023 Annual Incentive Plan, a key performance metric for Campion, Coleman, and Frank's cash bonuses was 2023 organic sales, which was given a weight of 50% in determining payouts.¹⁴ But for Byte's reported \$179 million contribution to organic sales in 2023, Dentsply's organic sales would have fallen below the minimum threshold required to qualify for a sales-based bonus under the AIP, and the organic sales portion of Defendants Coleman and Frank's 2023 cash bonuses would have been *erased*. The organic sales portion of their 2023 bonuses was worth about ***\$625,000 for Campion, \$250,000 for Coleman, and \$270,000 for Frank.***

244. Campion, Coleman, and Frank were also motivated to inflate Byte's organic sales to cause the vesting of the 2023 tranches of their 2022-2024 and 2023-2025 PRSUs. Specifically, the 2023 tranche of the 2022-2204 PRSUs had a minimum threshold of \$3.922 billion, and the 2023 tranche of the 2023-2025 PRSUs had a minimum threshold of \$3.838 billion. But for Byte's \$179 million contribution to 2023 organic sales, Dentsply's organic sales would have fallen below both minimum thresholds, and those portions would not have vested.

245. **2024 Compensation Incentives.** The Executive Defendants had a similar financial motive to maintain the Byte fraud throughout 2024. Specifically, Campion, Coleman, and Frank were motivated to inflate Dentsply's organic net sales in 2024 because Byte's performance impacted their cash bonuses. But for Byte's \$136.5 million contribution to organic net sales in

¹⁴ Dentsply's Annual Incentive Plan ("AIP") for 2023 made Defendants Campion, Coleman, and Frank eligible for target cash bonuses of 125%, 80%, and 75% of their base salaries, which were \$1,000,000, \$650,000, and \$728,000, respectively. The funding of half of those bonuses was tied to Dentsply's organic sales, which were set at a minimum threshold of \$3.838 billion.

2024, Dentsply's organic net sales would have fallen below the minimum AIP threshold, and the organic sales portion of their cash bonuses would have been *erased*. The organic sales portion of their 2024 bonuses were worth about **\$300,000 for Campion and \$130,000 for Frank** and would have been worth about **\$125,000 for Coleman** (but for his resignation).

246. These significant financial incentives are even more compelling in light of the timing of the Byte shutdown. As Dentsply revealed after the end of the Class Period, the shutdown of the Byte business in the fourth quarter of 2024 was fortuitously timed for the Campion and Frank (and Coleman but for his resignation). They had already achieved the threshold level of annual sales to qualify for their 2024 sales-based bonuses without relying on Byte's fourth quarter sales. In other words, they would have qualified for their 2024 sales-based bonuses regardless of whether Byte was discontinued in the fourth quarter of 2024 or the first quarter of 2025. In contrast, discontinuing Byte two quarters earlier (i.e., in the first month of the second quarter of 2024) would have decreased organic sales by \$98.8 million—or just \$10 million below the threshold level of \$3.607 billion needed to qualify for their 2024 organic sales-based bonuses.

247. In fact, shutting down Byte and removing its sales from Dentsply's total sales in both 2023 and 2024 would have reduced compensation by nearly **\$1 million for Defendant Campion, \$350,000 for Defendant Coleman, and \$400,000 for Defendant Frank**. As a result, they were motivated to delay the timing of the disclosure of the serious Byte injuries, Dentsply's FDA reporting violations, and their impact on the Byte business.

IX. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

248. Defendants made materially false and misleading statements, omissions, and half-truths during the Class Period in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

249. **First**, Defendants falsely reassured investors that, even though Byte was marketed direct-to-consumer, licensed and board-certified dentists and orthodontists exercised “**oversight and control of each customer’s clinical treatment**” with Byte. For example, Dentsply represented that “[l]icensed doctors and orthodontists with [patients] every step of the way”; that they would “**check in with customers throughout their journey**”; and that Dentsply would “**make it easy to get in touch,**” “**7 days a week,**” if patients “**need[ed] to consult the doctor.**” In reality, a dentist or orthodontist was involved, at most, only at a single point of approval at the outset of the treatment and had no ongoing role in monitoring the patient’s treatment. Even as many patients suffered serious injury and called Dentsply begging for help, the company refused to connect them with a dentist or orthodontist—as former employees and a patient attest.

250. **Second**, Defendants falsely reassured investors (and patients) that Byte would “**only accept customers who are great candidates for teledentistry,**” which Defendants defined as “Class I” malocclusion with “**mild to moderate spacing and crowding.**” If a patient was “Class II,” “Class III,” or “complex,” or if a patient’s impression revealed contraindications, Defendants represented that they refunded that patient and did not proceed with Byte. Indeed, Defendants touted, as a significant synergy of the Byte acquisition, that Dentsply would refer patients contraindicated for Byte to dentists for in-office care, thus driving sales of SureSmile and Dentsply’s other in-office products. In reality, Dentsply management directed the Byte sales force to ignore contraindications and “convert” contraindicated patients into sales. Predictably, sales to patients with complex cases and contraindications, coupled with the lack of oversight from a dentist or orthodontist, resulted in serious injuries to thousands of patients.

251. **Third**, in Dentsply’s SEC filings and in statements to the news media, Defendants falsely represented that Dentsply was in “**substantial compliance**” with applicable laws and

regulations, including FDA regulations specifically relating to medical-device regulations requiring Dentsply to report serious injuries to the FDA. For example, in its “Sustainability Reports” published during the Class Period, Dentsply represented that it was in “**compliance with applicable PMS [post-market surveillance] requirements**” for medical devices, including specifically “**FDA QSR 820**,” which required Dentsply to report serious patient injuries to the FDA within 30 days. In reality, Dentsply was neither in compliance nor substantial compliance with these laws. In fact, contrary to Defendants’ representations, Dentsply woefully violated these very regulations and failed to timely report **thousands** of serious patient injuries to the FDA during the Class Period.

A. False Statements Regarding Ongoing Control And Oversight By Licensed And Board-Certified Dentists And Orthodontists

1. January 4, 2021 Form 8-K And M&A Call With Analysts

252. On January 4, 2021, Dentsply filed a press release and investor presentation on Form 8-K and hosted a “M&A Call” for analysts and investors to announce the Byte acquisition. Defendants Casey, Gomez, and Gunsagar reviewed and approved the press release and investor presentation. They were quoted in the press release, pictured in the investor presentation, and participated in the call.

253. The press release included the following statement:

Byte’s **doctor-directed** clear aligner system provides customers nationwide access to at-home invisible aligners for a straighter, whiter smile. With a growing team of over 450 employees and headquartered in Los Angeles, **Byte’s nationwide network of licensed dentists and orthodontists prescribe and oversee every customer’s treatment plan**, delivering a top-rated consumer experience and results in up to half the time and cost of traditional methods. At under \$85 per month, Byte has found a way to make the inaccessible, accessible providing an easy, convenient and affordable way to upgrade your smile through the Byte Teledentistry platform. For more information on Byte, visit: www.byteme.com.

254. On the January 4, 2021 call, during prepared remarks, Defendant Gunsagar stated:

For those of you who may not be familiar with Byte, here's a quick primer. ... Our mission since Day 1 has always been clear, increased access and affordability to dental care for patients with our easy-to-use aligner system. Our nationwide consumer experience provides fast and convenient aligners with effective treatment planning, that is ***overseen by an extensive network of licensed dentists and orthodontists***. ...

You'll see why we're so confident in our platform and why we've been able to address unmet needs in dental care. Byte addresses some of the most important facets of a successful clear aligner experience. Not only do we offer fast results for mild-to-moderate orthodontic needs, our ***doctor-directed care*** and focus on customer service ***drive excellent patient outcomes***.

255. On that same call, in response to a question from an analyst Defendant Casey answered as follows:

Q: Wondering if you could talk about competitive positioning in the DTC channel. ***How does Byte differentiate versus Smile Direct, Candid, some of the other direct-to-consumer companies?***

A: A couple things, if you really look at the market, clear aligner market, there's a couple channels and there's a couple approaches, and let me kind of tell you how we think about it. ... Obviously, Invisalign tends to be a direct-to-consumer professional channel, Smile Direct has been started as much more of a retail and a direct-to-consumer business. ***Byte was built from the beginning*** around a direct-to-consumer business ***with a full network of license professionals involved***. ...

So, we feel pretty good about that. One of the things we look forward to going into the future, Tycho, is, look, we have been doing a ton of R&D on the SureSmile side and that we can bring over to Byte. ... But right now, look, we feel that Byte is one of the leaders if you look at kind of the direct-to-consumer space, ***whether it's a Candid, whether it's a Smile Direct, we feel we're extremely competitive from a product as well as a customer experience offering***.

256. The analyst credited Defendant Casey's response, writing that day that Byte sold "doctor-directed clear aligners for patients with mild to moderate orthodontic needs through a DTC system that leverages a nationwide network of dentists and orthodontists."

257. The statements set forth in ¶¶252-56 were materially false and misleading, and omitted to state material facts necessary in order to make them not misleading. Byte treatment was not "***doctor-directed***," "***prescribe[d] and oversee[n]***" by "***licensed dentists and orthodontists***," or

“overseen by an extensive network of licensed dentists and orthodontists.” In reality, as described by FE-4 and FE-2, the involvement of dentists and orthodontists in Byte patient treatment was limited to, at most, a one-time approval by a single dentist or orthodontist who devoted inadequate time or attention to the patient’s medical records. Further, as described by FE-4, FE-3, and further described in ¶108, dental assistants and customer service employees alike made changes to patients’ treatment plans (*e.g.*, changing the sequence in which the patient wore the aligners) without the approval of any dentist or orthodontist. Accordingly, the **“full network of license professionals involved”** was not a differentiator from SmileDirectClub and other direct-to-consumer clear aligners. In reality, as described above, Byte’s orthodontists and dentists sole involvement with patients’ treatment plans was the initial approval of the treatment plan, which was not a differentiator as this was required for all clear aligners under their FDA labeling

258. In announcing the acquisition, Defendants also made several statements highlighting that Byte treatment was focused only on treating patients with “mild to moderate occlusion” and for patients with only “mild to moderate orthodontic needs.” For example, in response to an analyst question regarding “what parts of the Byte technology do you see could be like an early win for SureSmile, either on just number of cases—additional cases in terms of data on teeth moving or something else,” Defendant Casey reiterated that Byte does **“a good job there targeting people with mild to moderate occlusion.”**

259. Similarly, another analyst asked Defendants, “As you look at your R&D objectives, do you think there is a point, I don’t know, 3, 5 years out or more, where sort of moderate and higher complexity cases are possible through DTC?” In reply, Defendant Casey stated:

As we think about the future, what can clear aligners treat safely, look, clear aligners are terrific. We think that we have a great product that goes through the dental channels that can handle Class I, Class II, Class III with SureSmile. And a

lot of that is going to be governed by what we think is the best clinical outcome for the patient.

On the Byte side, we're very focused on mild to moderate occlusion. Do we see that line moving? That's really going to be up to the local dental associations because one of the things that we're very proud of is that we are very, very compliant. We have a network that lets us operate in all 50 states. We'll work in a—appropriate fashion as we expand this outside the U.S., and we really think we'll work collaboratively to make sure that people are getting the right care.

So if over time, the technology gets better and local dental associations feel that the treatment paradigm can be altered, terrific. But that's not something that we're going to be pushing.

260. The statements set forth in ¶¶258-59 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially misleading to state that Byte was “focused” on patients with “mild to moderate orthodontic needs” because, in truth, Byte’s onboarding process did not target patients with only mild-to-moderate cases. Rather, as discussed *supra* ¶¶96-100, Dentsply’s prescription and approval process for Byte was not intended to disqualify patients based on contraindications or prescribe Byte only to patients with “mild to moderate orthodontic needs” and, in fact, did not do so.

2. Dentsply’s Website And Other Advertisements Throughout The Class Period

261. From the start of the Class Period until at least January 23, 2022, Dentsply made the following statements on its website for Byte, on a page titled “Teledentistry 101.”

Here at Byte, we have an army of medical and dental experts who work together to review cases, design treatment plans, and check in with customers throughout their journey. No matter what state you live in, you are covered. We have over 200 licensed doctors, dentists, and orthodontists across the country! It’s not a one-doctor-fits-all mentality, ***we work with the same trusted dentists and orthodontists you’d visit for regular braces or Invisalign.***

262. The statement set forth in ¶261 were was materially false and misleading, and omitted to state material facts necessary in order to make it not misleading. Rather than employ ***“medical and dental experts who work together to review cases, design treatment plans, and***

check in with customers throughout their journey”—i.e., throughout a patient’s Byte treatment—in truth, Byte dentists and orthodontists were **not** involved in patients’ treatment and did not “check in” with them. To the contrary, as described above in ¶¶95-109, dentists were involved only, at most, at one point—to “rubber stamp” a treatment plan developed by treatment planners who were not licensed dentists or orthodontists. Further, rather than being available for patients to “**check in,**” in reality, Dentsply did not allow patients to communicate with dentists about their treatment plan. To the contrary, as described by FE-4, FE-3, and as further described in ¶108, Dentsply customer service employees with little to no medical training whatsoever—**not** dentists or orthodontists—triaged adverse events and dispensed unqualified medical advice, including by telling patients to “backtrack” and re-use old aligners. In doing so, the customer service representatives did not consult with any dentist or orthodontist.

263. From before the Class Period until at least October 27, 2021, Dentsply made the following statements on its website for Byte, on a page titled “**Comprehensive doctor-directed care**”:

Remote monitoring. Safe, and convenient. **You have access to your care team 7 days a week, whether you need to consult the doctor,** or simply get questions answered, **we make it easy to get in touch.**

264. The statement in ¶263 above was materially false and misleading and omitted to state material facts necessary in order to make them not misleading. Dentsply did not “**make it easy**” to “**consult a doctor**” “**7 days a week.**” Specifically, as reported by FE-4 and FE-3, rather than have “access to” and the ability “to consult the doctor” concerning patients’ Byte treatment, in truth, Dentsply did not make any doctors available for consultation and, in fact, as further described by FE-2 and FE-3, repeatedly and affirmatively denied patient requests to speak to a doctor even when those patients suffered serious injuries.

265. For a time period including May 28, 2022, Dentsply made the following statement on its website for Byte, on the “About us” page:

Our team of customer care specialists, ***dentists, and orthodontists, direct each individual treatment plan,*** providing care that is as unique to you as your smile. Being a part of the Byte team means keeping the customers at the heart of everything we do.

266. From at least August 12, 2022 until after the Class Period, Dentsply made the following statement on its website for Byte, on the “About us” page:

We’re proud to work with a ***network of dentists and orthodontists who direct each individual treatment plan*** and provide care that is as unique as your smile. Being a part of the Byte team means keeping the customers at the heart of everything we do.

267. From at least July 31, 2023 until August 20, 2023, Dentsply made the following statement in a television commercial that was served to 50 million viewers:

At Byte, we totally get it. When it comes to your smile you want the best and you want it now; with ***treatment directed by real dentists*** for thousands less than braces. So don’t waste your day just for a trip to the dentist. Straighten your teeth from home or anywhere. Ready to transform your smile in months, not years, without compromise?

268. The statements set forth in ¶¶265-67 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. Specifically, it was materially false and misleading to state that “***dentists***” and “***orthodontists***” “***direct each individual treatment plan***” because, in reality, as described by FE-4, FE-3, and in ¶108, treatment plans were instead overseen by non-dentists, including by customer services employees without any medical training who instructed patients to “backtrack” and reuse old aligners or file down ill-fitting aligners themselves. In fact, as described by FE-2, dentists and orthodontists were only involved as a “rubber stamp” and one-time approval. And as further described by FE-2 and FE-3, Dentsply actively refused patient requests to speak to a doctor even when patients suffered serious adverse events.

269. From before the Class Period through at least September 20, 2021, Dentsply made the following statements on its website for Byte, on a page titled “Byte’s Expert Dental Network.”

Real people, real doctors. ***Safe and effective teledentistry requires comprehensive doctor directed care.*** Byte’s Expert Dental Network combines doctors of dentistry, dental surgery, orthodontics, and cosmetic dentistry to make sure each and every smile gets the treatment it deserves. . . . It’s a win/win, more healthy smiles across the country, especially for those who may not have had access or affordable options before!

Doctor Directed Care. ***Licensed doctors and orthodontists with you every step of the way.*** Dental assessment. Professional quality impressions. Aligners w/custom treatment plan. Care team check-ins. Dentist approved smile.

270. From at least January 23, 2022 until at least August 5, 2023, Dentsply made the following statements on its website for Byte, on a page titled “Byte’s Expert Dental Network.”

Real people, real doctors. ***Safe and effective teledentistry requires comprehensive doctor directed care.*** Byte’s Expert Dental Network combines doctors of dentistry, dental surgery, orthodontics, and cosmetic dentistry to make sure each and every smile gets the treatment it deserves. . . . It’s a win/win, more healthy smiles across the country, especially for those who may not have had access or affordable options before!

Doctor Directed Care. ***Licensed doctors and orthodontists with you without ever leaving home.*** Dental assessment. Professional quality impressions. Aligners w/custom treatment plan. Digital check-ins. Dentist approved smile.

271. The statements set forth in ¶¶269-70 were materially false and misleading, and omitted to state material facts necessary to make them not misleading. As detailed above, at the time of these statements, Byte did not offer “***comprehensive doctor directed care,***” and “***Licensed doctors and orthodontists***” were not with Byte patients “***every step of the way.***” Rather than provide “***teledentistry***” services or access to “***Licensed doctors and orthodontists . . . every step of the way,***” Byte did not offer any opportunity for a patient to communicate with a dentist. In reality, as described by FE-4 and FE-2, the involvement of dentists and orthodontists in Byte patient treatment plans was limited to, at most, a one-time approval by a single dentist or orthodontist who devoted inadequate time or attention to the patient’s medical records. In fact, as

further described by FE-2 and FE-3, Byte repeatedly and affirmatively denied patient requests to speak to a doctor even when those patients suffered serious injuries. Moreover, as described by FE-4, FE-3, and otherwise described in ¶108, dental assistants and customer service employees alike made changes to patients' treatment plans (*e.g.*, changing the sequence in which the patient wore the aligners) without the approval of or consulting with any dentist or orthodontist.

272. From at least June 19, 2021 to at least May 28, 2022, Dentsply made the following statements on its website for Byte, on a page titled "How Byte Compares to Smile Direct Club," under the heading "Professional supervision: what differences can you expect?"

Smile Direct Club relies on a network of 225 dentists and orthodontists. You'll work with someone licensed to do business in the state where you live. Every 90 days, you'll check in with that dentist when you log into your account.

. . . Byte has a nationwide network of over 200 licensed dentists and orthodontists. You'll be matched with a dental professional licensed in your state. ***Your Byte professional will assess every step of your smile improvement program.*** . . . You can access your team at any time by logging on.

Both Byte and Smile Direct Club offer clear aligners to improve smiles, but you will notice differences in timeframes, guarantees, and service levels.

273. The statements set forth in ¶272 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially false and misleading to state that the "dental professional" for Byte patients would "***assess every step of***" their "smile improvement program," and to convey that this communication and contact was more frequent and involved than the 90-day "check in" offered by SmileDirectClub. In reality, licensed dentists and orthodontists did not "assess every step" of patients' treatment plans, and in fact, patients had even ***less*** contact with such licensed dentists than SmileDirectClub's offer of 90 day check-ins. As described by FE-4 and FE-2, the involvement of dentists and orthodontists in Byte patient treatment plans was limited to, at most, a one-time approval by a single dentist or orthodontist who devoted inadequate time or attention to the patient's medical records. As further

described by FE-2 and FE-3, Byte repeatedly and affirmatively denied patient requests to speak to a doctor even when those patients suffered serious injuries. Moreover, as described by FE-4, FE-3, and otherwise described in ¶108, dental assistants and customer service employees alike made changes to patients' treatment plans (*e.g.*, changing the sequence in which the patient wore the aligners) without the approval of or consulting with any dentist or orthodontist.

3. September 2021 Dentsply Sirona World

274. On September 23, 2021, Dentsply hosted a meeting for analysts and investors, titled "Dentsply Sirona World 2021." During prepared remarks, Defendant Gunsagar stated:

Who is Byte, right? So we were acquired by Dentsply Sirona at the beginning of the year. And like Chidam had mentioned, we are consumer-focused today, right? ***Doctor directed, every treatment plan is overseen by a doctor in our network.*** And we provide clear aligners across the entire country. ...

Like I mentioned earlier, the at-home piece of it is very important, but ***the doctor direction piece is important as well, so making sure that all the treatment plans are really well diagnosed from our treatment planners all the way to our doctors.***

275. The statements set forth in ¶274 was materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially false and misleading to state that Byte treatment was "***doctor directed***" and "***overseen by a doctor***" because, in reality, the Byte treatment was neither. Rather, as described by FE-2, the involvement of dentists and orthodontists was limited to a one-time approval, and as described by FE-2 and FE-3, Byte and Dentsply refused patient requests to speak to a doctor even when patients suffered serious adverse events. And as further described by FE-2, even during that one-time approval, the licensed dentist or orthodontist would be permitted to devote inadequate time or attention to the patient's medical records. Moreover, as described by FE-4 and otherwise described in ¶108, dental assistants and customer service employees alike made changes to patients' treatment plans (*e.g.*, changing the sequence in which the patient wore the aligners) without the approval of any dentist

or orthodontist. Further, Dentsply secretly auto-reassigned treatment plans rejected by one or two doctors to another doctor, subjecting patients to unsafe and/or ineffective treatment plans rejected by one of two or even two of three doctors.

4. Dentsply's Form 10-Ks and 10-Qs

276. On March 1, 2021, Dentsply filed its Annual Report on Form 10-K for fiscal year 2020, signed by Defendants Casey and Gomez. The 10-K for 2020 stated:

On December 31, 2020, the Company acquired Straight Smile LLC ("Byte"), a leading provider in the direct-to-consumer, ***doctor-directed*** clear aligner market.

277. The 10-K for 2020 further stated:

On December 31, 2020, the effective date of the transaction, the Company acquired 100 % of the outstanding interests of Byte, a privately-held company, for approximately \$ 1.0 billion using cash on hand. Byte is a ***doctor-directed***, direct-to-consumer, clear aligner business. The acquisition is expected to enhance scale and accelerate the growth and profitability of the Company's combined clear aligners business.

278. On March 1, 2022, Dentsply filed its Annual Report on Form 10-K for fiscal year 2021, signed by Defendants Casey and Gomez. The 10-K for 2021 repeated the statements quoted in ¶¶276-77.

279. The 10-K for 2021 further stated:

[T]he Company's Byte business produces aligners which are sold direct to consumers under ***doctor-directed, personalized treatment plans***.

280. The 10-K for 2021 further stated:

Due in part to its direct-to-consumer model, the Company's Byte aligner business in the U.S. is subject to various state laws, rules and policies which govern the practice of dentistry within such state. ***Byte contracts with an expansive nationwide network of independent licensed dentists and orthodontists for the provision of clinical services, including the oversight and control of each customer's clinical treatment*** in order to comply with these regulations and ensure that the business does not violate rules pertaining to the corporate practice of dentistry.

281. On May 6, 2021, August 5, 2021, and November 4, 2021, Dentsply filed its Quarterly Reports on Form 10-Q for the first, second, and third quarters of 2021, respectively, each of which was signed by Defendants Casey and Gomez. Each of those Forms 10-Q referred back to and incorporated by reference “Part I, Item 1, ‘Business’” of Dentsply’s Form 10-K for fiscal year 2020, which included the statement about “oversight and control” quoted in ¶280.

282. On March 1, 2023, Dentsply filed its Annual Report on Form 10-K for fiscal year 2022, which was signed by Defendants Campion and Coleman. The Form 10-K for 2022 repeated the statements quoted in ¶280.

283. The Form 10-K for 2022 further stated that:

On December 31, 2020, we acquired Byte, a leading provider in the direct-to-consumer, ***doctor-directed*** aligner market. Byte’s business in the U.S. is subject to various state laws, rules and policies which govern the practice of dentistry within such state. ***Byte contracts with an expansive nationwide network of independent licensed dentists and orthodontists for the provision of clinical services, including the oversight and control of each customer’s clinical treatment;*** however, there can be no assurance that such business model will not be challenged as the corporate practice of dentistry by state governmental authorities, trade associations, or others. Additionally, future legislative or regulatory changes within such states may have a negative impact on Byte’s business model.

284. On February 29, 2024, Dentsply filed its Annual Report on Form 10-K for fiscal year 2023, which was signed by Defendants Campion and Coleman. The Form 10-K for 2023 repeated the statement quoted in ¶283.

285. The statements set forth above in ¶¶276-84, were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially false and misleading to state that Byte was “***doctor-directed***” and that “***each customer’s clinical treatment***” was not provided under the “***oversight and control***” of “***an expansive nationwide network of independent licensed dentists and orthodontists.***” In reality, as described by FE-2 and FE-4, the involvement of dentists and orthodontists was limited to a one-time

approval, and Dentsply refused patient requests to speak to a dentist or orthodontist even when patients suffered serious adverse events. Further, as described by FE-4, FE-3, and otherwise described in ¶108, dental assistants and customer service employees alike made changes to patients' treatment plans (*e.g.*, changing the sequence in which the patient wore the aligners) without the approval of or consulting any dentist or orthodontist.

5. January 16, 2024 Florida Senate Hearing

286. During the Class Period, Dentsply and Byte engaged in lobbying activities intended to stave off further regulation of the direct-to-consumer clear aligner market and on Byte in particular. On January 16, 2024, the Florida Senate Committee on Health Policy held a hearing on SB302, which proposed such restrictions. At that hearing, Dr. Angela McMullin, who claimed to have “worked as a dentist affiliated with Byte prescribing clear aligners,” testified expressly “on behalf of Byte and Dentsply Sirona to oppose SB302.”

287. In her testimony, Dr. Angela McMullin stated that Dentsply and Byte “ensure that each Florida patient receives an individualized treatment plan that is reviewed, prescribed, and ***overseen by a Florida licensed dentist or orthodontist.***” Dr. McMullin further stated that the “review process is a comprehensive one,” and that the dentist who prescribes the treatment plan can “advise the patient directly through the company’s portal.” Dr. McMullin also testified that “provided the patient is approved for treatment, ***the patient stays with that same Florida licensed dentist, . . . and if there are any issues they run into, the dentist is the one consulted on how to proceed.***”

288. The statements in ¶287 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially false and misleading to state that Byte patients’ “individualized treatment plans” were “***overseen by a . . . licensed dentist or orthodontist,***” and that, after beginning treatment, “***the patient stays with that***

same [] licensed dentist, . . . and if there are any issues they run into, the dentist is the one consulted on how to proceed,” whether in Florida or elsewhere. Rather than “oversee[]” patients’ treatment plans, in reality, and as described by FE-2 and FE-4, the involvement of dentists and orthodontists was limited, at most, to a one-time approval by a single dentist or orthodontist who devoted inadequate time and attention to the patient’s medical records. Moreover, rather than “stay with the same licensed dentist” throughout a treatment, in truth, and as corroborated by FE-2 and FE-3, Dentsply refused patient requests to speak to a dentist or orthodontist even when patients suffered serious adverse events. Further, as described by FE-4, FE-3, and in ¶108, rather than “consult[]” the patient’s prescribing “*dentist*” on “*how to proceed*” when “*any issues*” arose, dental assistants and customer service employees alike made changes to patients’ treatment plans (*e.g.*, changing the sequence in which the patient wore the aligners) when issues arose without consulting or obtaining the approval of any dentist or orthodontist. In addition, as FE-4 confirmed, Dentsply employees did not even have the means to consult with the patient’s prescribing dentist if they wanted to. Further, Dentsply secretly auto-reassigned treatment plans rejected by one or two doctors to another doctor, subjecting patients to unsafe and/or ineffective treatment plans rejected by one of two or even two of three doctors.

6. False Statements On Investor Conference Calls

289. On September 5, 2024, Dentsply and Defendants participated in the Morgan Stanley 22nd Annual Global Healthcare Conference for investors and securities analysts. At that conference, a Morgan Stanley analyst asked Defendants, “can you give us an update on both the DTC platform with Byte and what’s going on from a regulatory standpoint?” In reply, Defendant Campion stated, “On Byte the regulatory challenges, where we need more dental involvement, not that we have – ***all our treatment plans are overseen by a dental professional***, but some states have taken it to the next level.”

290. The statements set forth in ¶289 were materially false and misleading, and omitted to state material facts necessary in order to make them not misleading. All of Byte’s treatment plans were not “**overseen by a dental professional.**” In reality, as described by FE-2 and FE-4, the involvement of dentists and orthodontists was limited, at most, to a one-time approval by a single dentist or orthodontist who devoted inadequate time or attention to the patient’s medical records. Further, as described by FE-4, FE-3, and otherwise described in ¶108, dental assistants and customer service employees alike made changes to patients’ treatment plans (*e.g.*, changing the sequence in which the patient wore the aligners) without obtaining the approval of any dentist or orthodontist.

B. False Statements Regarding Customer Standards

1. Dentsply’s Website Throughout The Class Period

291. From before the Class Period through at least January 23, 2022, Dentsply made the following statements on its website for Byte, on a page titled “Teledentistry 101.”

Safety trumps everything. At the end of the day, teledentistry only works if it’s safe. Some cases are simple and straight forward and others are complicated. **Complex cases often require traditional in-person treatment** and facilities. Experienced medical professionals are the only ones who can assess each patient and decide if they are a candidate for remote treatment. Byte takes this seriously. **We only accept customers who are great candidates for teledentistry and can safely use Byte for improving their smile. We don’t compromise on safety.** Your smile is with you for life, so getting it right is important.

292. The statements in ¶291 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. Rather than “**only accept customers who are great candidates for teledentistry,**” in truth, Dentsply accepted patients who were poor candidates for teledentistry, who were contraindicated for Byte, and for whom Byte treatment posed significant safety risks. It was further false and misleading to state that Dentsply “**only**” accepted “**great candidates for teledentistry**” because, in reality, Byte’s treatment process was not

designed to identify those candidates and Dentsply in fact routinely accepted poor candidates who were contraindicated for the product. For example, as described by FE-2, patients with contraindications would often be approved for Byte treatment based on incomplete or insufficient medical information by a treatment planner who lacked medical training, and then a “rubber stamp” review by a licensed dentist—a process that was not designed to and did not “**only**” identify or accept appropriate candidates for Byte. Further, as a result, in truth, Dentsply did in fact “**compromise on safety**,” including as reflected in the thousands of serious injuries that Dentsply belatedly reported to the FDA. Further, Dentsply secretly auto-reassigned treatment plans rejected by one or two doctors to another doctor, subjecting patients to unsafe and/or ineffective treatment plans rejected by one of two or even two of three doctors.

293. From before the Class Period until at least September 20, 2021, Dentsply made the following statements on its website for Byte, on a page titled “Byte’s Expert Dental Network”:

How **our doctor directed care** works. . . . Match with a doctor. Once we have your dental impressions, this is where the pros take over. **First we match you with a licensed orthodontist in your state.** Using the quiz information you provided, and your submitted impressions, they confirm if you are indeed a candidate. **(If for some reason you don’t qualify, we’ll let you know asap, and REFUND your impression kit cost.** We aren’t in the business of taking money, just in the business of improving smiles.) **We only accept patients who are great candidates for teledentistry and clear aligners. This means mild to moderate spacing and crowding, and you meet specific dental health guidelines, so that you can safely use Byte for improving their smile.** Think about it, we WANT you to be successful and safe, that’s what this is all about!

294. From at least January 23, 2022 until at least August 5, 2023, Dentsply made the following statements on its website for Byte, on a page titled “Byte’s Expert Dental Network”:

How **our doctor directed care** works. . . . Get approved for Byte. Once we have your dental impressions, this is where the experts take over. Using the information you provided, and your submitted impressions, the team confirms if you are indeed a candidate. **(If for some reason you don’t qualify, we’ll let you know asap, and REFUND your impression kit cost.** We aren’t in the business of taking money, just in the business of improving smiles.) **We only accept customers who are great**

candidates for remote treatment and clear aligners. Think about it, we WANT you to be successful and safe, that's what this is all about!

295. From before the Class Period until at least October 27, 2021 Dentsply made the following statements on its website for Byte, on a page titled "Comprehensive doctor-directed care":

- Committed to safety. . . . ***[W]e thoroughly analyze each customer's impressions and information to ensure a safe and effective treatment plan. It's a risk-free process, including a full refund if you aren't a candidate.***

296. From at least January 9, 2022 until at least October 8, 2024, made the following statements on its website for Byte, on a page titled "Comprehensive doctor-directed care":

- Committed to safety. . . . ***Each customer's impressions and other information are thoroughly analyzed prior to designing a treatment plan. It's a risk-free process, including a full refund if you are not a candidate.***

297. From at least August 3, 2021 until at least May 22, 2022, Dentsply made the following statements on its website for Byte, on a page titled "FAQ":

- How do I know if Byte is right for me? . . . ***Your at-home impressions will give us the information we need to know if you are a good candidate for Byte treatment. If you're not, we'll refund the full price of the Impression Kit.***
- Can Byte Help with Crowding? Yes! . . . We recommend getting started with an impression kit so we can assess the severity of crowding and create the best treatment option for you. ***If you're not a candidate, we'll refund you the cost of the Impression Kit.***
- Can Byte help with spacing? Yes! . . . Since spacing may differ from person to person, sending us your impressions is the best way for us to look at an accurate representation of your current smile and create the best-looking smile for you. ***If you do not qualify for treatment, we'll refund you the cost of the Impression Kit!***
- Can Byte help with my overbite/underbite/crossbite? It depends . . . Get started with an Impression Kit so we can provide the best treatment option for you! ***No worries if you are not a candidate- we will refund you the cost.***
- Can Byte help with my midline? . . . Aligners cannot correct a midline, but can improve the appearance through better alignment. Get your Impression Kit

today and see what your midline could look like with our 3D model of your smile! ***If you are not a candidate, we'll refund you the cost.***

- Can I do Byte if I have veneers? Yes! Byte can move veneers and crowns as long as they are not on your molars. See what your personalized treatment plan looks like after buying and sending back your Impression Kit! ***If you're not a candidate, we'll refund you the cost of the Impression Kit.***
- Can I do Byte if I have a dental implant? It's possible. Our dentists will need to take a look at your impressions to know for sure. ***If you're not a candidate, you'll get a refund for the Impression Kit.***
- Can I use aligners if I have missing teeth? It's possible. Our dentists will need to take a look at your impressions to know for sure. ***If you're not a candidate, you'll get a refund for the Impression Kit.***
- Is my Impression Kit refundable? Your at-home impressions will give us the information we need are a good candidate for Byte treatment. ***If you're not, we'll refund the full price of the Impression Kit.***

298. From at least July 3, 2022 until at least October 8, 2024, Dentsply revised the previous statements on the "FAQ" page of its website for Byte to instead read:

- How do I know if Byte is right for me? . . . ***Your at-home impressions will be used to determine if you're a good candidate for Byte aligners. If you're not, you'll get a full refund for the price of the Impression Kit.***
- Can Byte help with spacing? Yes! . . . Since spacing may differ from person to person, ***sending us your impressions is the best way to get custom treatment plan prescribed for your unique smile. If you do not qualify for treatment, we'll refund you the cost of the Impression Kit!***
- Can Byte help with my midline? . . . Aligners cannot correct a midline, but can improve the appearance through better alignment. Get your Impression Kit today and see what your midline could look like with our 3D model of your smile! ***If you are not a candidate, we'll refund you the cost.***
- Can I do Byte if I have veneers? Yes! Byte can move veneers and crowns as long as they are not on your molars. See what your personalized treatment plan looks like after buying and sending back your Impression Kit! ***If you're not a candidate, we'll refund you the cost of the Impression Kit.***
- Can I do Byte if I have a dental implant? It's possible. Send in your impressions to find out for sure. ***If you're not a candidate, you'll get a refund for the Impression Kit.***

- Can I use aligners if I have missing teeth? It's possible. Send in your impressions to find out for sure. ***If you're not a candidate, you'll get a refund for the Impression Kit.***
- Is my Impression Kit refundable? Your at-home impressions will give us the information we need to see if you are a good candidate for Byte treatment. ***If you're not, we'll refund the full price of the Impression Kit.***

The statements in ¶¶293-98 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially false and misleading to state that Dentsply would “***only accept patients who are great candidates for teledentistry and clear aligners***” because, in truth, Dentsply accepted poor candidates for teledentistry and who were contraindicated for Byte. It was further false and misleading to state that Dentsply only accepted candidates with “***mild to moderate spacing and crowding***” and that it would “***refund the full price of the Impression Kit***” for prospective patients’ because, in truth, Dentsply routinely accepted candidates with contraindications and sought to sell Byte to contraindicated customers rather than refund patients. Rather, as discussed *supra* ¶¶96-100, contraindicated patients were often sold an impression kit, and if their treatment planner in Costa Rica rejected the patient due to contraindications, other treatment planners would be given the opportunity to overrule the patient’s self-identified contraindications, and the ultimate treatment plan would be approved by a “rubber stamp” review by a dentist. Further, dentists would often grant extraordinarily fast approvals and were not required to scroll through the patient’s medical history. Moreover, as described by FE-5 and FE-6, in an internal August 2022 meeting, Dentsply management instructed sales representatives to cease informing patients of their contraindications—which should have entitled those patients to impression kit refunds—and to instead attempt to “convert” the aligner sale anyway. As confirmed by , following this directive, Byte began to accept an increasing number of contraindicated patients, which immediately and meaningfully improved Byte’s “conversion”

rate. It was further misleading to convey that Dentsply only sold Byte to “great candidates” and that poor candidates would receive refunds because, in reality, Dentsply secretly auto-reassigned treatment plans that were rejected by one, even two doctors, to a third doctor—until the treatment plan was approved—which resulted in poor contraindicated candidates being prescribed Byte.

2. False Statements Concerning Byte’s Financial Performance And Conversion Rates

299. On March 29, 2022, Defendants participated in Piper Sandler Virtual Dental Day for investors and securities analysts. At that virtual conference, a Piper Sandler analyst asked Defendants, with regards to Byte’s conversion rate, “Have those conversion rates started to show any kind of life to them? Or is this more of like, hey, like let’s keep this as stable and we think some of the initiatives we have in place are going to support the growth in the second half of the year.” In reply, Defendant Casey stated:

There’s two specific activities there. BytePro is one of them where, look, if you’re not eligible for – if you – **Byte is basically Class I**. If you’re a Class II, Class III or ultimately you feel that you really want to be in touch with the dentist again, we’re cycling 600,000 to 800,000 unique visitors in the course of a month. If you’re talking in the 20,000 plus people who are basically looking to buy a trial kit from us and then the shape of the funnel, there are a significant number of people that we would like to see access dental care.

Like for instance, **if you have a cavity, you may be eligible for Byte, you might be really interested in Byte, but if you’ve got an unfixed cavity, and remember, this tends to be an underserved population, you need to get to a dentist to get that fixed to come back to fight**. So BytePro, in our mind, is another way of monetizing what we think of this patient traffic.

300. The statements set forth in ¶299 were materially false and misleading, and omitted to state material facts necessary in order to make them not misleading. It was not true that “**Byte is basically Class I**,” and that prospective patients who were contraindicated, including those with “**unifixed cavit[ies], . . . need to get to a dentist to get that fixed**,” before they could enroll in a Byte treatment plan, *i.e.*, “**come back to fight**.” In reality, rather than effectively screen out

prospective patients who were contraindicated, including those with Class II or Class III malocclusion, Byte's onboarding process encouraged sales to such candidates and, in fact, Dentsply sold Byte to patients with unfixed cavities and similar contraindicated conditions.

301. On February 28, 2023, Dentsply held an earnings call with analysts and investors to discuss the Company's financial results from the fourth quarter for the 2022 fiscal year. In prepared remarks, Defendant Coleman stated that "Byte [] saw a very strong growth despite slowing consumer spending trends as ***we're seeing improvement in customer conversion rates.***"

302. On May 3, 2023, Dentsply held an earnings call to discuss the Company's financial results from the first quarter of 2023. In prepared remarks, Defendant Coleman stated, "Our direct-to-consumer Aligner brand, ***Byte***, also saw strong growth despite slowing consumer spending trends, ***driven by higher customer conversion rates and lower customer acquisition costs***, which not only drove higher top line revenues but also better profitability."

303. The statements set forth in ¶¶301-02 were materially misleading and omitted to state material facts necessary in order to make them not misleading. It was misleading for Defendants to tout Byte's "***improve[d]***" or "***higher customer conversion rates***" and "***lower customer acquisition costs***" without disclosing that these metrics were in truth driven by Defendants' intentional efforts to cease rejecting contraindicated patients. As described by FE-5 and FE-6, the Company's senior management instructed Byte's sales force in August 2022 to cease informing patients of their contraindications—which should have entitled those patients to impression kit refunds—and to instead attempt to convert the treatment plan sale anyway. As confirmed by FE-5, Byte began to accept an increasing number of contraindicated patients following this directive, which was the source of Byte's meaningfully "improved" conversion rate.

304. On that same earnings call, an analyst from Evercore ISI Institutional Equities asked Defendants, “Can you also talk about the Aligner profitability. Where is the real drivers of that?” In reply, Defendant Coleman stated, “[T]he most important thing is really looking at the *quality of the funnel and how we’re targeting customers*. And we’re seeing an *increase in our overall customer conversion rates, which really helped to reduce customer acquisition costs* and drive increased profitability.”

305. Similarly, an analyst from William Blair asked Defendants with regards to “clear aligners . . . where are you guys seeing the most success? Maybe what channels specifically – I’m curious if you could talk a little bit about what is it about your technology that is able to allow you to deliver these fewer refinements and shorter treatment times compared to the competition? In reply, Defendant Coleman stated, “On the Byte side, I think *we’re doing a much better job of targeting customers and driving better customer conversion rates* that I mentioned earlier.”

306. On that same earnings call, an analyst from JP Morgan asked Defendants, “As you noted that SureSmile and Byte grew double digits in the quarter. So can you just walk us through how much of that performance in Clear Aligners has been driven by greenfield wins versus brownfield?” In reply, Defendant Campion stated, “[W]e have been passing or rolling through *an improved process at Byte in relation to customer acquisition*, ensuring that the *customers that we are bringing into the funnel are more likely than in the past to end up ordering aligners. We’ve worked on our sales incentive program and the sales training programs with our sales force and to onboard* SureSmile and *Byte*.”

307. On May 10, 2023, Defendants participated in the Bank of America Securities Healthcare Conference for investors and securities analysts. At that conference, a Bank of America analyst asked Defendants, “How do you—maybe start with SureSmile, how do you in the best

places that you think this product is positioned in the market in what it will become -- has become an increasingly competitive market?” In reply, Defendant Campion stated that “On the BYTE side, . . . Great conversion rate. We – ***our 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 in Salt Lake City has done.***”

308. On June 1, 2023, Dentsply and Defendants Campion and Coleman participated in Stifel’s Jaws & Paws Conference for investors and securities analysts. Defendant Campion stated, “We’ve streamlined how we run that business in the sense that ***we have a more focused funnel. We validate customers as they enter the funnel, so we don’t spend money sending an impression kit to a customer who is not likely to actually purchase. We’ve changed incentive plans.*** So we’re putting the building blocks in place for sustained growth in both SureSmile and Byte.”

309. On August 3, 2023, Dentsply held an earnings call to discuss the Company’s financial results from the second quarter of the 2023 fiscal year. In prepared remarks, Defendant Coleman stated, “Byte grew high-single digits, driven by ***improved customer conversion rates and lower customer acquisition costs.***” In further prepared remarks, Defendant Campion stated “***Byte continues to deliver*** top line growth and ***enhanced operational performance with higher customer conversion rates, effective patient engagement and lower customer acquisition costs.***”

310. On September 12, 2023, Defendants participated in Baird’s Global Healthcare Conference for investors and securities analysts. At this conference, an analyst from Baird asked Defendants, “We actually heard pretty good things about Byte’s competitive process and ability to convert customers even then, I think you’ve improved it since then. So on the CAC side, especially with Byte, where has that been trending?” In reply, Defendant Campion stated, “So as I said, ***we have narrowed our funnel down, but the neck of the funnel is wider. So the customers we bring in are more likely to purchase an aligner solution from us.*** And ***that’s as we refine our***

questioning on our surveys as they come into the funnel that we move potential customers to the side if we really don't think that they're going to end up purchasing. And our conversion rate has, I think, meaningfully improved this past 12 months.”

311. On November 9, 2023, Dentsply held its annual Investor Day. At the Investor Day, Defendant Frank stated that the *“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.”*

312. On November 15, 2023, Dentsply and Defendants participated in the 14th Annual Jefferies London Healthcare Conference for investors and securities analysts. At this conference, an analyst from Jefferies asked Defendants, “[W]hy are you committed to the Byte business at all?” In reply, Defendant Campion stated, “We have a smaller funnel than we've had in the past, but *our conversion rates have gone up.*”

313. Defendant’s statements above in ¶¶304-312 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially false and misleading to tout improvements to Byte’s sales funnel and its customer conversion rate, including by attributing those improvements to the *“quality” of the “funnel,”* a *“much better job of targeting customers,”* a *“more focused funnel,”* *“refine[ments]”* to *“our questioning on our surveys”* or *“change[s]”* in *“marketing strategy,”* and to *“validat[ing] customers as they enter the funnel,”* because in reality, Byte’s increased conversion rate was driven by Defendants’ decision to cease rejecting contraindicated patients. As described by FE-5FE-5 and FE-6, the Company’s senior management instructed Byte’s sales force in August 2022 to cease informing patients of their contraindications—which should have entitled those patients to impression kit refunds—and to instead attempt to convert the treatment plan sale anyway. As

confirmed by FE-5, Byte began to accept an increasing number of contraindicated patients following this directive, which was the source of Byte’s meaningfully “improved” conversion rate.

314. On January 10, 2024, Defendants participated in the JPMorgan 42nd Annual Healthcare Conference for investors and securities analysts. At that conference, an analyst with JPMorgan asked Defendants, “[Y]ou’re anticipating over 20% growth between SureSmile and Byte. So can you walk us through, what gives you confidence on these above-market growth targets and how achievable are they?” That analyst continued, with reference to SmileDirectClub, “And then where could we expect to see the highest growth in the next year given one of your peers recently halted operations?” In reply, Defendant Frank stated, “We have focused the last 12 months intently on profitably growing our direct-to-consumer business, ***focusing on the top of the funnel on our conversion rates, . . . [a]nd that positions us really well now to take advantage of this major shift that we’re seeing in the category with the leading company exiting the space.***”

315. Defendants’ statements above in ¶314 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially false and misleading to state that Byte’s conversion rates had improved due to the Company’s “focus[] on the top of the funnel” because, in truth, Byte’s conversion rate was driven by Defendants instruction to their sales force to cease rejecting customers on the basis of their contraindications. Moreover, it was materially false and misleading to state that Dentsply’s focus on Byte conversion rates had “position[ed]” the Company “really well . . . to take advantage” of SmileDirectClub’s exit, because by selling Byte treatment plans to contraindicated customers, Dentsply undermined Byte’s safety profile and provoked the FDA reaction that ultimately led to the shuttering of Byte’s business.

C. Defendants’ False Statements Regarding Dentsply’s Compliance With FDA Reporting Regulations

1. The FDA Regulations Requiring Dentsply To Report Byte Patient Injuries

316. Byte, like many of Dentsply’s products, was a medical device regulated by the FDA—a regulatory scheme central to Dentsply’s business that was intimately and well understood by each of the Executive Defendants.

317. Byte is a Class II medical device, meaning that it poses medium to high risk to patients and that “general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device”—and thus has a higher level of regulatory oversight than Class I (lowest risk) and less than Class III (highest risk) devices.¹⁵

318. Two interrelated FDA rules governing the marketing and sale of Byte’s aligners are at issue in this case. *First*, Dentsply was required to report injuries associated with the Byte product to the FDA. Specifically, the FDA’s Medical Device Reporting rule, 21 C.F.R. Part 803, requires manufacturers of medical devices like Dentsply to report to the FDA: (a) any “serious injury” that the device may have caused or contributed to; and (b) any malfunction that would be likely to cause a serious injury if it were to recur, even if the incident in question caused no injury. *See* 21 C.F.R. § 803.1(a).¹⁶ Medical Device Reporting is the foundation of the “postmarket

¹⁵ Dentsply (and Straight Smile) took the position that Byte was a Class II device when providing premarket notification to the FDA under Section 510(k) of the FD&C Act. Straight Smile obtained clearance for Byte on February 19, 2019 (device identifier K180346). Dentsply obtained a new clearance for Byte on October 18, 2023 (device identifier K230199).

¹⁶ Specifically, for a manufacturer, a “reportable event” is defined as “An event that manufacturers ... become aware of that reasonably suggests that one of their marketed devices: (i) May have caused or contributed to a death or serious injury, or (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer 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). “Serious injury” is defined as an injury that “(2) Results in permanent impairment of a body function or

surveillance” regime administered by the FDA. “These reports help [the FDA] to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.” 21 C.F.R. § 803.1(a).

319. The FDA relies upon adverse incident reports to identify safety issues and to allocate its limited investigative and enforcement resources. These reports are also a critical part of alerting healthcare professionals, the public, and investors to potential safety issues and trends with certain devices. Specifically, the FDA makes these medical device reports available to the public through its Manufacturer and User Facility Device Experience (MAUDE) database—which periodically publishes the reports it receives in an online database.

320. Healthcare professionals, investors, and analysts closely followed MAUDE reporting for Dentsply products and, indeed, specifically for Dentsply’s Byte product. In fact, near the end of the Class Period, in September 2024, Dentsply management was specifically asked about an “uptick” in MAUDE reports for Byte—and Dentsply executives responded by acknowledging they knew about the “uptick” and the reasons for it.

321. Moreover, FDA regulations specifically charged Dentsply senior management with overseeing and carrying out this reporting. Specifically, the FDA’s Quality System Regulation rule, 21 C.F.R. Part 820, requires “management with executive responsibility” to assume personal responsibility for compliance with the Medical Device Reporting rule. A manufacturer is required to “[s]ubmit reports of individual adverse events no later than 30 calendar days after the day that [it] become[s] aware of a reportable death, serious injury, or malfunction.” 21 C.F.R. §

permanent damage to a body structure, or (3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.” 21 C.F.R. § 803.3(w). “Malfunction” is defined as “the failure of a device to meet its performance specifications or otherwise perform as intended” including “all claims made in the labeling for the device.” 21 C.F.R. § 803.3(k).

803.10(c)(1). The FDA’s premarket clearance letters for Byte, dated February 19, 2019 and October 13, 2023, specifically warned Dentsply and Straight Smile: “You must comply with all the [FD&C] Act’s requirements, including, but not limited to: ... medical device reporting (reporting of medical device-related adverse events) (21 CFR 803).”

322. **Second**, FDA regulations also provide detailed requirements to ensure manufacturers effectively carry out their medical device reporting responsibilities—which are considered an essential part of a manufacturer’s “quality system,” for which FDA rules require “management with executive responsibility” to ensure compliance. For example, the FDA’s Quality System Regulation (21 C.F.R. Part 820) requires a manufacturer to evaluate all patient complaints “to determine whether the complaint represents an event which is required to be reported to FDA.” 21 C.F.R. § 820.198(a)(3). The Quality System Regulation also requires “management with executive responsibility” to, among other things, (i) “establish its policy and objectives for, and commitment to, quality” and to “ensure that the quality policy is understood, implemented, and maintained at all levels of the organization”; (ii) “review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency...to ensure that the quality system satisfies the requirements of this part and the manufacturer’s established quality policy and objectives”; and appoint an executive responsible for ensuring that “quality system requirements are effectively established and effectively maintained” and reporting on the “quality system to management with executive responsibility for review.” 21 C.F.R. § 820.20(a), (b)(3), (c). In other words, FDA regulations imposed upon Dentsply senior management clearly defined responsibility for ensuring timely and accurate reporting of serious injuries and other adverse events.

323. Significantly, the consequences for any failure by Dentsply to file required adverse event reports can be severe and potentially ruinous. Specifically, any sale of a medical device after failing to file required medical device reports with the FDA is a form of “misbranding,” 21 U.S.C. § 352(t)—violations that could potentially expose Dentsply to product recalls, monetary fines, the FDA’s refusal to approve other medical devices manufactured by Dentsply, and even criminal charges. *See* 21 U.S.C. § 333(a), (f).

324. Defendants represented to investors that they complied with these regulations. Those representations were important to investors, not only because of the potential legal repercussions, but also because medical device reports reflect upon the safety of the device, and an unsafe device is less valuable. Dentsply acknowledged as much in its SEC filings, warning investors that its compliance with these FDA regulations was a material “Risk Factor” and that its failure to “comply with these rules” could result in “significant civil and criminal penalties” and “could have a material adverse impact on Dentsply Sirona’s business.”

325. As alleged herein, contrary to Dentsply’s legal obligations under FDA laws and regulations, Dentsply repeatedly and knowingly failed to report hundreds of Byte injuries per month, deceiving both investors and regulators concerning the safety of the product.

2. False Compliance Statements Made At The 39th Annual JP Morgan Virtual Healthcare Conference

326. On January 13, 2021, at the 39th Annual JP Morgan Virtual Healthcare Conference, a JPMorgan analyst asked Defendants “How do you avoid some of the traps that SmileDirect” faced and had recently been the subject of intense media and investor scrutiny. In response, Defendant Casey stated that, unlike SmileDirect:

[Byte] was built from the ground up to be a DTC play. ***And we believe that the customer experience that had been really carefully curated at Byte was really a sustainable advantage for us.*** So that’s kind of how we settled on Byte. And again,

we've been running the business for a week. But everything we saw in diligence and now that we see even in this early stage excites us even more.

In terms of ***how do you avoid the traps for rapid growth***, I mean, one of the things that I believe the reasons that the founders at Byte and the Byte management team is looking at it, they wanted to avoid some of those mistakes. They wanted to be able to ***take advantage of the scale and the expertise that we have in*** globalizing businesses, things around supply chain, ***QA [Quality Assurance], RA [Regulatory Affairs]*** and other areas. ***We bring immediate credibility and can give them a solid foundation to build out expansion.***

327. The statements in ¶326 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was false and misleading for Defendant Casey to distinguish Byte from SmileDirectClub based on Byte's purported "***carefully curated***" customer experience and Dentsply's "***expertise***" in Quality Assurance and Regulatory Affairs. That is because, in truth, as described in ¶¶134-152, Byte had the same quality issues that plagued SmileDirectClub and Dentsply failed to report thousands of Byte serious injurious and utterly failed to follow appropriate Quality Assurance and Regulatory Affairs practices with respect to Byte. Those failures include Dentsply's failure to report hundreds of instances where Byte resulted in lost teeth—events that Dentsply's official Decision Tree designated as reportable to the FDA.

3. False Compliance Statements Made To *The Capitol Forum*

328. On June 28, 2024, *The Capitol Forum* published an article wherein a spokesperson for Dentsply was quoted as saying that the recent increase in Byte injuries reported to MAUDE was "***strictly related to our efforts to continuously improve our processes in alignment with current, global regulatory requirements***" and the Company's "steps to strengthen our post market surveillance and medical device reporting." The spokesperson was also quoted as stating that, at Dentsply, "***[A]ll 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.***"

329. The statements set forth in ¶328 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. Rather than “***strictly relate[] to***” the Company’s purported “***efforts to continuously improve our processes in alignment with current, global regulatory requirements,***” in reality, the uptick in Dentsply’s injury reports was motivated by the Company’s efforts to avoid an FDA enforcement action after Dentsply had failed to submit thousands of Byte injury reports to the FDA.

330. Nor was it the case that “[A]ll medical device reports are thoroughly investigated in accordance with 21 CFR 820,” which required Dentsply “to determine whether the complaint represents an event which is required to be reported to FDA.” In reality, at the time this statement was made, Dentsply was then aware of ***thousands*** of reports of serious Byte injuries that were required to be but had not been reported to the FDA—including reports of lost teeth that were specifically designated as reportable under Dentsply’s own internal policy. But rather than “thoroughly investigate” those reports “in accordance with 21 CFR 820,” which required them to be reported to the FDA, Defendants withheld these reports in order to avoid public scrutiny, including from state legislators who were specifically focused on the injury rates of direct-to-consumer clear aligners.

331. It was further materially misleading to state that there had been “***no changes in the quality, safety, or effectiveness of [] Byte products***” because that statement omitted the highly material fact that Dentsply deliberately sold Byte to contraindicated patients—an undisclosed practice that posed serious safety risks. As described by FE-5 and FE-6, in August 2022, senior management instructed the Byte sales force to cease informing patients of contraindications and to instead attempt to convert the treatment plan sale anyway—a practice that had a significant

undisclosed impact on Byte’s safety. Indeed, following the initiation of the August 2022 policy, the number of reported injuries from Byte patients spiked significantly.

332. On September 18, 2024, *The Capitol Forum* published an article wherein a spokesperson for Dentsply was quoted as saying:

The observed additional volume of reported events is strictly related to our efforts to continuously improve our post market surveillance processes. These efforts include prudently enhancing our reportability criteria so that FDA and the public are aware of a broader range of events experienced by our users. These enhancements have resulted in an increase in the number and type of complaints we report to FDA as medical device reports.

333. The spokesperson was also quoted as saying, “***Complaint rates for*** medical device reports remain within anticipated rates (<0.1%) across each of our ***Byte*** product SKUs which ***is consistent with other on-market orthodontic aligner solution complaint rates.***”

334. The statements set forth in ¶¶332-33 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. Rather than “***strictly relate[] to***” the Company’s purported “***efforts to continuously improve our processes in alignment with current, global regulatory requirements,***” in reality, the uptick in Dentsply’s injury reporting was motivated by the Company’s desperation to avoid an FDA enforcement action over its previously failure to submit these reports, including as Dentsply management admitted at a July 2024 meeting that “we know our complaints aren’t being filed correctly.” Further, rather than reflect an effort by Dentsply to “***continuously improve***” its “***post market surveillance processes,***” the increase in reports demonstrated the extraordinary injury rates that accompanied Byte usage, the lack of dental or orthodontist care and oversight in Byte treatment, and the consequences of Dentsply’s improper Byte sales practices. Indeed, at the time the statement was made, Dentsply was then in possession of 6,325 injury reports that were not timely filed with the FDA, and which evidenced substantial patient safety issues associated with the product.

335. It was also materially misleading to state that the “***observed additional volume of reported events***” was simply the result of a change in reporting practices because, in truth, the volume of reported events reflected Byte’s true safety profile, the lack of doctor oversight of Byte treatments, and Dentsply’s instruction to Byte’s sales representatives in August 2022 to cease informing prospective patients that they were contraindicated. As discussed *supra* ¶¶138-156, injury reports to Dentsply spiked following this instruction, which in turn led to the “observed additional volume of reported events” to the FDA.

336. It was also false and misleading to state that “***Complaint rates for . . . Byte product[s]***” were “***consistent with other on-market orthodontic aligner solution complaint rates.***” In reality, complaint rates for Byte products were far higher than any other on-market orthodontic aligner product at this time. Indeed, former employees who handled Byte complaints estimated that up to 25% of patients suffered injuries. Indeed, the FDA database suggests that Byte’s injury rates far exceed those of its competitors. For example, 165 out of the 183 reports submitted in August 2024 for sequential aligner products were for Byte while the Invisalign—the market share leader that has thousands more aligners out on the market—only accounted for 8 of the reports that month.

4. False Statements Disseminated Through William Blair Report

337. On September 27, 2024, analysts at William Blair published a report titled “Thoughts From DS World 2024; Dentsply Continues to Position Itself as the Digital Backbone for the Next Wave of Dentistry.” That report stated:

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.***

338. The statements set forth in ¶337 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was not true that the recent uptick in MAUDE filings was due to “***an increase in***” Dentsply’s management’s “***own reporting standards.***” In truth, Dentsply disregarded its own reporting standards throughout the Class Period. As described by FE-7, Dentsply’s internal policies already determined that, for example, loss of a tooth was a reportable event. However, Dentsply intentionally deviated from these standards to withhold injury reports from the FDA in order to preserve Byte’s commercial viability and ward off state legislative efforts. It was also false and misleading to state that Dentsply was merely “***catch[ing] up on some filings from ongoing cases***” when, in reality, at the time this statement was made, Dentsply was sitting on 6,325 Byte injury reports it had received months and in some cases years earlier that it had yet to file with the FDA.

5. False Compliance Statements In Dentsply’s “Sustainability Reports” For 2021, 2022, And 2023

339. Dentsply published its “Sustainability Report” for 2021 on its website on or about December 20, 2022. The report was reviewed and approved by Defendant Campion, who opened the report with a “Letter from the CEO” and was pictured on page 5.

340. Dentsply published its “Sustainability Report” for 2022 on its website on or about November 6, 2023. The report was reviewed and approved by Defendants Campion, Coleman, Frank, and Brackett. Campion opened the report with a “Letter from the CEO.” That was followed by a “Letter from the ESG Steering Committee,” signed by Brackett. Brackett was Dentsply’s Senior Vice President, Orthodontic Aligner Solutions & Customer Experience, and Head of Sustainability, and (for 2022) the Chair of the ESG Steering Committee. Coleman was a member of the ESG Steering Committee for 2022, and Frank of the Extended ESG Steering Committee for

2022. Campion and Brackett were pictured on page 6, and Brackett, Coleman, and Frank were pictured on page 15.

341. Dentsply published its “Sustainability Report” for 2023 on its website on or about September 27, 2024. The report was reviewed and approved by Defendants Campion and Coleman. Campion opened the report with a “Letter from the CEO.” Coleman was a member of the Extended ESG Steering Committee for 2023. Campion was pictured on pages 4 and 18, and Coleman was pictured on page 20.

342. The Sustainability Reports for 2021 and 2022 both stated:

Our Product Safety Program includes the following:

- ***A Complaints Management program that collects, monitors and investigates product complaints***
- ***A Post-Market Surveillance Process, per product group, to ensure compliance with applicable PMS requirements***
- A Risk Management program that covers design, manufacturing, and post-market surveillance
- A product testing program used throughout the lifecycle of the product including design, validation and verification, in-process and finished product testing
- ***A Quality Management System bespoke to each manufacturing entity, which governs safety, quality and compliance***
- A Quality Management System-related training program where personnel involved in R&D, manufacturing and quality control are trained to carry out their responsibilities

343. Similarly, the Sustainability Report for 2023 stated:

Our product safety program includes the following:

- ***Complaints Management program that collects, monitors, and investigates, where appropriate, any product complaints***
- ***Post Market Surveillance (“PMS”) Process, per product group, to ensure compliance with applicable PMS requirements***

- Risk Management program that covers the entire lifecycle of our products
- Product testing program used throughout the lifecycle of the product including design, validation, and verification, in-process and finished product testing
- ***Quality Management System with a dedicated training program, bespoke to each manufacturing entity***
- Personnel involved in R&D, manufacturing and quality control trained to correctly carry out their responsibilities

344. The Sustainability Reports for 2021 and 2022 both further stated: “***we comply with FDA QSR 820***”—the FDA post-market surveillance rule requiring Dentsply to report adverse events associated Byte within 30 days. Similarly, the Sustainability Report for 2023 identified that “***complying with FDA QSR 820***” was one of the actions the Company takes.

345. The statements set forth in ¶¶339-344 were materially false and misleading, and omitted to state material facts necessary in order to make them not misleading. As detailed above, at the time of these statements, Dentsply was not in compliance with “***applicable PMS*** [post-market surveillance] ***requirements***” or “***FDA QSR 820***” (21 C.F.R. part 820). Nor did the Company properly “***collect[], monitor[], and investigate[] product complaints,***” or maintain a suitable “***Quality Management System bespoke to***” Byte. Rather, throughout the Class Period, Dentsply was aware of ***thousands*** of reports of serious injuries suffered by Byte patients that were required to be reported to the FDA, including reports of lost teeth that were specifically designated as reportable under Dentsply’s own internal policies. Yet, rather than properly “investigate” those reports through a bespoke Quality Management System in compliance with “FDA QSR 820” (21 C.F.R. part 820)—which would have culminated in their timely reporting from Dentsply to the FDA—Defendants consciously chose to withhold these reports in order to avoid public scrutiny, including from state legislators who were specifically focused on the injury rates of direct-to-consumer clear aligners.

346. Specifically, from January 2021 to October 2022 (the month before the Sustainability Report for 2021 was published), Byte patients suffered at least 1,502 serious injuries, 1,474 of which (98%) were not timely reported to the FDA. By October 2023 (the month before the Sustainability Report for 2022 was published), Byte patients suffered at least 4,648 serious injuries, 4,509 of which (97%) were not timely reported to the FDA. By August 2024 (the month before the Sustainability Report for 2023 was published), Byte patients suffered at least 7,824 serious injuries, 6,519 of which (83%) were not timely reported to the FDA. It was misleading to tout Dentsply's complaints management program, post-market surveillance, and quality management system while omitting that Dentsply was failing to report thousands of serious patient injuries from Byte to the FDA.

347. In addition, two months prior to publishing the Sustainability Report for 2023, Dentsply "had a ***big meeting*** in July [2024], where they said 'Hey guys, ***we know our complaints aren't being filed correctly*** and here's how you should be doing them.'"

6. False Statements Regarding Compliance In Dentsply's 10-Ks And 10-Qs

348. Dentsply filed its Annual Reports on Form 10-K for fiscal year 2020, 2021, 2022, and 2023 on March 1, 2021, March 1, 2022, March 1, 2023, and February 29, 2024, respectively. The 10-Ks for 2020 and 2021 were each signed by Defendants Casey and Gomez. The 10-Ks for 2022 and 2023 were each signed by Defendants Campion and Coleman.

349. The 10-Ks for 2020, 2021, 2022, and 2023 each stated:

The majority of the Company's products are classified as medical devices and are subject to restrictions under domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders, including, but not limited to, the United States Food, Drug, and Cosmetic Act (the "FDCA") The FDCA requires these products, when sold in the United States, to be safe and effective for their intended use and to comply with the regulations administered by the United States Food and Drug Administration ("FDA"). ...

Dental and medical devices of the types sold by Dentsply Sirona are generally 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. ...

The Company believes it is in substantial compliance with the laws and regulations that regulate its business.

350. Dentsply filed its Quarterly Reports on Form 10-Q for the first, second, and third quarters of 2021 on May 6, 2021, August 5, 2021, and November 4, 2021, respectively. Each of those 10-Qs was signed by Defendants Casey and Gomez. The 10-Qs for 2021 told investors to “please refer to” “Part I, Item 1, ‘Business’” of Dentsply’s 10-K for fiscal year 2020, which included the statements quoted in ¶349.

351. The statements set forth in ¶349 were materially false and misleading, and omitted to state material facts necessary in order to make them not misleading. At the times of these statements, Defendants knew that Dentsply was neither in compliance nor substantial compliance with the FD&C Act or with FDA regulations including 21 C.F.R. Part 803 (Medical Device Reporting) and 21 C.F.R. Part 820 (Quality System Regulation). As described *supra* ¶¶130-152, Defendants knew that Dentsply had no effective system for reporting serious patient injuries caused by Byte to the FDA and that it was failing to timely report the vast majority of patient injuries caused by Byte. As a result of their failure to file adverse event reports with the FDA, Defendants also knew that the Byte aligners were misbranded.

352. Dentsply’s untimely reports of serious patient injuries were significant, both in absolute and percentage terms, on the dates of each of these disclosures.

Statement	Reference time period	Serious patient injuries not timely reported	Percentage of serious patient injuries not timely reported
10-Q for 2Q 2021	January to July 2021 ¹⁷	At least 16	At least 87%

¹⁷ Most of this period was not covered by Dentsply’s retrospective review.

10-Q for 3Q 2021	January to October 2021	At least 199	At least 99%
10-K for 2021	2021	At least 377	At least 99%
10-K for 2022	2022	At least 1,557	At least 97%
10-K for 2023	2023	At least 3,205	At least 96%

353. The Company's 10-Q filed July 31, 2024 stated:

Legislative changes in Nevada relating to teledentistry required us to discontinue new patient recruitment for our current direct-to-consumer aligner business model in the state during the second quarter. Additionally, enacted and pending legislative changes in certain other states including Florida and Illinois are expected to impact sales in the second half of 2024. These changes would require certain adjustments to our business model, some of which have been made preemptively and have started to negatively impact sales of direct-to-consumer aligners in those states. These adjustments include developing new features and modifying our process for engaging with customers as part of our direct-to-consumer aligner business models in response to existing and pending legislation. Our response to these legislative developments resulted in reduced sales of direct-to-consumer orthodontic aligners by approximately \$6 million during the second quarter of 2024, with a similar estimated impact for each of the remaining quarters of 2024, ***which we expect will be more than offset by organic growth.***"

354. The statements set forth in ¶353 were materially false and misleading, and omitted to state material facts necessary in order to make them not misleading. It was materially misleading for Defendants to downplay the impact of these three state legislative developments, and to represent that any reduction in Byte sales would not be "***more than offset by organic growth,***" while omitting to disclose that Dentsply had failed to report thousands of Byte injuries demonstrating Byte's true safety profile. In fact, at the time this statement was made, Dentsply had in its possession thousands of serious injury reports demonstrating Byte's true safety profile, management knew they could no longer continue withholding them from the FDA, and that these reports would have a disastrous impact on Byte's commercial viability once they were disclosed.

D. False Statements About Dentsply's Continued Investment In Byte

355. On February 29, 2024, Dentsply held an earnings call with analysts and investors to discuss the Company's financial results from the fourth quarter of the 2023 fiscal year. In response to an analyst question asking for "a bit more detail of whether the most significant investments are this year," Defendant Coleman stated:

I think first one I would highlight is the *Byte investments that we're making with the opportunity that we now see with the competitive dynamics. We're going to be investing more in the commercial clinical support area, treatment planners and infrastructure at Byte. We already started in the fourth quarter.* And we see a pretty immediate return on those investments. So, I mentioned on my prepared remarks, Byte is expected to grow over 20% in 2024. So, we're excited about the opportunity there. *We are putting more investments into Byte,* and we expect to see a much faster ramp, especially as we get into later in the year.

356. On May 2, 2024, Dentsply held an earnings call with analysts and investors to discuss the Company's financial results from the first quarter of the 2024 fiscal year. In response to an analyst question regarding "how sustainable [Byte's] growth is," Defendant Campion stated:

I think, for sure, we're benefiting from SDC. *We have invested behind the growth that we're seeing, increasing the number of treatment planners,* being very selective but increasing our commercial activities with respect to advertising. . . . We are driving profitable revenue growth and we continue to see profits accrue from our Byte business. And as Glenn has said, we do expect to be north of 20% growth for Byte this year.

357. On May 15, 2024, Dentsply and Defendant Coleman presented at the Bank of America Health Care Conference. In response to an analyst question regarding Coleman's "confidence around [Byte's] growth accelerating into the second half of the year," Defendant Coleman stated:

If I look at Byte, it's our direct-to-consumer business. We didn't see much of an uptick until one of the big competitors actually exited the market, which was December of last year. . . . But *we started to see the uptick at the beginning part of 2024. We invested in resources to support a ramp in revenue growth. So, more treatment planners,* more clinical people to support that business, more infrastructure to support that business. *That was all done in the early part of*

Q1. We saw the uptick, 18% growth in Q1. That should be the low watermark, though, for us this year. I expect we'll grow over 20% for the rest of the year.

358. The statements set forth in ¶¶355-357 were materially false and misleading and omitted to state material facts necessary in order to make them not misleading. It was materially misleading to state that Dentsply was “*investing in,*” “*increasing the number of treatment planners,*” and expanding the “*commercial clinical support area*” and expecting Byte to grow over 20% over 2024 while failing to disclose the highly material facts that Byte’s performance had been secretly driven by a sales strategy to sell to contraindicated patients; that Dentsply had failed to report thousands of serious patient injuries to the FDA as required; and that, in light of these significant undisclosed facts, Dentsply was not investing in Byte’s future growth and had in fact terminated approximately 50 of the 320 treatment planning employees in Costa Rica at the beginning of 2024.

X. LOSS CAUSATION

359. During the Class Period, as detailed in this complaint, Defendants made materially false and misleading statements and omissions, including statements regarding licensed dentists’ control and oversight over Byte treatment plans, Byte customer standards, and the Company’s compliance with legal and regulatory requirements, such as FDA reporting, and engaged in a scheme to deceive the market. This artificially inflated or maintained the price of Dentsply common stock and operated as a fraud or deceit on the Class. Later, when Defendants’ prior misrepresentations and risks concealed by the fraudulent conduct alleged in this complaint materialized and were disclosed to the market starting on October 24, 2024, the price of Dentsply common stock fell precipitously and in a statistically significant manner, as set forth above in ¶¶180-202. The disclosures that corrected the market price of Dentsply shares and reduced the artificial inflation caused by Defendants’ materially false and misleading statements and omissions

are summarized in the chart below, which identifies each corrective disclosure event, the price declines in Dentsply shares resulting from the event as compared to the prior day's close, and the percentage decline:

Date	Event	Price Change	% Change
10/24/2024-10/25/2024	Dentsply suspends sales and marketing of Byte, admits that Byte was sold to contraindicated patients, and announces expected impairment of goodwill from Byte acquisition.	\$24.41 to \$23.31	-4.51%
11/07/2024	Dentsply announces pending termination of all relevant Byte employees, goodwill impairment of \$145 million, and reduction in guidance for the year.	\$23.98 to \$17.26	-28.02%
1/14/2025	Dentsply announces that it will not be reinstating Byte's at-home treatment model.	\$18.66 to \$18.06	-3.50%
2/27/2025	Dentsply announces additional negative financial impact from Byte on net sales and the full write-off of the Byte goodwill.	\$18.81 to \$17.15	-8.83%.

360. As a result of their acquisition of Dentsply common stock during the Class Period and Defendants' material misstatements and omissions, Plaintiffs and other members of the Class (defined below) suffered economic loss, i.e., damages, under the federal securities laws. Defendants' materially false and misleading statements caused Dentsply common stock to trade at artificially inflated levels throughout the Class Period, reaching as high as \$69.12 on May 10, 2021.

361. By concealing from investors the adverse facts detailed herein, Defendants presented a misleading picture of Dentsply's business and prospects. As true facts about the Company were revealed to the market, the price of Dentsply common stock fell significantly. These declines removed the inflation from the price of Dentsply common stock, causing real economic loss to investors who had purchased Dentsply common stock during the Class Period.

362. The declines in the price of Dentsply common stock after the corrective disclosures came to light were a direct result of Defendants' fraudulent misrepresentations being revealed to investors and the market. The timing and magnitude of the price declines in Dentsply common stock negate any inference that the loss suffered by Lead Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct.

363. The economic loss, i.e., damages suffered by Lead Plaintiff and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Dentsply common stock and the subsequent significant decline in the value of Dentsply common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

XI. CLASS ACTION ALLEGATIONS

364. Lead Plaintiffs bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Dentsply common stock during the Class Period, i.e., from January 4, 2021 through February 26, 2025, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants; members of the immediate families of the Executive Defendants; Dentsply's subsidiaries and affiliates; any person who is or was an officer or director of Dentsply or its subsidiaries and affiliates during the Class Period; any entity in which any Defendant has a controlling interest; and the legal representatives, heirs, successors and assigns of any such excluded person or entity.

365. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Dentsply common stock is actively traded on the Nasdaq and there are 198,991,963 shares of Dentsply common stock outstanding as of February 14, 2025, according to Dentsply's latest Annual Report. While the exact number of Class members is unknown at this

time, and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Dentsply, its transfer agent, or its depository bank and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

366. Common questions of law and fact predominate and include:

- (a) whether Defendants violated the Exchange Act and SEC Rule 10b-5;
- (b) whether Defendants omitted and/or misrepresented material facts;
- (c) whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) whether Defendants knew or recklessly disregarded that their statements were false;
- (e) whether Defendants' statements and/or omissions artificially inflated the price of Dentsply common stock;
- (f) whether Defendants' conduct caused the members of the Class to sustain damages; and
- (g) the extent and appropriate measure of damages.

367. Lead Plaintiffs' claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

368. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

369. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden

of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XII. INAPPLICABILITY OF STATUTORY SAFE HARBOR

370. The PSLRA's statutory safe harbor or the bespeaks-caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the materially false and misleading statements and omissions pled in this Complaint.

371. None of the statements complained of herein was a forward-looking statement protected by the safe harbor. Instead, each was a historical statement or statement of purportedly current facts and conditions existing at the time or prior to when each statement was made, or a statement rendered materially misleading for omitting existing facts.

372. To the extent that any of the materially false and misleading statements alleged herein can be construed as forward-looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements. As alleged above in detail, given the then-existing facts contradicting Defendants' statements, any generalized risk disclosures made by Defendants were insufficient to insulate them from liability for their materially false and misleading statements.

373. To the extent the statutory safe harbor otherwise would apply to any materially false and misleading statements pleaded herein, Defendants are liable for those materially false and misleading forward-looking statements because at the time each of those statements was made, the speaker knew that the particular forward-looking statement was false or misleading, or the statement was authorized and/or approved by an executive officer of Dentsply who knew that the statement was materially false or misleading when made.

374. Moreover, to the extent that Dentsply or the other Defendants issued any disclosures purporting to warn or caution investors of certain "risks," those disclosures were also

materially false or misleading because they did not disclose the full scope of the risks and/or that the risks that were the subject of the warnings had already materialized, or that Dentsply and the other Defendants had actual knowledge of undisclosed material adverse facts that rendered the purportedly cautionary disclosures materially false or misleading.

XIII. THE PRESUMPTION OF RELIANCE

375. Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are predicated upon omissions of material fact that there was a duty to disclose.

376. Plaintiffs are also entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine because, during the Class Period:

- (a) Dentsply common stock met the requirements for listing and was listed and actively traded on the Nasdaq, a highly efficient and automated market;
- (b) As a regulated issuer, Dentsply filed periodic public reports with the SEC and the Nasdaq;
- (c) Dentsply was eligible to file registration statements with the SEC on Form S-3;
- (d) Dentsply regularly publicly communicated with investors via established market-communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- (e) The market reacted promptly to public information disseminated by and concerning Dentsply;
- (f) Dentsply was followed by securities analysts employed by numerous major brokerage firms, including UBS, JPMorgan, and BofA Securities, who wrote reports that were distributed to the sales forces and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

- (g) The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Dentsply common stock; and
- (h) Without knowledge of the misrepresented or omitted material facts alleged herein, Plaintiffs and other members of the Class purchased or acquired Dentsply common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed.

377. As a result of the foregoing, the market for Dentsply common stock promptly digested current information regarding Dentsply from all publicly available sources and reflected that information in the price of Dentsply common stock. Under these circumstances, all purchasers of Dentsply common stock during the Class Period suffered similar injury through their purchase of Dentsply common stock at artificially inflated prices, and the presumption of reliance applies.

XIV. CLAIMS FOR RELIEF

COUNT I

Section 10(b) of the Exchange Act and Rule 10b-5(b) Against All Defendants

378. Lead Plaintiff repeats, incorporates, and realleges each and every allegation set forth above as if fully set forth herein.

379. This Count is asserted on behalf of all members of the Class against Defendant Dentsply and the Executive Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(b) promulgated thereunder, 17 C.F.R. § 240.10b-5(b).

380. During the Class Period, Defendant Dentsply and the Executive Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) in that they made untrue statements of material fact and/or disseminated and/or approved and/or omitted to state material facts necessary to make the false or misleading statements specified above not misleading. Defendants' actions: (i) deceived the investing public, including Lead Plaintiffs and other Class members, as

alleged herein; and (ii) caused Lead Plaintiff and other members of the Class to purchase Dentsply common stock at artificially inflated prices.

381. Defendant Dentsply and the Executive Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails: made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and made the above statements intentionally or with a severely reckless disregard for the truth, which did: (i) deceive the investing public, including Lead Plaintiff and the Class, regarding, among other things, the safety of Byte treatment and economic value of the Byte business, including whether Byte treatment was overseen by doctors, whether byte was sold to contraindicated patients, and whether Dentsply was complying with FDA medical device regulations, including regulations requiring serious patient injuries to be reported to the FDA; (ii) artificially inflate and maintain the market price of Dentsply common stock; and (iii) cause Lead Plaintiffs and other members of the Class to purchase Dentsply common stock at artificially inflated prices and suffer losses when the true facts became known.

382. During the Class Period, Defendants made the false statements specified above, which they knew or recklessly disregarded to be false or misleading in that, in light of the circumstances under which they were made, the statements contained misrepresentations and/or failed to disclose material facts necessary in order to make the statements not misleading.

383. The Executive Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them. The Executive Defendants engaged in this misconduct to conceal Dentsply's

true condition from the investing public and to support the artificially inflated prices of the Company's shares. The Executive Defendants' state of mind is imputed to Dentsply.

384. Lead Plaintiffs and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Dentsply's shares. Lead Plaintiffs and the Class would not have purchased the Company's shares at the prices they paid, or at all, had they been aware that the market prices for Dentsply shares had been artificially inflated by Defendants' fraudulent course of conduct.

385. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases of the Company's shares during the Class Period.

386. By virtue of the foregoing, Dentsply and the Executive Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder.

COUNT II

Section 10(b) of the Exchange Act and Rule 10b-5(a), (c), Against All Defendants

387. Lead Plaintiff repeats, incorporates, and realleges each and every allegation set forth above as if fully set forth herein.

388. This Count is asserted on behalf of all members of the Class against the Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(a) and (c) promulgated thereunder, 17 C.F.R. § 240.10b-5(a), (c).

389. During the Class Period, Defendants "devised a plan and induced [Lead Plaintiffs and class members] to [purchase] their shares without disclosing to them material facts that reasonably could have been expected to influence their decisions to [purchase]." *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972). As alleged herein, Defendants' Defendant Dentsply and the Executive Defendants violated Section 10(b) of the Exchange Act and

Rules 10b-5(a) and (c) in that they (1) employed devices, schemes, and artifices to defraud; and (2) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Dentsply common stock during the Class Period in an effort to maintain artificially high market prices for Dentsply common stock.

390. Defendant Dentsply and the Executive Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiffs and the Class in connection with the purchase and sale of Dentsply common stock, which did: (i) deceive the investing public, including Lead Plaintiffs and the Class, regarding, among other things, the failure to timely report serious injuries to the FDA and its public-facing MAUDE database; (ii) artificially inflate and maintain the market price of Dentsply common stock; and (iii) cause Lead Plaintiffs and other members of the Class to purchase Dentsply common stock at artificially inflated prices and suffer losses when the true facts became known.

391. As part of their scheme to defraud investors in violation of Rule 10b-5(a) and (c), Dentsply and the Executive Defendants:

- (i) knowingly failed to report serious patient injuries caused by Byte to the FDA, in violation of their regulatory reporting obligations, in order to prevent such injuries from becoming publicly available to investors, legislators, regulators, medical professionals, patients, and others in the FDA's MAUDE database, as further described in ¶¶134-52;
- (ii) directed, oversaw, or approved deceptive lobbying and public relations efforts to counter legislative and regulatory attempts to ensure stricter regulations, controls and oversight over Byte's direct-to-consumer business model, including by disseminating false and misleading statements and data concerning Byte's safety profile, as further described in ¶¶173-79;

- (iii) disseminated false statements to dental, orthodontist, and other public organizations concerning Byte's safety record, including by omitting to disclose that Byte had resulted in thousands of serious patient injuries;
- (iv) required injured Byte customers to sign non-disclosure and non-disparagement agreements in order to further prevent such injuries from becoming publicly known and to deceive the public about Byte's safety record and patient experiences, as further described in ¶¶153-55;
- (v) deceived investors by disseminating false statements concerning Byte's treatment approval process, including by falsely promising patients that their Byte treatment would be overseen by a doctor and telling patients they were good candidates for Byte treatment when in reality Dentsply knew that they had contraindications or knew that they had not been screened for known contraindications, as further described in ¶¶110-17; and
- (vi) misled investors, the FDA, other public regulators, journalists, and state legislators concerning Dentsply's compliance with FDA reporting requirements by omitting that Dentsply knowingly and illegally failed to report thousands of those serious patient injuries to the FDA.

392. These deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Dentsply common stock during the Class Period in an effort to maintain artificially high market prices for Dentsply common stock.

393. As described above, Dentsply and the Executive Defendants acted with scienter throughout the Class Period, in that they either had actual knowledge of the misrepresentations or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them. Dentsply and the Executive Defendants engaged in this misconduct to conceal Dentsply's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

394. Lead Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Dentsply common stock, which

artificial inflation was removed from the stock when the true facts became known. Lead Plaintiffs and the Class would not have purchased Dentsply common stock at the prices they paid, or at all, had they been aware that the market prices for Dentsply common stock had been artificially inflated by the Executive Defendants' fraudulent course of conduct. It was also foreseeable to these Defendants that misrepresenting and concealing these material facts from the public would artificially inflate the price of Dentsply's common stock and that the revelation of the truth, would correct the artificial inflation and cause the price of Dentsply securities to decline.

395. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases of the Company's common stock.

396. Each and every defendant is sued as a primary participant in the wrongful and illegal conduct charged herein.

397. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rules 10b-5(a) and (c), promulgated thereunder.

COUNT III

Section 20(a) of the Exchange Act, Against the Individual Defendants

398. Lead Plaintiffs repeat and reallege every allegation above as if fully stated in this Count.

399. This Count is asserted on behalf of all members of the Class against the Executive Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

400. During the Class Period, the Executive Defendants acted as controlling persons of Dentsply within the meaning of Section 20(a) of the Exchange Act. By virtue of their positions and their power to control public statements about Dentsply, the Executive Defendants had the power and ability to control the actions of Dentsply and its employees. Dentsply violated Section

10(b) of the Exchange Act and Rule 10b-5, as set forth above. By reason of such conduct, the Executive Defendants are liable pursuant to Section 20(a) of the Exchange Act.

XV. PRAYER FOR RELIEF

401. WHEREFORE, Lead Plaintiffs pray for judgment as follows:

- (a) Determining that this action is a proper class action, certifying Lead Plaintiffs as Class representatives under Rule 23 of the Federal Rules of Civil Procedure and Lead Counsel as Class Counsel;
- (b) Awarding compensatory damages in favor of Lead Plaintiffs and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest;
- (c) Awarding Lead Plaintiffs' reasonable costs and expenses incurred in this action, including attorneys' fees and expenses; and
- (d) Awarding such equitable, injunctive or other relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMAND

Lead Plaintiffs demand a trial by jury.

Dated: May 9, 2025

/s/ Michael D. Blatchley
Michael D. Blatchley

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