

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

GARY HORN, individually and on behalf of all others similarly situated, Plaintiff, v. ABBOTT LABORATORIES and ABBOTT DIABETES CARE, INC., Defendants.	Case No. 1:26-cv-10711 <u>CLASS ACTION COMPLAINT</u> JURY TRIAL DEMANDED
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Plaintiff Gary Horn, (“Plaintiff”), individually and on behalf of all others similarly situated, brings this Class Action Complaint against Abbott Laboratories and Abbott Diabetes Care, Inc. (collectively “Abbott” or “Defendants”). Plaintiff makes the following allegations upon personal knowledge as to his own acts, and as to all other matters upon information and belief, based upon the investigation made by the undersigned attorneys, as follows:

INTRODUCTION

1. This consumer class action arises from Abbott’s systematic concealment of critical manufacturing defects in its FreeStyle Libre 3 and FreeStyle Libre 3 Plus sensors (the “Libre 3 Sensors” or “Sensors”) associated with Abbott’s FreeStyle Libre 3 Continuous Glucose Monitoring System (“FreeStyle CGM” or “FreeStyle Libre 3 System”). The FreeStyle Libre 3 System includes the Libre 3 Plus Sensor, Libre 3 Sensor, Libre app, and the Libre 3 Reader—an integrated system sold and marketed together. Abbott concealed these critical manufacturing defects while simultaneously making false and misleading representations regarding the accuracy, reliability, and safety of these medical devices.

2. Abbott manufactured, marketed, distributed, and sold defective glucose monitoring sensors that provided dangerously incorrect low glucose readings to diabetes patients, Plaintiff and Class Members, who relied upon these devices to make potentially life-or-death treatment decisions regarding insulin administration and carbohydrate intake. Despite knowledge of the defects, Abbott continued to aggressively market its FreeStyle CGM as the “most accurate” CGM available—a representation Abbott knew to be materially false and misleading. Rather than investigate complaints, warn consumers, correct the Sensor, or halt distribution, Abbott made the calculated decision to continue selling defective Libre 3 Sensors, choosing profits over patient safety.

3. Consumers, including Plaintiff and the other Class Members, paid a substantial premium for the FreeStyle CGM and Libre 3 Sensors based on Abbott’s misrepresentations and omissions, only to receive Sensors that were unreliable, failed to perform as promised, were subject to government recall and subsequent warning letter documenting Defendants’ continued failure to correct its manufacturing processes, and posed and continue to pose a serious safety risk. Abbott’s conduct violates multiple consumer protection and warranty statutes.

4. Each purchaser of a FreeStyle CGM unwittingly paid for a device with undisclosed and significant safety risks. These purchasers were damaged in that they paid more for the FreeStyle Libre 3 System and Sensors than they would have paid had they known about the safety, reliability, and accuracy issues with the Libre 3 Sensors.

5. Plaintiff seeks damages, restitution, and other remedies on behalf of himself and the proposed Class.

JURISDICTION AND VENUE

6. Plaintiff incorporates by reference all allegations of the preceding paragraphs as though fully set forth herein.

7. This Court has subject-matter jurisdiction under the Class Action Fairness Act of 2005 (“CAFA”), 28 U.S.C. § 1332(d), because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and costs, there are more than 100 Class Members, and at least one class member is a citizen of a state different from Defendants’.

8. This Court has personal jurisdiction over Defendants. Defendant Abbott Laboratories maintains its principal place of business in Abbott Park, Illinois, within this District, and Defendants purposefully directed marketing, sales, and post-market activities for the FreeStyle CGMs from and into this District. Plaintiff’s claims arise, in substantial part, from Defendants’ conduct originating from and occurring in this District, including decisions regarding labeling, warnings, quality systems, and recalls. Exercising jurisdiction over Defendants does not offend traditional notions of fair play and substantial justice.

9. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events and omissions giving rise to the claims of Plaintiff and the other Class Members occurred within this District, Defendant Abbott Diabetes Care Inc. resides in this District, and Defendants are subject to the Court’s personal jurisdiction here.

THE PARTIES

Plaintiff Gary Horn

10. Plaintiff Gary Horn is an individual and a citizen of the State of Connecticut, and a resident of West Hartford, Connecticut. Mr. Horn, a Type 2 diabetic, initially purchased the FreeStyle CGM in mid-2024 to monitor his blood glucose levels and help manage and control his diabetes. As part of his ongoing diabetes maintenance and use of the FreeStyle CGM, Mr.

Horn purchased and used Libre 3 Plus Sensors. Mr. Horn ceased using the FreeStyle CGM and corresponding Sensors upon learning of the defects and FDA recall.

11. Prior to purchasing the FreeStyle CGM, Mr. Horn saw advertising materials, including online advertisements, product videos, and statements on Defendants' website, which represented that the FreeStyle CGM was the most accurate continuous glucose monitor available, required no fingersticks, provided reliable real-time alerts, and offered improved safety and convenience over prior models. Immediately after receiving his FreeStyle CGM, but before using it, he reviewed the package insert, which provided him with more information about the product.

12. Had those advertisements and any other materials or statements Mr. Horn saw or heard not omitted that the Libre 3 Sensors were defective, inaccurate, at risk of critical alert failures, and adulterated, as later confirmed by the FDA's recalls, warning letter, and other determinations, he would not have purchased the FreeStyle CGM, would not have paid as much for it as he did, and/or would not have been required to continue purchasing the corresponding Libre 3 Plus Sensors.

13. Relying on these misrepresentations and omissions, Mr. Horn purchased the FreeStyle CGM. At the time Mr. Horn purchased his FreeStyle CGM, he paid a price based on the value of such a device free of such a defect. Mr. Horn thus suffered economic injury because he paid more for the FreeStyle CGM than he would have paid and/or paid more for the Libre 3 Sensors than he would have paid had the defects been disclosed.

14. As a result, Mr. Horn has experienced dangerously inaccurate glucose readings when compared to actual fingerstick measurements and failed alerts.

Defendants

15. Defendant Abbott Laboratories is an Illinois corporation, originally founded in Chicago in 1888 and incorporated in Illinois, with its current global headquarters located at 100 Abbott Park Road, Abbott Park, Illinois.

16. Defendant Abbott Diabetes Care, Inc. is a Delaware corporation with its principal place of business in Alameda, California.

17. At all relevant times, Defendants engaged in substantial business throughout the United States and within this District.

18. At all relevant times, Defendants were engaged in the business of designing, manufacturing, developing, preparing, processing, inspecting, testing, packaging, promoting, marketing, distributing, labeling, or selling for profit, either directly or indirectly, through an agent, affiliate, predecessor, or subsidiary, the FreeStyle CGMs.

COMMON FACTUAL ALLEGATIONS

A. THE CRITICAL ROLE OF ACCURATE GLUCOSE MONITORING

19. Diabetes is a chronic disease affecting over 40 million Americans, characterized by the body's inability to properly produce or respond to insulin, resulting in dangerous fluctuations in blood glucose levels. An estimated 115.2 million U.S. adults have prediabetes.¹

20. In order to effectively manage and/or control diabetes, both Type 1 and Type 2 diabetics must closely monitor and manage their blood glucose levels through exercise, diet, and medications, and must also supply their bodies with appropriate amounts of insulin based on daily routines.

¹ United States Diabetes Surveillance System, *National Diabetes Statistics Report*, CDC, <https://gis.cdc.gov/grasp/diabetes/diabetesatlas-statsreport.html> (showing the estimated number of diagnosed and undiagnosed diabetes in 2023).

21. Many diabetics rely on continuous blood glucose monitoring systems (“CGMs”) to continuously monitor their blood glucose levels and help manage and/or control diabetes. “A CGM is a [three-part] system that pairs a small sensor [with an attached transmitter] worn on the back of your upper arm [or abdomen] – with an app or reader that provides you with real-time glucose (commonly known as sugar) levels 24/7.”² CGMs represent a critical advancement in diabetes management, providing real-time glucose measurements to help patients avoid dangerous hypoglycemia (low blood sugar) and hyperglycemia (high blood sugar).

22. To help monitor their blood glucose levels and reduce their risk of progressing to diabetes, prediabetics have also come to rely on CGMs to track their reactions to certain foods and behaviors.

23. Plaintiff and the other Class Members rely on accurate glucose readings to make treatment decisions including: (a) insulin dosing calculations; (b) carbohydrate intake determinations; (c) timing of meals and medication; and (d) exercise, diet, and activity modifications.

24. Inaccurate glucose readings can result in severe adverse health consequences including hypoglycemia-induced seizures, loss of consciousness, coma, permanent brain damage, and death, or hyperglycemia-induced diabetic ketoacidosis, organ damage, and death. These are not theoretical risks—Abbott’s own reports to the FDA document 736 serious injuries and 7 deaths associated with the defective Sensors.

25. The population of diabetics relying on CGMs is especially vulnerable because they often experience hypoglycemia unawareness (an inability to perceive warning symptoms of

² FreeStyle Libre, *What is a CGM?*, ABBOTT, <https://www.freestyle.abbott/us-en/what-is-cgm.html>.

low blood sugar), making them entirely dependent on accurate CGM readings to avoid life-threatening episodes. Abbott marketed its FreeStyle CGM specifically to this vulnerable population, knowing that inaccurate readings could have catastrophic consequences.

26. Plaintiff and Class Members who received false low glucose readings were forced into an impossible situation: either trust the CGM reading and take action that could cause dangerous hyperglycemia or perform painful fingerstick tests that Abbott assured them were unnecessary. Many Class Members, having relied on Abbott's representations that the FreeStyle CGM "eliminates" the need for fingersticks, did not have blood glucose meters or testing supplies readily available when false alarms occurred, leaving them unable to verify readings and forced to treat for low blood sugar they did not actually have.

B. FREESTYLE CGM BACKGROUND

27. Defendants engaged in the design, manufacture, marketing, distribution, and sale of the FreeStyle CGMs, which included the FreeStyle Libre 3 Sensor (Model Numbers: 72081-01, 72080-01; UDI-DI: 00357599818005, 00357599819002) and FreeStyle Libre 3 Plus Sensor (Model Numbers: 78768-01, 78769-01; UDI-DI: 00357599844011, 00357599843014).

28. Defendants obtained FDA clearance for the FreeStyle Libre 3 CGM in or around 2022 and clearance for the modified and updated FreeStyle Libre 3 Plus in 2023. Defendants made "modifications to the cleared FreeStyle Libre 2 Flash Glucose Monitoring System to display real-time glucose data via Bluetooth without scanning the Sensor."³

³ See May 26, 2022 FDA Response Letter to Abbott Diabetes Care Inc. re K212132 FreeStyle Libre 3 Continuous Glucose Monitoring System, , https://www.accessdata.fda.gov/cdrh_docs/pdf21/K212132.pdf

29. Defendants represented to the FDA that the FreeStyle Libre 3 CGM was a “device with alarms capability indicated for the management of diabetes ...intended to replace blood glucose testing for diabetes treatment decisions.”⁴

30. Defendants represented to consumers that the Libre 3 Sensors were intended to “track glucose levels all day and night” significantly reducing the need for fingersticks, which can only read your glucose levels at that moment.⁵

31. Abbott’s diabetes care business divisional vice president, global medical affairs and chief medical officer proclaimed that “Abbott revolutionized glucose monitoring with [their] world-leading FreeStyle Libre technology – the first sensor to eliminate painful fingersticks.”⁶

32. Plaintiff and the other Class Members, who are all Type 1 or Type 2 diabetics, prediabetics, or guardians/personal representatives thereof, incurred costs for or paid for the FreeStyle CGM and Libre Sensors to help manage their blood glucose levels, or those of someone to whom they are a guardian/personal representative.

33. The FDA has determined that the Sensors are defective due to a manufacturing flaw. The processing flaw “may cause carbon build up in the sensor that may result in incorrect low glucose results,”⁷ even when users’ actual blood glucose levels are normal or elevated. According to the FDA, these inaccurate readings pose a serious safety risk because they may prompt users to take unnecessary corrective action or delay appropriate treatment, increasing the

⁴ *Id.*

⁵ FreeStyle Libre, CGM vs BGM: More data, less guesswork, no fingersticks*, ABBOTT, <https://www.freestyle.abbott/us-en/cgm-vs-bgm.html>.

⁶ Press Release, *Late-Breaking Data Demonstrate Abbott’s FreeStyle Libre 3 System is Most Accurate 14-Day Continuous Glucose Monitor*, ABBOTT MEDIA ROOM (June 5, 2022), <https://abbott.mediaroom.com/2022-06-05-Late-Breaking-Data-Demonstrate-Abbotts-FreeStyle-Libre-R-3-System-is-Most-Accurate-14-Day-Continuous-Glucose-Monitor>.

⁷ *Class 1 Device Recall FreeStyle Libre*, FOOD AND DRUG ADMINISTRATION (posted Jan. 14, 2026), <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=217500>.

risk of severe hypoglycemia, loss of consciousness, seizures, or death. The FDA classified the issue as a Class I recall—its most serious designation—after Abbott reported hundreds of serious adverse events and multiple deaths potentially associated with the defective Sensors, and the agency advised that affected devices be discontinued and replaced immediately.

C. DEFENDANTS' MARKETING REPRESENTATIONS AND CLAIMS

a. Claims of Superior Accuracy

34. Abbott marketed the FreeStyle CGM as having unsurpassed 14-day accuracy with the world's smallest, thinnest and most accurate 14-day glucose sensor, warranting consistent, reliable performance. Abbott highlighted the device's size and continuous reading capabilities compared to prior models.⁸



The world's smallest sensor^{III6}

The Libre 3 Plus sensor is the thinnest^{III}, most discreet⁶ sensor—smaller than 2 stacked pennies. No one needs to know you're wearing it!

- Sensors last up to 15 days
- Takes just minutes to change—only twice a month
- Can wear while showering, exercising, swimming^{III}, and even during an MRI^{##}

35. Abbott represented that the FreeStyle CGM achieved a mean absolute relative difference (MARD) of 7.9%, marketing it as the most accurate 14-day continuous glucose monitor (CGM) with readings sent directly to a smartphone every minute and the first CGM to demonstrate a sub-8% MARD.⁹

⁸ Press Release, *Abbott's FreeStyle Libre ® 3 Receives U.S. FDA Clearance – Features World's Smallest, Most Accurate 14-Day Glucose Sensor*, ABBOTT MEDIA ROOM (May 31, 2022), <https://abbott.mediaroom.com/2022-05-31-Abbotts-FreeStyle-Libre-R-3-Receives-U-S-FDA-Clearance-Features-Worlds-Smallest,-Thinnest-and-Most-Accurate-14-Day-Glucose-Sensor>; see also FreeStyle Libre, *What is a CGM*, ABBOTT, <https://www.freestyle.abbott/us-en/what-is-cgm.html>.

⁹ *Id.*

b. Representations Regarding Safety and Reliability

36. Abbott represented that the FreeStyle CGM was intended to replace blood glucose testing for diabetes treatment decisions and was suitable for use by persons age 4 and older (Libre 3 sensor) or age 2 and older (Libre 3 Plus sensor) with diabetes.

37. Abbott marketed the device as enabling users to discreetly check their glucose as often as they like without having to fingerstick and as providing life-changing benefits.

38. Abbott represented that 95% of patients would have a better understanding of their glucose fluctuations and gain 1 hour more in Time in Range per day compared to finger pricking.

39. Abbott's User Manual states the device detects trends and tracks patterns and aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

40. Defendants heavily promoted the "no fingersticks" message for treatment decisions. This representation was materially misleading and deceptive because (a) affected Sensors required confirmatory fingerstick testing when readings did not match symptoms or expectations—a condition that occurred frequently due to the defective Sensors; (b) the known prevalence of inaccurate low readings made confirmatory testing necessary for safety in ordinary use; (c) Abbott knew that many users, relying on the "no fingersticks" claim, would not have blood glucose meters or testing supplies readily available; and (d) Abbott continued to promote this message even after receiving thousands of complaints documenting the very inaccuracies that made fingerstick verification essential for safety.

41. Defendants make representations that using the FreeStyle Libre 3 CGM System "can increase [customers] peace of mind and improve [their] quality of life." They also claim

that loved ones and caregivers can get peace of mind as well by sharing glucose readings with the app.¹⁰

c. Value and Affordability Representations

42. Abbott marketed the FreeStyle CGM as being priced the same as previous versions and claimed it was available at a fraction of the cost of competitors, specifically stating it was a third of the cost of other CGMs available.¹¹

43. Abbott represented that most (commercially insured) patients will pay between \$0 to \$75 per month for Sensors¹², and that covered patients pay about 53 cents per day.

44. The actual retail price for the Libre 3 Sensors without insurance ranges from approximately \$224.72 to \$235 for a two-sensor (28-day) supply, amounting to over \$3,000 per year.¹³

45. Abbott promoted the device as offering access to breakthrough diabetes technologies that should not be out of reach for the people who can benefit most from them.

¹⁰ *FreeStyle Libre 3 Continuous Glucose Monitoring System App User's Manual*, https://freestyleserver.com/Payloads/IFU/2025/q4/ART48742-003_rev-B-pub.pdf.

¹¹ Press Release, Abbott's FreeStyle Libre 3 Receives U.S. FDA Clearance – Features World's Smallest, Thinnest and Most Accurate 14-Day Glucose Sensor, ABBOTT MEDIA ROOM (May 31, 2022), <https://abbott.mediaroom.com/2022-05-31-Abbotts-FreeStyle-Libre-R-3-Receives-U-S-FDA-Clearance-Features-Worlds-Smallest,-Thinnest-and-Most-Accurate-14-Day-Glucose-Sensor>.

¹² FreeStyle Libre, *How much does the FreeStyle Libre 3 system cost?*, ABBOTT, [https://www.support.freestyle.abbott/hc/en-us/articles/14795283859991-How-much-does-the-FreeStyle-Libre-3-system-cost#:~:text=Most%20\(commmercially%20insured\)%20patients%20will,Was%20this%20information%20helpful?](https://www.support.freestyle.abbott/hc/en-us/articles/14795283859991-How-much-does-the-FreeStyle-Libre-3-system-cost#:~:text=Most%20(commmercially%20insured)%20patients%20will,Was%20this%20information%20helpful?).

¹³ Keith Gardner, R.Ph., *How much is FreeStyle Libre 3 without insurance?* SingleCare.com (Nov. 6, 2025), <https://www.singlecare.com/blog/freestyle-libre-3-without-insurance/> [<https://web.archive.org/web/20251115210338/https://www.singlecare.com/blog/freestyle-libre-3-without-insurance/>].

d. Manufacturing Quality and Testing Representations

46. Abbott warranted through its packaging, labeling, marketing materials and User's Manual that the Libre 3 Sensors were manufactured according to proper quality control standards and would perform as intended throughout their labeled 14-day or 15-day wear period.¹⁴

47. Abbott represented in the User's Manual that users should review all product information before use and could rely on sensor readings to replace blood glucose testing for diabetes treatment decisions after the initial 12-hour warm-up period.¹⁵

D. THE MANUFACTURING DEFECT AND ABBOTT'S KNOWLEDGE

48. Defendants manufactured approximately 3 million defective Libre 3 Sensors¹⁶ on at least one defective production line that caused affected Sensors to provide incorrect low glucose readings during normal use. Internal testing, post-market surveillance, and adverse event reports confirmed systemic deviations from design specifications and labeled performance claims.

49. The Defect caused the affected Sensors to falsely indicate hypoglycemia (low blood sugar) when patients' actual glucose levels were normal or elevated, creating a systematic pattern of inaccurate readings in the affected Sensors that undermined their intended function of continuous glucose monitoring.

¹⁴ *Id.*; See *FreeStyle Libre 3 Continuous Glucose Monitoring System App User's Manual*, https://freestyleserver.com/Payloads/IFU/2025/q4/ART48742-003_rev-B-pub.pdf; see also FreeStyle Libre, *What is a CGM*, ABBOTT, <https://www.freestyle.abbott/us-en/what-is-cgm.html>.

¹⁵ See *FreeStyle Libre 3 Continuous Glucose Monitoring System App User's Manual*, FreeStyle-Abbott, https://freestyleserver.com/Payloads/IFU/2025/q4/ART48742-003_rev-B-pub.pdf.

¹⁶ See Product Details, FOOD AND DRUG ADMINISTRATION, <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-initiates-medical-device-correction-certain-freestyle-librer-3-and-freestyle-libre-3-plus>.

a. Abbott's Knowledge and Concealment

50. Abbott identified the Defect through its own internal testing and post-market surveillance, which confirmed that sensors manufactured on the defective production line were systematically generating inaccurate low glucose readings that deviated materially from true blood glucose values.

51. These internal findings demonstrated that the Defect was not random or user-related, but rather the result of a manufacturing process failure that directly affected sensor accuracy and reliability—core safety attributes of a continuous glucose monitoring device intended to replace fingerstick testing.

52. And despite possessing knowledge of the Defect, Abbott continued to manufacture, distribute, and sell the defective Sensors to consumers, healthcare providers, pharmacies, and third-party distributors throughout the United States and abroad, without issuing a timely warning, recall, or suspension of distribution.

53. The FreeStyle CGM was primarily marketed on the premise that it replaces traditional fingerstick testing for diabetes management. However, in the November 2025 “Urgent Medical Device Correction Notice”, Abbott instructed users to “use a blood glucose meter... when your sensor readings don’t match your symptoms or expectations.”¹⁷ Abbott’s marketing was fundamentally deceptive because the “no fingerstick” claim was only true when the device functioned perfectly, yet Abbott knew the sensors did not work and were prone to systemic manufacturing deviations that made fingerstick verification essential for safety.

¹⁷ FreeStyle Libre, *Urgent Medical Device Correction, FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors*, ABBOTT, <https://www.freestylecheck.com/us-en/home.html> 1/2.

54. Abbott also failed to promptly notify patients already using the affected Libre 3 Sensors, even though Abbott knew those patients were relying on them to make real-time diabetes treatment decisions, thereby exposing users to an unreasonable risk of severe hypoglycemia, hyperglycemia, injury, or death.

55. The FDA classified the November 2025 issue as an “Early Alert” for a “potentially high-risk” device problem.¹⁸ Abbott also reported 736 serious injuries as of November 14, 2025, but waited until November 24, 2025, to issue the public correction.¹⁹

56. Abbott prioritized corporate reputation and holiday-season sales over patient safety by withholding the public “Correction” notice for at least 10 days after internal data confirmed the scope of the injuries and deaths, depriving users of the opportunity to switch to safer monitoring methods during that critical time period.²⁰

57. Abbott did not publicly disclose the defect or initiate a broad corrective action until November 24, 2025, after the defect had manifested in real-world use and after at least 736 serious injuries and seven deaths had already been reported globally in connection with the defective sensors.²¹

58. Abbott’s delayed disclosure deprived consumers, caregivers, and healthcare providers of material safety information necessary to evaluate whether continued use of the sensors was safe and prevented timely mitigation of known risks.

¹⁸ See *Glucose Monitor Sensor Recall: Abbott Diabetes Care Removes Certain FreeStyle Libre 3 and FreeStyle Libre 3 Plus Sensors*, FDA.

¹⁹ Press Release, *Abbott Initiates Medical Device Correction for Certain FreeStyle Libre® 3 And FreeStyle Libre 3 Plus Sensors In The U.S.*, ABBOTT MEDIA ROOM (Nov. 24, 2025), <https://www.freestyle.abbott/us-en/cgm-vs-bgm.html>.

²⁰ *Id.*

²¹ *Id.*

b. FDA Warning Letter

59. On January 23, 2026, the FDA issued a Warning Letter to Abbott Diabetes Care Inc. finding that, “these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.”²²

60. The FDA stated that Defendants established “requirements to comply with 21 CFR 862.1355 [integrated continuous glucose monitoring system] but did not transfer these specifications to [their] third-party manufacturer or ensure ongoing monitoring of in process and finished product.”²³

61. The FDA also stated that, Abbott “failed to meet 21 CFR 862.1355(b)(3) special controls requirement that states: ‘design verification and validation must include adequate controls established during manufacturing and at product release to ensure the released product meets the performance specifications.’ No controls were established at final product release to ensure finished products meet performance specifications.”²⁴

62. Abbott’s November 14, 2025, response to the FDA was not “adequate”. The FDA found that Abbott’s “Sensor Manufacturing Process Monitoring lacks: (1) specific performance specifications for glucose clinical accuracy; (2) direct linkage to the accuracy performance requirements at product release; and (3) adequate procedures to detect sensors that could produce

²² FDA, Warning Letter to Abbott Diabetes Care, Inc., dated January 23, 2026, at p. 2, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/abbott-diabetes-care-inc-722046-01232026>.

²³ *Id.*

²⁴ *Id.*

erroneous glucose results. Your monitoring documents focus on general manufacturing parameters, biocontamination control, and facility requirements but inadequately address sensor glucose accuracy performance requirements. Your responsive attachments fail to demonstrate how the specific accuracy thresholds ((b)(4)) are translated into component-level specifications or systematically translated through all levels of manufacturing control.”²⁵

63. Defendant’s December 19, 2025 response was found by the FDA to once again be inadequate with the FDA finding that although Abbott’s “procedural updates were described, your firm did not provide objective evidence demonstrating that accuracy performance requirements have been fully transferred into production specifications, incorporated into the DMR, and implemented as acceptance procedures by manufacturing entities responsible for final assembly and release.”²⁶

64. The FDA directed Defendants to “investigate and determine the causes of the violations and take prompt action to correct the violations and bring the products into compliance.”²⁷

65. As of the filing of this Complaint, the FDA has not issued a close out letter confirming Defendants have addressed these violations and begun manufacturing its FreeStyle CGMs properly.

c. Prior Pattern of Similar Defects and Notice

66. The 2025 manufacturing Defect was not an isolated or unprecedented failure. Abbott had previously experienced—and was on notice of—accuracy defects affecting the same product line.

²⁵ *Id.*

²⁶ *Id.* at p. 3.

²⁷ *Id.* at p. 5.

67. In July 2024, Abbott issued a voluntary medical device correction for Libre 3 Sensors due to the Sensors providing incorrect high readings.²⁸

68. In August 2024, the FDA ultimately categorized the event as a Class I recall—the agency’s most serious designation, reserved for products that present a reasonable probability of causing serious adverse health consequences or death, including severe hypoglycemia, seizures, coma, permanent neurological injury, and death.²⁹

69. The November 2025 recall for incorrect low readings involves the same product line as the July 2024 recall for incorrect high readings. This seesaw of defects—from dangerously high to dangerously low inaccuracies within 18 months—demonstrates a systemic failure in Abbott’s Quality Management System (QMS) and a lack of effective Corrective and Preventive Actions (CAPA) required by FDA regulations (21 CFR § 820.100). Abbott’s repeated inability to manufacture Sensors that provide accurate readings, despite two Class I recalls and an FDA Warning Letter, establishes that Abbott lacks the quality systems necessary to safely produce life-critical medical devices and that Abbott’s representations regarding manufacturing quality were false when made.

70. That 2024 Class I recall placed Abbott on actual notice that its Libre 3 Sensor manufacturing and quality control processes were capable of producing dangerously inaccurate glucose readings, undermining the fundamental safety and efficacy of the system.

²⁸ *Abbott Issues Voluntary Medical Device Correction for a Small Number of FreeStyle Libre 3 Sensors in the U.S.*, ABBOTT MEDIA ROOM (July 24, 2024) <https://abbott.mediaroom.com/2024-07-24-Abbott-Issues-Voluntary-Medical-Device-Correction-for-a-Small-Number-of-FreeStyle-Libre-R-3-Sensors-in-the-US>.

²⁹ *Abbott Issues Voluntary Medical Device Correction for a Small Number of FreeStyle Libre 3 Sensors in the U.S.*, ABBOTT MEDIA ROOM (July 24, 2024) <https://abbott.mediaroom.com/2024-07-24-Abbott-Issues-Voluntary-Medical-Device-Correction-for-a-Small-Number-of-FreeStyle-Libre-R-3-Sensors-in-the-US>.

71. Despite this prior recall and clear regulatory warning less than one year earlier, Abbott continued to market the FreeStyle CGMs as delivering unsurpassed or industry-leading accuracy, while failing to disclose persistent and systemic manufacturing quality failures that compromised sensor performance.

72. User complaints from December 2025 highlight that readings fluctuate wildly based on body position (e.g., sitting up vs. lying down). While “compression lows” are a known CGM issue, the severity reported with the Libre 3 Plus Sensor suggests a potential defect in the sensor’s pressure sensitivity that Abbott failed to adequately mitigate or warn against. Beyond the manufacturing line defect, the Sensors suffer from a defect where they are overly sensitive to physical pressure or orientation, leading to “false low” alarms during sleep that cause significant psychological distress and sleep deprivation for patients and caregivers. On information and belief, Abbott knew of these issues at all relevant times.

73. Abbott’s conduct demonstrates a pattern of delayed disclosure, inadequate corrective action, and concealment of material safety risks, prioritizing continued sales and market share over patient safety and regulatory compliance.

E. SCOPE AND SEVERITY OF HARM

a. Scale of Distribution

74. Approximately 3 million Libre 3 Sensors manufactured on the defective production line were distributed in the United States and remain potentially in circulation.³⁰

³⁰ Press Release, Abbott Initiates Medical Device Correction For Certain FreeStyle Libre ® 3 and FreeStyle Libre 3 Plus Sensors In The U.S., ABBOTT MEDIA ROOM (Nov. 24, 2025), <https://abbott.mediaroom.com/press-releases?item=124718>.

75. Abbott has publicly disclosed that about half of those Sensors-approximately 1.5 million-had expired or had already been used by patients by the time the Defect was disclosed in November 2025.³¹

76. Therefore, an estimated 1.5 million defective sensors were still in inventory, in the supply chain, held by pharmacies or healthcare providers, or in patients' homes or on patients' bodies at the time Abbott and the FDA issued the safety alert.

77. Defendants' corrective notice and website advised consumers to confirm their sensors were potentially affected by the medical device correction and stated they would "replace any potentially affected sensors at no charge."³²

What if I have more than one sensor kit that is impacted? ^

For each sensor that is impacted, please enter your sensor serial number and provide your contact information for shipment of a replacement. Please note, you can only enter one sensor serial number at a time. Each time you enter a sensor serial number, you will need to provide your contact information for shipment of a replacement.

78. Due to the number of affected Sensors, replacements may not be easy to come by. As shown in the image below, Defendants website warns that they are having a difficult time

³¹ *Id.*

³² See Press Release, *Abbott Initiates Medical Device Correction For Certain FreeStyle Libre® 3 and FreeStyle Libre 3 Plus Sensors In The U.S.*, ABBOTT MEDIA ROOM (Nov. 24, 2025), <https://abbott.mediaroom.com/press-releases?item=124718>; *FreeStyle Libre - Frequently Asked Questions*, FreeStyle -Abbott, <https://www.freestylecheck.com/us-en/faq.html>.

keeping up with the demand. “We are handling your replacement order with highest priority. However, due to the high demand we are currently expecting some delay.”³³

b. A Broader Problem

79. The manufacturing Defect may be more extensive than Defendants know or are willing to admit. While answers to FAQs (frequently asked questions) on Abbott’s FreeStyle Libre website where consumers can check whether they are in possession of recalled Sensors state that “no action is necessary” if the “product was not included in the medical device corrections,” adverse events reported by consumers tend to disagree.³⁴

What if my product was not included in the medical device correction?

No action is necessary, and you can continue to use your Libre products.

³³ FreeStyle Libre, *Confirm Sensor Serial Number*, ABBOTT, <https://www.freestylecheck.com/us-en/product-lookup.html>.

³⁴ FreeStyle Libre, *Frequently Asked Questions*, ABBOTT <https://www.freestylecheck.com/us-en/faq.html>.

80. Several consumers have complained and reported low readings with Libre 3 Sensors that did not appear on Defendants' list of affected devices.

81. One consumer reported having "two sensors run into the same problems. In both situations, the sensor recorded low readings between 40-55 while the actual finger pricks showed 155 -165. I checked on the Abbott website (B)(6) since some of the sensors have been recalled. However, these were not on the list. So, I think there are many other defective sensors that have been left of [sic] the recall."³⁵

82. Another user report stated, "I use Libre 3+ Sensors ... my glucose numbers kept dropping to dangerous levels, so I ate additional carbs to compensate. But even after consuming plenty of carbs, my glucose readings remained low (in the 40s). When I used a traditional glucometer, I found my actual number was 205.... My sensor is not among those under scrutiny.... I hope you can look into this issue and get them to broaden the scope of their recall."³⁶

83. This customer reported getting multiple low readings of 70 or lower from an unaffected Libre3 Plus Sensor but finger stick results showed a normal range of 114-125, "per the website, this s/n is not on the recalled devices list. I am also attempting to report this issue with the manufacturer (abbot labs)."³⁷

³⁵ MAUDE Adverse Event Report: Abbott Diabetes Care Inc. Libre 3 Plus Sensor; Integrated Continuous Glucose Monitoring System, Factory Calibrated, FDA (Event Date Dec. 6, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23779430&pc=QLG.

³⁶ MAUDE Adverse Event Report: Abbott Diabetes Care Inc. Libre 3 Plus Sensor; Integrated Continuous Glucose Monitoring System, Factory Calibrated, FDA (Event Date Nov. 24, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23730753&pc=QBJ.

³⁷ MAUDE Adverse Event Report: Abbott Diabetes Care Inc. Libre 3 Plus Sensor; Integrated Continuous Glucose Monitoring System, Factory Calibrated, FDA (Event Date Dec. 7, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23806162&pc=QBJ.

84. This complaint states, “Libre 3 Plus Sensor had incorrect low glucose reading but serial number was determined not affected when input into Abbot’s [sic] tool to check for the defective sensors. This is the 3rd sensor this happened with over the past 3 weeks with a serial number that was supposedly not affected. I called Abbot each time and they are sending replacements.”³⁸

85. And yet another adverse event reported said, “Libre 3Plus Sensor reported low sugar levels falsely. I treated for low glucose resulting in high glucose levels. I verified on the website that my sensors were “not affected” by the recall but I have pics of the level then my app shows no record of the level being low like 2 minutes later.”³⁹

86. Another report stated that the customer had issues with 3 sensors over the past 3 weeks. Each sensor was “supposedly not affected.”⁴⁰

87. And yet another user experienced problems, so much so that they were hospitalized and when paramedics and hospital staff took readings, they never matched that of the CGM. Again, these sensors were not identified in the recall.⁴¹

³⁸ MAUDE Adverse Event Report: Abbott Diabetes Care Inc. Libre 3 Plus Sensor; Integrated Continuous Glucose Monitoring System, Factory Calibrated, FDA (Event Date Dec. 6, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23780282&pc=QBJ.

³⁹ MAUDE Adverse Event Report: Abbott Diabetes Care Inc. Libre 3 Plus Sensor; Integrated Continuous Glucose Monitoring System, Factory Calibrated, FDA (Event Date Jan. 17, 2026), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=24176968&pc=QBJ.

⁴⁰ MAUDE Adverse Event Report: Abbott Diabetes Care, Inc. Libre 3 Plus Sensor; Integrated Continuous Glucose Monitoring System, Factory Calibrated, FDA (event date Dec. 6, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23780282&pc=QBJ.

⁴¹ MAUDE Adverse Event Report: Abbott Diabetes Care, Inc. Libre 3 Plus Sensor; Integrated Continuous Glucose Monitoring System, Factory Calibrated, FDA (event date Dec. 3, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23770840&pc=QBJ.

c. Reported Adverse Events

88. As of November 14, 2025, Abbott reported 736 serious injuries associated with the defective sensors. Of these serious injuries, 57 occurred within the United States.⁴²

89. Abbott also acknowledged that seven deaths potentially linked to the defective sensors had occurred globally; none occurred in the United States.⁴³

90. Three months later, as of February 4, 2026, the FDA reported injuries from the recalled Libre 3 Sensors had reached 860.⁴⁴

91. These reported adverse events likely represent only a fraction of the true scale of harm. Studies consistently demonstrate that voluntary post-market surveillance systems like FDA's MedWatch capture only a small percentage of actual adverse events—by some estimates, as few as 1-10% of device-related injuries are reported. Moreover, delays in identifying causation in chronic care populations mean that many harms from inaccurate glucose measurements (e.g., metabolic crises, long-term complications from sustained hyperglycemia, or psychological harm from repeated false alarms) go unreported or misattributed.

92. As noted by this reporter, the discrepancies between the Libre 3 Sensors and a glucose meter are nothing short of alarming: “I discovered a difference of 100 points between my libre 3 plus sensor and contour stick and called [A]bbott. After checking the manufacture

⁴² Jonel Aleccia, *Faulty glucose monitors linked to 7 deaths and more than 700 injuries, FDA warns*, ASSOCIATED PRESS (Updated 5:45PM EDT Dec. 4, 2025), <https://www.statnews.com/2025/12/04/abbott-diabetes-care-faulty-glucose-monitors-deaths-injuries/>.

⁴³ *Id.*

⁴⁴ *US FDA says injuries from Abbott's recalled glucose sensors reach 860*, REUTERS (Feb. 4, 2026), <https://www.reuters.com/business/healthcare-pharmaceuticals/abbott-recalls-glucose-sensors-after-seven-deaths-linked-faulty-readings-2026-02-04/>.

numbers, they replaced two sensors. The sensors [I] received were closer to the stick numbers but so far never within 20 points difference.”⁴⁵

93. According to a customer, they were notified through their app that their Sensors were defective and giving incorrect low blood glucose readings and told to stop immediately. The customer was directed to check the serial numbers of all sensors they had, one on their arm and the other five kits they had, and all were “bad.”⁴⁶

d. Nature of Health Risks

94. The FDA characterized this issue as a “potentially high-risk” device problem requiring immediate public notification through an Early Alert.

95. Inaccurate readings can lead to prolonged hyperglycemia (high blood sugar) when patients skip insulin doses based on false low readings. As a result of sustained hyperglycemia caused by false low readings and delayed insulin dosing, Plaintiff and Class Members face increased risks of long-term complications.

96. According to Abbott’s own disclosures, incorrect low glucose readings over an extended period may lead to wrong treatment decisions for people living with diabetes, such as excessive carbohydrate intake or skipping or delaying insulin doses.

⁴⁵ MAUDE Adverse Event Report: Abbott Diabetes Care Inc. Libre 3 Plus Integrated Continuous Glucose Monitoring System, Factory Calibrated, FOOD AND DRUG ADMINISTRATION (Event Date July 22, 2025), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23802806&pc=QBJ.

⁴⁶ MAUDE Adverse Event Report: Abbott Diabetes Care Inc. Libre 3 Plus Integrated Continuous Glucose Monitoring System, Factory Calibrated, FOOD AND DRUG ADMINISTRATION (Nov. 25, 2025 event date), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=23681272&pc=QBJ.

97. Abbott acknowledged that these decisions may pose serious health risks, including potential injury or death, or other less serious complications.

98. The specific health risks associated with the defect include, but are not limited to:

- Unrecognized hyperglycemia due to false low readings;
- Diabetic ketoacidosis from delayed or skipped insulin doses;
- Long-term complications from sustained elevated blood glucose;
- Cardiovascular events;
- Acute metabolic crises;
- Unnecessary emergency medical interventions; and
- Psychological distress and loss of confidence in diabetes management.

99. The Defect caused real harm to real patients, including Plaintiff, yet Abbott chose to continue selling the defective Sensors rather than take prompt corrective action.

e. FreeStyle CGM and Sensor Warranties

100. Abbott expressly warranted in labeling, advertisements, packaging materials, press releases, and direct-to-consumer marketing that the FreeStyle CGMs and Libre 3 Sensors: (a) are the “most accurate” and “world’s smallest, thinnest” CGM sensors available; (b) provide FDA-cleared, real-time, minute-by-minute glucose readings; (c) deliver timely and audible alerts for low and high blood glucose that users can trust; (d) are accurate enough to replace fingerstick testing for diabetes treatment decisions; and (e) are manufactured under FDA-compliant quality systems.

101. In its Limited Warranty, Abbott warranted that the FreeStyle CGMs were free from defects in material and workmanship under normal use for a period of one year from the date of manufacture or the original date of purchase, whichever is later.

102. Abbott impliedly warranted in labeling, advertisements, packaging materials, and press releases that the FreeStyle CGM and Libre 3 Sensors are safe, not defective, accurate, and of high quality.

103. Abbott also impliedly warranted in labeling, advertisements, packaging materials, and press releases that the FreeStyle CGMs and Libre 3 Sensors were manufactured and sent to users in accordance with the FDA-cleared specifications and processes, and/or of the same quality as those cleared by the FDA.

104. Abbott also impliedly warranted that the devices sold were not adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) and/or misbranded under 21 U.S.C. § 352(o).

105. The warranty remedy provided by Abbott (replacement) in its recall notice is futile and fails of its essential purpose because: (a) Abbott continues to distribute Sensors using defective production and manufacturing processes; (b) replacement Sensors have also failed for many consumers demonstrating the inadequacy of the remedy; (c) the remedy does nothing to compensate Class Members for the overpayment, for the extended period they used defective devices while unaware of the defect, or for the physical and emotional harm caused by false readings; (d) the remedy is inadequate given that Abbott knew of complaints and failed to take corrective action; and (e) even now, consumer complaints indicate that Sensors not identified in the recall continue to provide inaccurate readings, suggesting the scope of the defect is broader than Abbott has disclosed.

106. Abbott's warranty limitations are unconscionable. Abbott's Limited Warranty explicitly states it "covers only the Reader" and "does not cover the sensor." Any attempt to disclaim warranties on the sensor itself is unconscionable and unenforceable because the sensor is the life-sustaining component of the FreeStyle CGM system. A consumer cannot use the

Reader without a functional sensor; therefore, the sensor and Reader are an inseparable medical system for the purposes of merchantability.

f. Fraudulent Omission Allegations

107. Absent discovery, Plaintiff is unaware of, and unable through reasonable investigation to obtain, the true names and identities of those individuals at Abbott responsible for failing to rectify the defects mentioned above and disseminating false and misleading marketing materials regarding the FreeStyle CGMs and corresponding Libre 3 Sensors. Plaintiff's claims arise out of Abbott's fraudulent concealment of these defects, and its representations about the efficacy, accuracy, and quality of those monitors.

108. Plaintiff alleges that Abbott knew, or was reckless in not knowing, about the defects at all relevant times, specifically at the time Plaintiff and the other members of the proposed Class acquired their FreeStyle CGMs and corresponding Libre 3 Sensors or related accessories—such as overpatches, adhesives, additional test strips, insulin pumps, and/or FreeStyle-compliant cell phones—required for the FreeStyle CGMs themselves or necessary because of the Libre 3 Sensor defects. Abbott was under a duty to disclose these defects based on: (a) its exclusive knowledge of manufacturing processes and quality control failures that caused the Defect; (b) its active concealment of the Defect through continued marketing emphasizing accuracy; (c) its ongoing affirmative misrepresentations about the accuracy and reliability of the Sensors; (d) its superior position of knowledge regarding FDA complaints, adverse event reports, and internal testing data; and (e) the life-threatening nature of the products and the vulnerability of consumers who rely on accurate CGM readings to manage diabetes.

109. Plaintiff makes the following specific fraud allegations with as much specificity as possible absent access to the information necessarily available only to Abbott:

- **Who:** Abbott actively concealed the defects from consumers, as alleged above. Plaintiff is unaware of, and therefore unable to identify, the true names and identities of specific individuals at Abbott responsible for such decisions.
- **What:** Abbott knew, or was reckless or negligent in not knowing, that the Libre 3 Sensors contained the defects. Abbott concealed these defects and made representations about the efficacy, quality, and accuracy of these monitors.
- **When:** Abbott concealed material information regarding the defects at all times, and it made representations about the efficacy, quality, and accuracy of the FreeStyle CGMs and corresponding Libre 3 Sensors starting at a time currently unknown to Plaintiff and continuing through the time of sale, on an ongoing basis, to this day, as alleged above. Abbott has still not disclosed the truth about the full scope of these defects to anyone outside of the company. It has taken insufficient actions to inform consumers about the true nature of these defects in the Sensors.
- **Where:** Abbott concealed material information regarding the true nature of the defects in every communication it had with Plaintiff and the other Class Members about the Libre 3 Sensors, and, particularly, its efficacy, quality, and accuracy. Plaintiff is not aware of any documents, communications, or other items in which Abbott has disclosed the truth about the full scope of the defects in the Sensors to anyone outside of Abbott. Such information is not adequately disclosed in any sales documents, displays, advertisements, warranties, manuals, or on Abbott's website.
- **How:** Abbott concealed the defects from Plaintiff and the other Class Members by making inaccurate representations about the efficacy, quality, and accuracy of the FreeStyle CGMs. Abbott actively concealed the truth about the existence, scope, and nature of the defects from Plaintiff and the

other Class Members at all times, even though it knew about the defects and knew that information about the defects would be important to a reasonable consumer. Abbott promised in its marketing materials that the FreeStyle CGMs had qualities that they do not have.

- **Why:** Abbott actively concealed material information about these defects in the Sensors for the purpose of inducing Plaintiff and the other Class Members to acquire the FreeStyle CGM, rather than using competitors' glucose monitors. Had Abbott disclosed the truth, for example in its advertisements or other materials or communications, Plaintiff and the other Class Members (and any reasonable consumer) would have been aware of them, and they would not have acquired the FreeStyle CGM or Libre 3 Sensors for them, or they would have paid less for them.

110. Defendants had a duty to disclose material facts because: (1) they possessed exclusive knowledge of the defects not known to consumers; (2) they actively concealed the defects while making partial representations (e.g., “no fingersticks,” “most accurate,” and reliability and safety claims) that were misleading absent disclosure; and (3) the defects go to safety—a central characteristic of a medical device—creating a duty to disclose.

TOLLING OF THE STATUTE OF LIMITATIONS

111. Plaintiff and the other Class Members could not have discovered through the exercise of reasonable diligence that their Libre 3 Sensors were defective within the time period of any applicable statutes of limitation.

112. Neither Plaintiff nor the Class Members knew or could have known of the defects of the Sensors, at least until after the FDA Class 1 recall was publicly issued.

a. Fraudulent Concealment Tolling

113. Throughout the time period relevant to this action, Abbott concealed from and failed to disclose to Plaintiff and the other Class Members vital information about the character, quality, nature, and risks of the Libre 3 Sensors.

114. Indeed, Abbott kept Plaintiff and the other Class Members ignorant of vital information essential to the pursuit of their claims. As a result, neither Plaintiff nor the other Class Members could have discovered the defects, even upon reasonable exercise of diligence.

115. Despite its knowledge of defects and the true character, quality, nature, and risks of the Libre 3 Sensors and the FreeStyle CGM, Abbott failed to disclose and concealed, and continue to conceal, this critical information from Plaintiff and the other Class Members, even though, at any point in time, it could have done so through individual correspondence, media release, or by other means.

116. Abbott affirmatively and actively concealed the defects by continuing to market the FreeStyle CGMs despite knowing the corresponding Sensors were defective.

117. Plaintiff and the other Class Members justifiably relied on Abbott to disclose the defects in the Sensors that they purchased, because those defects were hidden and not discoverable through reasonable efforts by Plaintiff and the other Class Members.

118. Thus, the running of all applicable statutes of limitation have been suspended with respect to any claims that Plaintiff and the other Class Members have sustained as a result of the defect, by virtue of the fraudulent concealment doctrine.

b. Estoppel

119. Abbott was under a continuous duty to disclose to Plaintiff and the other members of the Class the true character, quality, nature, and risks of the Libre 3 Sensors.

120. Abbott knowingly concealed the true character, quality, nature, and risks of the FreeStyle CGM.

121. Based on the foregoing, Abbott is estopped from relying on any statutes of limitations in defense of this action.

INJURIES AND DAMAGES

122. Plaintiff and the other Class Members reasonably relied on Abbott's misrepresentations and failure to disclose the Libre 3 Sensor defects. Had Abbott disclosed the truth, Plaintiff and the other Class Members would not have purchased, or would have paid less for, the FreeStyle CGM and Libre 3 Sensors. They suffered economic injury, including price-premium damages, out-of-pocket costs for replacements, loss of the benefit of the bargain, and time/money spent addressing inaccurate readings.

123. Abbott's omissions were a substantial factor in causing Plaintiff's and the other Class Members' injuries.

CLASS ACTION ALLEGATIONS

124. This action has been brought and may be properly maintained on behalf of the Class proposed herein under the criteria of Rule 23 of the Federal Rules of Civil Procedure.

125. Pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3), Plaintiff brings this action on behalf of himself and all others similarly situated (referred to throughout this Complaint as "Class Members") as representative of the following Class:

- **Nationwide Class:** All natural persons who purchased the FreeStyle CGM, corresponding Libre 3 and/or Libre 3 Plus Sensors, or any component thereof or accessory therefor, in the United States.

- **Connecticut Subclass:** All natural persons who purchased the FreeStyle CGM, Libre 3 and/or Libre 3 Plus Sensors, or any component thereof or accessory therefor, in the State of Connecticut.

126. The Class excludes Abbott's officers, directors, and employees; any entity in which Abbott has a controlling interest; and the affiliates, legal representatives, attorneys, successors, heirs, and assigns of Abbott. The Class also excludes members of the judiciary to whom this case is assigned, their families, and members of their staff.

127. This proposed class definition is based on the information available to Plaintiff at this time. Plaintiff may modify the class definition in an amended pleading or when he moves for class certification, as necessary to account for any newly learned or changed facts as the situation develops.

128. The members of the Class are so numerous and geographically dispersed that individual joinder of all Class Members is impracticable. Plaintiff is informed and believes that there are hundreds of thousands of Class Members, as well as tens of thousands of members of the Class from each state. While the precise number of Class Members is unknown to Plaintiff, it may be ascertained from Abbott's records. Class Members may be notified of the pendency of this action by recognized, Court-approved notice dissemination methods, which may include U.S. Mail, electronic mail, Internet postings, and/or published notice.

129. The members of the Class are readily ascertainable from the business records of Abbott.

130. There are questions of law and facts common to Plaintiff and the other Class Members, which predominate over any questions affecting only individual Class Members. These common questions of law and facts include, without limitation:

- whether Abbott designed, advertised, marketed, distributed, sold, or otherwise placed the FreeStyle CGM and Libre 3 Sensors into the stream of commerce in the United States;
- whether Abbott engaged in the conduct alleged herein;
- whether Abbott's alleged conduct violates applicable law;
- whether Abbott misled Class Members regarding the quality, benefits, and/or risks of the FreeStyle CGM and Sensors;
- whether Abbott had actual or imputed knowledge of the alleged defects and failed to disclose such defects and/or their risks to Plaintiff and the other Class Members;
- whether Abbott's acts, inactions, and practices complained of herein violated the state consumer protection statutes alleged herein;
- whether Abbott's acts, inactions, and practices complained of herein breached express warranties;
- whether Abbott's acts, inactions, and practices complained of herein breached the implied warranty of merchantability;
- whether Abbott's acts, inactions, and practices complained of herein constituted fraudulent omission;
- whether Abbott's acts, inactions, and practices complained of herein constituted unjust enrichment;
- whether Plaintiff and the other Class Members overpaid for their FreeStyle CGM and related Libre 3 Sensors as a result of the defects alleged herein;
- whether the Class Members are entitled to damages, restitution, equitable relief, statutory damages, civil penalties, punitive damages, exemplary damages, and/or other relief; and
- the amount and nature of relief to be awarded to Plaintiff and the other Class Members.

131. Plaintiff's claims are typical of those of the Class Members because all were exposed to the same omissions regarding the FreeStyle CGM. Plaintiff and the other Class Members all suffered similar harm as a result of Abbott's uniform conduct. Neither Plaintiff nor the other Class Members would have purchased the FreeStyle CGM and corresponding Libre 3 Sensors, or would have paid less for them, had they known of the defects and risks in the Sensors, as well as their lack of benefits.

132. Plaintiff and the other Class Members suffered damages as a direct and proximate result of the same wrongful practices in which Abbott engaged. Plaintiff's claims arise from the same practices and course of conduct that give rise to the claims of the other Class Members.

133. Plaintiff can and will fairly and adequately represent and protect the interests of Class Members, including those from states and jurisdictions where they do not reside. Plaintiff has no interests that conflict with the interests of the Class. In addition, Plaintiff has retained counsel competent and experienced in complex litigation and class actions, and Plaintiff intends to prosecute this action vigorously. The Class' interests will be fairly and adequately protected by Plaintiff and his counsel.

134. A class action is superior to any other available method for the fair and efficient adjudication of this controversy. The damages suffered by individual Class Members are relatively small compared to the burden and expense of individual litigation, making individual suits impracticable.

135. Class treatment of common issues avoids inconsistent or contradictory judgments, reduces delay and expense for all parties and the courts, and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by one tribunal. No unusual difficulties are likely to arise in managing this case as a class action.

136. Proceeding on a class-wide basis will conserve judicial resources and ensure that the rights of all Class Members are fairly and efficiently protected. The common issues arising from Abbott's conduct affecting Class Members, as described *supra*, predominate over any individualized issues. Adjudication of the common issues in a single action has important and desirable advantages of judicial economy.

CAUSES OF ACTION

137. Plaintiff brings these causes of action on behalf of the Class, as defined herein.

COUNT I **FRAUDULENT CONCEALMENT/OMISSION** **(On Behalf of Plaintiff and the Nationwide Class)**

138. Plaintiff repeats and realleges all factual averments as if fully set forth herein.

139. Plaintiff brings this claim individually and on behalf of the other members of the Nationwide Class (the "Class," for purposes of this Count).

140. Abbott was aware of the Libre 3 Sensor defects mentioned above, when it manufactured, marketed, and sold the devices to Plaintiff and the other Class Members.

141. Having been aware of the Libre 3 Sensor defects and, having known that Plaintiff and the other Class Members could not reasonably have been expected to know about them, Abbott had a duty to disclose the defects to Plaintiff and the other Class Members in connection with the sale of the FreeStyle CGMs, as these defects relate to important safety issues respecting the devices, which are used for managing diabetes, a life-threatening disease.

142. Defendants had a duty to disclose material facts because: (1) they possessed exclusive knowledge of the defects not known to consumers; (2) they actively concealed the defects while making partial representations (*e.g.*, "no fingersticks," "most accurate," accuracy, reliability, and safety claims) that were misleading absent disclosure; (3) the defects go to

safety—a central characteristic of a medical device—creating a duty to disclose; (4) the July 2024 Class I recall for the same product line placed Abbott on actual notice of systemic quality failures; and (5) Abbott’s representations created a duty to disclose subsequent information that rendered prior statements materially misleading.

143. Abbott did not disclose the defects to Plaintiff and the other Class Members in connection with the sale of the FreeStyle CGMs and/or subsequent sales of Libre 3 Sensors.

144. Abbott knew that these omissions would cause the false impression that the Libre 3 Sensors did not have the aforementioned defects.

145. The defects concern material information with respect to the sale of the FreeStyle CGMs, their corresponding Libre 3 Sensors, and sale of related products. Abbott’s omissions concern the defects mentioned above that can result in malfunctions including (but not limited to) inaccuracies in glucose readings.

146. The existence of these defects is a material fact that a reasonable person would have considered in deciding whether or not to choose, purchase (or to pay the same price for) the FreeStyle CGMs and the Libre 3 Sensors. In purchasing the FreeStyle CGMs and corresponding Sensors, Plaintiff and the other Class Members, who planned to use the FreeStyle CGM to help manage their diabetes, reasonably and justifiably relied on Abbott to disclose known material defects with respect to the Libre 3 Sensors. Only Abbott had the relevant information about these defects, and Plaintiff and the other Class Members would not have known of these defects otherwise.

147. Had Plaintiff and the other Class Members known of the defects, they would not have purchased the FreeStyle CGMs and Sensors, or would have paid less for the devices, due to the Libre 3 Sensor defects.

148. Through their omissions regarding the defects, Abbott intended to induce, and did induce, Plaintiff and the other Class Members to purchase FreeStyle CGMs and Sensors, they otherwise would not have purchased, or to pay more for FreeStyle CGMs and the Libre 3 Sensors than they otherwise would have paid.

149. As a direct and proximate result of Abbott's omissions, Plaintiff and the other Class Members either overpaid for the FreeStyle CGMs and Sensors or would not have purchased the FreeStyle CGMs and Sensors at all, had the defects been disclosed. Therefore, Plaintiff and the other Class Members have incurred damages—including but not limited to actual damages, compensatory damages, restitution, equitable relief, statutory damages and penalties, and punitive and exemplary damages—in an amount to be determined at trial.

COUNT II
UNJUST ENRICHMENT
(On Behalf of Plaintiff and the Nationwide Class)

150. Plaintiff repeats and realleges all factual averments as if fully set forth herein.

151. Plaintiff brings this claim individually and on behalf of the other members of the Nationwide Class (the "Class," for purposes of this Count).

152. Abbott has benefited from selling at an unjust profit defective FreeStyle CGMs and Libre 3 Sensors that had artificially inflated prices due to Abbott's concealment of defects, and Plaintiff and the other Class Members have overpaid for these devices.

153. Abbott has received and retained unjust benefits from Plaintiff and the other Class Members, and inequity has resulted.

154. It is inequitable and unconscionable for Abbott to retain these benefits.

155. Because Abbott concealed its fraud and deception, Plaintiff and the other Class Members were not aware of the true facts concerning the Libre 3 Sensors and did not benefit from Abbott's misconduct.

156. Abbott knowingly accepted the unjust benefits of its misconduct.

157. As a result of Abbott's misconduct, the amount of its restitution should be disgorged and returned to Plaintiff and the other Class Members in an amount to be determined at trial.

COUNT III
BREACH OF EXPRESS WARRANTY
(On Behalf of Plaintiff and the Nationwide Class)

158. Plaintiff repeats and realleges all factual averments as if fully set forth herein.

159. Plaintiff brings this claim individually and on behalf of the other members of the Nationwide Class (the "Class" for purposes of this Count).

160. Abbott made express warranties to Plaintiff and the Class in connection with the sale of the FreeStyle CGM and Libre 3 Sensors, including, but not limited to, representations that: (a) the Sensors are the "most accurate" CGM sensors available; (b) the Sensors provide accurate, real-time glucose readings that can replace fingerstick testing for diabetes treatment decisions; (c) the Sensors deliver reliable low and high glucose alarms; (d) the Sensors are manufactured in compliance with FDA quality standards; and (e) users can rely on the accuracy of Sensor readings for insulin dosing and treatment decisions.

161. These express warranties were part of the basis of the bargain between Abbott and Plaintiff and the Class, and were a material factor in Plaintiff's and the Class's decision to purchase the FreeStyle CGM and Libre 3 Sensors.

162. Abbott breached these express warranties because the FreeStyle CGM and Libre 3 Sensors: (a) are not the “most accurate” CGM sensors available due to the manufacturing defect that causes false low glucose readings; (b) do not provide accurate glucose readings that can replace fingerstick testing, as the defect causes systematic deviations from true blood glucose values; (c) do not deliver reliable low glucose alarms because the defect triggers false alarms; (d) were not manufactured in compliance with FDA quality standards, as documented by the FDA’s Warning Letter; and (e) cannot be relied upon for insulin dosing and treatment decisions due to the prevalence of inaccurate readings.

163. Abbott had actual knowledge of these breaches, as the FDA documented Abbott’s failure to comply with quality system regulations.

164. As a direct and proximate result of Abbott’s breach of express warranties, Plaintiff and the Class have suffered damages, including the purchase price or price premium paid for the FreeStyle CGM and Libre 3 Sensors, costs for replacement sensors and devices, costs for blood glucose meters and testing supplies necessitated by the defective Sensors, and other incidental and consequential damages in an amount to be determined at trial.

COUNT IV
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY
(On Behalf of Plaintiff and the Nationwide Class)

165. Plaintiff repeats and realleges all factual averments as if fully set forth herein.

166. Plaintiff brings this claim individually and on behalf of the other members of the Nationwide Class (the “Class” for purposes of this Count).

167. Abbott is a “merchant” with respect to the FreeStyle CGM and Libre 3 Sensors under the Uniform Commercial Code and applicable state law.

168. By placing the FreeStyle CGM and Libre 3 Sensors into the stream of commerce, Abbott impliedly warranted that the products were merchantable and fit for the ordinary purposes for which such goods are used, namely to provide accurate continuous glucose monitoring to assist in diabetes management.

169. The FreeStyle CGM and Libre 3 Sensors were not merchantable and were not fit for the ordinary purposes for which continuous glucose monitors are used because they contained manufacturing defects that caused them to provide dangerously inaccurate low glucose readings, thereby failing to perform their essential function of accurately monitoring blood glucose levels.

170. Plaintiff and the Class were in privity with Abbott because Abbott marketed and sold the FreeStyle CGM and Libre 3 Sensors directly to consumers through its website, retail partners, and pharmacies; Abbott's warranties ran with the products; and Abbott was the intended beneficiary of consumer purchases.

171. As a direct and proximate result of Abbott's breach of the implied warranty of merchantability, Plaintiff and the Class have suffered damages, including the purchase price or price premium paid for the FreeStyle CGM and Libre 3 Sensors, and other incidental and consequential damages in an amount to be determined at trial.

COUNT V

VIOLATIONS OF THE CONNECTICUT UNFAIR TRADE PRACTICES ACT

C.G.S.A. § 42-110b.

(On Behalf of Plaintiff and the Connecticut Subclass)

172. Plaintiff repeats and realleges all factual averments as if fully set forth herein.

173. Plaintiff brings this claim individually and on behalf of the other members of the Connecticut Subclass (the "Subclass" for purposes of this Count).

174. C.G.S.A. § 42-110b provides that "[n]o person shall engage in unfair methods of

competition and unfair or deceptive acts or practices in the conduct of any trade or commerce. Conn. Gen. Stat. Ann. § 42-110b(a).”

175. Abbott has engaged in unlawful, unfair or fraudulent business acts or practice by knowingly selling defective Libre 3 Sensor and omitting disclosure of material information, including the Sensors’ defects and risks.

176. Defendants’ conduct was unfair because it offends established public policy, is immoral, unethical, oppressive, and unscrupulous, and causes substantial injury to consumers that is not outweighed by any countervailing benefits to consumers or competition. Defendants knowingly sold defective medical devices while concealing material safety information, prioritizing profits over patient safety.

177. Pursuant to such actions, Abbott has benefited from selling the FreeStyle CGMs.

178. Defendants’ conduct was fraudulent because Defendants’ misrepresentations and omissions regarding the safety, accuracy, and reliability of the FreeStyle CGM and Libre 3 Sensors were likely to deceive reasonable consumers.

179. Plaintiff and the Class have suffered an “ascertainable loss of money or property” as a result of Defendants’ unfair competition. Plaintiff and the Class paid a premium price for the FreeStyle CGM and Libre 3 Sensors based on Defendants’ representations regarding accuracy and safety, which Defendants knew to be false or misleading.

180. Abbott knowingly accepted the unjust benefits of its misconduct. Defendants have received and retained benefits from Plaintiff and the other Class Members, and inequity has resulted, justifying “[an] award [of] punitive damages and ... such equitable relief as [the Court] deems necessary or proper.” Conn. Gen. Stat. Ann. § 42-110g.

181. Because Abbott concealed its fraud and deception, Plaintiff and the other Class Members were not aware of the true facts concerning the Libre 3 Sensors and did not benefit from Abbott's misconduct.

182. It is inequitable and unconscionable for Defendants to retain these benefits.

183. Plaintiff and the Class are entitled to damages, restitution, disgorgement of profits, and injunctive relief pursuant to the Connecticut Unfair Trade Practices Act, along with further relief the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all Class Members, respectfully requests that the Court enter judgment in their favor and against all Defendants, individually, jointly, and severally on the entire Complaint, and award Plaintiff and the Class the maximum relief permitted by law, as follows:

- A. For an Order certifying this action as a class action, designating Plaintiff as Class Representative, and appointing Plaintiff's Counsel to represent the Class;
- B. For an award of actual damages, compensatory damages, restitution, equitable relief, statutory damages, and statutory penalties, in an amount to be determined at trial and as allowable by law;
- C. For an award of punitive and exemplary damages, as allowable by law;
- D. For an award of attorneys' fees and costs, and any other expense, including reasonable expert witness fees;
- E. Pre- and post-judgment interest on any amounts awarded; and
- F. Such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff and the other Class Members hereby demand a jury trial for all claims so triable.