UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

CARLA WIGGINS, AS PERSONAL REPRESENTATIVE OF THE ESTATE OF CARLTON D. GAUTNEY, JR.,

Plaintiff, Case No.: 3:22-cv-02781

v.

MEDTRONIC MINIMED, INC.

Defendant.

_____/

COMPLAINT AND JURY TRIAL DEMANDED

Plaintiff, CARLA WIGGINS as Personal Representative of the Estate of CARLTON D. GAUTNEY, JR., hereinafter ("Plaintiff") by and through the undersigned counsel, brings this Complaint against Defendant, MEDTRONIC MINIMED, INC. As grounds thereof, Plaintiff states:

JURISDICTION AND VENUE

1. This is an action for damages in excess of Seventy Five Thousand Dollars ($75,000.00), exclusive of interest, costs, and attorney's fees, thus vesting this Court with jurisdiction under 28 U.S.C. §1332. Additionally, venue is proper pursuant to 28 U.S.C. §1391.

2. At all times material hereto, the decedent, Carlton D. Gautney, Jr. ("Carlton Gautney") was a citizen of the State of Alabama and a resident of Covington County, Alabama.

3. Carlton D. Gautney, Jr. died on May 17, 2020, at the age of 59, and was survived by his daughter, Carla Wiggins, who has also been named the Personal Representative of his Estate.

4. The subject events resulting in the malfunction of the product manufactured and distributed by the Defendant and the death of Carlton Gautney, occurred in Okaloosa County, Florida.

5. At all times material hereto, Defendant, MEDTRONIC MINIMED, INC., was and is a Foreign Corporation (incorporated in Delaware) which was doing business throughout the State of Florida for which it received substantial revenue. Its principal place of business is located at 18000 Devonshire Street, Northridge, California 91325.

6. Defendant, MEDTRONIC MINIMED, INC., submitted itself to the jurisdiction of this Honorable Court by, doing personally or through its agents, at all times material to this cause of action, the following acts:

(a) Conducting and engaging in substantial business and other activities in Florida by selling and/or delivering defective automated insulin delivery systems, including the Medtronic MiniMed 670G system, to persons, firms, or corporations in this state via its subsidiaries, shareholders, distributors, dealers, wholesalers, and brokers. Such

products were used by consumers in Florida in the ordinary course of commerce and trade;

(b) Selling and delivering automated insulin delivery systems, including the Medtronic MiniMed 670G System, to persons, firms, or corporations in this state via its subsidiaries, shareholders, distributors, dealers, wholesalers, and brokers. Such products were used by consumers in Florida in the ordinary course of commerce and trade; and

(c) Causing injury to persons in Florida, including decedent, Carlton Gautney. At or about the time said injuries occurred, Defendant engaged in solicitation activities in Florida to promote the sale, consumption, use of its products and such products were consumed within Florida in the ordinary course of commerce, and Defendant was engaged in substantial and not isolated activity within this state;

STATEMENT OF FACTS

7. Type 1 diabetes is typically diagnosed in children and young adults and was previously known as juvenile diabetes. In Type 1 diabetes, the body does not produce insulin. Insulin is a hormone produced by the pancreas that converts sugar and starch from food into the energy needed to live.

8. On May 17, 2020, Carlton Gautney was a Type 1 diabetic when he suffered a severe hypoglycemic episode resulting in his immediate and untimely death.

9. Because of his diabetic condition, Carlton Gautney managed his diabetes through the use of insulin pump therapy, specifically, by using the Medtronic MiniMed 670G System, to deliver the necessary amount of insulin into his blood stream to properly treat his diabetes. When functioning properly, these

devices and their components mimic the ways a healthy pancreas works by delivering continuous and controlled doses of rapid-acting insulin, 24 hours a day, to match the user's body's needs.

10. Since August 2018, Carlton Gautney used the MiniMed 670G System until the time of his severe hypoglycemic episode that resulted in his death on May 17, 2020. The subject MiniMed 670G insulin pump was sold and delivered to Carlton Gautney on or about May 2019.

11. On Saturday, May 16, 2020, at or around 4:38 A.M., Carlton Gautney consumed 1g of carbs and gave himself 0.8 units of bolus insulin. At 4:47 A.M., Carlton performed an infusion set change. At 7:59 A.M. and 8:04 A.M., he consumed a total of 6g of carbs and gave himself 1 unit of bolus insulin. Shortly after 8:00 A.M., Carlton left his home and travelled to Fort Walton Beach, Florida, arriving at or around 9:50 A.M.

12. At 11:34 A.M., Carlton stopped for lunch, where he consumed 60g of carbs and gave himself 10 units of bolus insulin. Carlton finished lunch at approximately 12:30 P.M.

13. At around 2:50 P.M. that same day, Carlton checked into his room at the Motel 6 in Destin, Florida. At 4:34 P.M., Carlton calibrated his sensor, his blood glucose was 137 mg/dL.

14. At around 6:11 P.M., Carlton consumed 12g of carbs and gave himself

2 units of bolus insulin. At 7:04 P.M., Carlton consumed 3g of carbs and gave himself 0.5 units of bolus insulin. At 7:43 P.M., he consumed 1g of carbs and gave himself 0.1 units of bolus insulin. At 7:47 P.M., he consumed 21g of carbs and gave himself 3.5 units of bolus insulin. His total daily dose of insulin for Saturday, May 16, 2020, was 38.2 units, with 53% accounting for his total basal delivery and 47% accounting for his total bolus delivery.

15. At 5:03 A.M. on Sunday, May 17, 2020, Carlton calibrated his sensor, his blood glucose was 147 mg/dL. A few minutes later at 5:09 A.M., he consumed 24g of carbs and gave himself 4 units of bolus insulin.

16. Several hours later on the morning of Sunday, May 17, 2020, Carlton Gautney suffered a severe hypoglycemic event caused by an overdose of insulin delivered by the MiniMed 670G insulin pump.

17. At 10:56 A.M., Carlton was found deceased, lying flat on his back, not moving, with legs facing the doorway and his knees extending off of the bed, and his left arm extended straight from his left shoulder, and his right arm curled in the shape of an L at head level—his body position consistent with a person who sat down and lost consciousness and fell backwards. Carlton was found with his MiniMed 670G System attached to his body.

18. The Medtronic MiniMed 670G insulin pump at issue is the subject of an FDA Class 1 Device Recall issued on February 7, 2020.

THE PRODUCT: THE MINIMED 670G SYSTEM

I. *The MiniMed 670G System*

19. The Medtronic MiniMed 670G System (hereinafter "the MiniMed 670G System") is comprised of the Medtronic MiniMed 670G insulin pump, the Guardian Link Transmitter, the Guardian Sensor, One-Press Serter, and the Contour Next Link 2.4 Glucose Meter. The insulin pump at issue is the Medtronic MiniMed 670G Pump MMT-1780KL (hereinafter "the Subject MiniMed 670G pump").

20. The MiniMed 670G insulin pump is an ambulatory, battery-operated, rate programmable micro-infusion pump designed to deliver insulin from a reservoir. The reservoir is driven by a motor to deliver determined basal rate profiles and user selected bolus amounts of insulin into the subcutaneous tissue through an infusion set.

21. The MiniMed 670G System includes SmartGuard Technology which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values, and to suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values.

II. *Pre-Market Approval of the MiniMed 670G System*

22. The MiniMed 670G System is a Class III medical device that was cleared for marketing by the FDA pursuant to the agency's pre-market approval

process on September 28, 2016. As a condition of approval, Medtronic was required to conduct and submit the results of non-clinical testing performed on the 670G pumps. Non-clinical studies focus on bench testing to support compliance with component and system requirement specifications and testing of hardware requirements and mechanical requirements.

III. *The December 2021 FDA Warning Letter*

23. From June 7, 2021 through July 7, 2021, the FDA inspected Medtronic's Northridge, California facility, which manufactures and distributes the MiniMed 600 Series insulin infusion pumps, which includes the subject MiniMed 670G insulin pump.

24. Subsequent to the FDA inspection, the FDA issued a warning letter dated December 9, 2021 ("Warning Letter"), informing Medtronic that the MiniMed 600 Series insulin infusion pumps being manufactured and distributed are adulterated in that "the methods used in, or the facilities or controls used for, the 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 the Federal Regulations (CFR), Part 820." A copy of the Warning Letter is attached as **Exhibit A.**

25. The Warning letter also informed Medtronic that the FDA found various violations during the FDA Inspection, *some* of which are included in the

Warning Letter. The Warning Letter also notes that other violations are outlined in FDA form 483, which is not available to the Plaintiff, but is not an all-inclusive list of every possible violation of deviation from law and regulation observed during the FDA inspection.

26. The Warning letter lists several federal regulations that Medtronic was violating in connection with manufacture and sale of the MiniMed 600 Series insulin infusion pumps, including sections 21 CFR 820.100(a), 21 CFR 820.198(c), 21 CFR 803.50(a)(1), 21 CFR 803.50(a)(2).

27. Medtronic's conduct that is the subject of the violations noted in the Warning Letter also existed at the time the subject MiniMed 670G insulin pump was manufactured at the facility discussed in the Warning Letter.

IV. *Manufacturing Defects With the MiniMed 670G Insulin Pump*

28. Carlton Gautney's MiniMed 670G insulin pump was manufactured with defects in the pump's clear retainer ring, which defects caused the Subject MiniMed 670G insulin pump to fail to allow the reservoir to properly seat within the pump, causing an over-delivery of insulin.

29. The manufacturing defects were the direct result of Medtronic's failure to comply with the relevant FDA regulations in manufacturing the MiniMed 670G insulin pump.

30. At the time of the manufacture of the subject MiniMed 670G insulin

pump, Medtronic had already determined that pump failures were occurring to users because of damaged and defectively manufactured retainer rings, and further knew that damaged retainer rings may result in the over-delivery of insulin, leading to hypoglycemia and potentially fatal consequences to the users of the pump.

31. Despite being aware of these facts and dangers, and in violation of 21 CFR 820.100, Medtronic failed to adequately establish and implement procedures for corrective and preventive action (CAPA) with respect to the MiniMed 600 Series insulin infusion pumps, including the subject MiniMed 670G insulin pump. Specifically, Medtronic failed to (1) adequately analyze all sources of quality data, (2) identify actions needed to correct nonconforming products, (3) appropriately verify or validate the change to its devices to ensure corrective and preventive actions taken were effective and did not adversely affect the finished device.

32. In further violation of 21 CFR 820.100, Medtronic failed to accurately calculate the risk associated with failed retainer rings in the MiniMed 600 Series Infusion Pumps as its risk calculation formula underestimated the probability of harm to users. As a result, Medtronic failed to properly notify users of the danger and remove the defective devices from the field and instead continued to allow pumps with defective retainer rings to be used by users.

33. In addition, even after Medtronic's Field Safety Notification of the MiniMed 600 Series Infusion Pumps in November of 2019, Medtronic failed to

implement changes in its methods and procedures needed to correct and prevent the recurrence of quality problems as required by the FDA regulations, including 21 CFR 820.100. Instead, the Field Safety Notification consisted only of a customer notification letter advising consumers to inspect their devices for retainer ring damage and if no damage was noted, to continue using the devices despite having already redesigned the retainer ring to prevent further risk in newer devices, leaving pumps with defective retainer rings in use by consumers.

34. 21 CFR 820.198 required, but Medtronic failed to review, evaluate, and investigate complaints involving the possible failure of the MiniMed 600 Series insulin infusion pump to meet any of its specifications.

35. Medtronic received over 74,000 complaints regarding the defective retainer rings; after initially investigating the increase in complaints of damaged retainer rings, Medtronic itself determined that the clear retainer ring was defective and required manufacturing and/or design changes to correct and prevent the use of defectively manufactured retainer rings.

36. Medtronic's failure to comply with the above regulations preceded the Warning Letter and existed when the subject MiniMed 670G insulin pump was manufactured, directly leading to the decedent using the subject MiniMed 670G pump with a defectively and dangerously manufactured clear retainer ring.

37. Moreover, Medtronic's failure to comply with the above regulations

resulted in Medtronic failing to determine that the subject MiniMed 670G insulin pump was manufactured and delivered to Carlton Gautney with non-conformities that caused it to function improperly resulting in the over-delivery of insulin to Carlton Gautney.

COUNT I– STRICT LIABILITY - MANUFACTURING DEFECT AGAINST MEDTRONIC MINIMED, INC.

38. Plaintiff realleges paragraphs 1—37, as if restated verbatim herein.

39. At all times material, MEDTRONIC MINIMED, INC. designed, manufactured, tested, inspected, marketed, sold, and distributed the subject MiniMed 670G insulin pump.

40. The subject MiniMed 670G insulin pump reached Carlton Gautney in the same manner it was placed into commerce by Medtronic and was not modified or changed before, during and after the time it was sent by Medtronic directly to Carlton Gautney.

41. The subject MiniMed 670G insulin pump was defective and unreasonably dangerous as a result of a manufacturing defect. Specifically, the subject MiniMed 670G insulin pump was defective and unreasonably dangerous in that the retainer ring failed to properly seat within the pump, causing an over-delivery of insulin, as experienced by Carlton Gautney on May 17, 2020.

42. The manufacturing defect is the direct result of Medtronic's failure to comply with applicable federal regulations noted above for manufacturing the

MiniMed 600 Series insulin infusion pumps, including the subject MiniMed 670G insulin pump, and for not detecting and fixing manufacturing defects with MiniMed 600 Series insulin infusion pumps before placing them into the stream of commerce.

43. The manufacturing defects with the subject MiniMed 670G insulin pump described above directly and proximately caused Carlton Gautney's sudden and unexpected death in that they directly, and in a natural and continuous sequence, produced or contributed to his death.

44. In light of the relevant circumstances as described herein, the actions of MEDTRONIC MINIMED, INC. were grossly negligent, wanton and willful, and sufficient for the imposition of punitive damages under §768.72, Fla. Stat.

45. As a direct and proximate result of the foregoing, the Estate of CARLTON GAUTNEY has incurred damages for funeral expenses paid by or on behalf of the Estate.

46. Further, as a direct and proximate result of the foregoing, CARLA WIGGINS, as surviving daughter, has suffered the loss of her father's companionship, instruction, guidance and mental pain and suffering, in the past and future.

WHEREFORE, Plaintiff, demands judgment against Defendant, MEDTRONIC MINIMED, INC., for damages, costs, punitive damages, and such

other relief as this Court deems just, and further demands a trial by jury on all issues triable as a matter of right.

COUNT II– NEGLIGENT MANUFACTURING AGAINST MEDTRONIC MINIMED, INC.

47. Plaintiff realleges paragraphs 1—37, as if restated verbatim herein.

48. At all times material, MEDTRONIC MINIMED, INC. designed, manufactured, tested, inspected, marketed, sold, and distributed the subject MiniMed 670G insulin pump.

49. The subject MiniMed 670G insulin pump reached Carlton Gautney in the same manner it was placed into commerce by MEDTRONIC MINIMED, INC., and was not modified or changed before, during and after the time it was sent by Medtronic directly to Carlton Gautney.

50. MEDTRONIC MINIMED, INC. negligently manufactured the subject MiniMed 670G insulin pump. Specifically, MEDTRONIC MINIMED, INC. manufactured the subject MiniMed 670G insulin pump in violation of the federal regulations noted above, which violations resulted in the subject MiniMed 670G insulin pump being manufactured with a defective retainer ring that caused it to fail to properly seat within the pump, causing an over-delivery of insulin, as experienced by Carlton Gautney on May 17, 2020.

51. As a result of MEDTRONIC MINIMED, INC.'s negligence in manufacturing the subject MiniMed 670G insulin pump, Carlton Gautney received an over-delivery of insulin, causing his sudden and unexpected death.

52. Carlton Gautney's death was the direct and proximate result of the negligent manufacturing defects with the subject MiniMed 670G insulin pump described above, in that they directly, and in a natural and continuous sequence, produced or contributed to his death.

53. In light of the relevant circumstances as described herein, the actions of MEDTRONIC MINIMED, INC. were grossly negligent, wanton and willful, and sufficient for the imposition of punitive damages under §768.72, Fla. Stat.

54. As a direct and proximate result of the foregoing, the Estate of CARLTON GAUTNEY has incurred damages for funeral expenses paid by or on behalf of the Estate.

55. Further, as a direct and proximate result of the foregoing, CARLA WIGGINS, as surviving daughter, has suffered the loss of her father's companionship, instruction, guidance and mental pain and suffering, in the past and future.

WHEREFORE, Plaintiff, demands judgment against Defendant, MEDTRONIC MINIMED, INC., for damages, costs, punitive damages, and such

other relief as this Court deems just, and further demands a trial by jury on all issues triable as a matter of right.

Dated this 3rd day of March 2022.

/s/ J. Scott Murphy
J. SCOTT MURPHY, ESQ.
FBN: 0373001
ANDREW F. KNOPF, ESQ.
FBN: 658871
PAUL | KNOPF | BIGGER
840 South Denning Drive, Suite 200
Winter Park, Florida 32789
Ph: (407) 622-2111
Fax: (407) 622-2112
scott@pkblawfirm.com
andrew@pkblawfirm.com
abla@pkblawfirm.com
leslie@pkblawfirm.com
Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on March 3, 2022, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system. I further certify that the foregoing document will be furnished to the above named Defendants via service of process.

/s/ J. Scott Murphy
J. SCOTT MURPHY, ESQ.
FBN: 0373001
ANDREW F. KNOPF, ESQ.
FBN: 658871
PAUL | KNOPF | BIGGER
840 South Denning Drive, Suite 200
Winter Park, Florida 32789
Ph: (407) 622-2111
Fax: (407) 622-2112
scott@pkblawfirm.com
andrew@pkblawfirm.com
abla@pkblawfirm.com
leslie@pkblawfirm.com
Attorneys for Plaintiff