IN THE UNITED STATE DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

CLAYTON WARMOTH,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. CIV-21-712-SLP
	)	
MEDTRONIC, INC., MEDTRONIC MINIMED INC.	)	
	)	
	)	
Defendants.	)	

COMPLAINT

COMES NOW, the Plaintiff, Clayton Warmoth, and for his claims for relief against the Defendant, Medtronic, Inc., Medtronic Minimed Inc., alleges and states as follows:

JURISDICTION AND VENUE

1. Plaintiff is, and at all times relevant to this action was, a citizen and resident of the State of Oklahoma with his place of residence on 1525 Emerwood Road, Moore, Oklahoma County, Oklahoma 73160.

2. Defendant Medtronic, Inc. is and at all times relevant to this action, was a resident and/or corporation with its principal place of residence and/or business in a state other than the State of Oklahoma.

3. Defendant Medtronic Minimed, Inc., is and at all times relevant to this action, was a resident and/or corporation with its principal place of residence and/or business in a state other than the State of Oklahoma.

4. Complete diversity of citizenship exists pursuant to 28 U.S.C. § 1332. At all times relevant to this cause of action, the Plaintiff/Defendants had the requisite minimum contacts with the State of Oklahoma, and the amount in controversy in this action exceeds Seventy-Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

5. The United States District Court for the Western District of Oklahoma is the proper venue for this matter pursuant to 28 U.S.C. § 1391. The events that give rise to this cause of action, distribution of the product to the Plaintiff, the malfunction of the product while in use by the Plaintiff and other acts and omissions forming the basis of the Plaintiffs claims took place in the Western District of Oklahoma. The Defendant named herein conducts substantial business in the Western District of Oklahoma, where the Plaintiff resides.

FACTUAL BACKGROUND

6. The Plaintiff, Clayton Warmoth, is a Type 1 diabetic. 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 energy needed to live.

7. Because of his diabetic condition, Clayton Warmoth managed his diabetes through the use of insulin pump therapy, specifically by using the Medtronic MiniMed 670G (MMT-1780) Insulin Pump ("the device"), to deliver the necessary amount of insulin into his blood stream to properly control his blood sugar and treat his diabetes. When functioning properly, the device and its components mimic a healthy pancreas by

delivering continuous and controlled doses of rapid-acting insulin, 24 hours a day, as needed in the user's body.

8. The Plaintiff began using the device in 2018 and used it to treat his diabetic condition until on or about July 15, 2019, when he suffered a hyperglycemic episode resulting in decreased motor functions and slurred speech.

9. On the morning of July 15, 2019, the Plaintiff, Clayton Warmoth, awoke and immediately noticed that he was having difficulty walking and speaking. As a result he was transported by ambulance to Integris Canadian Valley Hospital (a non-party herein) where he received testing which indicated his blood glucose level was 650 mg/dL.

10. The Medtronic MiniMed 670G (MMT-1780) Insulin Pump at issue was part of an FDA issued Class 1 Device Recall on November 21, 2019. Unfortunately, this was after Mr. Warmoth's injury.

11. The collective Defendants, along with their agents, and employees, negligently caused the defective insulin pumps to be designed, manufactured, assembled, distributed, and sold to members of the public and they further negligently failed to remove the recalled infusion sets from the marketplace and stream of commerce after they had knowledge of the defects as well as the recall.

12. The Defendants designed, manufactured, marketed and distributed the Medtronic MiniMed 670G (MMT-1780) Insulin Pump and Pro Set Infusion Sets, which were marketed to deliver insulin to a person with diabetes in measured amounts. The MiniMed pump was manufactured with a retainer ring designed to lock the patient's insulin cartridge into place in the pump's reservoir compartment. Pro Set Infusion Sets consist of

a membrane and disposable plastic tubes which transport insulin from the pump to the patient's body.

14. The Medtronic MiniMed 670G (MMT-1780) Insulin Pump and Pro Set Infusion Sets are used in conjunction with one another to help people with diabetes regulate their blood sugar by providing a constant source of insulin. They provide an alternative to daily injections of insulin as the pump connects to flexible plastic tubing that delivers insulin to the body. Users set the pump to deliver insulin throughout the day. It can be programmed to release larger doses at meals or at times when blood sugar levels are too high.

15. Clayton Warmoth had no way of knowing that the Medtronic MiniMed 670G (MMT-1780) Insulin Pump and Pro Set Infusion Sets that he used on the day of the incident were defective in design, manufacture, and marketing, and that even when used consistent with Defendants' instructions, they deliver incorrect and life-threatening doses of insulin.

THE COMPANIES

17. Medtronic MiniMed insulin pumps and infusion sets have been the subject of a myriad of problems and defects over the years. For example, in sharp contrast to Medtronic's Website, are statements from a June 1, 2009, letter from the United States Food and Drug Administration ("FDA") to William A. Hawkins, Medtronic's president and chief executive officer regarding Medtronic PR Operations Co., the firm where MiniMed pumps are manufactured. In criticizing Medtronic's manufacturing and reporting process, the FDA cited Medtronic for:

> Failure to report to the FDA no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device you have on the market: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to the death or serious injury, if the malfunction were to recur…

18. In contravention of applicable regulations, Medtronic has failed to report an incident involving a MiniMed insulin pump in which "device failure or malfunction may have contributed to or caused the user's hospitalization and the device's malfunction would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur."

19. The FDA also found fault with the personnel that Medtronic entrusted at its manufacturing facility in Puerto Rico when determining whether a Medtronic device was dangerous. Specifically, the FDA cited Medtronic for:

> Failure to have a person who is qualified to make a medical judgment reasonably conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury, if it were to recur, as required by [United States Federal Law.] Personnel qualified to make a medical judgment include physicians, nurses, risk managers and biomedical engineers under [United States Federal Law.]

20. According to FDA Investigators, this plant had a wide range of problems that included lax testing of products for defects, improper record keeping, and employing someone with insufficient training as a medical expert to determine danger or defects. Said employee only had a high school diploma with some additional in-house training. In listing these and other violations, the FDA concluded that the problems may be symptomatic of serious problems in Medtronic's manufacturing process and its quality controls.

21. None of the cited violations reflect Medtronic's promise to strive "without reserve for the greatest possible reliability and quality in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service."

22. On or about June 29, 2009, these issues led to a Class 1 recall of many of the Defendants' insulin infusion sets labeled Paradigm Quick-Set Infusion Sets. The recall included lots manufactured between 2007 and 2009. Approximately three million disposable infusion sets were recalled.

23. On or about June 7, 2013, Medtronic MiniMed Paradigm infusions were recalled via a Class 1 recall. The recall was issued "because of a potential safety issue that can occur if insulin or other fluids come in contact with the inside of the tubing connector. If this occurs it can temporarily block the vents that allow the pump to properly prime."

24. The 2013 recall admitted that "[t]his can result from too much or too little being delivered resulting in hypoglycemia and hyperglycemia which can be severe and lead to serious illness."

25. The 2013 recall was virtually identical to the 2017 recall with regard to the infusion set at issue in this case. The same problems – fluid causing a vent blockage – resulting in the same outcomes – over-delivery of insulin – are at issue in both recalls.

26. It is clear that Medtronic did not resolve the problem with their product that resulted in the 2013 recall. Medtronic marketed the subject infusion sets without fixing the problem, resulting in another recall for the same defect in 2017.

27. Past recalls and problems associated with Medtronic infusion sets did not result in Medtronic designing and marketing safer products for use by Clayton Warmoth.

THE CURRENT RECALL

28. On September 7, 2017, Medtronic issued an "Urgent Medical Device Recall" regarding Medtronic MiniMed Infusion Sets.

29. The Recall Notice states that "Medtronic has become aware of recent reports of potential over-delivery of insulin shortly after an infusion set change." Medtronic further notes that it has received reports of hypoglycemia requiring medical attention related to this issue, which Medtronic concedes can result in "hypoglycemia and in extreme cases, death."

30. The Recall Notice states that this problem is caused by fluid blocking the infusion set membrane during the priming/fill tubing process, which prevents the infusion set from working properly. The result can be fast delivery of multiple days' worth of insulin.

31. The Recall Notice also announces that Medtronic has an alternate infusion set design, which contains a "new and enhanced membrane material that significantly reduces the risk."

32. As a result of the defective MiniMed Infusion Sets, Clayton Warmoth did not receive enough insulin, which resulted in severe hyperglycemia and physical as well as mental/emotional injury.

33. On November 21, 2019, Medtronic also notified the FDA of a defect in its Medtronic MiniMed 670G (MMT-1780) Insulin Pump. The information supplied to the

FDA prompted a Class 1 recall of all devices distributed between 2016 and October 2019, which includes the Plaintiff's pump. According to Medtronic, defects in the locking retainer rings on Model 670G, prevent a patient's insulin reservoir from being properly seated within the pump when it is loaded.

34. The Plaintiff is now informed and believes that his pump likewise malfunctioned due to this defect resulting in hypoglycemic events. It was not until after his injury and the recent recall for all lots, that Plaintiff was ever made aware that this product was unreasonably dangerous and had contributed to his injury.

CLAIMS FOR RELIEF

I. STRICT PRODUCT LIABILITY

35. The Plaintiff incorporates by reference and realleges each and every allegation in this Complaint as the same though specifically set forth herein.

36. The Plaintiff hereby asserts a design defect claim pursuant to applicable Oklahoma law.

37. At all times relevant to the Complaint, the Defendants were in the business of designing, manufacturing, marketing, testing, labeling, selling and/or distributing Medtronic Model 670G (MMT-1780) Insulin Pumps and MiniMed Infusion Sets. The products at issue were defective and unreasonably dangerous at the time they left the hands of the respective Defendants. Defendants placed their products into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design of the products. The products

reached the Plaintiff in the same condition they were in at the time they left the Defendants and were placed into the stream of commerce.

38. Defendants' products were defective due to inadequate post-marketing warning and instructions, and/or inadequate testing and studies, and/or inadequate reporting regarding the results.

39. The defective and unreasonably dangerous conditions discussed herein existed when the products left Defendants' control. They existed when the Defendants sold the products. They existed when the Plaintiff received them. They were specifically known to Defendants and as to the infusion sets, had been the subject of recall since December 23, 2016, as was known to all the Defendants prior to the Plaintiff's injury on July 15, 2019.

40. Defendants' failure of said sets prior to September 2017, showed a willful, wanton and malicious want of care which raises the presumption of indifference to consequences. Specifically:

a. Defendants had a continuing duty to ensure that the products they provided were safe and used correctly through proper design, testing, research, adequate instruction, post-market surveillance, and appropriate modifications;

b. Defendants had a duty to anticipate the environment in which the products would be used and to design against reasonably foreseeable risk attending the products' use in that setting, including misuse or alteration;

c. Defendants had a continuing duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of their products;

d. Defendants had a continuing duty to assure the products they provided were properly labeled and true to the representations made by Defendants.

41. Defendants' products were defective in light of the dangers posed by their respective design and the likelihood of those avoidable dangers. Defendants' products were defective because the inherent risk of harm in Defendants' products' design outweighed the utility and benefits of the products.

42. Defendants' products were defective because reasonably cost-effective and feasible state-of-the-art alternatives existed at the time that would not have undermined the products' usefulness. Defendants were aware of effective substitutes for the products. The gravity and likelihood of dangers posed by the products' designs outweighed the feasibility, cost, and adverse consequences to the products' function of a safer alternative designs that Defendants reasonably should have adopted.

43. There were safer alternative designs that would have prevented or significantly reduced the risk of injury. It was reasonable as well as economically and technologically feasible at the time the products left the Defendants' control by the application of existing or reasonably achievable scientific knowledge. Plaintiff would show that both the pump and infusion sets in question were in the same condition when he

received them as when they left the Defendants', and they were used in accordance with the Defendants' instructions.

44. As a direct and proximate result of the design, manufacture and marketing defects and the Defendants' conduct alleged herein, Plaintiff sustained injuries and damages for which a cause of action is hereby stated.

II. NEGLIGENCE

45. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint in the same as though specifically set out herein again.

46. At all times relevant to this Complaint, Defendants knew or reasonably should have known that their products were unreasonably dangerous and defective when used as designed and directed.

47. Defendants had a duty to exercise reasonable care, and to comply with the then existing standard of care, in the design, testing, research, development, packaging, distribution, promotion, marketing, advertising, instruction and sale of their products, individually and collectively, deviated from reasonable and safe practices in the following ways, by:

a. Designing products defective in design and warnings/instructions;

b. Failing to conduct pre and post market safety tests and studies;

c. Failing to collect, analyze and report available data regarding the use of Defendants' products;

d. Failing to conduct adequate post-market monitoring and surveillance;

e. Failing to include adequate warnings about and/or instructions;

f. Failing to include adequate warnings and/or proper instructions regarding proper use of the products;

g. Failing to inform users that Defendants had not adequately tested or researched the product to determine its safety and risks;

h. Failing to educate and instruct user about the unique characteristics of their products and proper way to use them;

i. Failing to implement and execute corrective and preventative actions to eliminate injuries;

j. Continuing to promote and market the products despite ongoing failures and known defects, and in the case of the Pro Set infusion sets, recalls by their co-manufacturer on December 23, 2016.

48. Had Defendants designed safe products and/or undertaken the tests, studies, and steps described herein, the injuries and damages complained of would not have occurred.

49. Defendants held themselves out as experts and specialists and therefore possessed a higher degree of skill and learning.

50. Defendants' products were not fit for the ordinary purpose for which such goods were used. They were unmerchantable when used as directed and defective in design, and the Defendants' failure to provide adequate warnings and instructions also resulted in said products being unreasonably dangerous.

51. Defendants' products were dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Clayton Warmoth.

52. Injuries sustained by the Plaintiff, Clayton Warmoth, were both proximately caused and a reasonably foreseeable result of Defendants' defective products and conduct.

53. Defendants are bound for the care of their agents, servants, employees, officers and directors for the neglect of the same. Defendants are liable for the conduct of their agents, servants, employees, officers and directors committed in the course of the activities on behalf of and in furtherance of the companies. Defendants are liable for their agents, employees, officers and directors conduct attempting to advance Defendants' business. Defendants expressly and impliedly authorized and ratified the conduct of their agents, servants, employees, officers and directors. Defendants received significant benefits as a result of their agents', employees', servants', officers' and directors' conduct.

54. Defendants' conduct showed willful, wanton and malicious want of care that raises the presumption of conscious indifference to the consequences. Defendants' wrongdoing constituted gross negligence and said gross negligence proximately caused the injury to the Plaintiff and damages sustained as a result thereof.

III. BREACH OF EXPRESS WARRANTY

55. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein, again.

56. The Defendants represented and warranted to the Plaintiff that it's Medtronic MiniMed Infusion Sets and MiniMed 670G (MMT-1780) Insulin Pump were safe for use

in accordance with the Defendants' protocols. Said representations were in the form of marketing materials, device information and product materials provided to Clayton Warmoth. Clayton Warmoth justifiably relied on said representations and express warranties in electing to use said product.

57. The Medtronic MiniMed Infusion Sets and MiniMed 670G (MMT-1780) Insulin Pump at issue did not conform to Defendants' express representations and warranties.

58. At all relevant times, said products did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

59. At all relevant times, said products did not perform in accordance with the Defendants' representations.

60. As a direct and proximate consequence of the Defendants' conduct, the Plaintiff sustained injuries and was damaged. Plaintiff hereby asserts a claim for breach of express warranty pursuant to applicable Oklahoma law.

IV. BREACH OF IMPLIED WARRANTY

61. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

62. By designing, marketing and selling the products at issue, the Defendants impliedly warranted to the Plaintiff that said products were merchantable and fit for ordinary use.

63. Defendants' products were not fit for the ordinary purposes for which such goods are used. They were unmerchantable when used as directed and defective in design,

and the Defendants' failure to provide adequate warnings and instructions also resulted in said products being unreasonably dangerous. Defendants' products were dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the products' characteristics including Clayton Warmoth.

64. Defendants breached their implied warranty because the products were not safe, adequately packaged and labeled, did not conform to the representations Defendant made. They were not properly usable according to the labeling and instructions provided.

65. The Defendants' breaches of implied warranties, pursuant to Oklahoma law, proximately resulted in the damages sustained by the Plaintiff.

V. PUNITIVE DAMAGES

66. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

67. The conduct of the Defendants was reckless, willful, wanton and likely to lead to physical injury.

68. As a direct and proximate result of the willful, wanton, intentional acts, and/or the willful, wanton, intentional and reckless failures to act by each Defendant, Plaintiff suffered the aforementioned damages and, as such, Plaintiff demands that punitive damages be awarded against each Defendant.

VI. DAMAGES

69. As a direct result of the defects existing in the Medtronic MiniMed 670G (MMT-1780) Insulin Pump designed, manufactured, distributed, sold and/or placed into the stream of commerce by Defendants and as a direct and proximate cause of some or all

of the Defendants' breaches of duties and warranties described herein, Plaintiff, Clayton Warmoth endured mental anguish and emotional distress (both past and future); physical pain and suffering, including extreme hyperglycemia, along with orthopedic injury, and suffered neurological injury and caused neurological deficits and has incurred significant medical expenses in the past and will incur additional medical expenses in the future.

70. Defendants' acts, omissions and breaches as set forth herein were the proximate cause of Plaintiff's injuries, giving rise to Plaintiff's claims stated herein and entitling Plaintiff to all economic and non-economic damages available under law, including but not limited to pain and suffering, loss of enjoyment of life, loss of income and wages (past and future), medical expenses (past and future), punitive damages, and al other damages available at law.

71. As a direct and proximate result of the Defendants' aforementioned actions, Plaintiff, Clayton Warmoth, prays for judgment against Defendants, Medtronic, Inc. and Medtronic MiniMed, Inc. in an amount in excess of ($75,000.00).

WHEREFORE, PREMISES CONSIDERED, Plaintiff brings these causes of action against each Defendant (and each of its predecessors, successors, assigns, subsidiaries, and divisions) and demands judgment against each Defendant in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00), and in an amount that will compensate Plaintiff for all damages allowed by law resulting from the injury. All damages are demanded together with pre- and post-judgment interest, cost of this action expanded, and any other relief warranted by law or otherwise deemed appropriate.

Respectfully Submitted,

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