UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNION ASSET MANAGEMENT HOLDING AG, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. DEXCOM, INC., KEVIN R. SAYER, JACOB S. LEACH, JEREME M. SYLVAIN, and SEAN CHRISTENSEN, Defendants.	Case No. 25 Civ. 8912 (KPF) (consolidated with No. 25 Civ. 9370 (KPF)) **DEMAND FOR JURY TRIAL** **CLASS ACTION**

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS

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Lead Plaintiff Union Asset Management Holding AG ("Union" or "Lead Plaintiff"), by and through its counsel Bernstein Litowitz Berger & Grossmann LLP ("Lead Counsel"), brings this action on behalf of itself and all persons and entities who purchased the publicly traded common stock of Dexcom, Inc. ("Dexcom" or the "Company") between January 8, 2024 and September 17, 2025, inclusive (the "Class Period") and were damaged thereby (the "Class"). Lead Plaintiff asserts claims for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5(a)-(c) issued thereunder, against Defendants Dexcom; Kevin R. Sayer ("Sayer"); Jacob S. Leach ("Leach"); Jereme M. Sylvain ("Sylvain"); and Sean Christensen ("Christensen") (Sayer, Leach, Sylvain, and Christensen are collectively referred to as the "Individual Defendants" and, with Dexcom, as the "Defendants").

Lead Plaintiff alleges the following upon information and belief, except as to those allegations concerning Lead Plaintiff, which Lead Plaintiff alleges upon personal knowledge. Lead Plaintiff's information and belief is based upon Lead Counsel's investigation, which includes, among other things, review and analysis of: (i) Dexcom's regulatory filings with the U.S. Securities and Exchange Commission ("SEC"); (ii) press releases, presentations, and media reports issued and disseminated by Dexcom; (iii) analyst reports and media commentary concerning Dexcom; (iv) information supplied by former Dexcom employees, industry professionals, and other knowledgeable persons described below; (v) documents made public by the U.S. Food and Drug Administration ("FDA"); and (vi) other public information regarding Dexcom. Lead Counsel's investigation into the allegations contained in this Complaint is ongoing, and many of the relevant facts are known only by Defendants or are exclusively within their custody or control.

I. INTRODUCTION

1. This case arises from Defendants' false and misleading statements about Dexcom's central product, a device it sold to diabetes patients to monitor their blood sugar, the G7

"continuous glucose monitoring" system ("CGM"). Defendants misleadingly touted the G7 as the "most accurate CGM cleared by the FDA" even though they had secretly switched out a critical component of the device without FDA approval and knew from their own testing that the resulting device "was worse" than the original in "every accuracy metric." Defendants' statements about the G7's accuracy were at the core of the market's investment thesis for Dexcom stock. Thus, when the truth was revealed in a series of partial corrective disclosures—including a stunning revenue miss caused by disappointing sales of the faulty G7 and a scathing warning letter from the FDA detailing Dexcom's adulteration of the G7—Dexcom lost half of its market capitalization, causing investors to suffer severe losses.

2. Dexcom made substantially all its revenue through the sale of CGMs. Historically, Dexcom sought to capture the market for diabetes patients who use continuous glucose monitoring to make potentially life-or-death insulin dosing decisions ("insulin-intensive" patients) by emphasizing the industry-leading accuracy of Dexcom CGMs as their key competitive advantage.

3. Consistent with this approach, in early 2023 Dexcom launched the latest iteration of its CGM—the G7—with great fanfare, including a flashy Super Bowl commercial calling the G7 "***the most accurate CGM on the market***." Defendants bolstered their statements that the G7 was the "most accurate CGM" by pointing to a measure of accuracy known as the "Mean Absolute Relative Difference" (or "MARD")—the difference between the CGM's reading and the "true" glucose level measured by blood sample. CGM manufacturers commonly market their devices by referring to their MARD, and Dexcom repeatedly emphasized—at investor conferences, on earnings calls, and in annual SEC filings—that the G7 had a MARD of 8.2%, which was 0.7% points better than the 8.9% MARD of Dexcom's main competitor's CGM. Thus, leading into the Class Period, Defendants thoroughly conditioned the market to understand that the G7 was the

most accurate CGM in existence, in part because of its industry-leading MARD—assertions that were essential to the value proposition of Dexcom stock.[1]

4. However, as the FDA would later document, shortly before the Class Period began, Dexcom secretly altered a "critical component" of the G7's glucose sensor—the lynchpin of the device's touted accuracy. Specifically, by December 13, 2023, Dexcom switched the material used to manufacture a layer of the sensor, from a material provided by an external supplier to a different version of the material that Dexcom produced in-house. Dexcom made this change to save money and ensure that Dexcom could maintain an aggressive and uninterrupted production schedule for the G7, in order to meet lofty revenue guidance Dexcom issued to investors.

5. At the time of the switch, Dexcom ran tests to show the adulterated device's accuracy was equivalent to the original's, but found the opposite was true—as the FDA found, Dexcom learned that the change compromised the G7's supposed unrivaled accuracy, with Dexcom's analysis showing that "***every accuracy metric of sensors built with the [new material] … was worse***." Consistent with Dexcom's internal findings, accuracy-related complaints about the G7, which Defendants were required to track, ***more than tripled*** after the adulteration.

6. The adulterated G7's "worse" accuracy was significant both from a competitive market standpoint and from the standpoint of patients with diabetes. The difference between the G7's original MARD and its main competitor's MARD was small enough—0.7%—that even a slight downtick in the perceived accuracy of the G7 would tarnish its competitive standing in the market. And the change that Dexcom made was very significant to the "insulin-intensive" patients that Dexcom targeted. As the FDA found, Dexcom's adulteration of the G7 "***caused higher risks for users who rely on the sensors to dose insulin or make other diabetes treatment decisions***."

[1] Unless otherwise noted, all emphasis is added.

7. Nevertheless, Defendants did not seek FDA approval to market this adulterated device, as Defendants knew (or recklessly disregarded) they were required to do under federal law. Instead, in a December 28, 2023 submission seeking permission to modify the G7 so that it transmitted glucose readings directly to smartwatches, Defendants falsely told the FDA there had been no changes to the sensing system and that the new device was just "as safe and effective."

8. Nor did Defendants breathe a word of this critical, adverse change to investors or patients with diabetes. To the contrary, despite altering a "critical component" of the G7 and running tests that showed its accuracy was worse, Defendants acted publicly as if nothing had changed, continuing to state that the G7 was the "most accurate" CGM and continuing to cite its *pre-adulteration* 8.2% MARD.

9. For instance, on January 8, 2024, the first day of the Class Period, Dexcom's CEO, Defendant Sayer, told investors at an industry conference the G7 "***is the most accurate sensor on the market today***," even though Dexcom's testing had shown the G7's accuracy had been impaired by the secret change. A few weeks later, Dexcom's Vice President of Investor Relations, Defendant Christensen, similarly told a group of institutional investors that the "***G7 is the most accurate CGM that has been cleared by the FDA***." At another investor conference, Dexcom's CFO, Defendant Sylvain, stated that the G7 is "***the most accurate sensor on the market***."

10. Defendants' Class Period representations about the G7's accuracy were materially misleading because they failed to disclose that Defendants had changed a critical component of the device and that this impaired its accuracy in significant respects. Their continued statements about the G7's purported MARD were likewise materially misleading because they failed to disclose that this metric was based on tests of a device that was materially different from—and more accurate than—the subsequent, adulterated G7 that Dexcom was marketing and distributing.

11. Defendants' Class Period representations to investors that the adulterated G7 was "cleared by the FDA" were similarly materially false and misleading. The FDA had ***not*** approved the adulterated device. Defendants purposefully did ***not*** seek FDA approval for the adulteration. To the contrary, as noted, Defendants repeatedly misled the FDA by falsely stating in subsequent submissions about the G7 that nothing had changed with respect to the G7's physical and chemical components, or its safety and effectiveness—all of which was untrue.

12. Defendants continued to make these and other similar misrepresentations unabated throughout the Class Period. They did so even after a jarring ***tripling*** in customer complaints about the device; even after FDA inspections in 2024 resulted in findings that Dexcom had "adulterated" the G7; even after the inspections resulted in findings that Dexcom's manufacturing processes were materially deficient in numerous respects, rendering Dexcom unable to reliably produce G7s that performed to its stated accuracy metrics; and even after Dexcom received a letter from the FDA detailing (yet again) these regulatory violations (the "Warning Letter").

13. The truth emerged gradually and piecemeal, through a series of partial corrective disclosures from July 24, 2024 through September 19, 2025. Defendants continued to mislead investors during this time to minimize the disclosures and their impact on Dexcom's stock price.

14. First, on July 24, 2024, Dexcom released disappointing results for the second quarter of 2024 and reduced its full year revenue guidance. These developments stunned investors and caused Dexcom's stock price to plunge more than 40%, the largest decline in Dexcom's history. Defendants falsely ascribed the revenue miss to an "execution hiccup" when, in truth, it was driven by users turning away from Dexcom's adulterated, far less accurate product.

15. Second, on March 7, 2025, Dexcom was forced to disclose it had received the Warning Letter. The market reacted with what analysts described as "surprise" and "frustrat[ion]"

and Dexcom's stock price plummeted by more than 9%. Defendants attempted to downplay the significance of the Warning Letter by describing it as having "***nothing to do with product quality***," when, in fact, it detailed issues that went directly to the G7's accuracy and its impact on patients.

16. Third, on March 25, 2025, the FDA publicized the contents of the Warning Letter, disclosing to the market for the first time that Dexcom had adulterated the G7 and that the FDA had found pervasive manufacturing and quality control failures such that Dexcom was in violation of the FDA's Quality System Regulation ("QSR"). These failures included that Dexcom was arbitrarily and without documentation setting acceptable accuracy levels for the G7 it produced; was not properly testing the finished device's real-world accuracy; and was shipping devices without analyzing their performance under certain risky conditions, such as a low-oxygen environment or when a patient was using the device in conjunction with an automated insulin dosing system, which meant users may "make inappropriate diabetes management decisions."

17. Dexcom had gone on a media blitz to preemptively soften the blow of this revelation. This included telling analysts that Dexcom had "notified the FDA" of the adulteration and received clearance for it, that "***extensive testing showed the material met specifications***," and that the FDA's findings were "***not a product quality issue***." Later, the strategy of continued deception also included having Dexcom's COO, Defendant Leach, misrepresent the nature of the FDA's conclusions to the diabetes care community, stating that "***there's no actual claim that the performance of the sensor isn't as accurate as the old one***."

18. None of this was true. Dexcom ***had not*** sought or obtained FDA approval for the adulteration. Moreover, the pervasive manufacturing and quality control failures the FDA discovered and documented ***were*** about the G7's quality ***and*** about its accuracy.

19. Fourth, on August 25, 2025, a third party publicized a survey of medical providers recounting their own problems with the G7's accuracy. Analysts took note of this renewed focus on the G7's accuracy and Dexcom's stock price lost another 7.7% in value on this news.

20. The last shoe to drop came on September 18, 2025, in the form of a report by Hunterbrook Media that catalogued for the first time extensive evidence of Defendants' misconduct. This included detailed eye witness accounts of former Dexcom employees describing a toxic corporate culture of profits over patient safety and detailed stories of the harms Dexcom's G7 caused its patients, including death. Dexcom's stock price lost approximately 12% in value.

21. All told, Dexcom's stock price fell ***over 50%***, from a Class Period closing high of $140.45 per share in April 2024, to $67.45 per share on September 19, 2025. While investors suffered losses, Defendants engaged in substantial insider selling, including Class Period stock sales totaling over $15 million for Defendants Sayer and Sylvain.

22. Meanwhile, the consequences of Defendants' misconduct continue to be felt. Dexcom faces a series of personal injury lawsuits from patients with diabetes who were allegedly harmed by the G7. Many users and healthcare providers remain disillusioned with Dexcom's broken promises of best-in-class accuracy. Notably, the Warning Letter remains in place over a year after it was issued, further demonstrating the severity of the issues. Dexcom's stock price has not recovered and currently trades at approximately $64.02 per share, substantially less than half its Class Period high.

II. JURISDICTION AND VENUE

23. This Complaint asserts claims under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5(a)-(c) thereunder, 17 C.F.R. § 240.10b-5(a)-(c).

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

25. Venue is proper in this District under 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa, because certain acts giving rise to the violations complained of in this action, including the dissemination of materially false and misleading statements, occurred in substantial part in this District. Dexcom's common stock trades on the NASDAQ, which is headquartered in this District.

26. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Lead Plaintiff

27. Lead Plaintiff Union Asset Management Holding AG ("Union") is the parent holding company of the Union Investment Group. The Union Investment Group, based in Frankfurt-am-Main, Germany, was founded in 1956, and is one of Germany's leading asset managers for retail and institutional clients, with approximately €534.6 billion (approximately $626.98 billion) in assets as of December 30, 2025. As set forth in the certification filed with this Court (ECF No. 12-1), during the Class Period, Lead Plaintiff purchased Dexcom common stock through several investment funds managed by three Union subsidiaries and suffered substantial losses as a result of Defendants' conduct alleged herein.

B. Defendants

28. Dexcom develops, manufactures, and sells CGMs used by patients to monitor their blood glucose levels. Dexcom is incorporated in Delaware and maintains its principal executive offices in San Diego, California. Dexcom's common stock trades on NASDAQ, which is an efficient market, under ticker symbol "DXCM." As of September 30, 2025, Dexcom had over 400 million shares of common stock outstanding, owned by hundreds of thousands of investors.

29. Sayer served as Dexcom's Chief Executive Officer ("CEO") and Chairman of the Board of Directors from January 2015 to January 2026. Defendant Sayer took a temporary leave of absence toward the end of the Class Period, starting on September 14, 2025. During the Class Period, Defendant Sayer signed and certified each of the Company's quarterly and annual SEC filings and made statements to investors, securities analysts, and others about the G7 and its accuracy and reliability.

30. Leach was Dexcom's Chief Operating Officer ("COO") from August 2022 to January 1, 2026. Between September 14, 2025 and the end of the Class Period, Defendant Leach also served as Dexcom's interim CEO while Defendant Sayer was on a temporary leave of absence. Defendant Leach now serves as CEO and President of the Company following Defendant Sayer's departure. During the Class Period, Defendant Leach made statements to investors, securities analysts, and others about the G7 and its accuracy and reliability. Prior to serving as COO, Defendant Leach served as Dexcom's Chief Technology Officer from September 2018 to October 2022 and in various roles at Dexcom in engineering and research and development since 2004.

31. Sylvain has served as Dexcom's Chief Financial Officer ("CFO") since March 2021. During the Class Period, Defendant Sylvain signed and certified each of the Company's quarterly and annual SEC filings and made statements to investors, securities analysts, and others about the G7 and its accuracy and reliability. Prior to serving as CFO, Defendant Sylvain worked as Dexcom's Senior Vice President of Finance and Chief Accounting Officer from March 2020 to March 2021, and as Corporate Controller from September 2018 to March 2020.

32. Christensen served as Vice President of Financial Planning and Analysis and Investor Relations from September 2022 to at least March 2026. Prior to serving in this role, Defendant Christensen occupied various roles in investor relations at Dexcom. During the Class

Period, Defendant Christensen made statements to investors, securities analysts, and others about the G7 and its accuracy and reliability.

33. The Individual Defendants, because of their positions with Dexcom, possessed the power and authority to control the contents of Dexcom's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, institutional investors, and other members of the public. Each of the Individual Defendants was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to the public, and that the positive representations which were being made were then materially false and/or misleading.

IV. LEADING INTO THE CLASS PERIOD, DEXCOM FACES SIGNIFICANT BUSINESS PRESSURES AS IT LAUNCHES THE G7

A. Continuous Glucose Monitoring Systems—Dexcom's Only Product—Develop as Critical Tools for Diabetes Care

34. Dexcom develops, manufactures, and sells CGM systems, which are medical devices used by patients to track their blood glucose (i.e., blood sugar) levels. Historically and throughout the Class Period, including fiscal years 2023, 2024, and 2024, Dexcom derived ***all*** of its revenue from sales of its CGM systems.

35. Insulin is the hormone used to metabolize blood glucose, the body's principal source of energy. Individuals with diabetes cannot, depending on the type of diabetes, produce, secrete, or effectively utilize insulin. This, in turn, causes their blood sugar to rise above normal levels, which can lead to other health problems like heart disease, amputation, kidney failure, and blindness. People with diabetes often administer insulin to decrease blood sugar levels, but this

can drive blood sugar levels dangerously low, which in turn risks other acute complications like seizures, loss of consciousness, and death.

36. Prior to the development of CGMs, individuals with diabetes measured glucose by repeatedly pricking their fingers throughout the day, which was painful and could not continuously track blood sugar fluctuations or provide information on blood sugar trends. The introduction of CGMs in the early 2000s represented a revolution in diabetes care, because they require only a one-time insertion under the skin once every few days or even weeks. Further, CGMs measure and glucose levels continuously in real-time and predict blood glucose trajectory.

37. The accuracy of a CGM is critical because having an inaccurate blood glucose reading can cause serious health complications and even death. This is particularly the case for patients with Type 1 diabetes, who are unable to produce insulin, and a very small percentage of patients with Type 2 diabetes who cannot produce sufficient insulin. These patients are considered "insulin-intensive" because they must self-administer insulin to maintain glucose levels. Insulin-intensive patients rely on accurate CGMs to make precise decisions about insulin dosing. Other Type 2 patients are not insulin-intensive—they are, instead, insulin resistant.

38. To make decisions about which CGM is best to use, consumers rely in part on an industry-standard metric called the MARD (or Mean Absolute Relative Difference). The MARD measures the accuracy of the device and is calculated based on the average absolute difference between the glucose reading on the CGM (an interstitial glucose value) and a blood-glucose measurement directly via blood sample. Because accuracy is regarded as a critical metric, manufacturers like Dexcom market the accuracy of a CGM based largely on its MARD.

B. Leading Up to Its Decision to Adulterate the G7, Dexcom Comes Under Intense Competitive Pressures

39. In 2006, Dexcom received its first FDA approval for a CGM. Since then, Dexcom has battled its principal competitor, Abbott Laboratories ("Abbott"), for CGM primacy. As Dexcom explained in its Annual Report (Form 10-K) for the fiscal year ended December 31, 2024, filed with the SEC on February 18, 2025 ("Dexcom 2024 10-K"), Dexcom had "competed with Abbott and their Libre family of CGM products for many years."

40. Immediately before the Class Period, various competitive and other business pressures motivated Dexcom to significantly increase and speed up the production of its G7 devices—even, as it turned out, at the expense of product quality and accuracy.

41. ***Dexcom's Market Share Declined While Abbott Closed the CGM Accuracy Gap.*** Before and during the Class Period, Dexcom was losing market share to Abbott—a problem that intensified when Abbott developed a CGM that was purportedly more accurate than Dexcom's.

42. Historically, Dexcom differentiated its CGMs based on their higher accuracy, highlighting even small differences in accuracy between its devices and Abbott's. In 2018, Dexcom released its sixth generation CGM, the G6, which Dexcom publicly boasted was more accurate than any other CGM on the market. While Abbott's comparable "Freestyle Libre" 1 and 2 had MARDs of 9.4% and 9.3%, respectively, Dexcom claimed the G6 had a MARD of 9.0% and, with that, positioned the G6 as the gold standard for its target insulin-intensive population.

43. However, Abbott's CGMs had a distinct advantage over Dexcom's: pricing. Depending on insurance, the G6 could be two to three times more expensive than Abbott's CGMs.

44. Given the pricing advantage, prior to the Class Period, Abbott dominated the non-insulin intensive Type 2 diabetes population. Because these patients largely use CGMs to track

how lifestyle changes affected glucose levels, and not for precise insulin dosing, the cost-savings associated with Abbott CGMs outweighed any marginal trade-off in accuracy.

45. Because the Type 2 diabetes population represents most individuals with diabetes in the United States, Abbott benefited substantially from capturing this group. According to a report published by the International Diabetes Federation in 2021, Type 2 diabetes made up over 90% of diabetes cases globally and was projected to grow exponentially over the coming years. At the same time, because Type 1 diabetes is an autoimmune disorder affecting fewer individuals than Type 2 diabetes, the insulin-intensive population has maintained a relatively stable, smaller growth rate. Thus, while Dexcom had superior market share with individuals prioritizing accuracy, it was steadily losing ground to Abbott in the competition for total market share.

46. By April 17, 2019, Abbott had begun development for its newest CGM, the Freestyle Libre 3 ("Libre 3"). The Libre 3 was not only cheaper than the G6, but it also closed the accuracy gap with an 8.9% MARD—in other words, a MARD that was 0.1% points *better* than the G6's 9.0% MARD. Given that Dexcom's CGMs purported superior accuracy was its core competitive advantage, this development was particularly threatening to Dexcom's business, as this difference in accuracy could have tipped the insulin-intensive Type 1 diabetes market in Abbott's favor. Again, even minuscule differences in a device's accuracy in absolute numbers could and did make all the difference to Dexcom. Thus, it was of the utmost importance that Dexcom maintain the appearance of top accuracy in its next-generation device.

47. Analysts took note of the increasing pressures on Dexcom. In a January 6, 2021 Analyst Report, Raymond James reported that among the issues affecting Dexcom in 2021, "the impact of Abbott's Libre 3 on growth" would be "key." In a March 26, 2022 Analyst Report, CFRA analysts noted in their risk assessment of Dexcom that "DXCM only produces and sells one

type of product and faces formidable competition from much larger companies, primarily Abbott Laboratories and Medtronic." In a June 14, 2022 Analyst Report, Morningstar noted: "On the strength of its technology, Dexcom has captured an impressive slice of this CGM market, but a recent wave of innovation in the diabetes device market has intensified competitive pressure."

48. The increased competition eroded Dexcom's market share. In 2020, Dexcom and Abbott's estimated market shares were 45% and 42%, respectively. By 2022, after Abbott launched the Libre 3 on May 31, 2022, Abbott's estimated total market share in the U.S. increased to 53%, while Dexcom's estimated total market share declined to 41%. Dexcom's struggles to keep pace with Abbott continued into the Class Period, with at least one market intelligence firm estimating that Dexcom's share had fallen to 35.2% in 2024, while Abbott's had remained steady at 56.74%. Given this trend, it was more essential than ever for Dexcom not only to retain its advantage over the insulin-intensive population, but to penetrate the faster-growing population of patients with Type 2 diabetes who were not insulin-intensive.

49. ***Dexcom Tried to Access New Markets and Promised Investors Increasing Revenue.*** Faced with its declining market share, Dexcom came under pressure to reverse that trend, increase demand for its products, and deliver progressively higher revenue to investors.

50. Beginning in at least late 2020, Dexcom realized that it would need to sell its products to the larger and faster growing, non-insulin-intensive diabetes population. For example, at the Company's December 9, 2020 Investor Day, Defendant Sayer stated that the "second growth pillar" for Dexcom was the "Type 2 non-intensive business," promising that Dexcom was "on the cusp of major adoption of CGM technology in this large population."

51. One of the challenges in penetrating the non-insulin-intensive population was the higher cost of Dexcom's products. Another was access. Dexcom had historically sold and

distributed its CGMs through the Durable Medical Equipment ("DME") channel. In contrast to the retail pharmacy distribution channel, the DME channel involves a more complex prescribing process and a higher-touch clinical support model, including home shipping and ongoing patient assistance, but yields a higher per-unit reimbursement from insurers. In simple terms, patients could *not* fulfill their prescription of a Dexcom CGM by going to their pharmacy. Dexcom's historical, exclusive use of the DME channel was consistent with its positioning as a manufacturer of premium, clinically advanced devices, but severely restricted user access to its products.

52. In 2022 and 2023, as Defendant Sayer had discussed in 2020, Dexcom sought to penetrate the retail pharmacy distribution channel used primarily by the Type 2 population. Although the channel required manufacturers to pay rebates to pharmacy benefit managers to secure placement, which could reduce profit margins, this downside was potentially outweighed by the prospect of securing more of the massive non-insulin-intensive population long-term.

53. Dexcom repeatedly touted its expansion into new markets and the increase in demand this would generate. For example, Dexcom's April 22, 2024 Definitive Proxy Statement (Schedule 14A) ("Dexcom's 2024 Definitive Proxy Statement") stated that in 2023, Dexcom had "completed the largest expansion of coverage in [the] company's history" and highlighted the top two "Strategic Achievements" in the past year as: "[l]aunch[ing] Dexcom G7" and "[s]ignificantly expanded access in the United States with new coverage for people with type 2 diabetes."

54. Based on this expansion, Dexcom promised investors—immediately before and at the start of the Class Period—that it would generate increasing revenues. During the October 26, 2023 Q3 2023 Earnings Call, Dexcom increased its 2023 revenue guidance "more than $165 million." Similarly, during the January 8, 2024 J.P. Morgan Healthcare Conference and the February 8, 2024 Q4 2023 Earnings Call, Dexcom stated that it expected revenue growth between

16% and 21% in 2024, in part driven by expanding G7 sales. During the April 25, 2024 Q1 2024 Earnings Call, Dexcom again discussed "growing G7 demand" and "continued G7 demand," and then increased the low range of its guidance to 17% growth in 2024.

55. Rapid expansion meant that Dexcom needed to produce more CGMs than it had previously to keep up with any additional demand, which meant increasing its manufacturing capacity and access to manufacturing supplies. In 2023, various analysts noted this, acknowledging the "potential for higher volume through pharmacies" and Dexcom's "ramping production."

56. ***Dexcom's Margins Began to Decrease.*** Dexcom was facing significant pressure on its revenue margins due to the combination of the above factors. Specifically, as it transitioned to the less lucrative retail pharmacy channel, lowered prices, and ramped up production of new devices like the G7, Dexcom's profit margins declined steadily from 2021 through 2023. Dexcom's gross margin decreased from approximately 68.6% of total revenue in 2021, to 64.7% in 2022, to 63.25% in 2023, and to 60.5% in 2024. Decreasing margins were particularly problematic, as Dexcom had touted to the market a "long-term 65% gross margin," including during the February 9, 2023 Q4 2022 Earnings Call. According to an employee who worked at Dexcom's Mesa manufacturing facility from July 2023 through the end of 2024 as a Director of Manufacturing Operations ("Former Employee 1"), management at the facility recognized internally that if Dexcom's gross margin went below 60%, this would be "not good for investors."

57. Analysts took note of the decreasing margins. For example, in a February 8, 2023 Analyst Report, a Bernstein analyst attributed the decreasing margins to Dexcom going through a "transition" as it moved to the G7 from the G6. In a February 9, 2023 Analyst Report, a William Blair analyst similarly noted that there would be a "step-down" in margins in the first half of 2023 as "G7 production is ramped up and the company works on building up its manufacturing scale."

58. ***Dexcom Faced Supply Chain Risks and Struggled to Meet Demand.*** Leading up to and during the Class Period, Dexcom was exposed to the risk of sourcing critical materials from a single supplier, while confronting the pressure to scale its manufacturing capacity to keep up with Abbott's market share, and to lower costs to keep its margins from contracting even further.

59. Dexcom had been "capacity-constrained ever since [it] launched" the G6, as Defendant Sayer acknowledged in an interview during the January 2020 J.P. Morgan Healthcare Conference, which was published by Mobi Health News on January 21, 2020 in an article titled *Q&A: Dexcom CEO talks rapid pace of CGM innovation, what's coming in 2020 and beyond*. In the interview, Defendant Sayer also explained that Dexcom had "been running out of product every month ever since" the launch of the G6.

60. That historical constraint took on new urgency as Dexcom prepared to launch the G7 and pursue the significantly larger non-insulin-intensive market. By early 2023, Dexcom was already producing over 100,000 CGM sensors per day across its Mesa, Arizona and San Diego, California facilities, and had made its largest-ever capital investment in a new 900,000-square-foot manufacturing facility in Malaysia, which was expected to add capacity for 200 million sensors per year—roughly six times Dexcom's then-current capacity—starting sometime in 2024. In the meantime, however, Dexcom had to make do with the plants it had in the United States, while the manufacturing ramp-ups further compressed gross margins.

61. At the same time, Dexcom faced supply chain risks because it purchased certain critical components for its sensors from a single, third-party source. This included materials used to make, as Dexcom described them, the "polymers used to synthesize polymeric membranes for our sensors"—i.e., certain critical layers of Dexcom's CGM sensors. As Dexcom explained in its Annual Report (Form 10K) for the year 2022, filed on February 9, 2023, global supply chain

disruptions had already once hampered Dexcom's ability to produce CGMs. Analysts similarly noted that Dexcom's reliance on sole-source third-party suppliers for critical components could create bottlenecks that "might dampen the company's growth rate."

* * *

62. Against this backdrop, it was essential for Dexcom to protect its turf and maintain competitive market share in the insulin-intensive space by introducing a next-generation product with unmatched accuracy. Moreover, the combination of these competing pressures meant that, by the start of the Class Period, Dexcom also needed to continue to grow bigger and faster than ever, by significantly increasing, speeding up, and maintaining the production of its G7 devices to penetrate the larger non-insulin-intensive market—all while keeping costs down.

V. DEXCOM DEVELOPS AND LAUNCHES THE G7, TOUTING ITS SUPPOSED MARKET-LEADING ACCURACY, AND TURNING IT INTO THE SUBJECT OF INTENSE INVESTOR ATTENTION BY THE END OF 2023

63. Dexcom began clinical trials to develop its critical new CGM, the G7, in 2021.

64. On December 15, 2021, Dexcom submitted a proposal to the FDA to begin commercial distribution of the G7 in a form referred to as a "510(k) premarketing submission" (the "December 2021 510(k)"). The review process for a Form 510(k) submission is a faster and less intensive alternative to the standard pre-market approval process for an entirely new device and is permitted under the Federal Food, Drug, and Cosmetic Act (the "FDCA" or "Act") and regulations issued thereunder for the marketing of devices that are "substantially equivalent" to an already legally marketed "predicate device."[2]

[2] The term "510(k)" originates from Section 510(k) of the Food, Drugs, and Cosmetics Act, codified at 21 U.S.C. § 360(k), which requires device manufacturers to notify the FDA at least 90 days before commercially distributing certain FDA-regulated devices of the steps taken by the manufacturer to ensure that the device complies with the Act's various requirements. Form 510(k)s submitted by device manufacturers are eventually posted on the FDA's website.

65. In the December 2021 510(k), Dexcom sought FDA approval of the G7 by relying on the FDA's prior approval of the G6 as the "predicate device" and by presenting the results of two studies performed during G7 clinical trials. Study 1 evaluated safety and effectiveness and, according to Dexcom's December 2021 510(k), purportedly found that approximately 93.5% of G7 readings were within 20% of laboratory-grade glucose analyzer results for adults and that accuracy levels were generally maintained throughout the proposed 10-day wear period for the G7. Study 2 evaluated the device's ability to transmit real-time glucose data to a receiver or display device, using 60 subjects at two U.S. clinic sites. According to Dexcom, this study found that the G7 delivered glucose readings reliably 99.4% of the time during the 10-day wear period.

66. In early January 2022, at the J.P. Morgan Healthcare Conference, Dexcom revealed additional clinical trial data for the G7 for the first time, emphasizing its purportedly superior accuracy by citing specific accuracy measurements. Defendant Sayer reported that a 308-person trial demonstrated that the G7's MARD was 8.2% for adults and 8.1% for children.

67. During the conference, an analyst asked Defendant Sayer, "how are you thinking about, not just … penetration for CGM, but also share gains at this point? … Why would [patients] remain on a Libre given the accuracy of this product?" Demonstrating that Defendants understood that even small differences in perceived sensor accuracy—in this case, the small, 0.7% difference between the Libre 3's 8.9% MARD and the G7's 8.2% MARD—could have outsized effects on competitiveness and market share, Defendant Sayer replied: "We don't have the budgets of our larger competitors as far as going to markets. We don't have the infrastructure of our larger competitors, so we hang our hat on performance. And we knew that would be the case with G7, which is why we did a study this large to make sure we can validate the performance that we've been saying." Following this news, Dexcom's stock price increased from $115.58 on January 10,

2022, to $120.29 on January 11, 2022, and further increased to $122.59 on January 13, 2022, the final day of the conference, as the market digested the news.

68. Analysts credited Dexcom's statements about the supposed accuracy of the G7 and reported on its promise, including its potential to save Dexcom from the various competitive pressures it was facing. For example, on January 10, 2022, Canaccord Genuity reported that the G7 would be "key to offsetting competitive pressures and maintaining DXCM's position as an innovator." On January 18, 2022, Raymond James reported that the "[n]ew G7 data (MARD of 8.1%/8.2% peds/adults)" was expected to "better protect DXCM's insulin-intensive user base from competition, as this level of accuracy will be tough to replicate." Analysts also noted, in particular, that even the relatively small absolute difference between the G7's MARD and the MARD of competing devices was important enough to make a difference to Dexcom's business prospects and stock price. On February 3, 2022, BTIG upgraded Dexcom stock from "neutral" to "buy," reporting it was "impressed" DXCM was able to reach a "MARD of 8.2%" because this was "favorable when compared against the G6 MARD of 9.0% overall … as well as the Libre 2 MARD of 9.3%." In a March 14, 2022 report, BTIG again cited the 8.2% MARD to note that the "best-in-class accuracy," among other things, would allow Dexcom to "compete more effectively, especially in the type 2 market." Also on March 14, 2022, Raymond James reported that the G7 "serves to de-risk the stock and kick-off an exciting new product cycle," given it "improved MARD's further to 8.2% in adults, and 8.1% in pediatrics."

69. Throughout 2022, Dexcom continued to position the G7 as a transformative product, repeatedly emphasizing its accuracy. For example, on May 11, 2022, during the Bank of America Health Conference, Defendant Sylvain boasted about the G7's accuracy: "We think [] there really is no competition" because the G7 had the best "accuracy both clinically and real

world." Analysts continued to buy into this narrative. On July 28, 2022, at the Wells Fargo Conference, a Wells Fargo analyst described the G7 as a "major catalyst" for Dexcom "given the best-in-class clinical data."

70. On December 8, 2022, Dexcom obtained authorization from the FDA to market the G7—as it announced in a press release issued that day. The 510(k) "Decision Summary" issued by the FDA stated that the agency determined, based on the information submitted by Dexcom in the December 2021 510(k), that the device met safety and accuracy standards for CGMs. The FDA also reminded Dexcom of its obligation to comply with the Act's requirements for commercialized devices, including the requirements that Dexcom engage in post-market surveillance of how the device performed in the real world (in part, to comply with Dexcom's obligations to report adverse events to the FDA), and that it keep and maintain a "Quality Management System" and follow current best manufacturing practices. *See* 21 C.F.R. Part 820, Part 822.

71. In the following months, Dexcom and its executives continued to assert that the G7 would be the most accurate CGM device on the market.

72. On February 7, 2023, Dexcom announced the official, February 17, 2023 launch of the G7 for individuals with both types of diabetes, stating in a press release posted on its website that day: "with an overall MARD of 8.2%, Dexcom G7 is the most accurate CGM on the market." Once again, according to Dexcom, a change of merely 0.7% accuracy points (the difference between Libre 3's 8.9% MARD and the G7's 8.2% MARD) was significant enough to make all the difference. Dexcom also announced the upcoming premiere of a commercial during Super Bowl LVII in which, on February 12, 2023, Nick Jonas introduced the G7 to the world as the "most accurate sensor" for diabetes care. In the commercial, Nick Jonas stated that the sensor "was not magic, it just feels that way."

VI. SUMMARY OF THE FRAUD

A. Under Significant Pressure to Maintain Increased Production, Dexcom Secretly Adulterates the G7, Compromising Its Accuracy

1. Before the Class Period Begins, Dexcom Adulterates the G7 Without FDA Approval

73. Faced with the pressures described above to increase production of the G7 and keep costs down, Dexcom secretly changed the material it used for a critical component of the sensor—a change that impaired the G7's accuracy.

74. Unbeknownst to investors and consumers, on December 13, 2023, Dexcom changed the chemical material it used to manufacture a critical component of the G7 sensor, switching from a material it had previously obtained from a third-party supplier to a different version of the material Dexcom produced in-house. Dexcom did not apply for or obtain clearance for this change with the FDA, as it was required to do.

75. Dexcom's G7, like most recent CGMs, consists of three interrelated components or "systems": the sensor system, the transmitter system, and the receiver or display system. The sensor is the main unit responsible for measuring blood glucose and, thus, the accuracy of the CGM. It collects and measures glucose levels in interstitial fluid just under the skin after individuals insert the sensor into the upper arm or abdomen using a small, disposable insertion device, where it is then held in place by an adhesive patch. The sensor collects data that the transmitter converts into estimated glucose values and transmits to the receiver, which is a separate piece of hardware or software that, in the G7, could include a mobile application. The receiver displays glucose levels and alerts patients when glucose levels fall outside of a target range.

76. Dexcom's G7 sensors have a coating with multiple layers, and each affect the sensor's functionality. The innermost layer of the sensor contains an enzyme called "glucose oxidase" that catalyzes the oxidation of glucose into gluconic acid and hydrogen peroxide,

consuming oxygen in the process. In plain terms, the glucose oxidase accelerates the breakdown of glucose into two molecules. The resulting hydrogen peroxide produces an electrical current proportional to glucose concentration, which the sensor measures and the transmitter interprets.

77. For the CGM to deliver an accurate glucose level reading, this reaction must function without interference. To ensure this occurs, the sensor is enveloped in a protective outer membrane known as the "***resistance layer***," commonly made of a thermoplastic polyurethane. This membrane is critical to the accuracy of the sensor. It protects the glucose oxidase enzyme from the environment and limits the diffusion of molecules or ions, other than glucose, that could interfere with the desired chemical reaction and cause inaccurate glucose readings.

78. As noted above, on December 13, 2023, Dexcom unilaterally changed the material used in the resistance layer of the sensors, from a version Dexcom purchased from a third-party supplier—and that formed the basis of its December 2021 510(k) submission and accuracy tests—to a lower quality version of the material manufactured in-house. The switch positioned Dexcom to maintain high production levels for the G7, which would permit Dexcom to continue to aggressively expand sales and capture more market share.

79. Several former employees interviewed by Lead Counsel confirmed these facts. For example, Former Employee 1, who worked in Dexcom's Mesa, Arizona facility, confirmed that the change occurred to cut costs and eliminate single-supplier risk, that Dexcom's own research and development arm developed the new material, and that Dexcom had planned to build out the Mesa facility to permit production of the material onsite going forward. Similarly, a former employee in the procurement organization, who worked at Dexcom prior to 2023 and into the Class Period ("Former Employee 4") stated Dexcom wanted to de-risk its manufacturing process and find a cost-effective alternative material. *See also* ¶¶ 282-83.

80. As the FDA would later document, prior to introducing the adulterated G7s into the market, Dexcom attempted to prove the equivalence of the two ingredients, testing modified G7 sensors on 39 subjects at two sites. The study, however, determined the performance of sensors possessing the in-house material ***was not equivalent to*** the performance of the sensors with the original, externally-supplied membrane material: Dexcom's own study determined that its "primary endpoints were not met," as the FDA documented. Thus, when Dexcom continued to make statements about the G7's supposed accuracy based on studies and trials of the sensor with the original resistance layer ***after*** December 13, 2023, Dexcom understood or recklessly disregarded that this accuracy data was ***not*** applicable to the G7 as modified—or "adulterated," as the FDA would later describe the modification.

81. Given the concerning conclusion of its clinical study, Dexcom conducted a "failure investigation" aimed not at fixing the accuracy issue but at understanding why the original study failed. This study re-affirmed the findings of the first. Indeed, as the FDA later explained, Dexcom's own data showed that "***every accuracy metric of sensors*** built with [the new material] … was ***worse***," and that sensors had a "significantly different ratio" of glucose sensitivity leading to patients experiencing "differences in accuracy over the 10.5-day sensor wear period."

82. Former Employee 4's report corroborates this account. He stated that, at the time of the material change, the decision received significant scrutiny at Dexcom—scrutiny that confirmed the change of materials had a significant impact on the G7's accuracy. As Former Employee 4 explained, the key metric for success with respect to the sensor change project, as discussed at certain monthly meetings he attended, was equivalency—i.e., making sure that the chemical they were creating was as safe and effective as the sole-sourced existing material. Former Employee 4 further stated that issues with equivalency were discussed at the meetings and the

sentiment was that the project "was not meeting objectives." Further, Former Employee 4 confirmed that results of clinical trials and equivalency data related to the new material were presented and discussed during the monthly meetings, and that "all of that information was reviewed and explained to the audience of leaders in the meeting." *See also* ¶¶ 282-83.

83. Despite understanding that the new material made its sensor less accurate and would lead to patients experiencing worsening accuracy over the wear period of the sensor, Dexcom incorporated the new material into its manufacturing process. Notably, Dexcom did so without alerting the FDA or submitting the requisite new 510(k) submission, as required by law.

84. Generally, if a manufacturer modifies its device in a way that significantly affects the safety or effectiveness of the device, the manufacturer must make a new 510(k) submission. FDA regulations require a new 510(k) submission for devices in commercial distribution where a manufacturer makes a "change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process." 21 C.F.R. § 807.81(a)(3). Along those lines, FDA guidance from October 2017 entitled *Deciding When to Submit a 510(k) for a Change to an Existing Device, Guidance for Industry and Food and Drug Administration Staff*, available on the FDA's website, directs that manufacturers should make a new 510(k) submission where "a change or modification in the device could significantly affect the safety or effectiveness of the device" or with respect to "changes to materials [that] may unintentionally affect the performance of the device." Under this guidance, even if a manufacturer believes a new 510(k) submission is not required for a device, the manufacturer must perform confirmatory "routine verification and validation activities." If these activities produce "any unexpected results," manufacturers must "reconsider" their decision not to submit a 510(k).

85. Since the FDA's approval of the December 2021 510(k), Dexcom has made various additional 510(k) submissions for the G7—none of which referenced the accuracy-altering change to the resistance layer material. These submissions include: (i) a 510(k) submitted on April 14, 2023, requesting FDA approval to modify the material used for the G7's adhesive patch (the "April 2023 510(k)"); (ii) a 510(k) submitted on December 28, 2023, requesting FDA approval to allow users to display glucose data on smartwatches (the "December 2023 510(k)"); and (iii) a 510(k) submitted on April 1, 2024, requesting FDA approval to extend the "BLE communication range" (i.e., the Bluetooth range) of the device from 20 feet to 33 feet (the "April 2024 510(k)").

86. However, rather than alert the FDA of the critical change in the resistance layer material (as it was required to do), Dexcom's 510(k) submissions throughout the Class Period included forms explicitly representing that nothing had changed with respect to the G7's materials or its design or accuracy. For example, on December 28, 2023, shortly after Dexcom adulterated the G7, Dexcom submitted the December 2023 510(k) seeking approval to transmit glucose data to smartwatches. In the December 2023 510(k), Dexcom represented to the FDA that the proposed new device was "***as safe and effective as the predicate device*** **[the previously approved G7]** ***and does not raise different questions of safety and effectiveness***." Dexcom also represented that the new devices were "***physically identical to the predicate Dexcom G7 CGM system***," that it "shares ***identical*** hardware, ***material***, chemical composition, principle of operation and energy source with the predicate device," and that the proposed new G7 sensor's "***materials, hardware components, and packaging are identical*** to those of the predicate" G7 sensor.

87. On February 26, 2024, the FDA granted Dexcom's December 2023 510(k) submission, relying on Dexcom's representation that there had been "no changes" to the G7's sensing system and that the device was "physically identical" to the prior device, such that "all

studies originally used to establish analytical and clinical performance" could be relied upon for the new device.

88. Manufacturers must submit a Form 510(k) at least 90 days before marketing the proposed device to the public. Thus, had Dexcom submitted a 510(k) with respect to the resistance layer material adulteration as it was required to do, Dexcom would have been unable to produce the G7 sensors with the in-house material for many months, even if the FDA had eventually approved the new 510(k) after considering the studies Dexcom performed showing the adulterated sensor was less accurate than the marketed 8.2% MARD.

89. Moreover, because 510(k) submissions are available to the public on the FDA's website, had Dexcom submitted the required 510(k), the public—investors and patients—would have immediately realized that Dexcom's G7 was not as accurate as Dexcom claimed it to be, harming the G7's central value proposition to consumers and the market.

90. Defendants knew that members of the diabetes community monitored device changes that Dexcom sought approval for via the 510(k) submission process, as Defendants discussed these changes with users during public appearances. For example, on June 24, 2024, during an interview on the *Diabetech* podcast, a popular podcast targeting the diabetes care community, Defendant Sayer discussed the three changes Dexcom had made to the G7 pursuant to 510(k) submissions. *See* ¶¶ 85, 299. With respect to the change in adhesive material, the interviewer told Defendant Sayer that there had been "a lot of discussion … within the community" about the replacement policy Dexcom issued in connection with the adhesive change.

2. Consumers Experience the G7's Decreased Accuracy

91. Following the change to the resistance layer material in December 2023, customer complaints and adverse event reports regarding the G7 spiked dramatically, including those

submitted to the FDA. This provided Defendants even more notice of the adverse impact of the changed material, and ultimately impacted sales and stifled Dexcom's revenue.

92. The FDA requires device manufacturers such as Dexcom to "[s]ubmit reports of individual adverse events no later than 30 calendar days after the day that [the manufacturer] become[s] aware of a reportable death, serious injury, or malfunction." 21 C.F.R. § 803.10(c)(1). The FDA relies on these reports to identify safety issues and allocate investigative and enforcement resources. The FDA collects the reports it receives from manufacturers, patients, and healthcare providers in its Manufacturer and User Facility Device Experience ("MAUDE") database.

93. Between the date of release of the G7 on February 17, 2023 and December 12, 2023 (i.e., the day before Dexcom adulterated the sensor), the average number of monthly complaints filed about the G7 was approximately 4,000. Comparatively, between December 13, 2023, and December 15, 2025, the average number of monthly complaints spiked to ***over 10,000***. Moreover, between February 17, 2023 and December 12, 2023, there was one day when more than 500 complaints were filed about the G7. By contrast, between December 13, 2023, and December 15, 2025, there were ***412 days*** when more than 500 complaints were filed. Notably, compared to Abbott's Libre 3, the G7 was the subject of significantly more complaints. MAUDE shows ***approximately 240,000 complaints*** filed with respect to G7 adverse events that took place from January 1, 2024 through December 15, 2025. Comparatively, the database shows approximately 8,200 complaints filed with respect to Libre 3 adverse events that took place in that period, despite Abbott's larger market share. In other words, for the period starting after the G7 adulteration, the G7 was the subject of nearly ***30 times*** more adverse event reports than the Libre 3.

94. Filtering the complaints to approximate the number that appears related to accuracy of sensor readings further shows that the increase in total G7 complaints was related at least in part

to an increase in sensor accuracy issues. For the period between February 17, 2023 and December 12, 2023, the average number of monthly complaints about the G7 that relate to the accuracy of sensor readings was approximately 460 per month. For the period between December 13, 2023, and December 15, 2025, the average number of monthly complaints about the G7 that relate to the accuracy of sensor readings was approximately ***1,460 per month***—i.e., a ***threefold*** increase.[3]

95. In addition, it appears as if most of these complaints were input into MAUDE by Dexcom itself. According to the FDA's website, *About Manufacturer and User Facility Device Experience (MAUDE) Database*, reports that are ***not*** made by "manufacturers, importers, and user facilities" contain the letters "MW" at the beginning of the "Report Number" on MAUDE. According to Lead Counsel's investigation, the FDA MAUDE database contains 239,920 reports of adverse events with respect to the G7 that occurred from January 1, 2024 through December 15, 2025. Of these 239,920 reports, only 606 contain the letters "MW." By contrast, 239,308 reports contain a "manufacturer narrative" in the "Event Text" field of the reports. This indicates that Dexcom was aware of the spike in reports about the G7 following the December 2023 adulteration because Dexcom itself submitted the overwhelming majority—***99.74***%—of the MAUDE reports between January 1, 2024 and December 15, 2025.

96. The reports consistently highlighted the same issue: users' G7s were providing inaccurate glucose readings. For example, a December 30, 2023 report stated that a patient with gestational diabetes using the G7 had received "incorrect blood sugar data resulting in alarms for

[3] Lead Counsel derived this estimate of accuracy-related complaints by filtering the "Device Problem" column header of a spreadsheet generated by downloading the complaints from MAUDE. Under that column header, complaints are categorized by problem type, including for example "Activation Failure" or "Alarm Not Visible." To derive the number of complaints that appear to relate to accuracy, Lead Counsel filtered the "Device Problem" column by selecting only the entries categorized as: "High Readings"; "High Readings; Low Readings"; "Incorrect, Inadequate or Imprecise Result or Readings"; "Incorrect, Inadequate or Imprecise Result or Readings; Defective Device"; "Incorrect, Inadequate or Imprecise Result or Readings; High Readings"; "Incorrect, Inadequate or Imprecise Result or Readings; Low Readings"; "Low Readings"; "Low Readings; Device Sensing Problem"; "Product Quality Problem; Incorrect, Inadequate or Imprecise Result or Readings."

low blood sugar," and then the device "quit working 4 days before it was supposed to." The report continued: "The response from Dexcom has been inadequate and prior sensors starting [REDACTED] 2023 have been rife with quality issues related to accuracy. We have reached out to Dexcom and found their response to be lacking. This is life or death for diabetic patients and people with gestational diabetes and needs full regulatory attention." Similarly, a January 11, 2024, report stated that a parent had "switched [their] type 1 diabetic son (7yo) from the dexcom g6 to the dexcom g7. We have had nothing but issues. The biggest concern and most terrifying is how inaccurate the cgm readings are compared to finger sticks. His cgm was reading 43 at school, i arrive and did finger sticks; his glucose was 358!!!! … this is dangerous! he could have died …!!!"

97. In addition, online communities dedicated to documenting problems with the G7 appeared in early 2024, offering additional evidence that Dexcom's adulteration of the G7 dampened demand for the G7.

98. For example, on February 14, 2024, one Reddit user published a post titled, "G7 – How to file a FORMAL COMPLAINT form 3500 to the FDA," advising G7 patients to file a formal FDA complaint over the G7's sensor failures and inaccurate readings. The user wrote: "I am filing a formal complaint with the FDA regarding the ineffectiveness of the G7. I URGE those with similar experiences (posted below) to do the same," adding "[a]t the very least, Dexcom needs to halt all PLANS of phasing out the G6 until they can get the G7 right. And the G7 needs to be what they've promised: 'The most accurate sensor on the market.'" The post received dozens of replies from patients sharing their negative experiences with the G7. For example, one user replied, "G7 is a piece of trash Never reads correctly 100 to 150 points different than finger stic[k] meter … DEXCOM IS KILL-ING PEOPLE."

99. On April 9, 2024, a different Reddit user posted, "Dexcom G7: With a 70% failure rate in 2024 thus far, I filed a FDA complaint." The user explained: "After yet another Dexcom G7 sensor … realized that my failure rate in 2024 thus far was 70%, I filed a [FDA] complaint. I'd encourage everyone else to do the same as the FDA needs multiple data points before opening an investigation." The post received ***hundreds*** of comments. One user commented, "Thank you for this. After years of the G6, my insurance company made me go to the G7. Not only have I had sensors fail … and it's just overall a terrible piece of equipment. I am going to file right away."

100. Patients also complained to the Better Business Bureau, detailing aggravation with the G7's inaccurate readings. One patient wrote on February 28, 2024: "The G7 is absolute garbage. Worst product ever. Its always off by a MINIMUN [sic] of 40 points. Its going to kill someone. … Im constantly using finger sticks and wasting money." On March 15, 2024, another patient reported: "Two days ago my dexcom sugar showed LOW and beeper went off on and on. I calibrated turned on and off my phone. Did everything over and over that I've been told and still not work. It also did the opposite and said high when it wasn't. Not only does that throw off my treatment -when it goes low, I eat something with sugar--adding to my sugar and making my diabetes worse." On March 16, 2024, another user wrote about her son's experience:

> DEXCOM G7: 911 ALERT! My son with type 1 diabetes for 10 YEARS, has used Dexcom CGMs the entire time … After A+ experiences with every other earlier Dexcom VERSION …, this is ABYSMAL! Of his first 9 G7 sensors, each supposed to last 10 days, he has had to request replacement of 6! … Dexcom, this is SERIOUS to go from a stellar reputation to DANGEROUS. As an [sic] recent example, the G7 transmitter, was reading LOW much of the day. My son was giving himself glucose, the pump was programmed to STOP DELIVERY of insulin w a low. When my son checked his blood glucose, he was 570, when reading LOW. He attempted to calibrate the pump … and the Dexcom would not take the number, continuing to deliver LOW readings. Dangerous: could result in KETOACIDOSIS. His other 5 other sensors have failed within a day or two … My son is leaving for Europe … with ZERO confidence in the Dexcom G7. The clinic is closed to get a new prescription or a Freestyle Libre Plus 2, which is not available at pharmacies

> yet. We can try to go back to the G6 which worked better but this situation with Dexcom G7 is beyond dangerous, wasted time, and severe medical risk[.]

101. Patients on an online forum for Type 1 diabetes called "Breakthrough T1D," also shared their experiences with faulty, inaccurate G7 sensors. One patient posted in April 2024: "Letting everyone know that Dexcom limits user to only 3 replaced sensors in a rolling 90 day period-this INCLUDES replacement of faulty sensors giving very inaccurate readings. I've had 3 replacements this year, 2 for inaccurate sensors and 1 fell off." Another patient commented: "My main complaint is that Dexcom limits replacement of faulty sensors-meaning sensors … that continue to give very inaccurate readings even after 24+ hours of wear."

102. Similarly, a Facebook group titled "Dexcom G7 – Issues and Complaints" was created for G7 problems in June of 2024 and exploded to more than 58,000 members in just over one year. As a patient posted on June 19, 2024: "Ever since Dexcom came out with their G7 device, it has been one problem after the other … Sometimes the reading are totally off and at times connection issues with the sensor. From my experience, about 60% of the G7 devices have issues … Figured it would be nice to have a collection of issues that we face, grouped in a single place so that we raise public awareness and this might cause some action to be taken." On August 3, 2024, another patient posted: "The G7 is extremely inaccurate to the point of dangerous lows! When it reads 75 and your real reading is 49 that is a HUGE difference … time for mass recall." Another patient posted on January 15, 2025: "I constantly have issues with getting accurate reading using the Dexcom g7 sensor. Tonight it read 320 but after using my glucose meter my accurate blood sugar was 219." In dozens of reactions and comments other users shared similar experiences.

3. Defendants Had Real-Time Access to Data Confirming that the Adulterated G7 Was Less Accurate than the FDA-Approved G7

103. Through MAUDE, online communities, and other reporting systems, Dexcom and its senior executives had real-time access to track and monitor patient complaints about the G7's

decreased accuracy after it adulterated the device—as Defendants publicly acknowledged and as the FDA regulations required them to do.

104. Defendant Sayer regularly spoke on podcasts geared towards the diabetes community where he touted Dexcom's commitment to answering user complaints as reported online, including on MAUDE. On July 2, 2024, Defendant Sayer appeared on a podcast, *Diabetes Connections*, and confirmed: "We have all sorts of systems in place where we go through [the error codes from our product] literally at least monthly and … quarterly for sure for FDA purposes and our quality system purposes and we monitor those things." In this same podcast interview, Defendant Sayer stated that Dexcom had a "reliability standard" and considered "anything you could think of," including "the chemistry membranes of the sensor." Defendant Sayer also stated that, in determining to replace sensors with adhesive problems, Dexcom "went through our entire database, ***you know we have over a trillion data points of glucose data***." Defendant Leach similarly confirmed that Dexcom kept track of frequency of complaints, stating during the May 1, 2025 Q1 2025 Earnings Call that "sensor issues do happen and we've seen them on the boards, too." Dexcom also responded to issues and complaints about the G7 posted in Facebook groups. For example, in June 2025 the official Dexcom Facebook account responded to a user who explained she had "almost 2 dozen faulty sensors [in] just the last seven months," by stating it "understood how critical accurate readings are" and was "addressing these concerns."

105. Dexcom senior management was required by law to track and report device malfunctions that could cause or contribute to serious injury and to ensure timely and accurate reporting of adverse events. Specifically, the QSR, 21 C.F.R. Part 820, requires "management with executive responsibility" to assume personal responsibility for compliance with the "Medical Device Reporting" rule. This rule requires manufacturers 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. § 803.10(c)(1). A manufacturer must also evaluate all patient complaints "to determine whether the complaint represents an event which is required to be reported to FDA." *Id.* § 820.198(a)(3). The QSR 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 (iii) appoint an executive responsible for ensuring that "quality system requirements are effectively established and effectively maintained." *Id.* §§ 820.20(a), (b)(3), (c).

106. The FDA's approval letter for Dexcom's December 2021 510(k) reminded Dexcom that it was required to comply with the QSR—including "reporting of medical device-related adverse events." The FDA again reminded Dexcom of these obligations when it approved Dexcom's three subsequent 510(k)s with respect to the G7. *See* ¶¶ 85, 307.

B. Dexcom's Inadequate Manufacturing Processes for the G7 Further Undercut Dexcom's Statements About the Product's Reliability and Accuracy

107. The G7 qualifies as an "iCGM"—an "integrated" CGM system—because it is a CGM system that can be automatically connected to automated insulin-dosing systems. Thus, Dexcom is required to comply not only with the QSR as set forth above but also with "special control" regulations applicable to iCGMs. *See* 21 C.F.R. § 862.1355. These regulations are designed to ensure the quality and reliability of the devices that circulate to the public by imposing stringent manufacturing and product release obligations on device manufacturers, particularly when their devices are used for real-time dosing decisions.

108. At the start of the Class Period, Dexcom manufactured essentially all its CGMs at two locations, its facilities in Mesa, Arizona and San Diego, California, with a third manufacturing facility in Malaysia not fully functioning until around November 2024.

109. Even before the start of the Class Period, however, pervasive manufacturing and quality control failures existed at Dexcom's facilities, as the FDA determined. These deficiencies, certain of which are set forth below, rendered Dexcom unable to reliably manufacture and test devices in a way that met Dexcom's stated accuracy metrics, undermining the very foundation of Dexcom's accuracy representations to investors. As the FDA later uncovered in onsite inspections, Dexcom's manufacturing deficiencies violated various FDA regulations applicable to CGMs.

110. *First*, before manufacturing even began, Dexcom failed to properly document its "design inputs," such that it could not later verify or ensure that manufactured G7s performed as they were supposed to. Dexcom's manufacturing protocols established "design inputs"—variables that specified how the devices would be manufactured for the real world—including for key measures like MARD and "glucose sensitivity" (which measures how the sensor's electrical signal responds to *changes* in glucose concentrations, directly reflecting the sensor's accuracy over the course of the device's time of use). However, through most of 2024, Dexcom did not even document the MARD specifications it used as a design input. Accordingly, Dexcom was unable to demonstrate that it had "appropriately considered" the differences between the G7's clinical MARD (the one Dexcom repeated publicly) and the MARD Dexcom used and accepted in production, as the FDA later documented. With respect to glucose sensitivity, Dexcom documented the initial input but not requirements it had specified for the expected 10.5-day wear period. Thus, Dexcom could not properly verify whether the sensor was as accurate throughout and at the end of its wear period as it may have been at the outset.

111. In late 2024, under pressure from the FDA, *see* ¶ 219, Dexcom acknowledged most of these failures in its private correspondence with the FDA. In response, Dexcom began using and documenting a MARD design input for the G7 associated with ***the G6's*** clinical study, but even then, it only set a maximum acceptable MARD as the critical design specification. None of this fixed the design input problems. The G6's sensor uses a glucose algorithm different from the G7's, so setting the G7's acceptable MARD based on the G6's clinical study impacted the G7's accuracy. In addition, setting only a single parameter—maximum acceptable MARD—for a design input was insufficient to ensure the manufactured G7's accuracy would perform in the real world like it had in the clinical study.

112. Lead Counsel's investigation revealed additional details as to Dexcom's failure to set adequate MARD manufacturing values to achieve the 8.2% accuracy that Defendants stated publicly the G7 sensor achieved, and as to its failure to document its MARD design input.

113. Former Employee 1 explained that Dexcom's Mesa facility held daily morning meetings that encompassed all the departments in the facility, including with Former Employee 1's entire manufacturing teams, where daily production expectations were discussed. Based on attending these daily meetings, Former Employee 1 stated that at these meetings senior management conveyed acceptable MARD manufacturing thresholds for the day. Former Employee 1 stated that the MARD threshold directives came from Vice President Ian Topic, who reported to Executive Vice President of Global Operations Barry Regan. According to Former Employee 1, "Topic generally told them the daily MARD verbally" and Former Employee 1's team attended the daily stand-up meetings. Former Employee 1 also stated that, on occasion, the acceptable MARD thresholds could be conveyed directly by the head of the Mesa facility, Edward Carr.

114. According to Former Employee 1, the acceptable MARD threshold changed and ***could even range as high as 12.5% or 15%*** (i.e., nearly double the 8.2% figure Dexcom repeatedly publicized). Former Employee 1 recalled that: "at first it was anything under 15% MARD, but then they would retract that and say, wait only anything under 12%." According to Former Employee 1, on other occasions, management would direct "[w]e can't afford doing 15%, we have to bring it down to 12.5," but that even if a batch of manufactured sensors tested to a MARD of in between 12.5 and 15%, the Mesa facility employees were told to "come have a conversation about what to do" with those sensors. In plain terms, on any given day, Dexcom approved a G7 for distribution that Dexcom had tested for accuracy post-manufacturing and that had a real-world inaccuracy rate above the figure Dexcom repeatedly stated was the G7's MARD—based on Dexcom's own design. Former Employee 1 additionally confirmed that the daily MARD acceptance thresholds were not documented and did not appear in written design plans.

115. Former Employee 1's account is corroborated by Former Employee 2, a Systems Requirements Engineer contracted by Dexcom from December 2024 through August 2025, who wrote systems requirements for the G7 and worked on Dexcom's response to the FDA Warning Letter issued in March 2025. According to Former Employee 2, the FDA pointed to the lack of design requirements for the G7, particularly with respect to design requirements for MARD, explaining that the FDA found that "your requirements are not meeting the product expectations." Former Employee 2 further stated that from March to May of 2025, Dexcom quality assurance professionals tasked with addressing the FDA's concerns repeatedly asked what the MARD requirements were but could not get an answer from management. In other words, like Former Employee 1, Former Employee 2 stated that Dexcom had no MARD design requirements.

116. In sum, during the manufacturing process, Dexcom was setting MARD levels arbitrarily, without documentation, and at consistently higher percentages than the clinical MARD specification for the G7. Dexcom knowingly designed G7 sensors in a way that made it impossible to verify that the G7 sensors had the real-world accuracy Dexcom promised and, at some point, even began using ***the G6's*** clinical study MARD (which had been 9.0%, not 8.2%) as an acceptable design input. Given these deliberate choices by Dexcom, statements to investors that the G7 was the "most accurate" sensor in the market were materially false and misleading.

117. These failures contravened applicable CGM regulations, which require Dexcom to "demonstrate consistent analytical and clinical performance throughout the sensor wear period," 21 C.F.R. § 862.1355(b)(1), and regulations requiring manufacturers to maintain sufficient "design controls" in accordance with good manufacturing practices. *See id.* § 820.30.

118. *Second*, Dexcom did not properly monitor or document its "functional acceptance testing"—the final gate of testing before sensors were released to patients. In the final stages of manufacturing, companies like Dexcom perform "functional acceptance testing" as a type of "final check" to ensure that the components of the CGM operate as they should in the real world. As part of this testing, Dexcom placed each G7 sensor in solutions with different concentrations of glucose to test their accuracy and performance. The sensors were then either accepted or rejected based on metrics such as MARD and glucose sensitivity. The integrity of this process was critical to patient safety—and to representations about the G7's accuracy.

119. Dexcom's testing system at this last critical step presented several deficiencies. Most saliently, Dexcom was not monitoring the concentrations of glucose in the solutions used to test the finished sensors. This is important because those concentrations can fluctuate throughout the day due to evaporation, physical loss, and other factors. Without monitoring the dishes,

Dexcom could not verify how accurate the G7's glucose reading really was because it did not know how much glucose was in the test dishes to begin with.

120. In addition, Dexcom recorded a "pass" or "fail" result for each CGM, meaning it would pass a "good" sensor and reject a "bad" sensor, but did not preserve any of the underlying data—such as the MARD measurement and the glucose sensitivity slope—used to reach that result. Documenting simply whether a sensor worked or not, without recording the actual tested accuracy data, provided no way for the supposed accuracy rate results to be verified.

121. In short, Dexcom did not properly test the real-world accuracy of the G7s it manufactured and it did not properly document the results of those tests for later validation.

122. These failures directly contravened applicable FDA regulations, which require "adequate controls" to be "established during manufacturing and at product release," 21 C.F.R. § 862.1355(b)(3), and require manufacturers to "adequately validate a process whose results cannot be fully verified by subsequent inspection and test." *Id.* §§ 820.75(a), (b).

123. *Third*, Dexcom failed to adequately establish, control, and validate procedures with respect to acceptable finished products. One important problem was that Dexcom was not properly setting criteria for what error rate it would accept between the predicted initial glucose sensitivity measure and the actual initial glucose sensitivity measure, and between the predicted final glucose sensitivity measure (at the end of the device's use time) and the actual final glucose sensitivity measure. Because the G7's algorithm uses the initial and final glucose sensitivity measures to calculate and provide a glucose measurement, a significant error in these values could "contribute to inaccurate glucose readings," as the FDA later documented. But Dexcom was not even setting an acceptable error rate, which meant it was shipping sensors that should not have been accepted or were not performing properly.

124. This failure also related to the coating and thickness of sensors for the G7. During the manufacturing process, sensors are dipped into chemical solutions to apply coatings—including the resistance layer—that are critical to sensor accuracy. However, the acceptable ranges Dexcom set for key dipping parameters—such as dip speed, retract speed, and number of dips—were "extremely wide." These variations "could lead to significant variability in sensor sensitivity and clinical accuracy" in sensors that Dexcom still sold to the public, as the FDA later found. Dexcom's own Process Engineering Director acknowledged to the FDA that "sensors produced at the edge cases will likely exhibit non-conformities"—in other words, the accuracy of sensors produced at the outer edges of these ranges could be compromised.

125. Dexcom later told the FDA that its rationale for failing to adequately control the dipping process ***during manufacturing*** was that Dexcom would verify the finished sensors ***later on.*** But this later verification did not include key checks that confirm the accuracy of the sensor, including whether substances common in the body (like medication) interfere with the sensor's ability to deliver accurate readings. For example, acetaminophen (a common, over-the-counter pain reliever) can interfere with a CGM sensor because, when it is metabolized in the body, it creates an electrical signal that the sensor mistakes for glucose. Because this can render a CGM's reading inaccurate, one of the sensor's membrane layers is specifically designed to reduce acetaminophen interference, and manufacturers must test whether the coating sufficiently mitigates that interference. Yet Dexcom's testing did not include any verification of the acetaminophen interference effect on the finished sensor. The practical significance is that sensors with defective coatings—including those affecting clinical accuracy over even routine issues such as the presence of acetaminophen—could reach patients without detection.

126. Dexcom also failed to specify, before manufacturing, what sensor thickness it would accept in a G7. Instead, in determining whether a G7 was ready for distribution, Dexcom only set the average thickness it would accept across a batch, rather than setting an acceptable thickness for an individual sensor and testing sensor thickness individually. Moreover, Dexcom had no "documented rationale for basing acceptance criteria on the average thickness of … sensors," as the FDA later determined. This means that individual sensors with improper coating thickness could be shipped to patients if the overall batch average appeared acceptable, even though Dexcom knew that devices at the outer edges of coating thickness could be inaccurate.

127. As a result of these failures, Dexcom was shipping sensors with improperly calibrated glucose sensitivity slope values, which could "contribute to inaccurate glucose readings," and with thicknesses that Dexcom had not individually verified even though Dexcom had set acceptable thickness parameters within an extremely wide range, leading to sensors that produced unreliable and inaccurate glucose readings for patients.

128. The foregoing failures to establish, control, and validate acceptance criteria for manufactured G7s violated regulations requiring "adequate controls … during manufacturing ***and*** at product release," requiring that "the device must demonstrate clinically acceptable performance in the presence of clinically relevant levels of potential interfering substances" including, but not limited to, acetaminophen, 21 C.F.R. § 862.1355(b)(3), and requiring manufacturers to maintain sufficient "design controls" for their design outputs. *See id.* § 820.30(d).

129. *Fourth*, Dexcom failed to implement appropriate corrective and preventive action ("CAPA") procedures for manufacturing issues it became aware of.

130. One issue for which Dexcom instituted a CAPA was to investigate whether it was properly testing sensors for accuracy at various oxygen levels. In general, a low-oxygen

environment, such as when the area around the sensor is compressed due to pressure (like from sleeping in a certain position), can cause inaccurate CGM readings. To test for accuracy in low-oxygen environments, Dexcom tested sensors in dishes of varying oxygen concentrations. Because oxygen can dissolve over time, the level present in each dish needs to be checked both at the start, and throughout, the manufacturing process.

131. At some point before April 2024, Dexcom discovered that the dissolved oxygen in one of the G6's testing dishes was outside of specification. As a result, Dexcom instituted a CAPA in April 2024. Dexcom uncovered that ***all lots*** of manufactured sensors at both manufacturing facilities were potentially not tested in a low-oxygen environment. Moreover, Dexcom identified that the oxygen levels it was using were not consistent during the manufacturing process due to systemic failures. These included that manufacturing associates were not consistently checking or recording dissolved oxygen values, not notifying supervisors of out-of-specification conditions, and not scrapping sensors that were not tested in low-oxygen environments.

132. Even though the CAPA revealed to Dexcom that it was ***not*** properly running the critical low-oxygen environment test, after the CAPA Dexcom decided to release the sensors anyway, arguing that these deficiencies resulted in an "acceptable risk" because low-oxygen conditions were "generally transient." But, as the FDA later documented, this rationale was "not adequate" because it "failed to evaluate the potential risk to users of devices manufactured with sensors" that were not tested in the low-oxygen environment—meaning users received untested sensors that could provide inaccurate glucose readings.

133. Another issue for which Dexcom had previously initiated a CAPA was an increase in the failures of certain sensors' needles used for insertion. Rather than seeking to fix the problem,

the CAPA sought to reduce the rate of complaints associated with this failure to below a certain percent that the FDA later found was still "fivefold higher than the baseline complaint rate."

134. The failure to ensure that all sensors were appropriately tested in low-oxygen environments contravened applicable FDA regulations, which require "adequate controls" to be "established during manufacturing and at product release," 21 C.F.R. § 862.1355(b)(3), and require manufacturers to maintain sufficient "design controls" in accordance with current good manufacturing practices ("CGMP"). *See id.* § 820.30. Further, Dexcom's failure to institute CAPAs that adequately responded to issues identified violates federal quality system regulations setting forth CGMP requirements, which require that manufacturers establish and maintain procedures for implementing a CAPA. *See id.* § 820.100.

135. In plain terms, Dexcom discovered manufacturing and other problems that affected the accuracy of its sensors but, rather than institute a plan to fix the issues, Dexcom instituted plans that would permit it to ship nonconforming sensors to customers anyway.

136. *Finally,* Dexcom failed to conduct adequate and complete system hazard analyses for its CGM systems, including the G7.

137. One risk associated with using the G7 concerns its ability to pair with an insulin pump that automatically doses insulin when a patient's blood glucose levels reach certain specified thresholds and may restrict insulin when blood glucose levels fall low. Inaccurate CGMs pose serious risks to patients who use automatic insulin pumps, because an inaccurate glucose reading could cause such connected devices to incorrectly provide doses of insulin or incorrectly fail to restrict insulin, leading to serious health consequences, including death. As the FDA later found, Dexcom failed to "address the hazards and associated risks of using the [G7] in conjunction with an [automatic insulin device]."

138. In other words, Dexcom failed to consider and mitigate how inaccuracies in the G7 could expose patients that rely on the G7 to administer insulin to potentially fatal risks.

139. The failure to conduct adequate risk assessments violated FDA regulations that require medical device manufactures to establish adequate procedures for design validation and to ensure that devices conform to user needs and intended uses. *See* 21 C.F.R. § 820.30(g).

C. As the Class Period Begins, Defendants Mislead Investors and the FDA By Continuing to Trumpet the G7's Composition and Accuracy – While Profiting From their Misstatements

140. During the Class Period, Defendants falsely touted the G7 as the most accurate CGM in the market, despite their awareness or reckless disregard of: (1) the adulteration of the G7 on December 13, 2023, and the fact that the adulteration made the G7 less accurate than the G7 tested in clinical trials, and (2) the pervasive manufacturing and quality control failures at Dexcom's facilities that rendered Dexcom unable to reliably manufacture and test devices in a way that met Dexcom's stated accuracy metrics.

141. On January 8, 2024—the first day of the Class Period—Defendant Sayer, Dexcom's CEO and Chairman, presented at the J.P. Morgan Healthcare Conference alongside Defendant Sylvain, Dexcom's CFO. The J.P. Morgan Healthcare Conference is a yearly gathering of thousands of participants in the healthcare industry, including, according to some publications, thousands of investors, bankers, and the media, and receives widespread coverage.

142. In his presentation, Defendant Sayer boasted about the Company's record performance, announcing Dexcom's "first $1 billion quarter" and revenues "over $3.61 billion" for 2023. Sayer touted the G7 as the key driver of the Company's success, stating: "You can't achieve results like this, though, without having a great platform, and that's what our G7 is."

143. Tellingly, the first G7 characteristic Defendant Sayer emphasized as driving this "platform" was the G7's supposed accuracy, stating that "any medical technology that comes out,

the first thing you have to have is great science" and "***for G7, that great science starts with its accuracy. This is the most accurate sensor on the market today and the most accurate sensor that's ever been produced by us***." Further demonstrating Dexcom's strong desire to expand its user base, Defendant Sayer then urged patients with Type 2 diabetes, in particular, to "try to trust and rely on that data," noting the "25 million people in the U.S. alone who have diabetes [but] … who are not on insulin" and could "benefit tremendously from CGM."

144. Defendant Sylvain reinforced these representations, discussing the Company's guidance for 2024 revenue growth of 16% to 21%, gross margins of 63% to 64%, and "another year of record new patients" driven by the G7. Defendant Sayer noted that Dexcom had achieved this growth, including 35% patient growth and 24% revenue growth in the last year, "***without skipping a beat on the capacity and manufacturing side***," in part because Dexcom had built out a manufacturing plant in Malaysia. On January 8, 2024, Dexcom filed a Current Report (Form 8-K), where it similarly attributed its 2023 revenue to a "successful rollout of Dexcom G7."

145. In the PowerPoint presentation that accompanied Defendants Sayer and Sylvain's talk, Dexcom similarly described the G7 as "the new standard in CGM technology," with the first listed characteristic of the device being "***Most accurate***," pointing to information it had "on file" as the backup for this statement about the G7's accuracy.

146. Investors relied on Defendants' false and misleading statements about the G7's accuracy. For example, on January 9, 2024—the day after Defendant Sayer's presentation at the J.P. Morgan Healthcare Conference—William O'Neil + Co. issued a Buy recommendation for Dexcom, directly citing the G7's accuracy as a key competitive differentiator. The report stated: "Dexcom G7 is the most accurate CGM device cleared by the FDA with an overall mean absolute relative difference (MARD) of 8.2%."

147. One month later, on February 8, 2024, Dexcom filed its Annual Report (Form 10-K) for the fiscal year ended December 31, 2023 ("Dexcom 2023 10-K"), signed by Defendants Sayer and Sylvain.

148. Although Defendants were aware of (or at minimum recklessly disregarded) the change to the G7 sensor and the consequential decrease in accuracy, the Dexcom 2023 10-K nevertheless repeated statements about the G7's accuracy and quoted the specific MARD numbers that were based on the significantly different, unadulterated version of the device, stating: "***With an overall Mean Absolute Relative Difference, or MARD, of 8.2%, as well as 94.1% of values within 20% of their comparator, Dexcom G7 is the most accurate CGM cleared by the FDA***." Despite its failure to manufacture the G7 while testing for acetaminophen interference, Dexcom similarly repeated its statements about the G7's accuracy because it allows for "***more accurate glucose readings without interference from common medications … such as acetaminophen***."

149. Similarly, although Defendants were aware of (or recklessly disregarded) that Dexcom had started producing internally the key material needed for the G7's sensor's "resistance layer," rather than from an external supplier, the Dexcom 2023 10-K nevertheless stated Dexcom continued to "purchase certain components and materials used in manufacturing from single sources due to quality considerations, costs or constraints resulting from regulatory or other requirements," including "seals used for the applicator and certain polymers used to synthesize polymeric membranes for our sensors." The statement gave the misleading impression that the sourcing of key components had been unchanged, when the opposite was true.

150. During the February 8, 2024 Q4 2023 Earnings Call, Dexcom used a nearly identical "Dexcom Investor Presentation" to the one Dexcom had used at the J.P. Morgan Conference the month prior. The presentation described the G7 as "the new standard in CGM

technology," with the first listed characteristic of the device being "***Most accurate***," and pointing to information it had "on file" as the source of this data—even though the device had been adulterated, the adulteration made it significantly less accurate, and the data "on file" had been derived from a different (unadulterated) version of the device.

151. Following Dexcom's February 8, 2023, Q4 2023 Earnings Call and the filing of the Dexcom 2023 10-K, analysts issued a wave of favorable reports that relied upon these representations about the G7's accuracy. For example, on February 9, 2024, Robert W. Baird & Co. issued a report maintaining its "Outperform" rating with a $161 price target, stating that "DXCM has carved out a clear leadership position in the industry" based in part on its technology advantages, and concluding that Dexcom could "fairly easily deliver on its 15-20% [Long Range Plan] top-line growth targets, if not exceed the upper-end of those targets."

152. On February 20, 2024, Defendant Sylvain, Dexcom's CFO, sold 3,363 shares worth more than $392,000 at artificially inflated prices.

153. On March 5, 2024, Defendant Sean Christensen, Vice President of Finance and Investor Relations, made similar misrepresentations at the Raymond James Institutional Investors Conference, a major global gathering of public company executives and institutional investors from around the world. Specifically, Defendant Christensen stated: "With Dexcom G7, we have what we believe to be the standard in CGM technology around the world. ***G7 is the most accurate CGM that has been cleared by the FDA and offering that standard Dexcom performance that people have come to expect and trust over the years***."

154. Once again, analysts relied on these misrepresentations. For example, on March 6, 2024, the CGS International Analyst Report highlighted Dexcom's presentation at the March 5 Raymond James Conference, noting the Company's "competitive differentiation" and citing that

"DXCM has swaths of clinical data supporting their performance." The report noted that "DXCM presented to a standing room only audience (in both the presentation and breakout)," demonstrating the market's significant interest in the Company's representations.

155. In response, on March 6, 2024, Dexcom's stock price shot up $11.94, or more than 9.8%, to a close of $133.72, on trading volume that was nearly three times higher than the average daily trading volume over the last week.

156. Unfortunately for investors, the foregoing statements were materially false and misleading for multiple reasons. *First*, the statements that the G7 was "the most accurate sensor on the market today" and had an "overall Mean Absolute Relative Difference, or MARD, of 8.2%" were materially misleading because they were based on MARD data from clinical trials of G7 devices that were significantly different from, and more accurate than, the version of the G7 that Dexcom was manufacturing and distributing at the time. Specifically: (1) in December 2023, after arriving at the published MARD figures in clinical trials, Dexcom adulterated the G7 by making significant changes to a "critical component," *i.e.*, switching the membrane material used in the resistance layer of the glucose sensors to an inferior material produced in-house, *see* ¶¶ 74, 78-79; (2) Dexcom determined internally that the adulterated G7 was not equivalent to the version of the device that had yielded the published MARD figures, as its own study determined that "primary endpoints" used to establish equivalence between the original and the adulterated G7 "were not met," as the FDA later documented, *see* ¶ 80; *see also* ¶ 82; and (3) further, Dexcom determined that the adulterated version of the G7 performed worse across every accuracy metric compared to the G7 that produced the published MARD figures, with internal data showing that "every accuracy metric of sensors built with the [new material] … was worse" and that sensors had a "significantly different ratio" of glucose sensitivity. *See* ¶ 81; *see also* ¶ 82.

157. *Second*, the statements emphasizing the G7's accuracy were materially misleading for the independent reason that Dexcom was unable to manufacture and test devices in a way that ensured they reliably met Dexcom's stated accuracy metrics. For example, Dexcom: (1) was setting MARD levels arbitrarily, without documentation, and consistently higher than the clinical MARD specification for the G7, including at times as high as 15%, *see* ¶¶ 110-17; (2) did not properly test the real-world accuracy of the G7s it manufactured (failing to monitor glucose, oxygen, and acetaminophen concentrations in test dishes) and it did not properly document the results of those tests for later validation, meaning Dexcom did not know what the G7's real-world MARD actually was, *see* ¶¶ 118-22; (3) was shipping sensors without properly calibrating acceptable error codes for glucose sensitivity, which could "contribute to inaccurate glucose readings," *see* ¶¶ 123, 127-28; (4) was shipping sensors with thicknesses that Dexcom had not individually verified, leading to sensors that produced unreliable and inaccurate glucose readings, *see* ¶¶ 124-28; (5) discovered manufacturing and other problems that affected the accuracy of the sensors but, rather than institute a plan to fix the issues, Dexcom instituted plans that would permit it to ship nonconforming sensors to customers anyway, *see* ¶¶ 129-35; and (6) failed to consider and mitigate how these failures exposed patients that relied on the accuracy of the G7 to control their insulin doses to potentially fatal risks, *see* ¶¶ 136-39. These extensive, overlapping deficiencies, at minimum, substantially and materially undermined the basis for Defendants' unqualified and categorical statements about the G7's supposed market-leading accuracy.

158. *Third*, the repeated statements that the "Dexcom G7 is the most accurate CGM cleared by the FDA" were further materially misleading because the adulterated G7 sensors were not lawfully approved by the FDA for commercial sale. *See* ¶¶ 83-90, 215-16.

159. *Fourth*, the statements touting the G7's accuracy were materially misleading for the additional reason that the G7's accuracy worsened in the real world after Dexcom adulterated it, as shown by the dramatic spike in adverse event reports submitted to the FDA and other complaints regarding the G7 following the December 2023 adulteration. Notably, after Dexcom adulterated the G7, based on Lead Counsel's analysis of MAUDE, the number of complaints that appear to relate to the G7's accuracy increased by a factor of three. Additionally, between January 2024 and December 2025, the G7 received significantly more complaints (approximately 240,000) than Abbott's Libre 3 (approximately 8,200)—i.e., the G7 generated nearly thirty times more complaints than its primary competitor despite having a smaller market share. *See* ¶¶ 91-102.

160. As noted, market analysts and investors relied on Defendants' misleading statements about the G7's accuracy and what they meant for Dexcom's financial performance. Defendants' misleading statements caused Dexcom's stock price to rise from $123.98 just before the Class Period to its Class Period closing high of $140.45 on April 9, 2024.

161. Taking advantage of the artificially inflated prices, just days after Defendant Christensen's false and misleading statements at the Raymond James Conference and the subsequent spike in Dexcom's stock price, on March 12, 2024, Defendant Sayer sold more than 51,000 shares, reaping proceeds of $6,800,000. Weeks later, on April 8, 2024, with the market still in the dark about the G7's accuracy issues and with Dexcom's stock price near the Class Period closing high, Defendant Sayer sold nearly 50,000 additional shares worth approximately $6.9 million. In all, Sayer's sales on March 12 and April 8, 2024 represented 36.7% of his unrestricted, vested holdings. Sayer's timing was suspicious. By the close of April 8, 2024, the stock had been pushed to a near two-year high of $139.94, just short of the Class Period closing high the next day—a price that Dexcom's stock has not come near since.

162. Meanwhile, Defendants continued to mislead investors and the FDA.

163. On April 1, 2024, Dexcom submitted the April 2024 510(k) to the FDA, this time seeking approval to modify the G7's Bluetooth communication range from 20 to 33 feet. In the April 2024 510(k), Dexcom told the FDA: "***The subject device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness***." It also stated: "Nonclinical testing results … support that the device … is ***as safe and effective*** as the predicate device." On April 23, 2024, the FDA approved the modified G7, specifically relying on the foregoing misrepresentations and concluding that the "fundamental scientific technology of the modified device has not changed."

164. Similarly, on June 5, 2024, Defendant Sylvain, speaking at the William Blair Growth Stock Conference, described the G7 as Dexcom's "***trademark product, our flagship product***," and, once again, as "***the most accurate sensor in the market***."

D. The FDA Begins to Discover the Problems With Dexcom's Manufacturing

165. Between June 10, 2024 and June 14, 2024, the FDA inspected Dexcom's Mesa, Arizona facility and began to uncover some of the failings underlying Dexcom's manufacturing of the G7, as summarized above.

166. At the conclusion of this inspection, the FDA issued to Dexcom a Form 483 dated June 14, 2024 (the "June 2024 Form 483"). The FDA issues a Form 483 to management of a company if an investigator observes conditions or practices indicating that a regulated product may be in violation of applicable regulations such that enforcement action by the FDA—including to impose penalties or revoke a device manufacturer's ability to market a device—may be required.

167. The June 2024 Form 483 was issued to Edward J. Carr, Dexcom's Senior Site Director at Mesa, privately warning Dexcom that its manufacturing processes at the Mesa facility were severely problematic. The FDA identified two critical observations.

168. The FDA's first observation related to Dexcom's inadequate processes with respect to the coating and thickness of sensors for its G7. The FDA found that, as explained in ¶ 124 above, the acceptable ranges Dexcom set for key sensor dipping parameters were "extremely wide," producing coatings that are excessively thick, thin, or non-uniform, and Dexcom would still consider the sensors acceptable even though these "extreme" variations "could lead to ***significant variability in sensor sensitivity and clinical accuracy***."

169. That is, the FDA determined that the wide range of permitted settings lead to sensors that produced unreliable and inaccurate glucose readings for patients. This is the equivalent of a car manufacturer allowing its assembly line to install brake pads with dramatically different thicknesses without any quality check—some cars would brake normally, others would fail.

170. Moreover, according to the FDA, on June 13, 2024, Dexcom's own Process Engineering Director acknowledged to FDA investigators that this design process was a problem, acknowledging "that sensors produced at the edge cases will likely exhibit non-conformities." Dexcom's own leadership admitted that certain sensors will likely not meet specifications and could be defective, but they were still placed in circulation to users.

171. In response to the FDA's inspection, on June 14, 2024, Dexcom attempted to justify its approach to sensor coating by pointing to other calculations Dexcom purported to run, but the FDA rejected the justification. As the FDA explained, Dexcom "did not provide evidence demonstrating that the outputs" of the calculation "have been adequately validated through objective test data and that they are robust enough to control for process variabilities within the extremely wide allowable ranges"—in other words, Dexcom could not demonstrate that these calculations produced accurate or reliable results. Thus, Dexcom had no way of knowing whether the coating solutions it was using on sensors would result in sensors that worked properly.

172. As noted above, ¶ 141, Dexcom also told the FDA that its rationale for failing to control the dipping process was that Dexcom would verify the finished sensors later. But the FDA also found this inadequate because this verification did not include key checks that confirm the accuracy of the sensor, including whether substances like acetaminophen interfere with the sensor.

173. The FDA's second June 2024 Form 483 finding related to Dexcom's CAPA procedures. The FDA found that Dexcom had noticed an increased rate of complaints about its systems and, on September 21, 2023, expanded a then-existing CAPA to address the increasing complaints concerning the G7. However, Dexcom had only initiated three of the CAPA's eight corrective measures to address the increased complaints.

174. Later, on July 9 and October 9, 2024, Dexcom responded to the June 2024 Form 483. Charles R. Donlon, Dexcom's Senior Vice President of Quality Assurance, signed these responses. As noted below, ¶¶ 207-10, Dexcom's responses failed to cure the deficiencies.

E. The G7's Pervasive Accuracy Issues Lead to Significant Investor Losses When Dexcom Reported Poor Results and Guidance Cuts for the Second Quarter 2024, While Defendants Misrepresented the Reasons Behind the Poor Results

175. On June 5, 2024, at the William Blair Growth Stock Conference, Defendant Sylvain provided investors explicit assurances that Dexcom was "happy" with its "full year guidance" and "comfortable with where folks are sitting the quarter."

176. A few weeks later, however, the impact of the G7's compromised accuracy began to come to light when Dexcom announced disappointing second quarter results for fiscal year 2024. On July 25, 2024, Dexcom reported quarterly revenue of $1.004 billion—approximately 3.13% below consensus expectations of $1.036 to $1.04 billion—and lowered its full-year revenue guidance by approximately $300 million, from $4.20-$4.35 billion to $4.00-$4.05 billion.

177. Analysts were surprised and disappointed by the results and guidance cut. Analysts at UBS stated that the results were "a major surprise." Barclays analysts similarly noted the "[s]urprising sales shortfall," and that the news had "surprised investors." Wolfe Research analysts stated: "Numb [is] a good word to describe current state. Lots to process."

178. Immediately following this stunning news, Dexcom's stock price plummeted by more than 40%—the steepest decline in its history—from a closing price of $107.85 per share on July 25, to a closing price of $64.00 on July 26. *CNBC* published an article reporting that "Dexcom shares sank more than 40% on Friday, their steepest decline ever, after the diabetes management company reported disappointing revenue for the second quarter and offered weak guidance."

179. However, to reassure the market that there was nothing fundamentally wrong with their product—and to deflect attention from the product quality issues that were driving the shortfall—Defendants attributed Dexcom's underperformance to various sales execution issues.

180. For example, in its July 24, 2024 press release, Dexcom wrote that "[w]hile Dexcom advanced several key strategic initiatives in the second quarter, our execution did not meet our high standards." Additionally, in the July 25, 2024 Q2 2024 Earnings Call, Defendant Sayer told investors that "we have seen our share of new customers fall short of our expectations" and described the continued need to "enhance our competitive position and reestablish momentum." Sayer then added, "So what are we doing to enhance our competitive position and reestablish momentum? It starts with our product portfolio, which we continue to strengthen to put our sales team in a great position with clinicians." Sayer told investors that Dexcom had "***built upon the performance of G7, making it even better***," including through "a continuation of our monthly cadence of software updates," referring to the FDA's approval of the direct-to-watch feature, expanded Bluetooth connectivity, and a stronger adhesive. *See* ¶ 85.

181. In reality, the revenue miss and guidance reduction were not driven by sales "execution" issues but, rather, by quality issues affecting the G7's performance. A Software Engineer at Dexcom who worked as part of the G7 "quality team" from March 2022 through September 2024 at Dexcom's San Diego engineering facility ("Former Employee 3") stated that Dexcom's claim that salesforce restructuring was to blame for slower new patient starts was not true—sales were negatively affected by quality issues plaguing the G7 at that point. Former Employee 3 participated in monthly meetings in the first months of 2024, held in Dexcom's San Diego facility, which they described as "high-level engineering management meetings" attended by approximately fifteen Dexcom employees from San Diego and remotely, including "engineering VPs, Senior Directors and Managers." According to Former Employee 3, at these monthly meetings, it was repeatedly discussed that "the G7 quality issues were negatively impacting sales." Moreover, according to Former Employee 3, sales management and product management at Dexcom had pressured employees to convert patients from the G6 to the G7, but those efforts were unsuccessful because of the G7's quality issues such that, according to Former Employee 3, "it was quality and engineering, not sales." In short, Former Employee 3 stated that Dexcom's poor performance by the second quarter of 2024 and slower new patient starts were due to quality issues plaguing the G7.

182. Analysts, however, believed Defendants' excuses for the shortfall and continued to believe in the G7's accuracy. For example, on July 26, 2024, a Morningstar analyst published a report titled *Dexcom Earnings: Perfect Storm Pulls Down Revenue Growth, Margins, and Our Fair Value Estimate*. Despite the significant revenue miss and guidance reduction, the Morningstar report emphasized that "underlying demand for continuous glucose monitors, or CGMs, and

Dexcom's ***reputation for superior accuracy haven't changed***, which leaves us comfortable that the firm can get back on track as it irons out execution issues."

183. Similarly, on July 26, 2024, a BTIG analyst published a report, *Miss and Guidance Cut; Reduction Chalked Up to Identified Execution Issues*. Despite reducing its price target from $156 to $120, BTIG maintained its Buy rating, concluding: "With management repeatedly taking responsibility for its execution issues, we do not think the potential of the CGM market has changed or that a new competitive dynamic has suddenly emerged." BTIG analysts continued to rely upon Dexcom's "greater accuracy" as a central pillar of their Buy recommendation. Similarly, the analyst at UBS who had stated the earning results were "a major surprise" also believed, based on conversations with Dexcom executives, that "execution issues would be resolved."

F. Defendants Continue to Mislead Investors About the G7's Accuracy

184. Following the July 25 disclosure, Defendants continued to mislead the market about the G7's accuracy, assuring investors that the long-term investment thesis based on the G7's supposed accuracy was intact. For instance, during the September 4, 2024 Wells Fargo Securities Conference Presentation, Defendant Sayer dismissed the July 2024 earnings miss as an "execution hiccup" with respect to Dexcom's sales plans, and "not a reflection of the quality of our product."

185. Similarly, Dexcom's marketing materials continued to refer to the G7 as the most accurate monitor on the market and pointed the public to the clinical trial data cited in the FDA's original approval of the G7—data derived entirely from sensors manufactured with the original compound that Dexcom had already secretly replaced with an inferior material. In several Facebook advertisements from July 5, 2024, through December 18, 2024, Dexcom stated that the G7 was the "most accurate CGM," and directed the public to "Dexcom data on file, 2024" and to the clinical trial data cited in the FDA's original approval of the G7. In a Facebook ad posted on September 9, 2024, Dexcom went so far as to directly compare its accuracy data to that of its

competitor, Abbott, by citing the G7's original 510(k) approval and Abbott's 510(k) approval of the Libre 3—inviting the public to measure the G7's accuracy against the Libre 3 based on clinical trial data that no longer reflected the composition of the sensors Dexcom was actually selling.

186. Just weeks later, on October 24, 2024, during the Q3 2024 Earnings Call, Defendant Sayer again noted the G7's supposed accuracy to investors, stating that "***[t]he accuracy of Dexcom [G7] is tried-and-true and proven to these patients***." This statement was materially misleading for the same reasons as Defendants' prior accuracy statements, *see* ¶¶ 156-59, 376-79, including that, by the time Defendant Sayer made this statement, (i) Dexcom had been manufacturing and selling adulterated G7 sensors made with an in-house material that its own studies had shown was inferior to the FDA-approved material on every accuracy metric; and (ii) Dexcom suffered from systemic deficiencies in its manufacturing processes that rendered it unable to reliably manufacture and test devices in a way that met Dexcom's stated accuracy metrics.

G. As Dexcom Continued to Mislead Investors, the FDA Discovers Additional Problems with the G7's Accuracy and Further Highlights them to Dexcom

187. Between October 21, 2024 and November 7, 2024, the FDA conducted another on-site inspection of Dexcom's facilities, this time at its San Diego, California manufacturing facility. At the conclusion of this eleven-day inspection, the FDA issued another Form 483 to Dexcom (the "November 2024 Form 483"). The November 2024 Form 483 documented seven additional inspectional observations that exposed pervasive deficiencies in Dexcom's quality control systems, manufacturing processes, and design procedures, all of which affected the accuracy and reliability of Dexcom's G7 CGMs and constituted significant violations of FDA regulations. The November 2024 Form 483 also documented, most critically, Dexcom's adulteration of the G7.

1. The FDA Highlights That Dexcom Changed a Critical Component in Its G7 Sensors

188. The November 2024 Form 483 formally documented Dexcom's unauthorized December 2023 design change to the G7 sensor described above, characterizing it as a significant regulatory violation. The FDA noted that Dexcom changed a critical raw ingredient in the resistance layer of the G7 sensors—from a supplier-purchased compound to an in-house material—without seeking 510(k) approval, as Dexcom was required to do.

189. The FDA's investigation revealed that Dexcom had tried and ***failed*** to validate this design change. The November 2024 Form 483 stated that Dexcom's initial study attempted to show equivalence between the accuracy of the original and the adulterated sensor, but determined that "several of [Dexcom's] primary endpoints were ***not*** met." Dexcom then conducted a follow-up "failure investigation," collecting additional information outlining the obvious differences in the two sensors. However, as Dexcom's Vice President for Clinical Affairs admitted to the FDA, this "failure investigation" was "not designed to establish accuracy against a clinical truth standard," and instead was "largely designed to help understand and confirm the reasons for the failure of the first trial." In other words, Dexcom's second study was not designed to prove that the new material performed as accurately as the old material. It was intended as a diagnostic exercise to explain away why the first study failed.

190. Importantly, the November 2024 Form 483 also highlighted that Dexcom's internal data showed that "***every accuracy metric of sensors***" built with the in-house material "***was worse***" than sensors built with the supplier-purchased ingredient. Internal Dexcom memos also revealed that sensors built with the in-house material had a "significantly different ratio" of glucose sensitivity than the sensors with the FDA-approved ingredient, meaning that "patients using

sensors made with" the in-house material "may experience differences in accuracy over the 10.5-day sensor wear period."

191. The November 2024 Form 483 noted that Dexcom commercialized the sensors starting on December 13, 2023, despite knowing these deficiencies.

2. The FDA's Other Observations: Dexcom's Additional Extensive Flaws in Manufacturing the G7

192. The FDA's late 2024 inspection of Dexcom's San Diego facility also documented additional systemic failures in Dexcom's manufacturing processes that undermined Dexcom's sensor accuracy assurances.

193. *First*, the FDA observed that Dexcom's "design inputs" for both the G6 and G7 were "not adequate." As outlined above, *see* ¶¶ 110-17, through most of 2024 Dexcom did not document the MARD specifications it used as an input and, with respect to glucose sensitivity, documented the initial input but not the requirements for the expected 10.5-day wear period of the device. Thus, Dexcom was unable to demonstrate that it had "appropriately considered" the differences between the G7's clinical MARD and the MARD Dexcom would accept in production, and Dexcom could not properly verify whether the sensor was as accurate throughout and at the end of its wear period as it may have been at the outset.

194. *Second*, the FDA observed that Dexcom's "functional acceptance testing of glucose sensors" used in both the G6 and G7 was "not adequate." As outlined above, *see* ¶¶ 118-22, Dexcom's testing system at the last critical step of testing sensors for accuracy before they were released to patients presented several deficiencies. Most saliently, Dexcom was not monitoring the concentrations of glucose in the solutions used to test the finished sensors. Without such controls, Dexcom could not effectively verify whether the glucose reading was actually accurate.

195. The FDA also concluded that Dexcom's processes "cannot be fully verified by subsequent inspection and test" because Dexcom recorded a "pass" or "fail" result for each G7 but did not preserve any of the underlying data—such as the MARD measurement and the glucose sensitivity slope—used to reach that result. According to the FDA, this "failed to demonstrate" that the CGMs are "capable of producing repeatable and reproducible [glucose sensitivity] slope data," which, in conjunction with MARD, determines sensor accuracy. In other words, documenting simply whether a sensor worked or not, without recording the actual tested accuracy data, provided no way for the supposed accuracy rate results to be verified. *See* ¶ 120. Additionally, the November 2024 Form 483 observed that Dexcom's testing system did not incorporate margins of error into the acceptance criteria for glucose slope. As a result, sensors that were defective may have been accepted because the testing system failed to "ensure that nonconforming sensors are not inadvertently accepted on the lower and/or upper bounds of the test."

196. *Third*, the November 2024 Form 483 observed that Dexcom failed to adequately establish procedures for "design output." This failure related to the error rates Dexcom would accept between the predicted initial glucose sensitivity measures and the predicted final measures. Because the G7's algorithm uses these values to provide a glucose measurement, an error in these values could "contribute to inaccurate glucose readings." *See* ¶ 123.

197. The "design output" failure identified in the November 2024 Form 483 also related to the thickness of sensors for Dexcom's G7. In determining whether a G7 was ready for distribution, Dexcom surveyed entire batches of sensors rather than evaluating individual sensors alone. Dexcom sampled average thickness across a batch of sensors to determine whether the batch was delivering accurate readings but failed to do so for ***individual*** sensors. Thus, individual sensors with improper coating thickness could be shipped to patients if the overall batch average appeared

acceptable, even though Dexcom understood that devices at the outer edges of coating thickness could be inaccurate. *See* ¶¶ 124-27.

198. *Fourth*, the FDA cited additional deficiencies in Dexcom's CAPA procedures. As set forth above, *see* ¶¶ 131-32, in April 2024, Dexcom discovered an issue with its sensors in low-oxygen environments in all lots manufactured in Mesa to date and some of the lots manufactured in San Diego, and initiated a CAPA. The CAPA investigation revealed systemic failures, including manufacturing associates failing to scrap sensors that were not tested in low-oxygen environments. Moreover, the FDA found Dexcom's decision to release the sensors anyway "not adequate" because Dexcom "failed to evaluate the potential risk to users of devices manufactured with sensors" that were not tested in the low-oxygen environment—meaning users received untested sensors that could provide inaccurate glucose readings.

199. *Finally*, the FDA found that Dexcom had failed to document and take steps to mitigate risks associated with certain hazardous situations for its CGMs. In particular, risks to patients arise from pairing the CGM with an automated insulin pump, as the G7 was designed to do. All patients rely on the accuracy of their Dexcom CGMs to ensure that they are making correct care decisions, but this is particularly important for those using automated devices, as an inaccurate glucose reading could cause the devices to automatically trigger or fail to trigger, oversupplying or undersupplying insulin, leading to serious health consequences and even death. The FDA found that Dexcom had failed to "address the hazards and associated risks of using the [G7] in conjunction with an [automatic insulin device]." In other words, Dexcom failed to consider and mitigate the many quality testing and manufacturing control failures that the FDA had documented and how these failures could pose risks—potentially fatal risks—to patients who relied on the accuracy of the G7 to control their insulin doses. *See* ¶¶ 136-39, 230, 315.

200. At the inspection's conclusion, Dexcom promised to correct each of the FDA's failure observations documented in the November 2024 Form 483—though, as subsequent events would reveal, it did not do so.

201. Meanwhile, on November 15, 2024, and without disclosing these troubling developments to investors, Defendant Sylvain sold $264,000 worth of Dexcom stock.

H. Dexcom Doubles Down on Misleading Investors About the G7's Accuracy While Struggling to Answer the FDA's Findings

202. The Company privately responded to the November 2024 Form 483 on December 3, 2024 and January 7 and 10, 2025. In the December 3, 2024 response, Dexcom included a study meant to show sensor equivalence for sensors made with the two different resistance layer materials for the G7. The results showed "significant variation in the clinical performance" of the sensors manufactured using the new material because "the standard deviation of [the new material's] glucose sensitivity [was] ***twofold*** that of [the old material]," as the FDA later documented. Dexcom also stated that it would stop distributing G7s manufactured with the alternative material—though all the adulterated G7s Dexcom had already distributed remained in the market while healthcare providers and patients remained unaware of the adulteration.

203. Despite the FDA's findings and Dexcom's own internal studies showing that the sensors with the new material were less accurate, Defendants continued to mislead investors about the accuracy of the G7 and took no steps to disclose the issues flagged in the November 2024 Form 483 to investors. Notably, on February 13, 2025—over three months after the Company received the November 2024 Form 483—Defendant Leach misrepresented the G7's accuracy during the Q4 2024 Earnings Call, touting the G7 as "the ***most accurate sensor*** available." Then, on February 18, 2025, Dexcom released the Dexcom 2024 10-K and again misrepresented the G7: "***With an***

overall Mean Absolute Relative Difference, or MARD, of 8.2%, as well as 94.1% of values within 20% of their comparator, ***Dexcom G7 is the most accurate CGM cleared by the FDA***."

204. These statements were false and misleading because Dexcom had changed a key material in the G7's sensor coating without FDA approval, which it knew negatively impacted the accuracy of the device. Worse, by this point in time, and upon the FDA's intervention, Dexcom had been confronted with its own internal analysis, which had demonstrated that Dexcom knew the sensors made with the new material performed worse on "every accuracy metric." Moreover, at the time Defendants Leach and Dexcom made the above misstatements, the FDA had also explicitly notified Dexcom of the pervasive manufacturing and quality control failures at Dexcom's facilities that rendered Dexcom unable to reliably manufacture and test devices in a way that met Dexcom's stated accuracy metrics. Nor had the FDA "cleared" the adulterated G7.

205. In January 2025, investigative news journalists who obtained a copy of the November 2024 Form 483 reached out to Defendant Leach for comment on the form's allegations. Leach did not deny his awareness of the November 2024 Form 483, admitting instead that Dexcom "work[s] closely with [the FDA] on requisite inspections." At the time, the existence November 2024 Form 483 and Leach's comments were not made public, were published behind a pay-wall, and no other media outlets or market analysts picked up on the story.

206. However, in an attempt to keep investors and users from discovering that Dexcom had adulterated the G7 and had been forced to stop manufacturing and commercializing the adulterated version of the device, on February 13, 2025, Defendant Sylvain stated publicly during the Q4 2024 Earnings Call that G7 shortages occurring around that time were due to the mishandling of material "by one of our shipping partners" even though, in reality, the shortage was due to Dexcom having stopped production of the adulterated G7 in the previous weeks.

I. The FDA Privately Issues a Warning Letter to Dexcom, Reiterating the G7's Pervasive Accuracy Issues

207. On March 4, 2025, the FDA further escalated its investigation into Dexcom by issuing a Warning Letter addressed to Defendant Sayer, Dexcom's then-CEO and President. The FDA issues Warning Letters when it identifies significant violations of federal regulatory requirements under the FDCA, such as those that may lead to an enforcement action by the FDA and the potential punitive and remedial measures that may follow.

208. The Warning Letter identified many of the same violations that the FDA had already formally flagged to Dexcom in both the June 2024 Form 483 and the November 2024 Form 483, confirming that Dexcom had been on notice of these deficiencies for many months.

209. In plain terms, the Warning Letter again confirmed that: Dexcom had secretly changed a critical component of its G7 sensors without obtaining the required FDA approval; that Dexcom's own studies showed the new material performed worse than the FDA-approved material on every accuracy metric; and that Dexcom's broader manufacturing processes were so deficient that the Company could not reliably produce sensors that performed as advertised.

210. The Warning Letter also rejected many of Dexcom's responses to the FDA's findings from the June and November 2024 Form 483s or stated, at minimum, that Dexcom had not provided the agency with sufficient information to properly evaluate Dexcom's response. With respect to the adulteration of the G7, the Warning Letter concluded that Dexcom's responses had made matters worse because additional data showed the new material caused "higher risks for users who rely on the sensors to dose insulin or make other diabetes treatment decisions."

211. The FDA also required Dexcom to submit an additional response to the FDA within fifteen business days to note the "specific steps" taken to "address the noted violations," warned Dexcom that the letter "is not intended to be an all-inclusive list of the violations at its facilities,"

and encouraged Dexcom to "investigate and determine the causes of any violations" because the violations identified by the FDA "may be symptomatic of serious problems in [Dexcom's] manufacturing and quality management systems."

1. Dexcom's Violations Relating to the Unauthorized Design Change of The G7 Sensor

212. The most serious violation identified by the FDA related to Dexcom's December 2023 decision to secretly change a "critical component" in its G7 sensors—as the FDA had documented in the November 2024 Form 483. The FDA again noted that Dexcom had switched from the original, supplier-purchased compound to an in-house material without obtaining requisite FDA approval and without notifying patients or healthcare providers of this change.

213. The Warning Letter reiterated much of what the FDA had stated in the November 2024 Form 483 on these points, including: (i) Dexcom's initial clinical study attempted to show equivalence between the accuracy of the original and the adulterated sensor, but determined that there were significant differences in "performance of the sensors"; (ii) an additional follow up study (what the November 2024 Form 483 had referred to as the "failure investigation") confirmed the results of the first study—that the new sensors were not as accurate as the original; and (iii) despite these failed studies, Dexcom began commercial manufacturing and distribution of G7 sensors using the new, inferior material. *See* ¶¶ 187-91.

214. After reviewing Dexcom's responses to the Form 483s, provided in December 2024 and January 2025 as set forth above, the FDA determined that those responses were "inadequate." Specifically, the new testing used by Dexcom to attempt to remedy the issue once again showed that the new material was not as accurate as the old material: "the standard deviation of [the new material's] glucose sensitivity is twofold that of [the old material's]." According to the FDA, this "indicates significant variation in the clinical performance of sensors manufactured using" the new

material. Critically, this meant that the sensors coated with the new material caused "higher risks for users who rely on the sensors to dose insulin or make other diabetes treatment decisions." The Warning Letter also notes that Dexcom had ceased commercial distribution of G7 sensors containing the in-house material, but asked that Dexcom provide information on how it planned to address remaining adulterated sensors in the market.

215. In the Warning Letter, the FDA also explicitly rejected Dexcom's position, in response to the November 2024 Form 483, that the design change did not require a new premarket submission. The FDA stated it did "not agree your firm has shown equivalency between" the two compounds "to justify that such a change does not require a new premarket submission. The variability differences could significantly affect the safety or effectiveness of the device." In simple terms, the FDA rejected Dexcom's position because the design change to the resistance layer material was a significant change with adverse impacts on the device's accuracy.

216. Thus, notably, the FDA concluded that Dexcom's responses did not include the requisite "evidence to support" Dexcom's position that "sensors containing" the new material "perform as claimed in the G7 original 510(k)." The FDA emphasized that the pivotal clinical studies submitted in the original 510(k) submissions for the G7 devices "used exclusively" the sensors with the old, supplier-purchased material, and that the supplier-purchased material was a "critical component" in the G7 sensors. The FDA ultimately found that the G7 devices were "adulterated" under the FDCA because Dexcom "does not have approved applications for premarket approval" in effect, and also concluded that the devices were "misbranded under section 502(o) of the Act" because Dexcom "introduced or delivered for introduction into interstate commerce for commercial distribution these devices with major changes or modifications to the devices without submitting a new premarket notification to FDA."

2. Dexcom's Additional Manufacturing and Quality Control Violations

217. Beyond the unauthorized design change, the Warning Letter yet again documented as regulatory violations issues that the FDA had already formally documented in the June 2024 Form 483, the November 2024 Form 483, or both. Despite being on notice of each of these deficiencies for many months, Dexcom had not fully remediated any of them.

218. *First*, the Warning Letter reiterated the FDA's prior finding in the November 2024 Form 483, described above, *see* ¶ 193, that Dexcom had failed to define the requirements it would use to assess the MARD and the glucose sensitivity slope in the finished product, so it could not demonstrate through its design verification process that the G7 performed properly over the sensor's 10.5-day wear period.

219. The Warning Letter noted that Dexcom's response to this issue had "***acknowledge[d] [Dexcom's] failure to adequately document***" design inputs and that Dexcom had updated its primary design input documents to reference these parameters.

220. Nevertheless, the Warning Letter concluded Dexcom's overall responses to this point were "not adequate." One problem was that, while in its response to the November 2024 Form 483 Dexcom had acknowledged these failures and promised to correct them, in attempting to correct the issues, Dexcom used specifications associated with the G6. The FDA concluded Dexcom did "not adequately support the use of the same data from the G6 pivotal study to support the G7 device because the two sensors use different" algorithms to convert the measurement of energy into a glucose measurement, such that using the G6's specifications for the G7 could "impact the sensitivity to MARD." Plainly, Dexcom could not use the same testing parameters it had used for the G6 because it was a fundamentally different device from the G7, and these parameters were not useful in showing the performance of the G7.

221. Another problem was that Dexcom's proposed solution was to set only a maximum MARD value—set at the level of the worst-performing sensors in its clinical trials. This was inadequate because it could result in all commercial sensors being released with "borderline acceptable MARD," which was "inadequate to ensure the labeled clinical performance." This meant that Dexcom could release sensors with questionable accuracy while still claiming the devices met the better performance demonstrated in premarket testing. That is, Dexcom set its internal MARD standard at the floor—the very worst level of accuracy shown in its clinical trials—meaning that every sensor it shipped could perform at the absolute bottom of what its clinical data supported, and not at the level of the publicly-stated MARD.

222. Worse still, the FDA rejected Dexcom's attempts to remedy these deficiencies also on the basis that Dexcom had not even been routinely collecting the underlying data necessary to support meaningful accuracy specifications. The FDA noted that "CGM sensors exhibit varying degree of clinical accuracy and MARD is an important parameter to ensure sensor accuracy." Accordingly, the FDA concluded that a single parameter of maximum MARD was inadequate to ensure the labeled clinical performance. For this reason, Dexcom needed to specify additional parameters to "ensure that the mean/median MARD and standard deviation of commercial production" is representative of the clinical performance that Dexcom submitted to the FDA in the pre-market submission. As a result of these deficiencies, Dexcom could not ensure that the actual G7s produced and commercialized had the same MARD as the G7s used for the clinical trial that formed the basis of Dexcom's public statements about MARD.

223. *Second*, the Warning Letter confirmed that, as the FDA had found in the November 2024 Form 483, *see* ¶ 194, that at the final-stage process for testing of the accuracy of the devices

Dexcom was not verifying that the test solutions themselves contained the expected amounts of glucose, leading to inaccurate assessments of whether the sensors worked correctly.

224. The Warning Letter explained that, after the FDA identified these monitoring failures, Dexcom submitted responses claiming that it had implemented corrective measures. The FDA found each response inadequate. First, Dexcom's supposed correction of the sensor accuracy testing measures still did not select the proper health hazard assessment method, meaning that Dexcom's ultimate, on-site testing of the G7's sensor accuracy remained deficient. Second, Dexcom's acetaminophen testing standard—built around an allowable measure of how much a substance like acetaminophen can affect a glucose reading—was less stringent than the clinical performance Dexcom had originally promised the FDA in the original clinical study. This meant that while Dexcom was making it seem as if patients did not have to worry about acetaminophen interference impacting the sensor's accuracy, Dexcom still had not properly verified that this was in fact the case. In short, the Warning Letter found that despite having been warned of this deficiency since November, and despite Dexcom promising to implement appropriate "glucose concentration monitoring" and "acetaminophen testing across all Dexcom sensor manufacturing lines," Dexcom's remedial measures were still "not adequate." In essence, when testing whether its sensors accurately measure glucose, Dexcom was ***still*** not verifying that the test solutions themselves contained the correct amounts of glucose, leading to inaccurate assessments of whether the sensors worked correctly.

225. *Third*, the Warning Letter again confirmed—as the November 2024 Form 483 had previously documented, *see* ¶ 195—that Dexcom's data preservation practices remained deficient because they ***still*** recorded only "pass" or "fail" results "rather than documenting the measured results." The FDA again concluded that this binary approach failed to demonstrate that the testing

method produced "repeatable or reproducible" glucose sensitivity slope data, such that the sensor's true accuracy was impossible to assess.

226. The Warning Letter confirmed that Dexcom's testing system did not incorporate margins of error into the acceptance criteria for glucose slope. Thus, defective sensors that should have been rejected may have been accepted because the testing did not "ensure that nonconforming sensors are not inadvertently accepted on the lower and/or upper bounds of the test."

227. *Fourth*, the Warning Letter also repeated the FDA's prior finding—documented in both the June 2024 Form 483 and the November 2024 Form 483, *see* ¶¶ 168-73, 197—that Dexcom failed to establish adequate specifications for the thickness of sensor coatings used in manufacturing G7 devices. Dexcom's reliance on batch-average thickness, rather than individual sensor specifications, meant that defective sensors could be shipped if the batch average appeared acceptable. The FDA found, for the ***third*** time, that Dexcom had failed to correct this deficiency.

228. *Fifth*, the Warning Letter documented—as the FDA had in the November 2024 Form 483, *see* ¶ 198—that Dexcom's CAPA procedures were deficient, and that Dexcom's response concerning remediation of these deficiencies was inadequate because Dexcom had failed to adequately investigate or remediate its dissolved oxygen manufacturing defect.

229. According to the FDA, Dexcom's proffered response attempting to remedy the low-oxygen issue was insufficient. Dexcom had proposed that the sensor initiate a "data blanking" (i.e., a sensor reading which delivers a blank space on the glucose trend graph rather than a continuous line, which alerts the user to an issue) or "low glucose alarm" if the G7 was subject to a low-oxygen environment. The FDA determined this was inadequate because a low-oxygen environment "may develop slowly" and, in many cases, this would not register a CGM value low

enough to trigger the alarm. As such, the FDA stated the proposal was not "acceptable," and may lead to users making "inappropriate diabetes management decisions."

230. *Finally*, the Warning Letter again stated—as the FDA had in the November 2024 Form 483, *see* ¶ 199—that Dexcom had failed to establish procedures for adequate risk analyses for the use of its CGM systems, including the G7, with automated insulin dosing systems. As the FDA noted, these devices "are commonly used with [Dexcom's] G6 and G7 CGM devices." Dexcom's response to this finding was simply that it was "working with ... partners" that manufacture the insulin dosing devices to "inform" its assessment of risks—in other words, Dexcom had still not completed its analysis regarding the risks posed to patients using Dexcom CGMs with automated insulin dosing systems. Accordingly, the FDA found that Dexcom had not sufficiently addressed the violation described in the November 2024 Form 483.

J. The Market Learns About the Warning Letter—but Dexcom Continues to Mislead Investors, Including About the Warning Letter's Contents

1. The Market Learns About the Warning Letter's Existence as Dexcom Begins to Mislead Investors About Its Contents

231. On March 7, 2025, after the market closed, Dexcom revealed through a Form 8-K filed with the SEC that it had received the Warning Letter from the FDA "following inspections of the Company's facilities in San Diego, California, and Mesa, Arizona." The Company did not disclose the contents of the letter. Instead, in a carefully worded statement designed to control the narrative, Dexcom stated only that the "[W]arning [L]etter describes observed non-conformities in manufacturing processes and quality management system." Dexcom additionally assured that "[t]he [W]arning [L]etter does not restrict the Company's ability to produce, market, manufacture or distribute products, require recall of any products, nor restrict the Company's ability to seek FDA 510(k) clearance of new products."

232. Despite Defendants' carefully worded revelation of the Warning Letter, investors were surprised by this news. Dexcom's common stock price declined from its Friday, March 7, 2025 closing price of $77.84 to a closing price of $70.72 on Monday, March 10, 2025.

233. The Warning Letter's contents remained hidden from the public for weeks. Dexcom thus continued to control the narrative and misled investors about the Warning Letter's severity. Investors and the public were not told of any of the FDA's damning findings, including the critical finding that Dexcom had adulterated its G7 sensors and that Dexcom's own internal studies showed that the new material "performs worse than [the old material] for accuracy."

234. For example, on March 9, 2025, Dexcom's Investor Relations spoke to BTIG and downplayed the severity of the Warning Letter. Dexcom's statement was again carefully worded to divulge little information and to control the narrative. Dexcom told the analysts that "they had already implemented process controls three months ago in response to the Form 483s" and "the warning letter has no impact on the company's commercial operations." Relying on Defendants' representations, the analysts commented that they were "surprised by the news," but Dexcom would "be able to resolve the issues with little impact to commercial and regulatory operations."

235. Similarly, on March 9, 2025, Raymond James analysts commented that, while the Warning Letter was "not ideal," the "***conversation with management … gives us comfort that this is not a product quality issue***[.]" For their part, on March 10, 2025, Oppenheimer analysts wrote: "We caught up with management over the weekend … We don't believe any issues of product/patient safety were noted."

236. On March 10, 2025, Dexcom also falsely told UBS analysts that "the 7 observations [in the Warning Letter] ***have nothing to do with product quality*** and are rather very specific around certain manufacturing processes, i.e., the concentration of solutions used to test acetaminophen

sensitivity." William Blair analysts also parroted Dexcom's March 7, 2025 8-K language and reported on March 10: "While the Form 483 and subsequent warning letter have yet to be published (i.e., we are unclear on the number of observations made of the two sites and if they are the same for both facilities), the warning letter noted 'observed non-conformities in manufacturing processes and quality management system.'"

237. At the same time, on March 10, while investors remained in the dark about the contents of the Warning Letter, and the same day Defendants categorically stated the Warning Letter had "***nothing to do with product quality***," Defendant Sylvain sold 7,000 shares for approximately $516,000 in proceeds. Notably, this stock sale took place outside of a 10b-5 plan.

2. Defendants Increase Their Efforts to Mislead Investors About the G7 Accuracy Issues as the FDA Publishes the Warning Letter

238. In the days that followed, Defendants continued their public relations campaign to mislead investors about the seriousness of the FDA's findings in advance of the publication of the Warning Letter. These efforts misled the market and affected its reaction to the publication of the Warning Letter by the FDA itself later in March 2025.

239. At an industry conference from March 19 to 22, Defendant Leach gave an interview to industry outlet *MedTech Dive* during which he downplayed the seriousness of the Warning Letter and claimed that Dexcom had already addressed the FDA's concerns. Defendant Leach explained that the FDA had "spent a lot of time looking at how our design documents traced all the way through to our production testing, and how we build our sensors. They had some concerns about how we were doing that. ***We answered those concerns with better documentation around how we build sensors and why we do the testing we do.*** The [W]arning [L]etter is their response saying, 'You've answered a lot of our questions, but there's still some that we have open that we need to work together on.'" *MedTech Dive* published the misleading interview on March 25, 2025.

240. On the morning of March 25, 2025, the FDA published the Warning Letter, revealing its contents to the public for the first time. The Warning Letter revealed that Dexcom's G7s were "not in conformity with the CGMP requirements" and that Dexcom was selling devices that were "adulterated" because it had modified its sensors by replacing a "component used in the resistance layer of [its] sensors" without premarket approval.

241. The same day, before the market could fully react to the Warning Letter, Dexcom fed industry analysts misleading spin about the FDA's findings, including that Dexcom had previously disclosed the new resistance layer material to the FDA, which Dexcom falsely claimed the agency had approved. For instance, a Dexcom spokesperson spoke with Wells Fargo on March 25, 2025, whose analysts then repeated Dexcom's admissions that new sensor material "refers to a dipping material that [Dexcom] developed in-house (prev[ious] sourcing from a single, external supplier) in order to increase supply" but also repeated Dexcom's false statements that it had "***notified the FDA of this insourcing as part of another 510(k) submission in 2024***." Dexcom management fed J.P. Morgan analysts the same story and insisted that the Warning Letter was not a big deal because "***[t]he company included this in-sourcing in a 510(K) submission for something else last year and the FDA cleared it***." This led J.P. Morgan to conclude, on March 25, 2025: "This was basically a long way of saying the quality control/validation issues were not related to G6/G7 sensor quality, but the specifics of this production process, ***which to our knowledge have been addressed***." Similarly, after Dexcom contacted Citi, the analyst reported the Warning Letter did "not [involve] patient safety issues" and maintained its "Buy" rating.

242. Similarly, on March 27, 2025, *MedTech Dive* published an article, *Dexcom Rejects Claims of Unauthorized Device Changes in FDA Warning Letter*, where the publication noted it had received an email a few days prior from Dexcom's spokesperson Nadia Conrad. According to

the article, in the email Conrad claimed (falsely) that "no design changes were made" to Dexcom's sensors. Conrad further falsely claimed that the "company notified the FDA both informally and formally through 510(k) submissions, following the guidelines for non-significant changes." Conrad further explained that "'***Dexcom qualified a second source for one of its raw materials*** … to ensure an uninterrupted supply to customers,'" misleadingly adding that "***'extensive testing' showed the material met specifications***."

243. Dexcom's statements that it had notified the FDA informally and formally in 510(k) disclosures in a 510(k) submission that had been cleared in 2024 or later were false. Dexcom's 510(k) submissions since the December 2021 510(k) seeking approval to market the G7 did not concern changes to the resistance layer of the G7 sensor. This included the December 2023 510(k), *see* ¶¶ 85-87, and the April 2024 510(k), *see* ¶¶ 85, 163, 300. Nor were these changes disclosed to the FDA in other 510(k)s Dexcom submitted for these products, including the 510(k) the FDA cleared on August 15, 2024 with respect to the "Stelo" CGM, an over-the-counter CGM for people not on insulin that is a separate product from the G7, or the 510(k) the FDA cleared on February 21, 2025 extending the G7 sensor wear period from 10 days to 15 days for adult users.

244. Despite Defendants' efforts to obfuscate the seriousness of the Warning Letter and the FDA's findings, *MedTech Dive* reported that the Warning Letter revealed the "significant" design change and that the G7 was not as accurate. On March 26 it published an article, *Dexcom's FDA Warning Letter Reveals Unauthorized Changes to Sensors*, reporting that "Dexcom made a significant design change to a component used in its sensors and did not adequately validate the change, according to the warning letter." The article further reported that the Warning Letter found that "sensors with the new component were less accurate than those with the original component," and that Dexcom had ceased distribution of G7 sensors with the new sensor material.

245. Despite not learning the full truth about the severity of the G7's accuracy issues, and despite Defendants' efforts to affirmatively mislead investors about the Warning Letter's contents, the market reacted negatively to the news as it trickled out to investors. From March 25 through March 28, 2025, Dexcom's stock price declined more than 10%, falling from the previous close of $75.32 to $67.74.

3. Dexcom Continues to Mislead Investors Through the End of the Class Period

246. Following the publication of the Warning Letter, Dexcom was forced to admit publicly that it had changed the material in the resistance layer. For example, on April 22, 2025, Defendant Leach appeared on the *Diabetes Connections* podcast. The podcast host asked Leach whether Dexcom had "resolved" a "change Dexcom made to a component use in the resistance layer of its sensors," as identified in the Warning Letter. In response, Defendant Leach acknowledged that the FDA was referring to "a material that we introduced."

247. But investors still did not know the true consequences of Dexcom's adulteration of the G7 and its extensive manufacturing failures with respect to that product, in part because Defendants continued to misrepresent the quality issues with the G7 while assuring investors that they closely monitored customer complaints and manufacturing issues.

248. On the May 1, 2025 Q1 2025 Earnings Call, an analyst asked the company about certain "scary pictures" on "some of the chat boards and things like that," which were showing "some manufacturing issues on sensors." Defendant Leach denied the reports of "manufacturing issues," acknowledged that Dexcom keeps track of the trends in public complaints (stating "sensor issues do happen and we've seen them on the boards"), and falsely stated that "***there's no difference in frequency of those [sensor issues] from last year to this year***."

249. On June 26, 2025, a Facebook user posted on a Facebook group called "Dexcom G7 (10 & 15 day) Issues and Complaints," showing a message she received from Dexcom. The user noted she had "almost 2 dozen faulty sensors [in] just the last seven months," to which the official Dexcom Facebook account responded that Dexcom "understood how critical accurate readings are for diabetes management," and was "addressing these concerns."

250. Then, on July 21, 2025, Leach appeared on the *Diabetech* podcast and discussed the FDA warning letter, stating:

> [W]hat is important to note is that ***there's no actual claim that the performance of the sensor isn't as accurate as the old one***. What the real issue was is that when we qualified that new material, the FDA wanted to see us do some different things to be able to qualify it … [S]o during one of the inspections, [the FDA] started reviewing this and said 'Look, we would have preferred you do this differently in terms of the way you qualified it and also we would have preferred you tell us about the change ahead of time as like a submission, right?" … [T]hey basically came back and said, ***'[W]e'd prefer you do it differently.' … But you know ultimately in the product of the field it was not less accurate by any means.***

251. When asked whether those sensors were still in circulation, Defendant Leach replied: "we're not manufacturing with it anymore, but ***there's no reason—there's nothing wrong with those sensors***. It was more of a—just that moving forward we'll do a submission to get that material in there." During the same interview, Leach further assured the public that with respect to monitoring manufacturing issues that could cause accuracy problems with Dexcom's sensors, Dexcom had "all that data and we do analyze it all the time to look for any kind of trends or anything." And like he had stated on May 1, 2025, Defendant Leach reiterated that the Company reviews and analyzes customer complaints.

K. The Full Truth Is Finally Revealed

252. On August 25 and September 18, 2025, the market learned previously undisclosed facts about the G7's reliability and accuracy problems, further revealing the falsity of Defendants' prior statements to investors and the additional consequences of their scheme to defraud.

1. A Third-Party Survey Reveals Additional G7 Reliability Concerns as Used by Providers

253. According to analyst reports published contemporaneously, on August 25, 2025, a third-party survey of DME (Durable Medical Equipment) companies reported concerns about the G7's reliability. The survey, which multiple analysts referenced, indicated that DME providers—companies that distribute medical devices including CGMs to Medicare and other patients—were still experiencing issues with the G7's performance and reliability.

254. This disclosure revealed for the first time through an independent third-party source that the G7 was still experiencing reliability problems in the field, which contradicted Defendants' persistent misstatements that the G7 was the "most accurate CGM," and that the G7 exhibited the "standard Dexcom performance that people have come to expect and trust." The survey findings also contradicted Defendants' statements on March 10, 2025 to UBS analysts that the FDA Warning Letter observations had "nothing to do with product quality," and Leach's statements on July 21, 2025 that "the product in the field it was not less accurate by any means" and "there's no reason there's nothing wrong with those sensors."

255. The same day, August 25, 2025, Dexcom's common stock declined 7.7%, from a closing price of $82.26 on August 22, 2025, the prior trading day, to a closing price of $75.96 on trading volume that was double the average daily trading value the prior week.

256. Analysts also immediately responded to this negative information. On August 26, 2025, Jefferies LLC issued a research report, *Much Ado About Not Much? No New Reliability Issues, DME Checks Ok*, noting that "the only source of concern seems to be feedback from a small sample of DMEs in a 3rd party 'survey.'" While Jefferies attempted to downplay the survey's significance, it also acknowledged that "investors [were] scrambling to understand the move" and that the stock had suffered its worst single-day performance in some time.

257. On September 8, 2025, Oppenheimer & Co. Inc. downgraded Dexcom from "Outperform" to "Perform," citing "rising concerns about G7 accuracy/performance." The Oppenheimer report stated: "Field checks point to rising concerns about G7 accuracy/performance," including "poor accuracy" and others. Oppenheimer concluded: "It isn't obvious to us what percentage of G7s are supplied from Malaysia vs. Mesa facilities, but there seems to be a manufacturing/software quality control issue somewhere."

258. Even after these third-party reports concerning G7 reliability concerns, Defendants continued to make statements that concealed the full truth from the market. On September 3, 2025, at a Wells Fargo Healthcare Conference, an interviewer asked Defendant Leach about the "third party reports" highlighting "some concerns around G7 reliability and accuracy issues." In response, Defendant Leach downplayed any accuracy or reliability problems: "So if you look at our metrics, things like warranty replacements, complaint rates, performance of the sensor, accuracy, ***all of that has continued to improve over time [a]nd we haven't seen anything that has changed that trajectory***." He continued: "***When it comes to accuracy, days of wear, all those things, we've seen nothing but improvements in that***."

2. The Hunterbrook Report Reveals the Full Scope of G7 Safety and Quality Problems

259. On September 18, 2025, Hunterbrook Media published a report titled *Dexcom's Fatal Flaws* that revealed severe problems with the G7's safety, accuracy, and reliability (the "Hunterbrook Report").[4] The Hunterbrook Report disclosed information that had never been

[4] On its website, Hunterbrook Media describes itself as publishing "investigative and global reporting with no ads or paywalls" and its "mission" as "to bring visibility to under-covered areas and accountability to under-scrutinized sectors," and it also explains that it makes money through "**Investment**. When our reporting does not include Material Non-Public Information ("insider info"), we may share it with our affiliated fund." In the Hunterbrook Report, Hunterbrook Media disclosed that an affiliated entity, Hunterbrook Capital, was short Dexcom stock, stating: "Based on Hunterbrook Media's reporting, Hunterbrook Capital is short $DXCM at the time of publication, and hedging with a basket of derivatives that may include securities named in this article."

publicly revealed, including examples of patient deaths and hospitalizations linked to G7 failures, extensive former employee accounts, physician reports of widespread G7 problems, and detailed analysis of FDA complaint data showing dramatic increases in accuracy complaints following the December 2023 adulteration.

260. The Hunterbrook Report disclosed that G7 users had been hospitalized and had died after receiving inaccurate glucose readings from their devices. For example, the report detailed the death of William Harold Sosbe in June 2025, who died while wearing a G7 that data from Dexcom showed had experienced "severe signal loss" for months leading up to his death, with readings stopping entirely two days before he passed. Sosbe's sister stated: "He trusted it and he's dead," believing her brother had taken incorrect insulin doses for months based on inaccurate G7 readings.

261. The report also disclosed numerous other cases of serious patient harm. Diana Bates Knight's six-year-old daughter with Type 1 diabetes was rushed to the emergency room when her G7 misread her blood sugar "by hundreds of points," causing a life-threatening complication. Bob Hawkinson passed out behind the wheel when his G7 failed to alert him to dangerously low blood sugar. Courtney Duffy was found unresponsive by her roommate and woke up in an ambulance after her G7 failed to connect to her automated insulin pump. The report further disclosed that a personal injury law firm investigating the G7 had been contacted by more than 400 people with nearly 60 claims involving alleged hospitalizations and "several claims involv[ing] a user's death."

262. The Hunterbrook Report also contained accounts from endocrinologists and healthcare providers documenting the G7's extensive problems, including its sensor's inaccuracy. Multiple physicians told Hunterbrook they had "stopped putting patients on the G7 altogether." The program director of a diabetes center in California stated that he had become "increasingly frustrated with Dexcom 'gaslighting' its customers" and "providing no public recognition and no

recognition to doctors who are prescribing this." An endocrinologist at NYU Langone reported that "many patients report[ed] issues with the G7 this year." These physician accounts contradicted Defendants' misrepresentations about the G7's accuracy and reliability, and revealed that Dexcom had concealed known problems from the medical community.

263. The Hunterbrook Report also disclosed detailed accounts from multiple former Dexcom employees describing a corporate culture that prioritized margins over patient safety. A former regional account executive stated: "Dexcom is trying to hold on to large revenue margins. And whenever you try and do that, ***you are going to run into an area where you compromise the product, and I think they've done that***." A former senior scientist described that the electrochemistry and membrane teams—responsible for the sensor component that the FDA found was changed without authorization—were led by managers with weak scientific credentials, stating "[t]he technical level was very low." Edward Carr, the former senior director of manufacturing at Dexcom's Mesa, Arizona facility that received the June 2024 Form 483 stated: "Dexcom definitely dropped the ball," adding that because Dexcom had grown "so fast, so quick, they could not really produce really good data and analysis to show [how] they had come up with the manufacturing processes." These insider accounts revealed systemic problems in Dexcom's approach to the G7's development and manufacturing, and the consequences of those problems for the device's accuracy and the patients who wore it, all of which Defendants had gone to great lengths to try to obscure during the Class Period even as the truth was slowly revealed.

264. The Hunterbrook Report also disclosed a dramatic spike in G7 accuracy complaints following Dexcom's December 2023 adulteration—analysis that had never been publicly disclosed or acknowledged by Defendants. The report included detailed analysis of FDA adverse event data showing that "[a]ccuracy complaints comprise about 13% of all G7 reports, more than

double the nearly 6% rate for the older G6 model." More significantly, the report documented that "G7 accuracy reports spiked dramatically for devices manufactured after December 2023, just when, as the FDA revealed, Dexcom implemented its unauthorized material change." The Hunterbrook Report included a chart, based on Hunterbrook Media's own culling and analysis of the database, showing the accuracy complaint rate approximately tripling for devices manufactured after the material switch.

265. The Hunterbrook Report disclosure further corrected and revealed the falsity of Defendants' materially misleading statements made throughout the Class Period. Specifically, the Hunterbrook Report, among other things: (1) exposed the falsity of Defendants' repeated representations that the G7 was "the most accurate CGM," *see* ¶¶ 140-55, 184-86, 203; (2) undercut Defendants' lulling statements that the FDA Warning Letter observations had "nothing to do with product quality" and that the modified sensors had "no reason there's nothing wrong" with them, *see* ¶¶ 234-42, 248-51, by disclosing patient deaths, hospitalizations, and extensive quality problems; (3) undermined Defendants' statements that Dexcom maintained a "robust" Quality Management System in "compliance with applicable US and international regulatory requirements," *see* ¶¶ 425, 432, by disclosing systemic manufacturing problems, weak technical leadership, and a corporate culture that prioritized margins over safety; and (4) contradicted Defendant Leach's September 3, 2025 statements that G7 accuracy and performance metrics had "continued to improve over time" and shown "nothing but improvements," *see* ¶ 258, by documenting extensive evidence of deteriorating performance and escalating problems.

266. The Hunterbrook Report also disclosed information about recent executive departures that further revealed the extent of Dexcom's internal problems, including the "Vice President of Global Operations, and Head of Engineering." The report further disclosed that

Defendant Sayer had stepped down "suddenly on 'temporary medical leave'" just days after Hunterbrook first reached out with a request for comment, despite previous reports that Sayer would serve as CEO until early 2026. The Hunterbrook Report also disclosed: "No insider appears to have purchased Dexcom stock since early 2020," while disclosing a chart showing extensive insider selling throughout the Class Period. These disclosures about executive turnover and insider trading patterns provided additional evidence of Defendants' knowledge of the G7's problems and further undermined investor confidence in Dexcom's prior representations.

267. Analysts immediately reacted to the Hunterbrook Report, acknowledging the severity and extent of the G7 problems. For example, Citi issued a research note stating: "DXCM is pressured following a short report and concerns about reports in MAUDE database," and confirmed that complaints had increased. Similarly, UBS issued a note stating that Dexcom's "shares [were] under pressure amidst continued accuracy concerns for G7."

268. Dexcom's common stock declined by approximately 12% over the two trading sessions following the publication of the Hunterbrook Report. The stock fell from a closing price of $76.44 per share on September 17, 2025 (the trading day before the report's publication), to a closing price of $67.45 on September 19, 2025—a decline of $8.99 per share. As explained below, as of the filing of this Complaint, Dexcom's stock price has not recovered.

VII. POST-CLASS PERIOD DEVELOPMENTS

269. After the Class Period, additional facts have continued to corroborate Lead Plaintiff's claims.

270. Additional MAUDE reports filed with the FDA documented continuing harm to patients using the G7. One report, submitted by Dexcom itself to the FDA on September 18, 2025—as Dexcom was legally required to do—detailed the death of a patient using the G7. According to the report of the incident, initially brought to Dexcom's attention by the healthcare

provider, the patient had been showing signs of high blood sugar, but the patient's G7 showed a low blood sugar reading. Based on that inaccurate reading, the patient was given additional glucose and died after a blood sugar reading showed her blood sugar was in fact dangerously high.

271. On October 26, 2025, *Newsweek* published an article titled "'It's Life-Threatening'—Dexcom G7 Users Say Glucose Monitor Is Failing Them," describing that:

> Over the past year, patients and caregivers have reported inconsistencies with the G7's readings—sharp highs when blood sugar is actually stable, or plummeting lows that don't match fingerstick tests. These discrepancies have led to confusion, fear, and, in some cases, physical danger. And while many say Dexcom is aware of the issue, users describe the company's response as limited primarily to silence, apologies, and sporadic replacements.

272. The article included accounts from G7 users who had experienced life-threatening events due to inaccurate readings from the G7, including from (i) a patient whose G7 had missed her "dangerously low" blood glucose level; a mother of a four-year-old who had "reverted to the older G6 model and raised $25,000 … to purchase a diabetes-alert service dog"; (ii) the mother of a six-year-old whose "finger-stick tests showed [the G7s] were often 60 to 80 points off" and said "'the devices [Dexcom is] putting out aren't safe'"; and (iii) a longtime Dexcom customer who surveyed online communities and found a "striking … 70 percent failure rate among the users he surveyed."

273. On October 30, 2025, Dexcom reported earnings for the third quarter of 2025, including margins that continued to decline—from 64% in the third quarter of 2024 to 61% in the third quarter of 2025. In his opening remarks, Defendant Leach, now interim CEO, stated he "recognize[s] the investment community is attempting to interpret data on [the] topic" of the "customer experience," an artful reference to the quality issues plaguing the G7 that came to light that quarter. A research analyst asked whether the "commentary around G7 and G7 performance" had "been disruptive" to signing up new customers. Defendant Sylvain was forced to admit

"there's likely been a bit of an impact" on signing up new customers. Similarly, after an analyst asked about "attrition rates" as Dexcom "dealt with some of the quality issues," Defendant Sylvain acknowledged that Dexcom "pay[s] a lot of attention" to these questions, including with a weekly report, while Defendant Leach acknowledged that "when customers have issues, they tell their prescribers about it." Dexcom's stock price declined nearly 15% the following day.

274. Nor have Dexcom's issues with the FDA been resolved. In fact, those issues are so severe that, as of the date of the filing of this Complaint, the Warning Letter remains in effect—approximately one year after it was issued and 16 months after the November 2024 Form 483.

275. Indeed, additional regulatory actions, including an enforcement action by the agency, remain a distinct possibility. The Warning Letter itself explained it was "not intended to be an all-inclusive list of the violations at [Dexcom's] facility," required that Dexcom submit a response within fifteen business days, explained that a "follow up inspection will be required to assure that corrections and/or corrective actions are adequate," and advised Dexcom it "should investigate and determine the causes of any violations" because the issues the FDA had identified "may be symptomatic of serious problems in your firm's manufacturing and quality management systems." Accordingly, on February 12, 2026, Dexcom filed its Annual Report (Form 10-K) for the fiscal year ended December 31, 2025, confirming that the letter involved problems with "manufacturing processes" and "quality management" that remain unresolved: "[W]e cannot give any assurances that the FDA will be satisfied with our response or as to the date we expect to resolve the matters included in the FDA Warning Letter. Until the issues cited in the [W]arning [L]etter are resolved to the FDA's satisfaction, additional legal or regulatory action may be taken without further notice."

276. Dexcom has become the subject of numerous lawsuits, including wrongful death, product liability, negligence, and false advertising class and individual actions, alleging that the G7 produced dangerously inaccurate glucose readings and caused harm to users, including based on Dexcom's adulteration of the G7. On September 29, 2025, a consumer class filed a complaint against Dexcom, alleging that the change in materials to the G7 sensors caused the G7s to have "considerably greater variability" than readings from sensors made with the previous FDA-approved materials, creating higher risks for consumers. *See Levens et al. v. Dexcom, Inc.*, No. 25 Civ. 02565 (S.D. Cal. Sept. 29, 2025). On October 15, 2025, a consumer class filed a complaint against Dexcom alleging that while Dexcom had marketed the G7 as "the most accurate" CGM, Dexcom had misled patients about the device's safety, accuracy, efficacy, and reliability. *See Grisoli v. Dexcom, Inc.*, No. 25 Civ. 2333 (C.D. Cal. Oct. 15, 2025). One law firm investigating the G7 has stated it had been contacted by more than 400 people with nearly 60 claims involving alleged hospitalizations and user deaths. On March 5, 2026, the firm filed a complaint against Dexcom in California Superior Court on behalf of an individual asserting that the G7 failed to provide accurate glucose readings, leading to the plaintiff's death. *See May v. Dexcom, Inc.*, 26CU012528C (Cal. Sup. Ct. Mar. 5, 2026).

277. Given the ongoing quality issues and the erosion of trust in the G7's reliability, Dexcom's stock price has not recovered, dropping to an intraday trading low of $54.11 during the 52-week period ending in February 2026. As of April 10, 2026, it was trading at $64.02—less than half of its Class Period closing high of $140.45. Analysts have attributed this poor stock performance to the quality issues that plagued the G7. For example, on January 16, 2026, Bernstein Research analysts noted: "2025 had its share of problems—mounting concerns on G7 quality (FDA [W]arning [L]etter issued in March 2025 and a rising incidence of reports on FDA's

MAUDE database), fears about slower growth in new starts / potential share loss to Abbott, and negative gross margin surprises (as the company dealt with inventory issues and higher scrap rates at manufacturing facilities, lowering 2025 gross margin guide from ~64.5% at the start of the year down to end at ~61%)."

VIII. ADDITIONAL SCIENTER ALLEGATIONS

278. Numerous facts, including those set forth above and summarized below, give rise to the strong inference that Defendants knowingly or recklessly misled investors about the accuracy of the G7, the status of their compliance with FDA regulations with respect to the G7, the content of the FDA's communications to Dexcom regarding the G7, Dexcom's quality assurance and control practices with respect to the G7, and the already materialized risks to Dexcom arising from the foregoing matters.

A. Defendants Knew or Recklessly Disregarded the True Facts Showing Their Class Period Statements Were Materially False or Misleading

1. Defendants Knew or Recklessly Disregarded that the G7 Had Been Adulterated and Its Accuracy Had Been Compromised

279. By December 13, 2023, Dexcom intentionally changed the material it used in the resistance layer of the G7's glucose sensors—a component critical to the device's accuracy—from a supplier-purchased compound to a formulation that Dexcom developed internally. By its very nature, the decision to change a critical component of the Company's flagship product was a strategic decision that was not made by lower-level employees or without the knowledge of Defendants. The strategic importance of the sensor's accuracy, as repeatedly publicized by Defendants themselves, meant that Defendants closely monitored the G7's accuracy and had ready access to information about the device's accuracy.

280. Moreover, Dexcom former employees confirmed the strong inference that the decision to adulterate the G7 was not made by lower-level employees operating outside the chain of command but was, instead, a strategic decision dictated by senior management.

281. Former Employee 1, a former Director of Manufacturing Operations at Dexcom's Mesa facility from July 2023 through December 2024, stated that Former Employee 1 was "told" by Dexcom Vice President Ian Topic "that they were going to use material A instead of material B." According to Former Employee 1, the purpose of the switch was to "make it a cheaper process and material." According to Former Employee 1, Dexcom's decision to change the material was also driven by its desire to find a second source for its components. According to Former Employee 1, Dexcom's research and development department developed the new material, and Dexcom was planning to build a second building in its Mesa facility to produce the new material.

282. Former Employee 4, a former employee in the procurement organization who worked at Dexcom at relevant times before 2023 and into the Class Period, confirmed this account and stated that the change in material for the sensor resistance layer was regularly discussed in monthly in-person and zoom Project Review Board ("PRB") meetings held in San Diego. According to Former Employee 4, who personally attended, the Executive Vice President, Global Operations, Barry Regan, who reported directly to Defendant Leach, ran the PRB meetings. In attendance at the meetings were Regan's staff of Vice Presidents for all the Company's departments, including Operations, Quality, Engineering, Procurement, and R&D. Besides VPs, all Senior Directors and Directors were mandatory attendees. Former Employee 4 stated that, in all, between 30 and 50 people attended each meeting. Former Employee 4 recalled that starting no later than early 2023, Former Employee 4 was present at PRB meetings when management discussed replacing the resistance layer material with an in-house formulation. According to

Former Employee 4, technical staff in charge of the project regularly presented on its progress at the PRB meeting. According to Former Employee 4, because the old resistance layer material was procured from a sole source, that created a risk to Dexcom's operations, and Dexcom wanted to de-risk its manufacturing process and find a cost-effective alternative material.

283. At the time, this decision received scrutiny at Dexcom—scrutiny that confirmed the change of materials had a significant impact on the G7's accuracy. Indeed, Dexcom studied the impact of its decision to adulterate the G7 before the Class Period began and knew that the change negatively impacted the accuracy of the products it shipped to consumers. Former Employee 4 confirmed that these discussions took place during the monthly PRB meetings with Executive Vice President Regan. According to Former Employee 4, the key metric for success discussed at the PRB meetings was equivalency—i.e., making sure that the chemical they were creating was as safe and effective as the sole-sourced existing material. Former Employee 4 further stated that issues with equivalency were discussed at the PRB meetings and the sentiment was that the project "was not meeting objectives." Further, Former Employee 4 confirmed that results of clinical trials and equivalency data related to the new material were presented and discussed during the PRB meetings, and that "all of that information was reviewed and explained to the audience of leaders in the meeting."

284. Consistent with these Former Employee reports, the FDA documented that, by no later than December 13, 2023, internal Dexcom clinical studies showed that the change in material for the resistance layer of the glucose sensor was not equivalent to the prior version and negatively impacted the accuracy of the device. Dexcom performed a clinical study on 39 subjects at two clinical sites to determine the equivalence of the supplier-purchased material and the in-house

material. This clinical study failed to demonstrate equivalence—or, as the FDA later documented, "several of [Dexcom's] primary endpoints were not met."

285. Following the failed first clinical study of the G7s with the new material, Dexcom conducted a "failure investigation," which Dexcom's Vice President for Clinical Affairs admitted to the FDA "was not designed to establish accuracy against a clinical truth standard" and was instead "largely designed to help understand and confirm the reasons for the failure of the first trial." In other words, the Company was fully aware that its trial investigating the effectiveness of the new material had failed and showed that the sensors it was producing and shipping to customers were not as accurate as those made before the change in material.

286. This additional trial, in turn, revealed to Dexcom—by no later than December 13, 2023—that "every accuracy metric of sensors built with the [new material] … was worse" than sensors built with the original, FDA-approved material. The trial data further alerted Dexcom that sensors built with the new material had "a significantly different ratio" for glucose sensitivity compared to the previous sensors with the FDA-approved coating, meaning that "patients using sensors made with" the new material "may experience differences in accuracy over the 10.5-day sensor wear period." Thus, Dexcom knew before the Class Period began that the adulterated G7 sensors it was manufacturing and distributing were significantly less accurate than the G7 sensors that Dexcom had used to generate the MARD data it was touting to investors.

287. Later, during the Class Period and in response to the FDA's determination that Dexcom had adulterated the device, Dexcom submitted additional clinical data to the FDA in a continued attempt to convince the agency that the adulterated device's decreased accuracy was not significant. However, this effort also failed and only revealed that there was "significant variation in the clinical performance of sensors" in the adulterated devices and that "[t]he larger inaccuracies

in" the adulterated devices "cause higher risks for users who rely on the sensors to dose insulin or make other diabetes treatment decisions."

288. After the FDA exposed the adulteration to the public, Defendants were unable to deny that it had occurred or that they knew about it. For example, on April 22, 2025, Defendant Leach appeared on the *Diabetes Connections* podcast. During that appearance the host noted that the FDA had been "talking about a change Dexcom made to a component used in the resistance layer of its sensors" and asked Leach: "Is that resolved?" In response, Defendant Leach did not deny that the adulteration occurred. To the contrary, he acknowledged what the Warning Letter showed—that the FDA was referring to "a material that we introduced."

289. Pursuing this fundamental change in the composition of the G7's sensor involved making decisions and giving directions about sourcing, logistics, supply chain management, manufacturing, clinical trials, reporting, and testing—all concerning Dexcom's flagship product. Similarly, constructing a building to manufacture enough supply of a critical raw ingredient for the G7 involved significant expenditures and planning. Such widespread corporate activities and modifications to Dexcom's core manufacturing processes with respect to the device at the center of its corporate strategy could only have occurred with the specific knowledge and/or approval, or at the direction, of the Individual Defendants—Dexcom's key decisionmakers and officers.

290. To the extent Defendants contend that they were unaware of such incredibly prominent facts, it was severely reckless, at minimum, for them to make repeated, unqualified statements about the G7's accuracy without bothering to familiarize themselves with such critical information, readily available to them, before they spoke.

2. Defendants Knew or Recklessly Disregarded Dexcom Had to Seek FDA Approval for the Change to the G7 But Chose Not To, and Instead Misled the FDA and Investors About That Decision.

291. Defendants also knowingly failed to seek the required FDA approval before manufacturing and distributing the adulterated G7 sensors.

292. The FDCA and FDA regulations issued thereunder require device manufacturers like Dexcom to make a new 510(k) submission seeking approval from the FDA to market a modified device when a change to the device could "significantly affect [the] safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process." 21 U.S.C. § 807.81(a)(3)(i).

293. Before and throughout the Class Period, Defendants were aware of or were reckless in not knowing these requirements because: (i) they govern Dexcom's entire line of business; (ii) further demonstrating their familiarity with these requirements, Defendants made 510(k) submissions to the FDA with respect to their CGMs over the course of many years, including with respect to modifications to the G7 that were far ***less*** significant than the change in the resistance layer material, such as permitting the glucose readings to be displayed on a smartwatch or extending the G7's Bluetooth range; and (iii) the FDA periodically reminded Defendants of these requirements as set forth in the paragraph immediately below.

294. The FDA specifically reminded Defendants of their obligations to comply with the Act's requirements when the agency approved the December 2021 510(k) for the G7, and when the agency approved subsequent modifications to the G7 through the 510(k) process, including with respect to the April 2023 510(k), the December 2023 510(k), and the April 2024 510(k) submissions. Specifically, in approving Dexcom's 510(k) submissions related to the G7, the FDA warned Dexcom it could market the G7 only "subject to the general controls provisions of the [FDCA]," and that "[t]he general controls provisions of the Act include requirements for annual

registration, listing of devices, good manufacturing practice, labeling, ***and prohibitions against misbranding and adulteration***." The FDA also highlighted to Dexcom its obligations to "comply with all the Act's requirements," including the "registration and listing" provisions requiring manufacturers to make a 510(k) submission when there is a "change or modification" to a legally marketed device and that change "could significantly affect [its] safety or effectiveness."

295. In addition, FDA guidance provides more information for device manufacturers as to when a new 510(k) submission is needed. Under this guidance, when a device manufacturer like Dexcom modifies a previously cleared medical device in a way that could significantly affect its safety or effectiveness—including "changes to materials [that] may unintentionally affect the performance of the device"—the manufacturer is required to submit a new 510(k) premarket notification to the FDA and may not commercially distribute the modified device until receiving FDA clearance. Moreover, the guidance explains that the regulations require that even where a manufacturer believes that a new 510(k) submission is not required, the manufacturer must perform confirmatory "routine verification and validation activities," and states that if those activities produce "any unexpected results," the manufacturer must "reconsider[]" its decision not to submit a 510(k). *See also* ¶ 84.

296. This is precisely what happened here with respect to the testing that Defendants conducted in advance of the December 13, 2023 commercialization of the new, adulterated G7. Defendants' own clinical studies showed that the new material was ***not*** equivalent to the original material and was significantly less accurate. Moreover, Former Employee 4 confirmed that Dexcom management, including Executive Vice President Regan, discussed the decision whether to seek FDA approval for the material change.

297. Yet, Defendants chose not to submit a new 510(k) to the FDA. Defendants' failure to submit the required 510(k) was not inadvertent—it was a deliberate decision driven by business imperatives. Had Dexcom submitted a 510(k) as to the resistance layer material change as required, the Company would have been unable to manufacture G7 sensors with the in-house material for at least 90 days while the FDA reviewed the submission, materially impacting Dexcom's business, undermining its corporate objectives of retaining and growing its market share amid increasing competition, and jeopardizing its ability to meet its increasing revenue guidance to investors.

298. Moreover, Defendants understood that, had Dexcom made the 510(k) submission it was required to make, the diabetes care community would have eventually seen the FDA's decision on the submission on the FDA's website and realized that Dexcom had made a key change to a critical component of the G7. This, in turn, would have damaged Dexcom's critical value proposition for the G7—its accuracy.

299. Defendants were aware that members of the diabetes care community monitored the device changes for which Dexcom sought approval via the 510(k) submissions process because Defendants frequently discussed these changes with CGM users, including in public appearances. For example, during a June 24, 2024 interview with the *Diabetech* podcast, Defendant Sayer discussed the three changes Dexcom had recently made to the G7 pursuant to 510(k) submissions—the change in adhesive material, the "direct-to-watch" feature, and the increased Bluetooth range for the device. With respect to the first, the interviewer told Defendant Sayer that there had been "a lot of discussion … within the community" about the replacement policy Dexcom issued in connection with the adhesive change. Similarly, during a June 20, 2024 podcast with *Beyond Type 1*, Defendant Leach discussed the recent integration between the G7 and the Apple Watch, and stated this change occurred because Dexcom "listen[s] to [its] users."

300. Rather than seek the FDA clearance Defendants knew they were legally required to obtain, in subsequent 510(k) submissions, Dexcom misled the FDA about whether it had changed the composition of the G7. In the 510(k) submissions Dexcom filed during the relevant period—which included the December 2023 510(k) filed a few days after Defendants adulterated the G7 and right before the start of the Class Period and the April 2024 510(k) filed a few weeks later—Dexcom represented to the FDA that the "subject device shares identical hardware, material, chemical composition, principle of operation and energy source with the predicate device," was "as safe and effective" as the G7 the FDA had previously cleared for distribution, "and does not raise different questions of safety and effectiveness." Dexcom also stated that the new G7 was "***physically identical to the predicate Dexcom CGM system***" and the G7 sensor's "***materials, hardware components, and packaging are identical*** to those of the predicate device." Dexcom made these representations even though Dexcom had conducted trials that specifically revealed the adulterated device's effectiveness was significantly lower than the original device's.

301. At a minimum, the correct information about the G7's accuracy problems was readily available to Defendants because they possessed critical information about the G7's accuracy in their own failed studies—information that directly conflicted with their public statements. By misrepresenting the status of the adulterated G7 to the FDA and by making statements about the accuracy of the G7 while either knowing that the statements were false or recklessly failing to investigate their accuracy before making them, Defendants acted with scienter.

3. Defendants Were Aware of or Recklessly Disregarded the Spike in Customer Complaints Following Their Adulteration of the G7

302. An analysis of data from the FDA's MAUDE database demonstrates that customer complaints about the G7 that appear to relate to its accuracy more than tripled following the December 2023 adulteration.

303. Between the date of release of the G7 on February 17, 2023 and December 12, 2023, the day just before Dexcom adulterated the sensor the average number of complaints about the G7 filed per month was over 4,000. Comparatively, between December 13, 2023 and December 15, 2025, the average number of complaints filed per month was ***over 10,000.*** During this period, there were ***412 days*** when the number of complaints filed about the G7 exceeded 500. From February 17, 2023 to December 12, 2023, there was ***one day*** when the number of complaints filed about the G7 exceeded 500. Moreover, filtering the complaints to approximate the number of G7 complaints that appear to be related to accuracy shows that the monthly rate of accuracy-related complaints filed during the second (post-adulteration) period was over ***three times*** higher than the rate of accuracy-related complaints filed during the first (pre-adulteration) period. *See* ¶¶ 93-94.

304. Between January 1, 2024 and December 15, 2025, there were approximately 240,000 complaints filed on the FDA's MAUDE database concerning G7 adverse events related to accuracy that took place in 2024 or 2025. By contrast, there were approximately 8,200 complaints filed concerning Abbott's competing Libre 3. Thus, the G7 generated nearly thirty times more complaints than its primary competitor, despite Abbott having a larger market share.

305. Defendants were aware of or recklessly disregarded this dramatic spike in patient complaints regarding the accuracy of the G7 following the December 2023 adulteration because they submitted essentially all the MAUDE reports—according to Lead Counsel's analysis, approximately ***99.74%*** of the relevant reports indicate a "manufacturer narrative" in the event description and thus appear to have been filed by Dexcom itself. *See* ¶ 95.

306. Moreover, Defendants were required to monitor this information to potentially submit reports of adverse events under applicable FDA regulations, and because they in fact tracked customer complaints about their principal product, the G7, as they publicly admitted. As a

device manufacturer, Dexcom was required by FDA regulations to "[s]ubmit reports of individual adverse events no later than 30 calendar days after the day that [the manufacturer] become[s] aware of a reportable death, serious injury, or malfunction." 21 C.F.R. § 803.10(c)(1).

307. Moreover, Dexcom was required to track and report device malfunctions that could cause or contribute to serious injury. The FDA expressly reminded Dexcom of this obligation in the December 7, 2022 letter approving the Company's original December 2021 510(k) for the G7. That letter reminded Dexcom that it was required to comply with the FDCA's requirements regarding "reporting of medical device-related adverse events" as well as "post-market surveillance." *See* 21 C.F.R. Part 822. The FDA issued similar reminders when it approved each of Dexcom's subsequent 510(k) submissions for the G7.

308. In addition, throughout the Class Period, Defendants represented—to investors and members of the diabetes-care community—that Defendants in fact tracked any issues that users identified with Dexcom's CGMs. For example, during a June 20, 2024 interview with the podcast *Beyond Type 1*, Defendant Leach stated that Dexcom "listen[s] to [its] users" and had made product design changes in response to "what users want." During a July 2, 2024 interview with *Diabetes Connections*, Defendant Sayer stated that with respect to the G7, "[w]e monitor the error codes from our product. We have all sorts of systems in place where we go through those literally at least monthly and … quarterly for sure for FDA purposes and our quality system purposes and we monitor those things and we make sure those things are improving. We look at what isn't improving and then we try and fix it." Defendant Sayer also stated that, in determining to replace certain sensors, Dexcom "went through our entire database, ***you know we have over a trillion data points of glucose data***." Similarly, Defendant Leach confirmed during the May 1, 2025, Q1 2025 Earnings Call that "sensor issues do happen and we've seen them on the boards, too."

309. When corporate officers hold themselves out as knowledgeable about a subject and then make repeated misstatements about that subject, the inference arises that they either knew the statements were false or were reckless in failing to verify the accuracy of their claims before speaking. In addition, the representations that Defendants monitored, paid careful attention to, and responded to customer complaints all support a strong inference that Defendants were aware of, or at a minimum were reckless in not knowing, the dramatic spike in accuracy-related complaints following Dexcom's December 2023 adulteration of the G7, and complaints regarding the G7 were about thirty times more frequent than for its main competitor's devices.

310. Moreover, many of the complaints that were filed documented serious harm to patients relying on the G7 for life-and-death insulin dosing decisions. For example, a December 30, 2023 adverse event report stated that a pregnant patient with gestational diabetes using the G7 had received "incorrect blood sugar data resulting in alarms for low blood sugar." The report continued: "The response from Dexcom has been inadequate and prior sensors starting [REDACTED] 2023 have been rife with quality issues related to accuracy. We have reached out to Dexcom and found their response to be lacking. This is life or death for diabetic patients and people with gestational diabetes and needs full regulatory attention." Similarly, a January 11, 2024 report stated that a parent had "switched [their] type 1 diabetic son (7yo) from the dexcom g6 to the dexcom g7. We have had nothing but issues. The biggest concern and most terrifying is how inaccurate the cgm readings are compared to finger sticks. His cgm was reading 43 at school, i arrive and did finger sticks; his glucose was 358!!!! . . . this is dangerous! he could have died in that scenario!!!" These reports, filed within weeks of Dexcom's December 2023 adulteration, provided Defendants with additional notice that the adulterated G7 sensors were less accurate than the FDA-approved version (and were in fact causing life-threatening inaccuracies).

311. At a minimum, this information about the G7's accuracy problems was readily available to Defendants, which supports a strong inference of scienter, particularly given that Defendants said that they monitored such information, as they were required to do.

4. Dexcom Received Formal Notice of Its Regulatory Violations from the FDA.

312. Defendants also received formal notice from the FDA—through two Form 483s and a Warning Letter—documenting that the G7 was adulterated, that it was not approved by the FDA but should have been the subject of a new 510(k) submission, and that it suffered from serious manufacturing and quality control deficiencies that undermined the accuracy and reliability of the device. Yet Defendants continued to publicly tout the G7 as "the most accurate sensor on the market" that was "cleared by the FDA," and made misleading statements about the scope of the FDA's concerns, Dexcom's regulatory compliance program, and the risks facing the company.

313. On June 14, 2024, following an eleven-day inspection of Dexcom's Mesa, Arizona manufacturing facility, the FDA issued the June 2024 Form 483 to Dexcom, directed to the head of that facility. *See* ¶¶ 166-73. The June 2024 Form 483 kicked off a "corporate emergency," according to an employee's statements to Hunterbrook Media, as senior Dexcom leadership was immediately apprised of the June 2024 Form 483. The June 2024 Form 483 in fact documented that Dexcom had failed to adequately control and validate the processes used for sensor dipping during manufacturing of the G7, such that Dexcom's own Process Engineering Director admitted to FDA investigators that sensors produced at the edge of Dexcom's allowable ranges "will likely exhibit non-conformities." Thus, by no later than June 14, 2024, Defendants knew that Dexcom's manufacturing process did not reliably produce accurate devices and that their statements about the G7's accuracy were undermined by Dexcom's defective manufacturing processes.

314. On November 7, 2024, following an additional inspection of Dexcom's San Diego, California manufacturing facility, the FDA issued the November 2024 Form 483. The November 2024 Form 483 explicitly noted that Dexcom changed a critical raw ingredient in the resistance layer of the G7 sensors—from a supplier-purchased compound to an in-house material—without making a 510(k) submission, that Dexcom was required to make that submission to seek FDA approval to commercialize the adulterated device, and that Dexcom's own studies had confirmed that sensors made with the new material were less accurate than the FDA-approved sensors because "every accuracy metric of sensors built with the [new material] … was worse" than sensors built with the original material. *See* ¶¶ 188-90.

315. The November 2024 Form 483 also documented several manufacturing deficiencies at the San Diego facility, including, as set forth above, ¶¶ 192-99, as to quality control systems, manufacturing processes, and design procedures, all of which further undermined the accuracy and reliability of Dexcom's G7 CGMs. The FDA found, among other things, that Dexcom: (1) was setting acceptable MARD levels arbitrarily and without documentation; (2) tested the accuracy of the finished sensor without controlling for environmental parameters leading to inaccurate assessments of whether the sensors worked correctly; (3) recorded test results only as "pass" or "fail" rather than documenting actual MARD and glucose sensitivity slope measurements, which "failed to demonstrate" that the sensors were "capable of producing repeatable and reproducible" accuracy data; (4) failed to establish acceptance criteria for glucose sensitivity slope error rates in manufactured CGMs, which could "contribute to inaccurate glucose readings"; (5) shipped individual sensors with improper coating thickness if the overall batch average appeared acceptable, even though devices at the outer edges of coating thickness could be inaccurate; (6) shipped untested sensors despite identifying that some sensors were not properly

tested in low-oxygen environments; and (7) failed to consider and mitigate how these failures exposed patients who relied on the accuracy of the G7 to control their insulin doses to potentially fatal risks. The FDA's identification of these issues meant that Defendants received additional confirmation that their statements about the G7's accuracy were, at a minimum, misleading—as were Defendants' statements that they complied with FDA regulations.

316. On March 4, 2025, the FDA escalated its investigation of Dexcom by issuing a Warning Letter addressed to Defendant Sayer, Dexcom's then-CEO and President. The Warning Letter reiterated the same violations that the FDA had already flagged to Dexcom in both the June 2024 Form 483 and the November 2024 Form 483, confirming that Dexcom had been on notice of these deficiencies for months. Thus, Defendants were again told that (i) Dexcom's G7 CGMs containing the new material were "adulterated" under the FDCA because Dexcom had changed a "critical component" in the resistance layer of its G7 sensors without obtaining the required FDA approval; (ii) Dexcom should have made a 510(k) submission with respect to this new device, but did not; (iii) Dexcom's own studies showed the new material performed worse than the FDA-approved material on every accuracy metric; and (iv) Dexcom's deficiencies in its manufacturing and quality control processes were significant, which rendered Dexcom unable to reliably manufacture and test devices in a way that met Dexcom's stated accuracy metrics. *See* ¶¶ 207-30.

317. Despite receiving the June 2024 Form 483, the November 2024 Form 483, and the Warning Letter, Defendants continued to make materially false and misleading statements about the G7's accuracy throughout the Class Period. For example, on June 23, 2024, just nine days after receiving the June 2024 Form 483, Defendant Sayer stated that the G7 was "the most accurate sensor on the market still" and that it would "remain so." Over three months after receiving the November 2024 Form 483, Defendant Leach told investors during the February 13, 2025 Q4 2024

Earnings Call that the G7 was "the most accurate sensor available." And on February 18, 2025—after receiving both Form 483s—Defendants filed the Dexcom 2024 10-K, which again quoted false or materially misleading statistics, stating that the G7 had an "overall Mean Absolute Relative Difference, or MARD, of 8.2%" and that the "Dexcom G7 is the most accurate CGM cleared by the FDA." The receipt of these FDA documents, combined with Defendants' continued misstatements, demonstrates that Defendants made statements about the G7's accuracy, FDA compliance, quality assurance program, and business risks while knowing they were false or misleading, or at a minimum made with reckless disregard for the truth.

B. Defendants' Misstatements Concerned the Most Critical Aspect of Dexcom's Most Significant Product—the Accuracy of the Sensor for the G7

318. Dexcom derived 100% of its revenue from CGM systems before and throughout the Class Period. As Dexcom reported in the Dexcom 2023 10-K, "Disposable sensor and other revenue comprised approximately 90% of total revenue and Reusable Hardware revenue comprised approximately 10% of total revenue for the twelve months ended December 31, 2023." Every dollar Dexcom earned came from its CGM business, making anything related to its CGMs, especially the accuracy and reliability of its devices, the foundation of the Company's performance and, therefore, the principal focus of Dexcom's senior executives, like the Individual Defendants.

319. Moreover, at the start of and throughout the Class Period, the G7 was Dexcom's flagship device and the cornerstone of its growth strategy, as Defendants repeatedly emphasized. For example, on the February 9, 2023, Q4 2022 Earnings Call, Defendant Sayer described the G7 as "the new gold standard in diabetes technology" and "the most accurate, easy-to-use and accessible CGM ever produced." Defendant Sylvain likewise emphasized the G7's importance to Dexcom's business, describing it during a June 5, 2024 William Blair Growth Stock Conference as "our trademark product, our flagship product." Dexcom was simultaneously phasing out its G6

device in favor of the G7, making the success of its launch essential to the Company's ability to grow its market position and meet lofty revenue targets. Later in the Class Period, when Dexcom released two new CGMs (the G7 that lasted 15 days and the Stelo) it relied on the regulatory approval of the G7 and on the market's understanding of the G7 in marketing those new devices.

320. Given the strategic importance of the G7 to Dexcom, and how Defendants emphasized the G7's supposedly superior accuracy at every turn, having internal knowledge of any accuracy problems with the product was of the utmost importance to the Company's prospects. Thus, it was highly likely that the Individual Defendants were fully informed of all G7-related developments—including with respect to its accuracy, the product's core distinguishing feature—and if they were not, the failure to inform themselves was severely reckless.

321. In addition, the FDA inspections that concerned the G7's manufacturing problems took place at Dexcom's only fully operating manufacturing facilities at the time of the inspections, and they affected Dexcom's core products at the time—the G6 and G7. Dexcom's Malaysia facility was not fully operational until November 2024, after the FDA had already conducted its initial inspections and issued the June and November 2024 Forms 483. Defendants could not plausibly state that they were unaware of manufacturing problems that pervaded their only manufacturing operations and affected their only revenue-generating products.

322. This inference is confirmed by Edward Carr, Dexcom's former Senior Site Director at the Mesa facility, to whom the June 2024 Form 483 was addressed, and who according to the Hunterbrook Report stated that a routine FDA inspection turned into a "corporate emergency," with corporate leaders flying in from headquarters.

323. A former employee that spoke to Lead Counsel also confirmed that the G7 was Dexcom's most important product and that everyone at Dexcom was involved with the device.

Specifically, Former Employee 5, a Senior Staff Scientist in Clinical Research from April 2021 to May 2025, stated that G7 sensor quality issues were a very well-known issue among everyone at the Company, including up to the CEO, because if you worked at Dexcom you were in some way connected to working on the G7, and the sensor issue was the main problem the G7 had.

324. In sum, the G7 was Dexcom's flagship product, the key source of Dexcom's revenue, and the linchpin of its competitive strategy against Abbott. The accuracy of the G7's sensor was the single most important characteristic of the device and the primary basis upon which Dexcom differentiated the G7 from other CGMs in the market. The FDA's findings regarding manufacturing deficiencies and the unauthorized change to the resistance layer material affected every manufacturing facility Dexcom operated and triggered a corporate crisis that involved senior leadership. Under these circumstances, it strains credulity to suggest that the Individual Defendants—the most senior executives at Dexcom who were responsible for the Company's strategy, operations, and SEC filings—were unaware of the facts rendering their public statements about the G7's accuracy materially false and misleading.

325. These core operations facts bolster the strong inference of scienter established by the evidence of Defendants' knowledge, including their internal clinical studies, the dramatic spike in customer complaints documented in the MAUDE database, and the FDA's formal findings.

C. Defendants Personally Emphasized the Accuracy of the G7 to Investors at Every Opportunity

326. Precisely because the accuracy of the G7 was the most important issue for Dexcom and investors, Defendants repeatedly emphasized the G7's accuracy in their public statements to investors at every opportunity, before and during the Class Period. Indeed, as set forth above, in virtually every investor conference, in every SEC filing, and in most earnings calls during the Class Period, the Individual Defendants underscored the G7's purportedly superior accuracy.

327. The Individual Defendants positioned the unmatched accuracy of the G7 as Dexcom's key competitive advantage and the principal reason for investors to buy the stock. As just one example, at the outset of the Class Period, at the January 8, 2024 J.P. Morgan Healthcare Conference, Defendant Sayer specifically tied Dexcom's financial results for the preceding quarter to the G7's accuracy, stating the G7 was "the most accurate sensor on the market today and the most accurate sensor that's ever been produced by us." As just one more example, on March 5, 2024, Defendant Christensen, at the Raymond James Institutional Investors Conference stated that the "G7 is the most accurate CGM that has been cleared by the FDA and offering that standard Dexcom performance that people have come to expect and trust over the years."

328. Having repeatedly emphasized the G7's accuracy to investors as the Company's key competitive advantage and the central plank of the Dexcom investment thesis, it was incumbent upon Defendants to be familiar with all the important facts concerning that purported accuracy. If Defendants fulfilled this duty, then they knew that the device had been adulterated, that its accuracy had been compromised, and that its manufacturing was plagued with material deficiencies. If Defendants did not fulfill their duty to be familiar with the key facts concerning the G7's accuracy, then this failure was highly reckless, particularly when the information was readily available, as noted above. In either case, a strong inference of scienter exists.

D. Management Directed Employees to Sacrifice Quality to Reduce Costs and Meet Production Goals

329. Dexcom's failure to comply with applicable quality standards was not the result of rogue employees or isolated manufacturing problems, but a systemic failure dictated by senior management to cut costs, reduce manufacturing time, and meet accelerating production goals. Lead Counsel's investigation unearthed multiple former Dexcom employees who confirmed that the decision to adulterate the G7 (as set forth above) and the quality control failures identified by

the FDA all originated from management directives that reflected a broader corporate culture that prioritized production volume and cost savings over patient safety and regulatory compliance.

330. ***Management dictated relaxed MARD thresholds***. Former employees confirmed that management dictated the relaxed standards that undermined the accuracy representations Defendants made to investors.

331. For example, Former Employee 1, a former Director of Manufacturing Operations at Dexcom's Mesa facility, stated that the acceptable MARD threshold changed periodically and ***could even range as high as between 12.5% and 15%*** (the latter figure being nearly double the 8.2% figure Dexcom repeatedly stated publicly). Thus, on any given day, Dexcom approved a G7 for distribution that it had specifically tested for accuracy post-manufacturing and that had a real-world inaccuracy rate above the figure Dexcom repeatedly stated was the G7's MARD. Former Employee 1 recalled that, "at first it was anything under 15% MARD, but then they would retract that and say, wait only anything under 12%." According to Former Employee 1, on other occasions, management would indicate that because "[w]e can't afford doing 15%, we have to bring it down to 12.5," but that even in those circumstances, if a batch of manufactured sensors tested to a MARD of between 12.5 and 15%, the Mesa facility employees were told to "come have a conversation about what to do" with those sensors. Former Employee 1 confirmed that senior management conveyed acceptable MARD manufacturing thresholds for the day at daily meetings in the Mesa facility. Former Employee 1 confirmed that the MARD threshold directives came from Vice President Ian Topic, who reported to Executive Vice President of Global Operations Barry Regan. According to Former Employee 1, "Topic generally told them the daily MARD over messenger or verbally" and Former Employee 1 instructed his team on the acceptable MARD thresholds during daily stand-up meetings. Former Employee 1 also stated that, on occasion, the

acceptable MARD thresholds could be conveyed to employees directly by Edward Carr (the head of the Mesa facility).

332. Former Employee 1's first-hand account is corroborated by the FDA's conclusion that Dexcom had failed to properly define the requirements it used to assess the acceptable MARD threshold with respect to the CGMs it was manufacturing. Indeed, Former Employee 1's account is further corroborated by Former Employee 2, a contracted Systems Requirements Engineer from December 2024 through August 2025, who worked on Dexcom's response to the FDA Warning Letter. Former Employee 2 stated that from March to May of 2025, Dexcom quality assurance professionals tasked with addressing the FDA's concerns repeatedly asked what the MARD requirements were, but could not get an answer from management.

333. ***Management directed employees to conceal quality problems from the FDA.*** During Lead Counsel's investigation, a former employee confirmed that management not only dictated relaxed quality standards but directed employees to conceal certain quality problems from the FDA. Specifically, a Manufacturing Manager at Dexcom's Mesa facility from September 2021 through August 2024 ("Former Employee 6") stated that employees "were directly told not to talk about drift if the FDA came in." Former Employee 6 explained that "drift"—a measure of how the sensor's accuracy changes over the course of its multi-day wear period referred to in the FDA's Warning Letter to Dexcom as the "glucose sensitivity slope"—"was only talked about with the G7 and was always discussed negatively for that product; drift was a problem for the G7." Former Employee 6 further explained that drift was a persistent known problem with the G7 sensors and was discussed along with other sensor quality issues during weekly "roll up" meetings on Tuesdays, in which each department presented updates to management. Executive Vice President of Global Operations Barry Regan, along with Vice President Ian Topic, attended the meetings.

334. According to Former Employee 6, he was told not to discuss drift with the FDA on at least two occasions. The first time was on the morning of the FDA's inspection of the Mesa facility in June of 2024. At that time, a manager told Former Employee 6 not to talk about drift, and if it came up to steer the FDA inspectors away from the subject. The second time was following the FDA's June 2024 inspection, as management knew there would likely be follow up FDA visits stemming from the inspection. At this time, it was made clear to Former Employee 6 that the directive came from Vice President Ian Topic, who "relocated from California to Arizona" and "was very hands-on" in daily manager meetings. That senior management directed employees to avoid discussing a known quality issue with the FDA during inspections further supports a strong inference of scienter.

335. ***The culture at Dexcom was "Product First, Patient Second."*** Multiple former employees confirmed that senior management cultivated a culture that prioritized production volume and cost savings over patient safety and regulatory compliance. Former Employee 1 characterized the culture at Dexcom as "product first, patient second." Former Employee 1 stated that "[t]he executives at Dexcom were not patient first, it was always about the numbers," and that "[t]he executive leadership only cared about getting as many units out as possible."

336. Former Employee 6 similarly confirmed that "[t]he primary culture at Dexcom was always to produce more" and that "Topic pushed quantity over quality, at least subtly." Former Employee 6 recalled one instance in late 2023 or early 2024 in which Ed Carr, the Senior Site Director for the Mesa facility, attempted to bypass the quality assurance process and push out a batch of sensors that was missing required signatures from quality personnel. The Quality Assurance Manager, Edgar Valdez believed it was a "major quality issue," but Carr nevertheless

pressed the quality department to release the sensors and asked if they could backdate the signatures to push the product through even though it had not passed the quality assurance process.

337. Other former employees corroborated that management pressure to cut corners on quality was pervasive throughout the organization. Former Employee 2, a contracted Systems Requirements Engineer, who wrote systems requirements for the G7 from December 2024 to May 2025, stated that at Dexcom, "management was constantly pushing, pushing, pushing, and pressuring its developers, testers and quality assurance to be faster." According to Former Employee 2, Chief Technology Officer Girish Naganathan was personally involved in rushing projects that require adequate development and testing of requirements and would email employees pressuring them they "MUST" complete features by certain deadlines even when "most working on the project thought this was impossible." Former Employee 2 recalled that Naganathan sent emails pressuring the entire G7 product team to complete the latest version of the G7's software, version 2.9, by March 11, 2025. According to Former Employee 2, because of the rush to complete projects for the release, requirements for the G7 were being written ***after*** the software development was already done. This led to lapses in software testing for the G7 to make sure that the device met system requirements. Further, Former Employee 2 explained that product management kept pushing the G7 project team to meet the release deadline even though management was told that the requirements were not ready for release because the quality assurance team questioned how the requirements were written. According to Former Employee 2, product management "absolutely" ignored the quality teams' concerns because Naganathan was coming down on them to get the release done by the March 11, 2025 deadline.

338. In another instance, Former Employee 2 recalled that Dexcom management ignored issues regarding "tracing," a software development practice that tracks the relationship between

user/product requirements at the top level, down to system requirements, then sub-system requirements, and then software or hardware functions at the bottom. In the Warning Letter, the FDA noted Dexcom's commitment to develop "trace matrices" as part of a new Dexcom CAPA to address Dexcom's failure to document certain MARD and glucose sensor sensitivity parameters. Starting in May 2025, as part of Former Employee 2's job helping Dexcom respond to the Warning Letter, Former Employee 2 identified 1,000 to 1,500 "bad" tracings, i.e., failures to trace product specifications down to software functions, which needed to be fixed to satisfy Dexcom's promise to the FDA. However, whenever Former Employee 2 brought these issues to her supervisor, Sri Harsha Maramraju, Senior Manager of Systems Design Engineering, who reported to Naganathan, Former Employee 2 was told not to worry about it, and that they could explain the deficiencies away. By the time Former Employee 2 left in August 2025, nothing had been done to address the tracing issues Former Employee 2 had identified. Former Employee 2 added that as a "quality engineer who takes work processes seriously, Dexcom needs to be held responsible."

339. In sum, the evidence from multiple former Dexcom employees indicates that the regulatory violations and quality control failures at the heart of this action were not isolated incidents or the work of rogue employees, but rather were the direct and foreseeable result of a corporate culture—dictated from senior management—that prioritized production speed, volume, and cost savings over patient safety and regulatory compliance. From the decision to adulterate the G7 by switching to an inferior in-house material, to the relaxed MARD thresholds that allowed sensors with dramatically worse accuracy to be shipped to patients, to the directives to conceal quality problems from the FDA, the pattern of conduct witnessed by several former employees supports a strong inference that Defendants acted with scienter.

E. Defendants Sayer and Sylvain Knew or Recklessly Disregarded the Manufacturing Problems Plaguing the G7 Because They Oversaw Dexcom's Legally Required Manufacturing Processes and Quality Control Systems

340. As noted, and as the FDA reminded Defendants when it approved their G7-related 510(k) submissions, Dexcom was subject to the QSR, 21 C.F.R. Part 820, as a device manufacturer that commercially distributed an FDA-regulated medical device, the G7.

341. Defendants Sayer and Sylvain were directly involved with and oversaw Dexcom's systems for compliance with applicable federal regulations. According to Dexcom's 2024 Annual Sustainability Report, the Company's "Corporate Sustainability Steering Committee" consisted of five senior Company Officers, including Defendant Sylvain, and it reported directly to the Chief Executive Officer—Defendant Sayer. Significantly, the organizational chart in Dexcom's 2024 Annual Sustainability Report depicted "Product Quality" as reporting directly to this committee, meaning that Defendants Sayer and Sylvain had oversight responsibility over the Company's quality function—the very function that failed to prevent the G7's adulteration and the systemic manufacturing deficiencies identified by the FDA—and therefore knew or recklessly disregarded the various issues affecting the Company's compliance with the QSR.

F. The Magnitude and Pervasiveness of the G7's Quality Issues Further Support a Strong Inference of Scienter.

342. The magnitude and pervasiveness of the manufacturing problems support an inference that Defendants were aware of or recklessly disregarded these problems, particularly given that the problems affected Dexcom's core product and only operational facilities. Here, the G7's quality and accuracy problems were not minor or isolated; they were systemic and pervasive.

343. At the time the FDA conducted the 2024 inspections that led to the Forms 483 and the Warning Letter, the FDA inspected Dexcom's only two fully operational manufacturing

facilities. Thus, the FDA's inspections and reports concerned essentially all Dexcom's manufacturing capabilities, not a minor or isolated portion of its manufacturing resources.

344. The quality control problems the FDA found were pervasive and intractable—they were not minor issues that could be easily dismissed or ignored. As the Warning Letter itself stated, the letter was "not intended to be an all-inclusive list of the violations at [Dexcom's] facility" and could be "symptomatic of serious problems in [Dexcom's] manufacturing and quality management systems." And, even though after the site inspections, Dexcom submitted to the FDA five responses from its Senior Vice President, Quality Assurance (on July 9, October 9, and December 3, 2024, and on January 7 and 10, 2025), with respect to the issues previously identified by the FDA, the FDA "reviewed [Dexcom's] responses and determined they are not adequate" or could not "determine the adequacy" (as the FDA stated in the Warning Letter).

345. Notably, in response to the FDA's discovery that Dexcom had adulterated the G7's resistance layer, Dexcom had "provided new testing, including Sensor Level Performance Equivalency" between the original and the adulterated G7. But the FDA concluded that these studies confirmed the lack of equivalence between the two products, because the "standard deviation … of … glucose sensitivity [wa]s twofold" for the adulterated device, meaning there was a "significant variation in the clinical performance of" the adulterated sensors such that the FDA determined Dexcom's response was "inadequate."

346. Similarly, with respect to Dexcom's practice of manufacturing sensors with wide-ranging thickness—first identified by the FDA in the June 2024 Form 483—the Warning Letter explained the FDA "cannot determine [the] adequacy" of Dexcom's response because Dexcom itself was still conducting "additional analysis of the ranges for … thickness" and because

Dexcom's responses "include[d] records showing [Dexcom had] not established" chemical formulation criteria for the thickness of certain parts of the sensors.

347. Another pervasive problem was the one that had led to the firm-initiated CAPA in place since April 2024. Dexcom "was not consistently monitoring or recording the values of dissolved oxygen" in the manufacturing "across both … [the] San Diego … and Mesa … facilities," such that "all [CGM] lots may have been potentially impacted." However, Dexcom's response to this problem was "inadequate" because it did "not provide the support documentation of the[] reported reviews" Dexcom purportedly conducted to remediate the issues.

348. Moreover, the issues were not isolated in time—they persisted through most of the Class Period. The CAPA with respect to dissolved oxygen began in April 2024 and had not been resolved as of March 2025. The issues identified in the June 2024 Form 483 persisted nine months later. Nor have Dexcom's issues with the FDA been resolved—to the contrary, the problems are so significant that the Warning Letter remains in place over a year after it was issued.

G. Defendants Had a Motive to Conceal the Adulteration of the G7 and to Make Misleading Statements about Its Accuracy

349. Lead Plaintiff is not required to plead any motive to allege scienter. Nevertheless, the Complaint explains why Defendants would have concealed the adulteration of the G7 and misrepresented its accuracy.

1. After Adulterating the G7, Defendants Had Strong Motives to Continue to Tout the G7 as the Most Accurate Sensor Approved by the FDA

350. Before and throughout the Class Period, Defendants understood that the G7's perceived accuracy was critical to its commercial success. They accordingly had powerful motives to deceive the public, including investors, about the adulterated sensor's accuracy.

351. Historically, Dexcom marketed CGMs with purportedly higher levels of accuracy as the differentiating factor and key competitive advantage over Abbott. For example, Dexcom's G6 had a stated MARD of 9.0% while Abbott's cheaper "Freestyle Libre" 1 and 2 CGMs had MARDs of 9.4% and 9.3%, respectively. This advantage had helped Dexcom maintain an edge over the smaller, insulin-intensive market, while ceding the non-insulin-intensive market to Abbott. However, given in part the different growth rates of the two segments (the insulin-dependent group being relatively stable while the non-insulin-dependent group grew rapidly) this effectively meant that Dexcom was consistently and concerningly losing market share to Abbott.

352. Thus, Defendants understood that any issues with the accuracy of Dexcom's CGMs would strike at the very heart of the Company's business model and threaten its competitive position—and that even small perceived differences in accuracy could make a significant difference in customer adoption and market share. A sensor that delivers inaccurate glucose readings is not desirable to an insulin-intensive patient who depends on that data to make potentially life-and-death insulin dosing decisions.

353. Dexcom's competitive advantage problem worsened when Abbott announced in 2019 that it was going to launch its latest CGM, the Libre 3, and that the model would be cheaper ***and more accurate*** than the G6, with an 8.9% MARD compared to the G6's 9.0%. Given that Dexcom's CGM's accuracy was its core competitive advantage, this development was particularly threatening to Dexcom's business. These very small differences in accuracy could have potentially tipped the insulin-intensive diabetes market in Abbott's favor.

354. When Dexcom announced the G7 before the Class Period, its purported superior accuracy to Abbott's Libre 3—at 8.2% MARD—was therefore key to Dexcom's positioning of the device. Defendants repeatedly told the market that the accuracy of Dexcom's sensors was again

Dexcom's key competitive edge, critical for maintaining dominance in the insulin-intensive market. According to Defendants and analysts, the small differences between Abbott's Libre 3's MARD and Dexcom's G7's MARD was highly significant. For example, during the January 2022 J.P. Morgan Healthcare Conference, when an analyst asked Defendant Sayer how Dexcom planned to compete for share gains against Abbott, Sayer emphasized that the G7's accuracy was the basis for Dexcom's competitive position, stating that the G7 "is the most accurate sensor on the market today." Similarly, on March 8, 2023 a Morningstar analyst wrote, with respect to the Libre 3, that "Abbott's improvements mean the two firms will be competing even more directly for Type 1 patients" and that "Abbott's … has just ratcheted up the competitive pressure on Dexcom."

355. Defendants thus positioned sensor accuracy as the foundation of Dexcom's competitive strategy, making it imperative that the market and investors *believe* that the G7 was in fact more accurate than the competition. This provided Defendants with a powerful motive to deceive the public, including investors, when Defendants found out that the G7 had become less accurate. It also provided Defendants with powerful motives to ensure the truth about the G7's compromised accuracy was not known to investors or the diabetes care community. At a minimum, it provided Defendants with a powerful motive to recklessly disregard any problems with the G7's accuracy, including manufacturing control and quality problems that could have affected it.

2. Defendants Sayer and Sylvain Sold Stock During the Class Period

356. Defendants Sayer and Sylvain sold significant amounts of Dexcom stock while possessing material, non-public information that the G7, Dexcom's flagship product, had been adulterated and was less accurate than before.

357. ***Defendant Sayer's Insider Sales***. Defendant Sayer, Dexcom's CEO, President, and Chairman during nearly all the Class Period, sold a substantial volume of Dexcom stock while in possession of material, non-public information about the G7's impaired accuracy and quality

issues. During the Class Period, Defendant Sayer sold 100,965 shares of Dexcom common stock for total proceeds of approximately $13.68 million. These sales were made pursuant to a Rule 10b5-1 trading plan that Defendant Sayer adopted on December 12, 2023, ***the very day before*** Dexcom began manufacturing the adulterated G7 sensors on December 13, 2023. In other words, at the time of Defendant Sayer's adoption of this trading plan, Dexcom had already decided to adulterate the G7, and had already conducted its internal study showing that the adulterated G7 was not equivalent to the original and Defendants knew the adulterated sensor was not as accurate as the version that the FDA had approved. When Defendant Sayer adopted the plan, he knew or recklessly disregarded the adulterated, less accurate G7 would go into production the next day.

358. Defendant Sayer's sales occurred on March 12 and April 8, 2024, with the latter sales coming just as Defendants' material misstatements helped push the stock to its April 9, 2024 high (to a price it has not reached in nearly two years since). Specifically, on March 12, 2024, Defendant Sayer sold a total of 51,332 shares across four transactions for approximately $6.81 million. On April 8, 2024, Sayer sold an additional 49,633 shares across two transactions for approximately $6.86 million, a total of $13.68 million Class Period Dexcom stock sales.

359. Defendant Sayer's sales during the Class Period were substantial both in absolute terms and as a percentage of his holdings. His sales of over $13.68 million represented a significant monetization of his equity position in Dexcom at a time when he knew or recklessly disregarded that the G7's accuracy had been compromised by Dexcom's adulteration. By the time the FDA issued the June 2024 Form 483, Sayer had liquidated 36.7% of his unrestricted, vested holdings.

360. ***Defendant Sylvain's Insider Sales***. Defendant Sylvain, Dexcom's CFO during the Class Period, similarly sold a substantial volume of Dexcom stock during the Class Period while in possession of material, non-public information about the G7's accuracy and quality issues.

During the Class Period, Defendant Sylvain sold a total of 18,687 shares of Dexcom common stock for approximately $1.53 million. Like Defendant Sayer, Defendant Sylvain adopted a Rule 10b5-1 trading plan immediately before Dexcom adulterated the G7 on December 13, 2023, adopting his plan on November 21, 2023. He later amended the plan on August 6, 2024, after Dexcom had received the June 2024 Form 483 but before Dexcom had discussed it publicly.

361. The timing of Defendant Sylvain's sales is also suspicious. On November 15, 2024, just eight days after the FDA concluded its inspection of Dexcom's San Diego facility and issued the November 2024 Form 483 documenting Dexcom's adulteration of the G7 and several other failures, Sylvain sold 3,500 shares for proceeds of approximately $264,000. Defendant Sylvain made this sale before investors knew the FDA's findings regarding the adulterated sensors. Even more suspiciously, on March 10, 2025, just three days after Dexcom disclosed that it had received a Warning Letter from the FDA, but before the full contents of the Warning Letter were made public. Sylvain sold an additional 7,000 shares across three transactions for proceeds of $517,000. The March 10, 2025, sales were ***not*** made pursuant to a 10b5-1 plan, and the Form 4 for these transactions contained no notation indicating they were made under a pre-arranged trading plan.

362. ***Pattern of Stock Sales.*** Defendants' Class Period sales were not consistent with prior trading patterns and are further suspicious for that reason. First, Defendants' Class Period sales were made after they knew, or recklessly disregarded, that the G7 had been adulterated and that the Company's accuracy representations were no longer supported by the clinical data. Thus, even if Defendants had sold stock at similar volumes in prior periods, those prior sales did not involve the same material, non-public information.

363. Second, comparing Defendants' Class Period and pre-Class Period sales underscores the suspiciousness of Defendants' sales. During the approximately twenty-month

period from April 28, 2022, through January 7, 2024 (the "Prior Period"), Defendant Sayer sold 116,120 shares for proceeds of approximately $12.64 million. During the approximately twenty-month Class Period from January 8, 2024, through September 17, 2025, Defendant Sayer sold 100,965 shares for proceeds of approximately $13.68 million. While the number of shares sold was slightly lower during the Class Period, Defendant Sayer's sales were highly concentrated in the early months of the Class Period—March and April 2024—shortly after the adulteration occurred. Similarly, Defendant Sylvain sold 9,644 shares for proceeds of approximately $1.2 million during the Prior Period, compared to 18,687 shares for proceeds of approximately $1.53 million during the Class Period—representing an increase in both volume and proceeds.

364. Notably, neither Defendant Sayer nor Defendant Sylvain made any open market purchases of stock during the Class Period. All their acquisitions of Dexcom stock came through Company awards for which they did not pay. This absence of insider purchases during the Class Period—a period during which Defendants were publicly touting the G7 as "the most accurate CGM" on the market—is consistent with Defendants Sylvain's and Sayer's knowledge that the G7 had been adulterated, that the Company's public statements were materially misleading, and that Dexcom's stock was overvalued.

IX. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

365. Throughout the Class Period, Defendants made numerous materially false and/or misleading statements, which were disseminated to investors through calls, public filings, press releases, presentations, Company statements, social media platforms, and news and media outlets. Each misstatement was either affirmatively false or was a misleading "half-truth" that omitted material information necessary to make the statement not misleading. Both are equally actionable under the federal securities laws. Defendants' materially false and misleading statements and omissions fall into four principal categories: (i) the accuracy of Dexcom's flagship G7 CGM, its

status as approved by the FDA, and the reasons for Dexcom's second quarter 2024 earnings miss, (ii) the nature and extent of the FDA's concerns regarding the G7's accuracy, and its manufacturing process, quality controls, and validation, (iii) the status of Dexcom's quality assurance program, and (iv) the nature and existence of risks facing the Company.

A. False and Misleading Statements Concerning the Accuracy of the G7

366. Leading up to the start of the Class Period on January 8, 2024, Dexcom had represented to the market that its G7 CGM was critical to Dexcom's success and was the most accurate CGM device approved by the FDA, frequently comparing the G7's accuracy (as measured by MARD) to that of Dexcom's principal competitor's product—Abbott's Libre 3. For instance, Dexcom announced the official launch of the G7 with a February 7, 2023 press release on its website stating: "with an overall MARD of 8.2%, Dexcom G7 is the most accurate CGM on the market." A few days later, shortly after the G7's approval and rollout, on a February 9, 2023, Q4 2022 Earnings Call, Defendant Kevin Sayer assured investors that the G7 was "the most accurate, easy-to-use and accessible CGM ever produced," that Dexcom "will remain the most accurate system in the world," and that "G7 is going to be a better experience than G6." The G7's rollout was crucial to Dexcom's ability to maintain competitive market share against Abbott's Freestyle Libre 3, particularly in retaining its dominance among insulin-intensive patients who prioritized accuracy. Market analysts relied heavily on these accuracy statements, with multiple firms citing the G7's supposed 8.2% MARD and "best-in-class" accuracy as key reasons for recommending Dexcom stock.

367. **Statement #1.** On January 8, 2024, at the J.P. Morgan Healthcare Conference, Defendant Kevin Sayer stated that "for [the] G7, that great science starts with its accuracy," and that the G7 was "***the most accurate sensor on the market today and the most accurate sensor that's ever been produced by us***." The presentation slides shown and/or provided to investors that

day also stated that the G7 was the "new standard in CGM technology" and had the "***most accurate***" sensor available.

368. **Statement #2.** On February 8, 2024, Dexcom filed the Dexcom 2023 10-K, signed by Defendants Sayer and Sylvain. In that report, Dexcom stated that the G7 had an "***overall Mean Absolute Relative Difference, or MARD, of 8.2%, as well as 94.1% of values within 20% of their comparator***," and further that the "***Dexcom G7 is the most accurate CGM cleared by the FDA***."

369. **Statement #3.** On February 8, 2024, in the Q4 2023 Earnings Call, Defendant Sayer stated that the "***G7 is the most accurate CGM ever launched*** and the market's reception to G7 has been exceptional." The presentation slides shown and/or provided to investors that day repeated the statements that the G7 was the "new standard" and "***most accurate***" sensor available.

370. **Statement #4.** On March 5, 2024, at the Raymond James Institutional Investors Conference, Defendant Sean Christensen stated that the "***G7 is the most accurate CGM that has been cleared by the FDA and offering that standard Dexcom performance that people have come to expect and trust over the years***." The accompanying presentation included the same slide stating that the G7 was the "***most accurate***" sensor available as the presentation used for the January 8, 2024, Conference and the February 8, 2024, Q4 2023 Earnings Call.

371. **Statement #5.** On April 3, 2024, Dexcom issued its 2023 Annual Sustainability Report, which contained a "letter from our CEO," Defendant Sayer, addressed "To our stakeholders." In the report, Dexcom stated that the G7 provided "***the most accurate sensor technology***."

372. **Statement #6.** On April 25, 2024, on the Q1 2024 Earnings Call, Defendant Sayer stated, "***With the launch of [the] G7, we extended our leadership in sensor accuracy***."

373. **Statement #7.** On June 5, 2024, at the William Blair Growth Stock Conference, Defendant Sylvain told the gathered analysts and investors that the G7 was "our trademark product, our flagship product … ***It's the most accurate sensor on the market.***" The presentation slides shown and/or provided to investors that day also stated that the G7 was the "***most accurate***" CGM on the market.

374. **Statement #8.** From January 22, 2024, through June 5, 2024, Dexcom also ran several Facebook advertisements, referring to the G7 as the "***most accurate***" CGM, and directed the public to "Dexcom data on file, 2023."

375. Statements #1-#8 were materially false and misleading, and omitted material facts. For the four reasons set forth immediately below, it was materially false and misleading for Defendants to state that the G7 was "the most accurate sensor on the market today;" "the most accurate sensor that's ever been produced by us;" "the most accurate CGM cleared by the FDA;" "the most accurate CGM ever launched;" "the most accurate sensor technology;" and industry-leading in its "accuracy;" that the G7 had an "overall Mean Absolute Relative Difference, or MARD, of 8.2%;" and that the G7 represented the "standard Dexcom performance that people have come to expect and trust over the years."

376. *First*, unknown to investors, the accuracy statements and MARD data were based on trials of G7 devices that were significantly different from, and more accurate than, the version of the G7 that Dexcom was then manufacturing and distributing. Specifically: (1) in December 2023, after arriving at the published MARD figures in clinical trials, Dexcom adulterated the G7 by changing a "critical component," *i.e.*, switching the membrane material used in the resistance layer of the glucose sensors to a material produced in-house, *see, e.g.*, ¶¶ 74, 78-79; (2) Dexcom determined internally that the adulterated G7 was not equivalent to the version of the device that

had yielded the published MARD figures, as its own internal studies determined that the "primary endpoints" used to try to establish equivalence between the original G7 and the adulterated G7 "were not met," *see, e.g.*, ¶¶ 80, 82, 189-90; and (3) further, Dexcom determined that the adulterated G7 performed worse across every accuracy metric than the G7 that produced the published MARD figures, with internal data showing that "every accuracy metric of sensors built with the [new material] … was worse" and that the sensors had a "significantly different ratio" of glucose sensitivity. *See, e.g.*, ¶¶ 81-82, 189-90.

377. *Second*, the statements regarding the G7's accuracy were materially misleading for the independent reason that Dexcom was unable to reliably manufacture and test devices to ensure that they met its stated accuracy metrics. Dexcom: (1) was setting MARD levels arbitrarily, without documentation, and consistently higher than the clinical MARD specification for the G7, including at times as high as 15%, *see, e.g.*, ¶¶ 110-17; (2) did not properly test the real-world accuracy of the G7s it manufactured (failing to monitor glucose concentrations in test dishes) and it did not properly document the results of those tests for later validation, meaning Dexcom did not know what the G7's MARD actually was, *see, e.g.*, ¶¶ 118-22; (3) was shipping sensors without properly calibrating acceptable error codes for glucose sensitivity, which could lead to acceptance of sensors that should not have been accepted or were not performing properly, and "contribute to inaccurate glucose readings," *see, e.g.*, ¶¶ 123, 128; (4) was shipping sensors with thickness coatings that Dexcom had not individually verified even though Dexcom had set acceptable thickness parameters within an extremely wide range, leading to sensors that produced unreliable and inaccurate glucose readings for patients, *see, e.g.*, ¶¶ 124-28; (5) discovered manufacturing and other problems that affected the accuracy of the sensors but, rather than institute a plan to fix the issues, Dexcom instituted plans that would permit it to ship nonconforming sensors to

customers anyway, *see, e.g.*, ¶¶ 129-35; and (6) failed to consider and mitigate the potentially fatal risks to patients who used Dexcom's CGMs in conjunction with automated insulin dosing systems, *see, e.g.*, ¶¶ 136-39. These extensive, overlapping deficiencies, at minimum, materially undermined the basis for Defendants' unqualified and categorical statements about the G7's supposed market-leading accuracy.

378. *Third*, the repeated statements that the "Dexcom G7 is the most accurate CGM cleared by the FDA" were materially misleading for the independent reason that the adulterated G7 sensors Dexcom manufactured and distributed after December 13, 2023 were ***not*** lawfully approved by the FDA for commercial sale. Instead, those G7 devices were "adulterated" within the meaning of the FDCA, 21 U.S.C. § 351(f)(1)(B), and Dexcom did not have approval to distribute them. Further, the adulterated G7 devices were "misbranded" because Dexcom introduced these devices with major changes without submitting a new premarket notification to the FDA, as required by the Act and regulations issued thereunder. *See id.* §§ 352(o), 360(k); *see also* 21 C.F.R. § 807.81(a)(3). Rather than seek the required FDA approval, Dexcom: (1) concealed its design change from the FDA; (2) misleadingly told the FDA that the subject device is "as safe and effective as the predicate device and does not raise different questions of safety and effectiveness," that the adulterated G7 was "physically identical to the predicate Dexcom CGM system," that the "subject device shares identical hardware, material, chemical composition, principle of operation and energy source with the predicate device," and that the G7's sensor's "materials, hardware components, and packaging are identical to those of the predicate device"; and (3) continued to commercially manufacture and distribute sensors containing the unapproved in-house material for over a year without the requisite FDA approval. *See* ¶¶ 83-90, 215-16.

379. *Fourth*, the statements touting the G7's accuracy were materially misleading for the independent reason that the G7's accuracy worsened in the real world after Dexcom adulterated the device, as shown by the dramatic spike in adverse event reports submitted to the FDA and other customer complaints regarding the G7 following the adulteration. Notably, after Dexcom adulterated the device, based on analysis of MAUDE data, the rate of monthly of complaints about the G7 that appear related to its accuracy more than tripled and the G7 received significantly more complaints for events occurring in 2024 or 2025 (approximately 240,000) than Abbott's Libre 3 (approximately 8,200)—meaning it generated nearly thirty times more complaints than its primary competitor despite having a smaller market share. *See also* ¶¶ 93-102, 260-64, 304.

380. Dexcom's misleading statements regarding the G7's accuracy continued even after the FDA discovered that Dexcom had failed to institute adequate manufacturing controls and testing at its Mesa facility and issued the June 2024 Form 483, triggering a "corporate emergency."

381. **Statement #9.** On June 23, 2024, in an interview with Drug Delivery Business, Defendant Sayer misrepresented the G7 as "***the most accurate sensor on the market still***," and that it will "***remain so***," adding that the "***G7 is noticeably better than [the] G6 was, at least clinically***."

382. **Statement #10.** On July 25, 2024, Defendants announced disappointing second quarter results for fiscal year 2024, reporting quarterly revenue approximately 3.13% below consensus and lowering full-year revenue guidance by 5-7%, or approximately $300 million. In a press release issued that day, seeking to reassure the market and dispel any notion that the weak performance was due to quality problems with its flagship product, Defendants falsely attributed Dexcom's underperformance to various one-off sales "***execution***" issues, with Defendant Sayer stating: "***[w]hile Dexcom advanced several key strategic initiatives in the second quarter, our***

execution did not meet our high standards." During the July 25, 2024, Q2 2024 Earnings Call, Defendant Sayer similarly falsely attributed the revenue miss to "***execution***" issues such as a "U.S. salesforce realignment expansion." Sayer further stated Dexcom had "***built upon the performance of G7, making it even better***," and the presentation shown and/or given to investors that day continued to aver that the G7 was the "new standard" and "***most accurate***" CGM available.

383. **Statement #11.** On September 4, 2024, during a Company Conference Presentation hosted by analysts from Wells Fargo Securities, Defendant Sayer again dismissed the July 2024 earnings miss as an "***execution hiccup***." During the conference, Defendants Sayer and Sylvain were asked a series of questions about the "headwinds" for lower new patient starts and lower guidance announced with second quarter results. Summing up his response, Sayer stated: "***This is an execution hiccup … It's not a reflection of the quality of our product***."

384. **Statement #12**. On September 9, 2024, Dexcom posted an ad on Facebook stating that the G7 was the "***most accurate CGM***," and cited both the G7's original 510(k) approval and Abbott's 510(k) approval of the Libre 3 as the source of this statement—thereby inviting the public to measure the G7's purported MARD accuracy against the Libre 3's, as the MARD data was presented in those 510(k) submissions.

385. **Statement #13.** On September 28, 2024, in an interview with the *Diabetes Strong* podcast, Defendant Leach stated, "***G7 is the most accurate sensor we've ever created***." Later, the interviewer asked Defendant Leach: "What do you offer that maybe some of the other … CGM providers here in the U.S. don't really provide?" Defendant Leach stated, "***It starts with the sensor, right? And the performance and accuracy of the product is unmatched by anything out there. And so I think our number one, you know, advantage here is the sensors as accurate as any sensor available***."

386. **Statement #14.** On October 24, 2024, during the Q3 2024 Earnings Call, Defendant Sayer was asked about competition in the Type 1 diabetes market and how Dexcom intended to "defend [its] position there." Sayer responded: "Over time, our reputation in this market and one of the places we've been always strong is in this type 1 market because that has been where we have had the largest market share advantage for a very long time, and we intend to maintain that through the higher quality of our product. And at the end of the day, it matters. ***The accuracy of Dexcom is tried and true and proven to these patients***." The presentation or given to investors continued to aver that the G7 was the "new standard" and "***most accurate***" CGM available.

387. Statements #9-#14 were materially false and misleading and omitted material facts for the reasons set forth below.

388. Statements #9-#10 and #12-#14, regarding the accuracy and quality of the G7, were materially misleading for the same four reasons set forth in ¶¶ 376-79 above. These statements were materially misleading for the additional reason that they were made after Dexcom received the June 2024 Form 483 from the FDA, which described critical deficiencies in Dexcom's manufacturing process, putting Dexcom on additional notice that it was unable to reliably manufacture and test devices to meet its stated accuracy metrics. Specifically, the FDA found that Dexcom's allowable ranges for key dipping parameters—such as dip speed, retract speed, and dwell time—were "extremely wide," which could result in sensors with wildly inconsistent coatings and, therefore, "significant variability in sensor sensitivity and clinical accuracy." The FDA further documented that on June 13, 2024, Dexcom's own Process Engineering Director acknowledged to FDA investigators that "sensors produced at the edge cases will likely exhibit non-conformities." *See* ¶¶ 124, 166-73. Accordingly, statements #9-#10 and #12-#14, about the G7's accuracy and quality, were materially misleading because they omitted that Dexcom had just

received formal notice from the FDA that its manufacturing processes suffered from deficiencies that undermined the accuracy and reliability of its sensors.

389. Statements #10 and #11 blamed Dexcom's poor second quarter results on "execution hiccup[s]" like salesforce restructuring, and stated that the disappointing results were "not a reflection of the quality of our product." These statements were materially misleading because Dexcom's underperformance was in fact driven by issues with the G7's quality and accuracy. As detailed further above, ¶ 181, Former Employee 3 reported that Dexcom's poor performance and slower new patient starts was due to quality issues plaguing the G7 that, among other things, led to patients being unwilling to upgrade to the G7 from the G6. Former Employee 3 participated in monthly meetings in the first months of 2024, held at Dexcom's San Diego facility, which he described as "high-level engineering management meetings" attended by approximately fifteen Dexcom employees from San Diego and remotely, including "engineering VPs, Senior Directors and Managers." At the meetings, it was repeatedly discussed that "the G7 quality issues were negatively impacting sales." Former Employee 3's eyewitness account is corroborated by a spike in consumer complaints to the FDA, the Better Business Bureau, and on social media, regarding the G7's accuracy immediately following the December 2023 adulteration, *see* ¶¶ 93-102, showing that consumers who prized accuracy turned away from the adulterated and poorly-manufactured G7, which did not deliver on its promised, industry-leading accuracy.

390. Defendants continued to mislead the market about the accuracy of the G7 even after receiving a second Form 483, the November 2024 Form 483.

391. **Statement #15.** On November 8, 2024, in a "Dexcom Investor Presentation" given the day after Dexcom received the November 2024 Form 483, Defendants continued to state that the G7 was the "new standard" and "***most accurate***" CGM available.

392. **Statement #16.** On February 13, 2025, during the Q4 2024 Earnings Call, in response to an analyst question about the accuracy of Dexcom's sensors, Defendant Leach misrepresented the G7 as "***the most accurate sensor available***."

393. **Statement #17.** On February 18, 2025, in the Dexcom 2024 10-K, signed by Defendants Sayer and Sylvain, Dexcom again stated that the G7 had an "***overall Mean Absolute Relative Difference, or MARD, of 8.2%***," and once again stated that the "***Dexcom G7 is the most accurate CGM cleared by the FDA***."

394. Statements #15-#17 were materially false and misleading, and omitted material facts, for the same five reasons set forth in ¶¶ 376-79, 388, above.

395. Statements #15-#17, regarding the G7's accuracy and quality, were further materially misleading because they were made approximately three months after Dexcom received the November 2024 Form 483 from the FDA. Most notably, the November 2024 Form 483 formally documented that Dexcom had changed a critical raw ingredient in the resistance layer of the G7 sensors, from a supplier-purchased compound to an in-house material, without seeking or obtaining FDA approval. The FDA's investigation further revealed that Dexcom had tried and failed to validate this design change: Dexcom's initial clinical study, intended to "determine the equivalence of the two ingredients," found that "primary endpoints were not met," and Dexcom's own internal data showed that "every accuracy metric of sensors" built with the new material "was worse" than sensors built with the original material. *See* ¶¶ 188-91.

396. The November 2024 Form 483 also documented several additional manufacturing deficiencies at Dexcom's San Diego facility, including, as set forth above, *see* ¶¶ 193-99, as to manufacturing processes and parameters, design procedures, and quality control systems, all of which further undermined the accuracy and reliability of Dexcom's G7 CGMs. The FDA found,

among other things, that Dexcom: (1) set acceptable MARD levels arbitrarily and without documentation; (2) tested the accuracy of finished sensors without controlling for environmental parameters, leading to inaccurate assessments of whether the sensors worked correctly; (3) recorded test results only as "pass" or "fail" rather than documenting actual MARD and glucose sensitivity slope measurements, which "failed to demonstrate" that the sensors were "capable of producing repeatable and reproducible" accuracy data; (4) failed to program glucose sensitivity slope error rates even though they could "contribute to inaccurate glucose readings;" (5) shipped sensors with improper coating thickness if the overall batch average appeared acceptable, even though devices at the outer edges of thickness could be inaccurate; (6) shipped sensors despite identifying that some sensors were not properly tested in low-oxygen environments; and (7) failed to consider and mitigate the potentially fatal risks to patients who used Dexcom's CGMs in conjunction with automated insulin dosing systems.

397. These findings were significant because they showed that Dexcom was unable to reliably manufacture and test devices to meet its stated accuracy metrics and that Dexcom could not ensure the G7 sensors it was manufacturing and selling performed as accurately as the FDA-approved device it had touted to investors. Thus, Defendants' statements about the G7's accuracy were materially misleading for the additional reason that they omitted Dexcom's receipt of a second, formal FDA notice of serious violations that undermined the accuracy of its sensors.

B. False Statements Concerning the Nature of the FDA's Findings

398. On March 7, 2025, after the market closed, Dexcom issued a Form 8-K revealing the existence of the Warning Letter and the June 2024 and November 2024 Forms 483. Defendants revealed only that "[t]he warning letter describes observed non-conformities in manufacturing processes and quality management system." Downplaying the seriousness of the Warning Letter, and even though Defendants had ceased commercialization of the adulterated G7 following the

FDA's second inspection, Defendants assured investors that "[t]he warning letter does not restrict the Company's ability to produce, market, manufacture or distribute products." Defendants did not disclose the severity of the findings, including the most critical finding—that Dexcom had released adulterated products by replacing the key resistance layer compound in its sensors with an inferior compound, without FDA approval. Nor did they reveal the other FDA findings undermining Dexcom's statements about the accuracy of the G7. Instead, seeking to preempt and proactively quell investor concern, Defendants embarked on a public relations campaign to mischaracterize the Warning Letter's findings and mislead investors about its significance.

399. **Statement #18.** On March 9, 2025, equity research analysts at BTIG reported on a conversation they had with "Dexcom's IR [Investor Relations]," which Defendant Christensen headed, in which Dexcom told BTIG that "they ***had*** already implemented process controls three months ago in response to the Form 483s." BTIG also noted that "Management reiterated that ***the warning letter has no impact on the company's commercial operations***."

400. **Statement #19.** On March 9, 2025, equity analysts affiliated with Raymond James reported on a "conversation with management on Friday night," March 7, which "gives us comfort that ***this is not a product quality issue***," that "DXCM emphasized ***that there are no quality issues with its product***," and that the "sensors are performing as expected, and the 'non-conformities' ***do not impact the end user***."

401. **Statement #20.** On March 10, 2025, equity analysts at Baird reported that "[i]n speaking with management about this issue, we learned the FDA's concerns are ***focused entirely on manufacturing processes***, many of which DXCM believes already addressed and/or remediated (the FDA did not re-inspect DXCM's facilities after last year's inspections and prior

to issuing its Warning Letter). Notably, the FDA's ***observations/concerns don't mention overall product quality issues***."

402. **Statement #21.** On March 10, 2025, UBS analysts reported that Dexcom management assured them that "the 7 observations [in the Warning Letter] ***have nothing to do with product quality*** and are rather very specific around certain manufacturing processes, i.e., the concentration of solution used to test acetaminophen sensitivity."

403. **Statement #22.** On March 25, 2025, *MedTech Dive* published an interview that Defendant Leach had given to the outlet the week before. When asked about the Warning Letter, Leach had stated that the FDA had "spent a lot of time looking at how our design documents traced all the way through to our production testing, and how we build our sensors. They had some concerns about how we were doing that. ***We answered those concerns with better documentation around how we build sensors and why we do the testing we do.*** The [W]arning [L]etter is their response saying, 'You've answered a lot of our questions, but there's still some that we have open that we need to work together on.'"

404. Statements #18-#22 were materially false and misleading, and omitted material facts.

405. Statement #18, that the Warning Letter "has no impact on [Dexcom's] commercial operations," was misleading for two reasons. First, in direct response to the FDA's findings that the G7 was adulterated and being commercially distributed without FDA approval, Dexcom ceased commercial distribution of G7 sensors containing the unapproved material. *See* ¶ 214. Second, the G7's quality problems identified in the Warning Letter *had* already impacted Dexcom's commercial operations. As set forth in ¶ 181 above, Former Employee 3 stated that Dexcom's poor performance and slower new patient starts in the second quarter of 2024 were due to quality issues

plaguing the G7 that negatively impacted G7 sales and led to patients being unwilling to upgrade to the G7 from the G6, as the explosion in patient complaints about the G7's accuracy post-adulteration independently confirms. *See* ¶¶ 93-102.

406. Statements #19-#22—asserting that the Warning Letter did not concern "a product quality issue," that there are "no quality issues with [Dexcom's] product," that the issues "do not impact the end user," that the FDA had been "focused entirely on manufacturing processes" and its "observations/concerns don't mention overall product quality issues," or "have nothing to do with product quality," and that Dexcom had "answered" the FDA's questions with "better documentation"—were materially false and misleading and omitted material facts because the Warning Letter ***was*** squarely about product quality and was ***not*** simply focused on "manufacturing processes." The Warning Letter included findings about the chemical adulteration of the device and the resulting decrease in accuracy that Dexcom itself had documented following this change. The Warning Letter directly concerned the G7's quality in a way that was not simply about manufacturing "process" and that ***did*** directly impact the G7's end users. For instance, the Warning Letter specifically stated that the new sensor "performs worse … for accuracy" and that the "larger inaccuracies" in the adulterated sensors "cause higher risks for users who rely on the sensors to dose insulin or make other diabetes treatment decisions." In sum, as stated in detail above, the FDA's findings in the Warning Letter go to the very heart of the G7's quality and accuracy, as the FDA concluded that Dexcom had changed a critical component in its sensors without approval, that Dexcom's own tests showed the new material was less accurate than the original, that this change could significantly impact patients, and that Dexcom's manufacturing and testing processes were so deficient that the Company could not reliably produce sensors that performed as advertised. Moreover, Dexcom ***had not*** answered the FDA's concerns with "better

documentation." To the contrary, the FDA had rejected most of Dexcom's responses to the FDA's concerns as "inadequate," and the documentation Dexcom provided with respect to the change in the chemical composition of the resistance layer—which Dexcom's statement to *MedTech Dive* misleadingly omitted—had ***increased*** the FDA's concerns with the adulteration. *See* ¶¶ 207-30; *see also* ¶¶ 107-39.

407. Defendants made additional materially false and misleading statements and omissions when the FDA published the contents of the Warning Letter on March 25, 2025. Defendants attempted to step on and diminish the news by falsely denying the FDA findings, continuing to misleadingly downplay their importance, and feeding analysts additional misleading statements about the FDA's findings, including that Dexcom had sought and obtained regulatory approval for the adulterated G7.

408. **Statement #23.** On March 25, 2025, Dexcom management spoke with Wells Fargo analysts, who repeated in a report Dexcom's explanation that new sensor material "refers to a dipping material that DXCM developed in-house (prev sourcing from a single, external supplier) in order to increase supply. ***DXCM notified the FDA of this insourcing as part of another 510(k) submission in 2024.*** According to DXCM, the [Warning Letter] is stating that the ***FDA wants more information on this dual-sourcing as its own 510(k) filing, which DXCM can provide***."

409. **Statement #24.** On March 25, 2025, Dexcom management fed J.P. Morgan the same story and insisted that the Warning Letter was not a big deal because "***[t]he company included this in-sourcing in a 510(k) submission for something else last year and the FDA cleared it***." This led J.P. Morgan to conclude: "This was basically a long way of saying the quality control/validation issues were not related to G6/G7 sensor quality, but the specifics of this production process, which to our knowledge have been addressed."

410. Statements #23 and #24 were materially false and misleading and omitted material facts.

411. Statements #23-#24, that Dexcom had previously disclosed and obtained FDA approval for the new sensor material through prior 510(k) submissions, including "as part of another 510(k) submission in 2024" or "in a 510(k) submission for something else last year," were materially false and misleading for three reasons. *First*, Dexcom ***had not*** sought and received FDA approval for the new sensor material through a 510(k) submission. None of the 510(k) submissions that the FDA cleared for Dexcom's CGM devices in 2024 or before the Warning Letter concerned or disclosed a change in the material used for the resistance layer of the G7 sensors. Specifically, after initially clearing the G7 pursuant to the December 2021 510(k) and as set forth above, the FDA: (1) on May 15, 2023 cleared 510(k) K231081, which changed the material used to adhere the sensor to the body; (2) on February 26, 2024 cleared 510(k) K234133, which added smartphones as a display option for the G7; (3) on April 23, 2024 cleared 510(k) K240902, which updated the Bluetooth wireless communication range for the G7 from 20 feet to 33 feet; (4) on August 15, 2024 cleared 510(k) K234070 for the Stelo Glucose Biosensor System, an over-the-counter CGM for people not on insulin that is a separate product from the G7; and (5) on February 21, 2025 cleared 510(k) K243214, which extended the G7 sensor wear period to 15 days for adults. None of these 510(k) submissions involved or disclosed the change to the resistance layer material that was the subject of the Warning Letter. *See also* ¶¶ 83-90, 163, 188, 243.

412. *Second*, in the Warning Letter the FDA stated that Dexcom was in violation of the Act because it had commercially distributed the adulterated G7 "without submitting a new premarket notification to FDA, as required by Section 510(k) of the Act." *See* ¶ 216.

413. *Third*, far from disclosing the material change and obtaining approval, in the 510(k) submissions noted above Dexcom typically falsely represented to the FDA that the subject device is "***as safe and effective as the predicate device and does not raise different questions of safety and effectiveness***." It also stated that the new G7 was "***physically identical to the predicate Dexcom G7 CGM system***," that the "subject device shares ***identical hardware, material, chemical composition, principle of operation and energy source with the predicate device***," and that the G7's sensor's "***materials, hardware components, and packaging are identical*** to those of the predicate device." It also stated, for example in the April 2024 510(k): "Nonclinical testing results … support that the device … ***is as safe and effective*** as the predicate device." *See* ¶¶ 86, 163.

414. Statements #18-#21 and #23-#24 are properly attributed to Defendant Sayer because, as Dexcom's CEO, he had ultimate authority over the contents of those statements and because he routinely spoke about regulatory issues affecting Dexcom. For example, during his opening remarks for Dexcom's May 1, 2025 Q1 2025 Earnings Call, Defendant Sayer stated "I would also like to address the [W]arning [L]etter that our company received from the FDA in March. This letter was related to observations made by the agency following the inspections of our San Diego and Mesa facilities during 2024. We take any FDA recommendations very seriously." Moreover, investors would expect that the CEO would have ultimate authority over the contents of and would have reviewed any comments from "management" (to whom the analysts in Statements #18-#21 and #23-#24 formally attribute those statements) about an issue as critical as the FDA Warning Letter. In fact, given the importance of the Warning Letter, and reports that the original FDA inspection set off a "corporate emergency," *see* ¶¶ 313, 322, it is implausible to believe that Dexcom made a series of statements to analysts about this key corporate development without Defendant Sayer's review and approval.

415. Statements #18-#21 and #23-#24 are also properly attributed to Defendant Leach because, as Dexcom's COO—the individual in charge of Dexcom's operations including manufacturing—he had ultimate authority over the contents of those statements and because he became Dexcom's public spokesperson with respect to the quality issues identified in the Warning Letter, as demonstrated, among others, by his speaking Statements #22, #25, and #26 herein, which are about the same topics and subject matters as Statements #18-#21, and #23-#24. *See* ¶¶ 403, 418, 420. Relatedly, it would be implausible to believe that Dexcom made a series of statements to analysts about the exact same issues as to which Defendant Leach spoke repeatedly without Defendant Leach's knowledge, review, and approval.

416. Statements #18-#21 and #23-#24 are also properly attributed to Defendant Christensen because, as Vice President of Investor Relations, he had ultimate authority over their contents and became one of Dexcom's spokespersons with respect to the issues identified in the Warning Letter. Statement #18 was attributed to Dexcom's "Investor Relations," the department he oversaw. It would be implausible to believe that Dexcom would make these statements to investors about a critical issue affecting Dexcom without Defendant Christensen's review and approval, given that he headed the Investor Relations function and spoke himself on these issues.

417. In the ensuing months, Defendants continued to mislead the public about the FDA's findings and the accuracy issues that the agency uncovered, including after an August 25, 2025, third-party survey reported on "accuracy issues" with the G7.

418. **Statement #25.** On July 21, 2025, Defendant Leach spoke with the podcast *Diabetech* in an interview titled *Dexcom Exec Interview: Sensor Failures, Recalls, and The Future of CGM*. During the podcast, the interviewer stated that "Dexcom had received an FDA warning letter due to a change in a mechanism you were using from a third party to your own," and "that

this resulted in less accurate sensors." When asked "what happened here and how the accuracy was affected," Defendant Leach was forced to admit that Dexcom had adulterated the G7, but otherwise pushed back, falsely asserting that there was no accuracy issue:

> ***Yeah so I think what is important to note is that there's no actual claim that the performance of the sensor isn't as accurate as the old one***. … And so while we still very much felt that what we did was appropriate, we took their feedback and said okay we won't manufacture sensors with that material until we redo a validation in the way you want to see it. ***But you know ultimately in the product of the field it was not less accurate by any means. We did show them all the things that they would want to see to be able to verify it***.

419. When the interviewer followed up and asked about whether any of the adulterated sensors made with the unapproved resistance layer material were still in circulation, Defendant Leach flatly denied there was any problem at all stating, "we're not manufacturing with [the new material] anymore, ***but there's no reason there's nothing wrong with those sensors***."

420. **Statement #26.** On September 3, 2025, at the Wells Fargo Healthcare Conference, an interviewer asked Defendant Leach about "concerns around G7 reliability and accuracy issues" stemming from the third-party survey released in late August. *See* ¶¶ 253-58. In response, Defendant Leach downplayed any accuracy or reliability problems: "So if you look at our metrics, things like warranty replacements, ***complaint rates, performance of the sensor accuracy, all of that has continued to improve over time.*** And ***we haven't seen anything that has changed that trajectory***." He continued: "***When it comes to accuracy, days of wear, all those things, we've seen nothing but improvements in that***."

421. Statements #25 and #26 were materially false and misleading, and omitted material facts.

422. Among other things, it was materially false and misleading to state that "there's no actual claim that the performance of the sensor isn't as accurate as the old one," "the product in the field it was not less accurate by any means," that "there's nothing wrong with those sensors,"

and that the "complaint rate, performance of the sensor, accuracy, all of that has continued to improve over time" or has "seen nothing but improvements," for the same reasons set forth in ¶ 406, above. Specifically: (1) contrary to Leach's assertion that there was "no actual claim" about accuracy, the FDA explicitly concluded that Dexcom's own testing showed the new material "performs worse than [the old material] for accuracy" and that the "larger inaccuracies" in sensors coated with the new material "cause higher risks for users who rely on the sensors to dose insulin or make other diabetes treatment decisions," and the Warning Letter also discussed whether Dexcom was properly testing for "accuracy in the presence of acetaminophen," noted that Dexcom's failure to monitor the test dishes was "likely to have … impact on glucose reading accuracy," and that sensors not tested in low-oxygen environments meant "users may be able to view the inaccurate CGM readings and make inappropriate diabetes management decisions" ; (2) the FDA found that Dexcom's various own studies to validate the new material failed—specifically, "several of [Dexcom's] primary endpoints" used to establish the equivalence between the original and the adulterated G7 "were not met," and internal Dexcom data showed that "every accuracy metric of sensors" built with the new material "was worse" than sensors built with the original material, and that a third study had showed "large inaccuracies" in the adulterated sensors, which "cause higher risks for users who rely on the sensors to dose insulin"; and (3) contrary to Leach's claim that "there's nothing wrong with those sensors," the FDA determined that the G7 devices were "adulterated" because Dexcom had changed a critical component without regulatory approval, and that Dexcom's design, manufacturing, validation, and testing processes were so deficient that Dexcom was unable to reliably manufacture and test devices to ensure that they met its stated accuracy metrics. *See also* ¶¶ 166-73, 188-200, 207-30.

423. Statement #26 is also materially false and misleading for the independent reason that complaints regarding the G7 spiked following the introduction of the new sensor material in December 2023 and remained elevated—and even increased—throughout the Class Period, such that Dexcom could not truthfully claim to have not "seen nothing but improvements" in complaints and accuracy rates. *See also* ¶¶ 93-102, 260-64.

C. False Statements Concerning Dexcom's Quality Assurance and Compliance Programs

424. Defendants also made misleading statements concerning Dexcom's purportedly stringent quality control standards and its compliance with federal regulations.

425. **Statement #27.** On April 3, 2024, Defendants issued a 2023 Annual Sustainability Report, with an opening letter to Dexcom's "stakeholders" from Defendant Sayer. The report stated, "***We maintain a robust global Quality Management System (QMS) in compliance with applicable US and international regulatory requirements. This includes compliance with key regulations and standards like the FDA Quality System Regulation (QSR)***."

426. Statement #27 was materially false and misleading, and omitted material facts.

427. It was materially false and misleading to state that Dexcom maintained a "robust" Quality Management System that was "in compliance" with U.S. regulations, including the QSR, because at the time of this statement Dexcom's manufacturing processes did not meet U.S. regulatory requirements and standards in multiple respects, as set forth in detail above. *First*, Dexcom secretly changed a critical component in its G7 sensors without FDA approval. This adulteration meant Dexcom's manufacturing facilities and controls were not in conformity with the QSR at 21 C.F.R. Part 820, 21 C.F.R. ¶ 820.30(i). *See* ¶¶ 74-82, 212-16.

428. *Second*, Dexcom violated regulations requiring it to "maintain sufficient "design controls" in accordance with good manufacturing practices, and regulations requiring proper

documentation and validation of design inputs. *See* 21 C.F.R.§§ 820.30(c), (d), (g), and (i). Dexcom initially did not document the MARD specifications it used as the input and, with respect to glucose sensitivity, Dexcom documented the initial input, but not the requirements for the 10.5-day wear period. Later, in response to FDA pressure, Dexcom began using a MARD design input for the G7 associated with *the G6's* clinical study and began documenting certain design inputs but only set a maximum acceptable MARD as the critical design specification. None of these changes fixed the design input problems. The FDA accordingly concluded Dexcom violated applicable QSR provisions. *See* ¶¶ 110-17, 218-22.

429. *Third*, as the FDA found, Dexcom failed to establish adequate manufacturing controls and testing procedures as required under 21 C.F.R. §§ 820.75(a) and (b). Most saliently, Dexcom was not monitoring the concentrations of glucose in the solutions used to test the finished sensors. Dexcom also recorded a "pass" or "fail" result for each CGM but did not preserve any of the underlying data—such as the measurement of MARD and the glucose sensitivity slope. This "failed to demonstrate" that the sensors were "capable of producing repeatable and reproducible" accuracy data in violation of applicable QSR provisions. *See* ¶¶ 120-123, 128, 223-25.

430. *Fourth*, as the FDA found, Dexcom violated QSR provisions requiring manufacturers to maintain sufficient controls for their "design outputs." *See* 21 C.F.R. § 820.30(d). Dexcom was shipping sensors with thicknesses that Dexcom had not individually verified even though Dexcom had set acceptable thickness parameters within an extremely wide range. Dexcom's own Process Engineering Director admitted to FDA investigators that sensors produced at the edge of these allowable ranges "will likely exhibit non-conformities." *See* ¶¶ 124-28, 227.

431. *Fifth*, as the FDA found, Dexcom failed to implement adequate CAPA procedures as required under 21 C.F.R. § 820.100(a). When Dexcom discovered that dissolved oxygen content

in its manufacturing process was outside of specification—a condition that can cause inaccurate glucose readings—Dexcom's own investigation revealed additional problems with low-oxygen environment testing. Yet Dexcom decided to ship sensors that had not been tested in low-oxygen environments. *See* ¶¶ 129-35, 228-29.

432. *Sixth*, as the FDA found, Dexcom had not adequately assessed the risks posed to patients using Dexcom's CGM's with automated insulin dosing systems. This failure violated regulations requiring adequate procedures to ensure that devices conform to defined user needs and intended uses, as required under 21 C.F.R. § 820.30(g). *See* ¶¶ 136-39, 230.

433. **Statement #28.** On February 18, 2025, Dexcom filed the Dexcom 2024 10-K, signed by Defendants Sayer and Sylvain. Despite receiving the June and November 2024 Form 483s and being formally notified of the myriad regulatory violations at Dexcom's facilities, the Dexcom 2024 10-K stated, "***We are committed to quality and believe that is best achieved through a safe and healthy workplace as well as a Quality Management System that is compliant with all applicable regulatory requirements and which is continuously being improved.***"

434. Statement #28 was materially false and misleading, and omitted material facts.

435. It was materially false and misleading to represent that Dexcom believed that its QMS was "compliant with all applicable regulatory requirements and which is continuously being improved," because, at minimum, that statement did not fairly align with the information in Defendants' possession or reasonably available to Defendants. Indeed, at the time of this statement, the FDA had repeatedly informed Defendants that Dexcom's manufacturing processes did not meet U.S. regulatory requirements and standards in multiple respects, as set forth in ¶¶ 427-32 above.

D. False Statements Concerning Risks to Dexcom's Business

436. During the Class Period, Defendants knowingly or recklessly made materially false and misleading statements concerning the business risks facing Dexcom, including the statements set forth below. Dexcom misleadingly presented these risks as hypothetical and contingent, when in fact the risks had already come to pass.

437. **Statement #29.** On February 8, 2024, Dexcom filed the Dexcom 2023 10-K, which was signed by Defendants Sayer and Sylvain and was made available on Dexcom's website.

438. The Dexcom 2023 10-K included numerous hypothetical risk factors affecting the Company's business, including:

- "***[A]ny changes to our manufacturing processes may trigger the need for submissions or notifications to, and in some cases advance approval from, the FDA or other regulatory authorities because of the potential impact of changes on our previously cleared, approved and/or authorized devices***. Our facilities are subject to inspections by the FDA and corresponding state and international agencies on an ongoing basis, and we must comply with Good Manufacturing Practices and the FDA Quality System Regulation, as well as certain state requirements. ***We may be unable to adequately maintain, develop and expand our manufacturing process and operations or maintain compliance with FDA and state and international agency requirements***";
- "Any subsequent modifications of our cleared products that could significantly affect their safety or effectiveness (for example, a significant change in design or manufacture), or that would constitute a major change in its intended use, ***will require us to obtain a new 510(k) clearance*** or could require a new de novo

submission or a PMA. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer's determination. ***If*** the FDA disagrees with a manufacturer's determination, the FDA ***may*** require the manufacturer to cease marketing and/or recall the modified device until appropriate clearance or approval is obtained";

- "The commencement or completion of any of our clinical trials ***may*** be … inadequate to support approval of FDA marketing applications or supplements, for numerous reasons, including, but not limited to, the following: regulatory inspections of our clinical trials or manufacturing facilities may results [sic] in allegations or findings of noncompliance and, among other things, require us to undertake corrective action[;] … the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and the FDA concludes that the results from our trial and/or trial design are inadequate to demonstrate safety and effectiveness of the product"; and
- "We conduct business in a heavily regulated industry and ***if we fail to comply with applicable laws and government regulations, we could*** become subject to penalties, be excluded from participation in government programs, and/or ***be required to make significant changes to our operations***."

439. **Statement #30.** On April 25, 2024, Dexcom filed its Quarterly Report (Form 10-Q) for the quarter ending March 31, 2024, which Defendants Sylvain and Sayer signed, where it incorporated by reference the risk factors set forth in Statement #29 above.

440. Statements #29-#30 were materially false and misleading, and omitted material facts.

441. It was misleading to state the foregoing risks as hypothetical issues that "could" or "may" happen, or to discuss a potential need to submit a 510(k) for a new product, because the hypothetical issues that Dexcom purportedly warned investors could or may happen, had in fact, already come to pass—including the need to make a new 510(k) submission for the adulterated G7. Moreover, Dexcom's hypothetical statements that there could be "changes to our manufacturing processes" or "modifications to cleared products that could significantly affect their safety and effectiveness" that would require a new 510(k) or other FDA approval, had in fact already occurred. The statement that Dexcom "***may*** be unable to … maintain compliance with FDA … requirements" was materially false and misleading for the same reason. By December 13, 2023, Dexcom had already made a significant change to the resistance layer of its sensors and substituted in a new nonconforming material that made the G7 sensor less accurate and had already triggered the need for a submission or notification to the FDA, and Dexcom had already failed to maintain compliance with FDA requirements. Moreover, Defendants had already adulterated the G7 in violation of FDA requirements and Defendants' manufacturing facilities had already lapsed into numerous quality control failures and regulatory violations.

442. It was similarly materially misleading for Dexcom to state that "[a]ny subsequent modifications" of its "cleared products" "will require [Dexcom] to obtain a new 510(k) clearance," without also disclosing that Dexcom had already made such a modification to its cleared product while failing to obtain the required clearance.

443. Similarly, the statements that "data obtained from the studies and trials may be inadequate to support approval" and "commencement or completion of any of our clinical trials

may be … inadequate to support approval" were materially misleading because these things had already occurred. Prior to instituting the change in sensor material, Dexcom had already conducted clinical trials and gathered data showing that the new in-house material was inferior and not equivalent to the old supplier-based sensor material, rendering that data inadequate to support their approval by the FDA. *See* ¶¶ 80-82, 189-90, 213-14.

444. Further, the statement that Dexcom would be subject to penalties or be required to change its operations "if" it failed to comply with applicable laws and government regulations was materially false and misleading, and omitted material facts, because, for the reasons set forth herein, Dexcom already was in violation of those requirements.

445. **Statement #31.** On July 25, 2024, Dexcom filed its Quarterly Report (Form 10-Q) for quarter ending June 30, 2024, which Defendants Sayer and Sylvain signed, where it incorporated by reference the risk factors set forth in the Dexcom 2023 Form 10-K, including those set forth in Statement #29 above.

446. **Statement #32.** On October 24, 2024, Dexcom filed its Quarterly Report (Form 10-Q) for quarter ending September 30, 2024, which Defendants Sayer and Sylvain signed, where it incorporated by reference the risk factors set forth in the Dexcom 2023 Form 10-K, including those set forth in Statement #29 above.

447. **Statement #33.** On February 18, 2025, Dexcom filed the Dexcom 2024 10-K, which Defendants Sayer and Sylvain signed, where it repeated verbatim the relevant risk factors set forth in Statement #29 above.

448. Statements #31-#33 were materially false and misleading and omitted material facts for the same reasons as Statements #29-#30, as set forth above in ¶¶ 441-44.

449. Statements #31-#33 were also materially false and misleading, and omitted material facts, for the additional, independent reason that stating as a hypothetical that "the government … ***could*** … challenge our practices," and "***if*** we fail to comply with applicable laws and government regulations, we ***could*** be required to make significant changes to our operations" was materially misleading because as of those dates the FDA ***had already*** issued the June 2024 Forms 483 and ***had already*** notified Dexcom that its manufacturing processes did not meet regulatory requirements, and ***had already*** challenged Dexcom's practices, and ***had already*** required or resulted in corrective action and significant changes to Dexcom's operations. *See* ¶¶ 166-73.

450. Statement #33 was also materially false and misleading, and omitted material facts, for the additional, independent reason that the FDA ***had already*** issued the November 2024 Form 483, notifying Dexcom of several more manufacturing processes that did not meet regulatory requirements and required corrective action, and which led to Dexcom ceasing manufacturing the G7 with the adulterated material. *See* ¶¶ 187-200. Statement #33, couching as a hypothetical what would happen "***if*** the FDA disagrees" with Dexcom's actions, including that "the FDA ***may*** require [us] … to cease marketing and/or recall the modified device until appropriate clearance or approval is obtained" or "the FDA ***may*** request additional clinical data," or "clinical trials ***may*** be … inadequate … [if] the FDA concludes that the results from our trial and/or trial design are inadequate to demonstrate safety and effectiveness of the product," was materially misleading and omitted material facts because these things had all already in fact occurred. The FDA had already issued the November 2024 Form 483 finding that Dexcom failed to verify and validate a change to the material used in the manufacture of the G7 sensor. The FDA had further found by the November 2024 Form 483 that Dexcom's clinical data did not support the efficacy of the new material. Moreover, by no later than January 10, 2025, Dexcom had already been required to

supply the FDA with additional clinical data and had ceased all manufacturing and distribution of the G7 sensor with the new, inferior material.

X. LOSS CAUSATION

451. Defendants' fraud, as alleged herein, directly and proximately caused the economic losses under the federal securities laws, i.e., damages suffered by Lead Plaintiff and the Class. There was a causal connection between Defendants' fraud and the losses described herein.

452. Throughout the Class Period, Lead Plaintiff and the members of the Class purchased or otherwise acquired Dexcom common stock at artificially inflated prices and were damaged when Dexcom's stock price declined in response to the partial disclosures. Dexcom's stock was or remained artificially inflated because of Defendants' materially false and misleading statements and omissions and Defendants' scheme to defraud.

453. The artificial inflation in Dexcom's stock price was removed—and Dexcom's stock price significantly declined, causing investors to suffer extensive losses—when the facts and/or conditions concealed from investors by Defendants' material misrepresentations and omissions and scheme to defraud were revealed to the market in a series of partial disclosures concerning or connected to the facts misrepresented or concealed by Defendants and to Defendants' scheme to defraud. These partial disclosures occurred on: (1) July 25, 2024, when Dexcom announced disappointing second quarter results for the second quarter of fiscal year 2024 and lowered its earnings guidance for the full 2024 year; (2) March 7, 2025, when Dexcom revealed through a Form 8-K filed with the SEC that it had received the Warning Letter from the FDA; (3) March 25, 2025, when the FDA published the Warning Letter; (4) August 25, 2025, when a third party survey of DME providers reported on ongoing quality problems with the G7; and (5) September 18, 2025, when Hunterbrook Media published the Hunterbrook Report.

454. *First*, on July 25, 2024, after market close, Dexcom announced disappointing results for the second quarter of 2024, approximately 3.13% below expectations, and was forced to lower its full-year revenue guidance by approximately $300 million, from $4.20-$4.35 billion to $4.00-$4.05 billion. Through this disclosure, the consequences of Dexcom compromising on product accuracy and manufacturing controls (i.e., slowing sales resulting from fewer patients trusting the G7's accuracy) began to come to light. As discussed above, Dexcom's CGM business was its entire line of business, and the G7 was its most important product, including during the second quarter of 2024. When Dexcom adulterated the G7 sensor's resistance layer, it significantly and negatively impacted the device's accuracy and, in so doing, materially impacted the principal reason certain patients had preferred Dexcom's products over its competitors' and the linchpin of Dexcom's strategy to penetrate new populations in the market. As a result, Dexcom's sales began to slow and it was forced to lower its earnings guidance.

455. Analysts were surprised by this news and disappointed by the results. Analysts at UBS in a July 25, 2024 Analyst Report stated that the results were "a major surprise," Barclays analysts, on that same day, similarly noted the news had "surprised investors," and Wolfe Research analysts said they felt "[n]umb" at the "current state" of the Company. Immediately following this news, Dexcom's common stock price plummeted by more than 40%—the steepest decline in Company history—from a closing price of $107.85 per share on July 25, 2024, to a closing price of $64.00 on July 26, 2024, on trading volume that was over ten times higher than the average daily trading volume for the prior week.

456. While this corrective disclosure began to dissipate some of the inflation in Dexcom's stock, it did not dissipate all of it or reveal the full truth. In fact, Defendants made additional materially misleading statements after this disclosure, including falsely attributing the

revenue miss and guidance cut to salesforce issues and later describing the results as an "execution issue." Moreover, Defendants continued publicly falsely referring to the G7 as the "most accurate" CGM, including in advertisements and during subsequent earnings calls with investors. Accordingly, and including because of these additional misstatements, Dexcom's stock price remained artificially inflated following the July 25, 2024 corrective disclosure.

457. *Second*, on March 7, 2025, after market close, Dexcom revealed through a Form 8-K filed with the SEC that it had received the Warning Letter from the FDA "following inspections of the Company's facilities in San Diego, California, and Mesa, Arizona." While Dexcom did not disclose the letter's contents, Dexcom stated that the "warning letter describes observed non-conformities in manufacturing processes and quality management system." Thus, this news also revealed facts previously unknown to the market, including the FDA's issuance of two Form 483s, and made the market aware for the first time that Dexcom was facing serious regulatory scrutiny in the form of a Warning Letter.

458. Investors were surprised by this news. On March 9, 2025, BTIG analysts, for example, noted their "surprise," while an analyst on that same day at Wolfe Research noted feeling "[f]rustrated" because the Warning Letter "draws fresh blood" after the "whiff" Dexcom revealed in the July 25, 2024 disclosure. The following trading session, March 10, 2025, Dexcom's common stock declined by more than 9%, from a closing price of $77.84 per share on Friday, March 7, 2025, to a closing price of $70.72, on trading volume that was nearly twice as high as the average daily trading volume for the prior week.

459. While this corrective disclosure dissipated some of the inflation in Dexcom's stock, it did not fully dissipate the inflation or reveal the full truth. In fact, Defendants made additional materially misleading statements after this disclosure, including falsely telling analysts that the

issues identified by the FDA "have nothing to do with product quality." Analysts credited this explanation in concluding that Dexcom would be able to resolve the issues identified by the FDA with "minimal" impact. For example, BTIG analysts commented that while they were "surprised by the news," they expected Dexcom to "resolve the issue with little impact to commercial or regulatory operations." Raymond James analysts commented that, while the Warning Letter was "not ideal," the "conversation with management … gives us comfort that this is not a product quality issue." On March 10, 2025, Oppenheimer analysts wrote: "We caught up with management … we don't believe any issues of product/patient safety were noted." Moreover, Defendants continued publicly falsely referring to the G7 as the "most accurate" CGM, including in advertisements and during subsequent earnings calls with investors. Accordingly, and including because of these additional misstatements, Dexcom's stock price remained artificially inflated following the March 7, 2025 corrective disclosure.

460. ***Third,*** on March 25, 2025, during market hours, the FDA published the Warning Letter, revealing its contents to the public for the first time. The information the FDA disclosed for the first time included that Dexcom was selling an "adulterated" version of its flagship product, the G7 CGM, after Dexcom had replaced a "component used in the resistance layer of [its] sensors" without premarket approval. The Warning Letter also revealed that Dexcom conducted studies to demonstrate the equivalence of the adulterated sensors to the old ones but had instead only shown the adulterated sensor "performs worse ... for accuracy." The Warning Letter also described the extensive problems that the FDA had identified in Dexcom's manufacturing process for the G7, including that Dexcom was arbitrarily setting acceptable MARD levels without documentation and was testing the G7's accuracy without adequately monitoring or controlling the concentrations of critical substances needed to conduct this accuracy verification process in a reliable way.

461. However, before the Warning Letter became public, Dexcom took preemptive steps to minimize its impact on the market. For example, during an industry conference from March 19 to 22, 2025, Defendant Leach falsely explained that the Warning Letter was nothing more than the FDA telling Dexcom that the FDA still had some "questions" that were "open that we need to work together on" with respect to Dexcom's design and production processes. Similarly, on March 25, 2025, as the Warning Letter became public, two analysts reported on information provided to them by Dexcom executives, including false and misleading statements from Dexcom that the Warning Letter did not relate to G7 "quality" issues and that Dexcom had received approval from the FDA for the change to the G7's sensor material.

462. Dexcom's efforts to minimize the impact of the Warning Letter and mislead the market in the days immediately before and immediately after the Warning Letter was revealed to the public, did have a dampening and delaying effect on the stock price reaction. Nevertheless, the market took note of the FDA's determinations and reacted negatively to the news. From March 25 through March 28, 2025, Dexcom's stock price slid more than 10%, falling from the previous close of $75.32 to $67.74.

463. While this corrective disclosure dissipated some of the inflation in Dexcom's stock, it did not dissipate all of it or reveal the full truth. In fact, Defendants made additional materially misleading statements after this disclosure. These included falsely asserting that Dexcom had properly disclosed the new material to the FDA in its 510(k) submissions (when it had not); that the FDA had cleared the new material (when it had not); telling analysts in a March 27, 2025 email by a Dexcom spokesperson that "***extensive testing showed the material met specifications***," when in fact Dexcom's own testing of the adulterated sensor showed precisely the opposite; and Defendant Leach stating in a July 21, 2025 *Diabetech* podcast that the FDA had made "no claim

that the performance of the sensor isn't as accurate as the old one." Analysts credited these explanations. Accordingly, and including because of these additional misstatements, Dexcom's stock price remained artificially inflated following the March 25, 2025 corrective disclosure.

464. *Fourth***,** according to analyst reports published contemporaneously on August 25, 2025, a third-party issued an independent survey of DME provider-companies reporting significant concerns about the G7's reliability in the field.

465. Various analysts discussed this third-party report negatively. In response to this disclosure, Dexcom's common stock declined 7.7%, from a closing price of $82.26 on August 22, 2025, the prior trading day, to a closing price of $75.96 on trading volume that was double the average daily trading value the prior week.

466. While this corrective disclosure dissipated some of the inflation in Dexcom's stock, it did not dissipate all of it or reveal the full truth. As noted, Defendants made additional materially misleading misstatements after this disclosure. This included Defendant Leach's public statement on September 3, 2025 that Dexcom had "seen nothing but improvements" in the G7's accuracy and complaint rates. As a result of the misleading response to this disclosure, Dexcom's stock price remained artificially inflated.

467. *Fifth***,** on September 18, 2025, Hunterbrook Media issued the Hunterbrook Report, entitled "Dexcom's Fatal Flaws," revealing the full extent of the G7's safety, accuracy, and reliability problems—and the full scope of the consequences of Dexcom's manufacturing failures on its user base and Dexcom itself. The Hunterbrook Report disclosed information that had never been publicly revealed before, including examples of patient deaths and hospitalizations linked to G7 failures, former employee accounts recounting a corporate culture that prioritized profits over

safety, physician reports of widespread G7 problems, and FDA complaint data showing dramatic increases in accuracy complaints following the December 2023 adulteration.

468. From September 18 to 19, 2025, following the Hunterbrook Report, Dexcom's common stock declined by approximately 12%. In total, the stock fell from a closing price of $76.44 per share on September 17, 2025 (the trading day before the report's publication), to a closing price of $67.45 on September 19, 2025—a decline of $8.99 per share, on trading volume that was three times higher than the average daily trading value the prior week. On September 19, 2025, the stock fell from a closing price of $75.78 on September 18 (when the Hunterbrook Report was published during the trading day), to a closing price of $67.45 on trading volume that was nearly five times higher than the daily trading volume in the week before the Hunterbrook Report was published.

469. It was entirely foreseeable that Defendants' materially false and misleading statements and omissions and their scheme to defraud discussed herein would artificially inflate or maintain the existing artificial inflation of Dexcom's stock price. It was also foreseeable to Defendants that the disclosures described above would cause Dexcom's stock price to fall as the artificial inflation caused by Defendants' misstatements and omissions was removed. Thus, the stock price declines described above were directly and proximately caused by Defendants' materially false and misleading statements and omissions and by their scheme to defraud.

XI. THE INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

470. The statutory safe harbor or the bespeaks-caution doctrine applicable to forward-looking statements under certain circumstances do not apply to any of the materially false and misleading statements and omissions pleaded in this Complaint.

471. None of the statements complained of herein was a forward-looking statement. Instead, each was a historical statement or a 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.

472. To the extent that any of the materially false and misleading statements alleged herein can be construed as forward-looking or that the statutory safe harbor otherwise would apply, 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.

473. 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 a Dexcom executive officer who knew that the statement was materially false or misleading when made.

474. Moreover, to the extent that Dexcom 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 that the risks that were the subject of the warnings had materialized, or that Dexcom and the other Defendants had actual knowledge of or recklessly disregarded undisclosed material adverse facts that rendered the purportedly cautionary disclosures materially false or misleading.

XII. THE PRESUMPTION OF RELIANCE

475. The Class is entitled to a presumption of reliance on Defendants' materially false or misleading statements and omissions pursuant to the fraud-on-the-market doctrine because, at

all relevant times, the market for Dexcom's common stock was efficient for the following reasons, among others:

- Dexcom common stock met the requirements for listing, and was listed and actively traded, on the NASDAQ, a highly efficient and automated market;
- Dexcom's common stock traded at high weekly volumes;
- As a regulated issuer, Dexcom filed periodic public reports with the SEC;
- Dexcom regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as public and publicized appearances at investor conferences and communications with the financial press, securities analysts, and other similar reporting services;
- Several securities analysts employed by major brokerage firms followed Dexcom and wrote reports that were distributed to the sales force and certain customers of the respective brokerage firms, and were otherwise available and entered the public marketplace; and
- There was a cause-and-effect relationship between unexpected corporate events or financial releases and movements in Dexcom's stock price.

476. As a result of the foregoing, the market for Dexcom's common stock reasonably and promptly digested current information regarding Dexcom from all publicly accessible sources and reflected such information in Dexcom's stock price during the Class Period. Under these circumstances, all purchasers of Dexcom common stock during the Class Period suffered similar

injury through their purchase of Dexcom common stock at artificially inflated prices, and a presumption of reliance applies.

477. A Class-wide presumption of reliance is also appropriate in this action under the United States Supreme Court's holding in *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 for which there is a duty to disclose. Because this action involves Defendants' failure to disclose material adverse information regarding Dexcom's business—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in that a reasonable investor might have considered them important in making investment decisions. Given the importance of the G7's accuracy to Dexcom's competitive standing and the impact regulatory action could have on Dexcom's future revenue, that requirement is satisfied here.

XIII. CLASS ACTION ALLEGATIONS

478. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(3) on behalf of the Class—all persons and entities who purchased or otherwise acquired publicly traded Dexcom common stock during the Class Period and were damaged thereby.

479. Excluded from the Class are Defendants and their immediate families, Dexcom's officers and directors at all relevant times, members of their immediate families, and Defendants' legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

480. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Dexcom's common stock actively traded on the NASDAQ stock market. As of September 30, 2025, there were approximately 390 million shares

of Dexcom shares outstanding. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are at least thousands of members of the Class. Class members who purchased Dexcom common stock may be identified from records maintained by Dexcom or its transfer agent(s) and may be notified of this class action using a form of notice like that customarily used in securities class actions. Disposition of the Class's claims in a class action will provide substantial benefits to the parties and the Court.

481. Lead Plaintiff's claims are typical of Class members' claims, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal securities laws as complained of herein.

482. Lead Plaintiff will fairly and adequately protect Class members' interests and have retained competent counsel, experienced in class actions and securities litigation. Lead Plaintiff has no interest that conflicts with the interests of the Class.

483. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of fact and law common to the Class are:

- whether Defendants' misrepresentations and omissions as alleged herein violated the federal securities laws;
- whether Defendants' scheme as alleged herein violated the federal securities laws;
- whether the Individual Defendants are personally liable for the alleged misrepresentations, omissions, and scheme described herein;
- whether Defendants' misrepresentations and omissions and fraudulent scheme

as alleged herein caused the Class members to suffer a compensable loss; and

- whether the members of the Class have sustained damages, and the proper measure of damages.

484. A class action is superior to all other available methods for the fair and efficient adjudication of this action. Joinder of all Class members is impracticable. Additionally, the damages suffered by some individual Class members may be relatively small, such that the burden and expense of individual litigation would make it practically impossible for those such members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XIV. CLAIMS FOR RELIEF

COUNT ONE

For Violations of Section 10(b) of the Exchange Act and SEC Rules 10b-5(b)
(Against All Defendants)

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

486. During the Class Period, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) issued thereunder, by making untrue statements of material fact or omitting to state material facts necessary to make their statements, in light of the circumstances under which they were made, not misleading. Defendants' actions: (i) deceived the investing public, including Lead Plaintiff and other Class members, as alleged herein; and (ii) caused Lead Plaintiff and other Class members to purchase Dexcom common stock at artificially inflated prices.

487. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, intentionally or with reckless disregard for the truth, made various untrue and/or misleading statements of material fact 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, in connection with the purchase or sale of securities, which did: (i) deceive the investing public, including Lead Plaintiff and the Class, regarding, among other things, the accuracy and quality of the G7, the regulatory approval status of the adulterated G7, the reasons for earnings misses, the status of Dexcom's quality assurance program, the nature and extent of the FDA's concerns regarding the manufacturing process and validation for the G7, and the nature and existence of risks facing the Company as a result of these matters; (ii) artificially inflate and maintain the market price of Dexcom's common stock; and (iii) cause Lead Plaintiff and other members of the Class to purchase Dexcom common stock at artificially inflated prices and suffer losses when the true facts became known.

488. The Individual Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein or were reckless in not knowing the true facts that were available to them. Defendants engaged in this misconduct to conceal Dexcom's true condition from the investing public and to support the artificially inflated prices of Dexcom's common stock. The Individual Defendants' state of mind is imputed to Dexcom.

489. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Dexcom's common stock. Lead Plaintiff and the Class would not have purchased Dexcom's common stock at the prices they paid, or at all, had they been aware that the market prices for Dexcom's common stock had been artificially inflated by Defendants' fraudulent course of conduct.

490. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their respective purchases of Dexcom's common stock during the Class Period.

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

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

COUNT TWO

For Violations of Section 10(b) of the Exchange Act and SEC Rules 10b-5(a), (c) (Against All Defendants)

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

494. During the Class Period, Defendants devised a plan to deceive and induced Lead Plaintiff and members of the Class to purchase Dexcom common stock without disclosing to them material facts that reasonably could have been expected to influence their decisions to purchase, and they violated Section 10(b) of the Exchange Act and Rule 10b-5(a)-(c) issued thereunder, in that Defendants: (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 Plaintiff and the Class.

495. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, intentionally or with reckless disregard for the truth, employed devices, schemes, and artifices to defraud and engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of Dexcom's common stock, which did (i) deceive the investing public, including Lead Plaintiff and the Class, regarding, among other things, the accuracy and quality of the G7, the regulatory approval status of the adulterated G7, the reasons for earnings misses, the status of Dexcom's quality assurance program, the nature and extent of the FDA's concerns regarding the

manufacturing process and validation for the G7, and the nature and existence of risks facing the Company as a result of these matters; (ii) artificially inflate and maintain the market price of Dexcom's common stock; and (iii) cause Lead Plaintiff and other members of the Class to purchase Dexcom common stock at artificially inflated prices and suffer losses when the true facts became known.

496. As part of their scheme to defraud investors in violation of Exchange Act Section 10(b) and Rules 10b-5(a) and (c) issued thereunder, Defendants:

- adulterated the resistance layer of the G7's sensor;
- commercially distributed the adulterated G7 while knowing that the adulterated device's accuracy was lower than the accuracy of the device they had obtained FDA approval for;
- failed to make the required regulatory submissions to manufacture and distribute the adulterated device;
- affirmatively misled the FDA about the G7's status in regulatory submissions;
- instructed employees to conceal manufacturing issues from the FDA;
- took steps to obscure independently identified problems with the G7's manufacturing processes, and shipped non-conforming G7s;
- made additional false and misleading statements to equity analysts, the investing public, and members of the diabetes care community about the contents and significance of key corporate developments, such as their earnings miss for the second quarter of 2024 and the Warning Letter and its contents and potential consequences, to prevent the full truth from being revealed; and
- failed to implement design and manufacturing controls in conformance with

applicable regulatory standards, which Defendants knew or recklessly disregarded made them unable to reliably (i) assess the accuracy of the G7s they sold to the public, and (ii) produce G7s according to Defendants' own accuracy metrics.

497. As described above, 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, or acted with intent to deceive. Defendants engaged in this misconduct to conceal Dexcom's true condition from the investing public and to support the artificially inflated prices of Dexcom's common stock. The Individual Defendants' state of mind is imputed to Dexcom.

498. Lead Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Dexcom's common stock, which artificial inflation was removed from the stock when the true facts became known. Lead Plaintiff and the Class would not have purchased Dexcom's common stock at the prices they paid, or at all, had they been aware that the market prices for Dexcom's common stock had been artificially inflated by Defendants' fraudulent course of conduct. It was also foreseeable to Defendants that misrepresenting and concealing these material facts from the public and engaging in a scheme to defraud the public would artificially inflate Dexcom's common stock's price and that the revelation of the truth would correct the artificial inflation and cause the price of Dexcom's common stock to decline.

499. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases of Dexcom's common stock during the Class Period.

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

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

COUNT THREE

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

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

503. The Individual Defendants each acted as a controlling person of Dexcom within the meaning of Section 20(a) of the Exchange Act, as alleged herein.

504. By reason of their high-level positions of control and authority as Dexcom's most senior officers, the Individual Defendants had the authority to influence and control, and did influence and control, the decision-making and activities of Dexcom and its employees, and to cause Dexcom to engage in the wrongful conduct complained of herein. The Individual Defendants were able to influence and control, and did influence and control, directly and indirectly, the content and dissemination of the public statements made by Dexcom during the Class Period, thereby causing the dissemination of the materially false and misleading statements and omissions of material fact as alleged herein. Individual Defendants Sayer, Sylvain, Leach, and Christensen were virtually the exclusive Dexcom officers who communicated with investors on earnings calls and at investor conferences on Dexcom's behalf. The Individual Defendants were provided with, or had unlimited access to, copies of Dexcom's press releases, public filings, and other statements alleged by Lead Plaintiff to be misleading prior to and/or shortly after those statements were made

and had the ability to prevent the issuance of the statements or to cause the statements to be corrected.

505. As set forth above, Dexcom violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint.

506. By virtue of their positions as a controlling person of Dexcom and as a result of their own aforementioned conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as, Dexcom is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, to Lead Plaintiff and the other members of the Class who purchased or otherwise acquired Dexcom common stock. As detailed above, during all relevant times; Defendant Sayer served as Dexcom's CEO and Chairman of its Board for most of the Class Period; Defendant Leach served as Dexcom's COO for most of the Class Period and also served as its interim CEO; Defendant Sylvain served as Dexcom's CFO throughout the Class Period; and Defendant Christensen was Dexcom's Vice President of Finance and Investor Relations throughout the Class Period.

507. As a direct and proximate result of the Individual Defendants' conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchase or acquisition of Dexcom common stock.

XV. PRAYER FOR RELIEF

508. WHEREFORE, Lead Plaintiff prays for judgment as follows:

- Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure on behalf of the Class defined herein;
- Awarding compensatory damages in favor of Lead Plaintiff and the Class against Defendants, jointly and severally, for all damages sustained as a result

of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

- Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and
- Awarding such equitable, injunctive or other further relief as the Court may deem just and proper.

XVI. JURY DEMAND

509. Lead Plaintiff hereby demands a trial by jury.

Dated: April 10, 2026

/s/ *Jorge G. Tenreiro*
Jorge G. Tenreiro

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