IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

WILLIAM F. MILLS Plaintiffs, v. MEDTRONIC MINIMED, INC. a Delaware corporation; MINIMED DISTRIBUTION CORP. a Delaware corporation; and MEDTRONIC, INC., a Minnesota corporation Defendants.	Civil Action No. PLAINTIFFS' ORIGINAL COMPLAINT DEMAND FOR JURY TRIAL

Plaintiff WILLIAM F. MILLS, by and through his counsel Trief & Olk and Houssiere, Durant, & Houssiere, LLP, allege as follows:

I. INTRODUCTION

1. This case arises out of William Mills's use of a defective Medtronic MiniMed Paradigm Insulin Pump, defective Paradigm insulin reservoirs, and defective Paradigm insulin infusion sets.

2. Although Defendants knew—as early as 2010—that severe problems existed with respect to the design, manufacturing, warnings, and function of the insulin pump, insulin reservoirs, and insulin infusion sets, they failed to take sufficient action to correct these defects and have allowed these products to remain on the market. As a result of Defendants' negligence, recklessness, failure to warn, failure to properly design the products at issue, failure to properly manufacture the products at issue, and breaches of express and implied warranties, in 2012, William Mills experienced severe hypoglycemia caused by the malfunction of the insulin pump and infusion sets he had been utilizing, resulting in subsequent injuries and hospitalization.

II. PARTIES

3. At all relevant times, Plaintiff WILLIAM F. MILLS was residing in, and was

residents of, the State of New York.

4. Defendant MEDTRONIC MINIMED, INC. is and at all relevant times a corporation duly organized under the laws of Delaware, with its principal place of business at 18000 Devonshire Street, in the City of Northridge, County of Los Angeles, State of California. Defendant MEDTRONIC MINIMED, INC. may be served by serving its registered agent of record, CT Corporation System at 818 West 7th St., Los Angeles, California 90017.

5. Defendant MINIMED DISTRIBTUION CORP is and, at all relevant times, was a corporation duly organized under the laws of Delaware, registered to conduct business, and routinely conducting business, in the State of New York, with its principal place of business in California at 18000 Devonshire Street, Northridge, California 91325. Defendant MINIMED DISTRIBUTION CORP may be served by serving its registered agent of record, CT Corporation System at 111 Eighth Avenue, New York, New York 10011.

6. At all relevant times, Defendants MEDTRONIC MINIMED and MINIMED DISTRIBUTION CORP were involved in the discovery, design, assembly, manufacture, testing packaging, labelling, marketing, distribution, sale, and/or was otherwise involved in placing into the stream of commerce the medical devices called the MiniMed Paradigm® Insulin Pump and the Medtronic Quick-set Infusion Sets.

7. Defendant MEDTRONIC, INC. is and at all relevant times was a corporation duly organized under the laws of Delaware, with its principal place of business in the City of Minneapolis, State of Minnesota. Defendant Medtronic, Inc. is the parent and sole owner of Defendant Medtronic MiniMed, Inc. Defendant Medtronic, Inc. routinely conducts business in the state of New York and is registered to conduct business in New York. Defendant Medtronic, Inc. may be served by serving its registered agent of record, CT Corporation System at 111 Eighth Avenue, New York, New York 10011.

8. At all relevant times, MEDTRONIC, INC. was and is involved in the discovery, design, assembly, manufacture, testing packaging, labelling, marketing, distribution, sale, and/or was otherwise involved in placing into the stream of commerce the medical devices called the

Minimed Paradigm® Insulin Pump and the Quick-set Infusion Sets. MEDTRONIC MINIMED, INC., MINIMED DISTRIBUTION CORP, and MEDTRONIC, INC. are collectively herein referred to as "MEDTRONIC."

III. JURISDICTION AND VENUE

9. The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs. This civil action is between citizens of different states. Each Defendant maintains sufficient minimum contacts with the State of New York such that the exercise of jurisdiction over each Defendant by New York courts would not offed traditional notions of fair play and substantial justice. By reason of the foregoing circumstances, this Court has diversity jurisdiction over this lawsuit. 28 U.S.C. § 1332(a)(1).

10. Venue is proper in this District because is a judicial district in which a substantial part of the events or omissions giving rise to Plaintiff's claim occurred. 28 U.S.C. § 1391(a)(2).

IV. GENERAL ALLEGATIONS

A. Pump Malfunction

11. Plaintiff William Mills was diagnosed with Type II diabetes in or about 2002.

12. Type II diabetes is a chronic condition usually caused by genetic factors, environmental factors, or viruses in which the pancreas produces little or no insulin, a hormone needed to allow sugar (glucose) to enter cells to produce energy. Individuals with Type II diabetes have to inject the insulin that their bodies need. Some Type II diabetes patients employ a syringe or insulin pen to inject insulin as needed, while others use an insulin pump. An insulin pump is a small, computerized device that is worn on the belt and allows for insulin delivery to the body through small, flexible tubes inserted under the skin.

13. An insulin pump stores a cylindrical vial of insulin. This insulin is supplied to an individual at a constant rate, known as a basal rate. The patient may also force the pump to deliver a set amount of insulin as needed. This forced delivery of insulin is called a bolus.

14. Insulin is transported from the reservoir in the pump to the patient's blood stream through a tube and needle system, called a "cannula" or a "quickset."

15. In or about 2010, William Mills began using a Medtronic MiniMed Paradigm Insulin Pump with model number MMT-523NAS.

16. On or about June 26th, 2012, William Mills was utilizing the Medtronic MiniMed Paradigm insulin pump, Paradigm reservoir, and Paradigm infusion sets, in a reasonable and foreseeable manner, in an effort to manage and control his diabetes.

17. On or about June 26th, 2012, in the early morning, Mr. Mills awoke to use the bathroom. While in the bathroom, Mr. Mills felt dizzy, lost consciousness, and fell, causing injury. The injury included, among other things, damage to Mr. Mills's face and hip.

18. Paramedics were contacted and arrived at Mr. Mills's location, were he was diagnosed with low blood sugar, or hypoglycemia. On or about June 26th, 2012, Mr. Mills presented to the Emergency Room, and on or about June 29th, 2012 a CT scan confirmed a small to moderate left subdural hematoma, which required additional healthcare.

19. As a direct and proximate result of Defendants' acts and omissions, Plaintiff's Medtronic MiniMed Paradigm insulin pump malfunctioned, causing an over delivery of insulin, resulting in hypoglycemia, and Plaintiff has suffered and will continue to suffer damages.

B. Recalls and Warning by FDA concerning Medtronic MiniMed Insulin Pumps

20. On June 1, 2009, the United States Drug Administration issued a Warning Letter to Medtronic regarding its plant in Juncos, Puerto Rico, where Medtronic has manufactured MiniMed Insulin Pumps (the 2009 "FDA Warning Letter").

21. The 2009 FDA Warning Letter concluded that instead of reporting adverse events within 30 days as required under 21 C.F.R. 803.50(a), Medtronic waited 18 months before reporting "that a device malfunction occurred" in which a patient complained that his/her MiniMed Paradigm Insulin Pump malfunctioned. The agency admonished Medtronic for misstating the severity of the complaint and wrongly characterizing the malfunction as "unlikely to result in death or injury if it were to recur." More specifically, the patient at issue had notified Medtronic of a blood glucose level of 456, and the MiniMed Paradigm Insulin Pump had failed to alarm when it stopped delivering insulin. The patient was subsequently hospitalized for

diabetic ketoacidosis.

22. The 2009 FDA Warning Letter also admonished Medtronic for using an unqualified individual to reach medical conclusions 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, as required by 21 C.F.R. 803.20(c)(2). The FDA's investigators determined that "a product reporting specialist" was making decision about Medical Device Reporting (MDR) reportability for the MiniMed Paradigm Insulin Pumps. The training record for the particular employee showed that he/she had only a high school diploma with some additional in-house training.

23. On June 29, 2009, Medtronic issued a Class I recall (the highest recall category) for its Quick-set Infusion Sets for the Medtronic MiniMed Paradigm Insulin Pump because the "infusion sets may not allow the insulin pump to vent air pressure properly" and "could potentially result in the device delivering too much or too little insulin" thereby possibly causing "serious injury or death." The recall was expressly limited to "Lot 8" Paradigm Quick-Set infusion sets manufactured and distributed from December 1, 2007, through June 18, 2009. An infusion set is a thin plastic tube used to deliver insulin from an insulin pump to a diabetic patient.

24. On March 25, 2013, Medtronic issued an "Important Medical Device Safety Information" regarding another issue with the MiniMed Paradigm Insulin Pump. This letter warned patients that the "drive support cap" that holds the pump motor in place could loosen and, if pushed back into place, could result in "unintended delivery of insulin and associated severe hypoglycemia."

25. On April 10, 2013, Medtronic announced a Class 2 Recall (No. Z-1085-2013) of certain Medtronic MiniMed Paradigm Insulin Infusion Pumps, including Model No. MMT-512NAS. This recall resulted from a violation of the applicable Good Manufacturing Products to component controls. According to the Recall Notice, the caps on these pumps' "drive support cap may become detached from the pump's case and protrude from the lower right side of the

pump. When the pump is expose (sic) to water it may result in damage to the pump's internal electronics. This moisture damage can prevent the pump's buttons from working properly or can cause the pump to alarm."

26. On June 7, 2013, Medtronic sent another "urgent medical device safety notification" regarding a Class I recall (the highest classification of recalls) as a result of problems with the MiniMed Insulin Pump's tubing connectors. Specifically, "if insulin or other fluids [were to] come in contact with the inside of the" tubing connector, then the insulin or fluid could "temporarily block the vents in the connector that allow the pump to properly prime" and could "result in too much or too little insulin being delivered, which may cause hypoglycemia or hyperglycemia" which in turn could cause "loss of consciousness or death."

27. On July 3, 2013, Medtronic issued another "Urgent Medical Device Recall" based on leaks occurring in the MiniMed Insulin Pump's reservoirs. Specifically, the recall stated that "[a] leak in the reservoir may result in delivery of less insulin than intended, and if there is an insulin blockage in the infusion set, the pump may not alarm."

28. On September 19, 2013, the FDA issued a voluminous second Warning Letter to Medtronic outlining over 20 safety concerns with Medtronic's practices and procedures related to the MiniMed Insulin Pump ("2013 FDA Warning Letter").

29. The 2013 FDA Warning Letter relayed that Medtronic has failed "to establish and maintain procedures for implementing corrective and preventive action as required by [FDA regulations]." More particularly, Medtronic "failed to verify or validate corrective actions to ensure that each action is effective and does not adversely affect the finished device" and "did not identify actions needed to correct the deficiency."

30. The 2013 FDA Warning Letter also noted that Medtronic failed to follow "process validation procedures and policies," for which the "root cause was...insufficient training and lack of attention to detail." Afterwards, Medtronic produced no documentation to verify or validate that training as a corrective action was effective and would prevent recurrence of [Medtronic's] employees not following process validation procedures and policies."

31. The 2013 FDA Warning Letter also cited "problems related to transferring designed changes from [Medtronic's] Northridge (NR) site to...[the] Medtronic Puerto Rico Operations Company." Again, the file "was closed with no evidence that effectiveness checks were completed for the corrective action identified...to ensure that [the] corrective action was effective and does not adversely affect the finished product."

32. The 2013 FDA Warning Letter admonished Medtronic because it "failed to identify actions needed to correct and prevent recurrence of the Paradigm Insulin Infusion Pumps (MMT-5XX, 7XX) device failure."

33. Other safety concerns at Medtronic highlighted by the 2013 FDA Warning Letter include:

a. "Failure to review and evaluate all complaints to determine whether an investigation is necessary and to maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate when no investigation is made, as required by [FDA laws]." The letter goes on to cite four instances where patients had problems with the MiniMed Insulin Pump but Medtronic failed to sufficiently investigate the problems;

b. "Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation, as required by [FDA laws]";

c. "Failure to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by [FDA laws]";

d. "Failure to establish and maintain procedures for acceptance of incoming product, as required by [FDA laws]";

e. "Failure to ensure that when results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures, as required by [FDA laws]";

f. "Failure to establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met, as required by [FDA laws]";

g. "Failure to review and evaluate a process and perform revalidation where appropriate when changes or process deviations occur, as required by [FDA laws]";

h. "Failure to ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results, as required by [FDA laws]";

i. "Failure to ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed and installed to facilitate maintenance, adjustment, cleaning, and use as required by [FDA laws]";

j. "Failure to document acceptance activities as required by [FDA laws]";

k. "Failure to establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics, as required by [FDA laws]";

l. "Failure to make readily available for review and copying by FDA employees all records required by [FDA laws]";

m. "Failure to report to the [FDA] no later than 30 calendar days after [Medtronic] received or otherwise became aware of information, from any source that reasonably suggests that a device that you firm markets may have caused or contributed to a death or serious injury, as required by [FDA laws]"; and

n. "Failure to report to the [FDA] no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that your firm markets has malfunctioned and your device or a similar device that your firm markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by [FDA laws]."

34. As a result of these violations—some of which went back years earlier—the FDA

determined that these devices "are adulterated within the meaning of section 501(h) of the [Medical Device] 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 (C.F.R.), Part 820."

35. The FDA also determined the Medtronic Paradigm Insulin Infusion Pumps are "misbranded" within the meaning of the Federal Drugs and Cosmetic Act ("FDCA") in that "your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act [pertaining to medical device reporting]." The Agency noted that

> [s]ignificant violations include, ***but are not limited to***, the following:
> Failure to report to the agency no later than 30 calendar days after your firm received or otherwise became aware of information, from any source that reasonably suggests that a device that your firm markets may have caused or contributed to a death or serious injury, as required by 21 C.F.R. 803(a)(1). For example, complaint [REDACTED] includes information that reasonably suggests that a malfunction of your device resulted in over delivery of insulin that may have caused or contributed to a life threatening injury (i.e. diabetic coma) to the patient. You became aware of the event on November 5, 2010, and FDA received a serious injury [report] on May 9, 2011 which is beyond the 30 day calendar timeframe.
>
> Failure to report to the agency no later than 30 calendar days after the day that your firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that your firm markets has malfunctioned and your device or a similar device that your firm markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur as required by 21 C.F.R. 803.50(a)(2). For example, the information in complaint [REDACTED] states that "a pump gave boluses without input and no alarms." No patient information was available. You were aware of information from a previous complaint [REDACTED] in which a malfunction of the device resulted in over delivery of insulin that led to a patient injury. Therefore, the event meets the definition of a malfunction that would be likely to cause or contribute to a reportable serious injury, if the malfunction of a same or similar device were to recur. You became aware of the event on January 15, 2011, and the FDA received the malfunction [report] on March 15, 2011, which is beyond the 30 calendar day timeframe.

The FDA concluded that Medtronic's responses to this violation and corrective actions were "not adequate."

36. At the times and places aforementioned, and at all times herein relevant, the Medtronic Defendants were under a duty to conform to and manufacture their products in accordance with federal law and in particular with the provisions of the FDCA, and particularly with Current Good Manufacturing Practice ("CGMP") requirements of the Qualify System regulation found at Title 21 C.F.R. 820, *et seq*., which "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, an servicing of all finished devices intended for human use," and which are "intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act." 21 C.F.R. 820.1.

37. At all relevant times, the Medtronic Defendants were in violation of the CGMP requirements and had been cited by the FDA for manufacturing "adulterated" and "misbranded" products as a result of their non-compliance and non-conformance with CGMP requirements.

38. With respect to the manufacture, labeling, and distribution of William Mills's pump, Medtronic was not in compliance with CGMP's, and the pump and associated equipment did not comply with the FDCA and applicable regulations and were, therefore, not in conformance with federal law governing the manufacture and performance of the insulin pumps.

39. The failure to conform to CGMPs and other applicable regulations means that Defendants were unable to verify, in accordance with FDA regulations, that the pump and/or related equipment was safe and effective, fully conformed to specifications, and free of defects which could lead to malfunctions, having the potential to cause or contribute to serious bodily injury, or death.

40. Additionally, at all relevant times, the pump at issue malfunctioned, failing to deliver insulin as intended and programmed, and it therefore did not perform in accordance with or conform to the specifications which formed the basis of the FDA's approval to market the device.

41. Additionally, at all relevant times, defendants misrepresented to the public, to Plaintiff William Mills, and to Mr. William Mills's physicians, that the subject Medtronic

MiniMed Paradigm Insulin Pump and its related parts would regulate the blood sugar more closely than traditional insulin injections, and would result in a lower incidence of hypoglycemia and hyperglycemia. These representations were not approved by the FDA, nor founded in valid studies, and defendants knew them to be false at the time they made these misrepresentations. The FDCA requires medical device manufactures to disclose all material facts in advertising and labeling, 21 U.S.C. §321(n), and false or misleading labeling is considered "misbranding," 21 U.S.C. § 352(a), (q)(1), which is prohibited. 21 U.S.C. § 331(b). As such, the Medtronic MiniMed Paradigm Insulin Pump and its related parts were misbranded in light of the deceptive manner in which they were labeled and promoted.

C. Additional Allegations in Support of Punitive Damages Against The Medtronic Defendants

42. At all relevant times, the Medtronic Defendants ["Medtronic"] willfully ignored and/or concealed known risks associated with their defective pumps and infusions sets, including those at issue in this case.

43. As evidenced by the FDA's 2009 Warning Letter, Defendants were on notice regarding the defective condition of both the pump and infusion sets at issue prior to Plaintiff William Mills's injuries and failed to take corrective action, failed to recall the device, failed to report adverse events to the FDA, and failed to warn Plaintiff William Mills and his physicians of life-threatening complications associated with the products at issue.

44. As further evidenced by the FDA's 2013 Warning Letter, Medtronic failed to report adverse events to the FDA in a timely manner: "For example, [Medtronic] does not investigate complaints with reported high or low blood glucose level (sic) for any adverse events or hospitalization as the result of the insulin infusion pump failure and to ensure that actions needed to correct the failure are implemented. You do not document the rationale for the decision not to investigate or the individual responsible for the decision."

45. The FDA specifically cited an incident where Medtronic became aware on

November 5, 2010, wherein a patient utilizing a Paradigm Infusion Pump suffered either "a death or serious injury." Medtronic failed to report this event to the FDA until May 9, 2011, outside the mandated 30-day timeframe.

46. As indicated in the FDA's 2013 Warning Letter, "[y]our (b)(4) process used in the (b)(4) does not define the monitoring procedure for the essential process parameters (i.e., (b)(4)) as part of process control to ensure reliability. In addition, the firm indicated that it has not been monitoring the process parameters for the (b)(4) used in the manufacture of the Paradigm Insulin Infusion Pumps since 2002."

47. The FDA's 2013 Warning Letter also cited Medtronic for "failure to document acceptance activities required by 21 C.F.R. 820.80, as required by 21 C.F.R. 820.80(e). For example, your management stated that records of all failing in-process test results for the Paradigm Insulin Infusion Pumps MMT-5xx and 7xx series and the Guardian glucose monitoring system are not maintained. In addition, the following Paradigm Insulin Infusion Pumps and Guardian assembly procedures (work instructions) do not require that all failed in-process test results be recorded in the device history file, to be recorded as a nonconformance, or to be recorded in any other document:

- Operation 40- (b)(4), AP7005274-040 Vers. D-H valid dates 4/27/2005-12/12/2012 for the Paradigm Insulin Infusion Pumps and the Guardian Glucose Monitoring System;
- Operation 2055- (b)(4), AP7005274 2055 Ver. B valid date 1/14/2010 for the Paradigm Insulin Infusion Pumps;
- Operation 2060- (b)(4), AP7005274-2060 Vers. C-H valid dates 5/09/2008-12/20/2012 for the Paradigm Insulin Infusion Pumps and the Guardian Glucose Monitoring System;
- Operation 2070- (b)(4), AP7005274-2070 Ver. F valid date 7/19/2011 for the Paradigm Insulin Infusion Pump and the Guardian Glucose Monitoring System;
- Operation 2100- (b)(4) AP7005274-2100 Vers. A-F valid dates 5/14/2007-12/20/2012 for the Paradigm Insulin Infusion Pumps and the Guardian Glucose Monitoring System;
- Operation 2170- (b)(4) AP7005274-2170 Vers. D-F valid dates 9/16/2010-4/30/2011 for the Paradigm Insulin Infusion Pumps; and
- Operation 2200- (b)(4) AP7005274-2200 Vers. G-K valid dates 1/14/10-1/06/2011 for the Paradigm Insulin Infusion Pumps and the Guardian Glucose Monitoring System.

Notably, many of these violations persisted over many years and were occurring long before Plaintiff William Mills's injury.

48. Therefore, there is clear and convincing evidence that Medtronic was aware that their products posed a substantial risk of harm and death and that Medtronic acted willfully, wantonly, maliciously, and oppressively, with intentional disregard to the high probability and substantial certainty of injury, egregiously, recklessly and deliberately disregarding the rights and safety of Plaintiff William Mills.

V. CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
Strict Products Liability – Failure To Warn

49. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

50. Defendants, had a duty to warn Plaintiff William Mills and his physicians about the latent defects in and the dangers associated with using the Medtronic MiniMed Paradigm Pump, the Medtronic insulin reservoirs, and the Paradigm insulin infusion set of which they were aware, or in the exercise of ordinary care, should have been aware, at the time the pump, reservoirs, and/or quick sets left the Defendants' control.

51. Defendants designed, manufactured, configured, assembled, marketed, advertised, sold for consideration, and provided at all relevant times, the Medtronic MiniMed Paradigm Pump, the Medtronic insulin reservoirs, the Medtronic insulin infusion sets, and the related parts used by William Mills at the time of his injury.

52. At the time Defendants, designed, manufactured, configured, assembled, marketed, advertised, sold for consideration, and provided at all relevant times the Medtronic MiniMed Paradigm Pump, the Medtronic insulin reservoirs, the Medtronic insulin infusion sets, all of which contained defects and risks (including the risk that too much or too little insulin would be delivered) capable of causing death or serious injury, such defects and risks were known or, through the use of scientific knowledge then available, knowable to Defendants.

53. At all times herein mentioned, said risks and defects presented a substantial danger of death or serious injury to consumers using the Medtronic MiniMed Paradigm Pump, the Medtronic insulin reservoirs, and the Medtronic insulin infusion sets, including Plaintiff William Mills.

54. Defendants breached their duty by failing to warn Plaintiff and his physicians of these dangers, particularly the danger that the defects in the products at issue could cause too much or too little insulin to be delivered, thereby causing life-threatening injuries and/or death.

55. Defendants knew that the pump, reservoirs, and quick sets would be purchased and used without inspection for defects in the design of the product.

56. The Medtronic MiniMed Paradigm Pump, Model No. MMT-523NAS, used by Plaintiff William Mills at the time of his injury, was defective when it left the control of each of these Defendants.

57. The Medtronic MiniMed reservoir used by Plaintiff William Mills at the time of his injury was defective when it left the control of each of these Defendants.

58. The Medtronic Quick Set used by Plaintiff William Mills at the time of his injury was defective when it left the control of each of these Defendants.

59. At all relevant times, the substantial dangers involved in the reasonably foreseeable uses of the pump and quick sets (which were made dangerous by their defective design, manufacturing, and lack of sufficient warnings) caused each of these devices to have an unreasonably dangerous propensity to cause catastrophic injuries, and were known or knowable to Defendants.

60. The warnings accompanying the pump, reservoirs, and/or infusion sets product did not adequately warn Plaintiff William Mills and his physicians, in light the risks known or knowable to Defendants, of the dangers associated with these devices, including, but not limited to, life-threatening injuries and/or death.

61. The warnings accompanying the pump, reservoirs, and/or infusion sets failed to provide the level of information that an ordinary physician or consumer would expect when

using the product in a manner reasonably foreseeable to Defendants. Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to these three devices, including but not limited to the risk of serious injury and death.

62. Defendants failed to provide adequate warnings, instructions, guidelines or admonitions to members of the consuming public, including Plaintiff William Mills and his physicians, of the design and manufacturing defects that existed in the pump, reservoirs, and/or infusion sets at issue in this case, and which were known or knowable to Defendants.

63. Defendants also failed to report to the FDA, as they were required to by federal law, the growing number of adverse events associated with the use of the Paradigm Pump, MMT-523. By failing to report these adverse events to the FDA, Defendants failed to warn Plaintiff William Mills and his physicians of these adverse events.

64. Defendants knew that these substantial dangers are not readily recognizable to an ordinary consumer or physicians, and that consumers and physicians would purchase the Paradigm Pump, Medtronic insulin reservoirs and Medtronic insulin infusion sets without inspection.

65. Defendants' failure to warn of these substantial dangers rendered the subject Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets unreasonably dangerous to consumers such as Plaintiff William Mills.

66. If Defendants had given adequate instructions and warnings regarding the Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets, these instructions and warnings could have reduced the risk of harm to members of the public, including Plaintiff William Mills.

67. At the time of Plaintiff William Mills's injury, Plaintiff was using his Medtronic Paradigm Pump, reservoirs, and insulin infusion sets in a manner that was reasonably foreseeable by Defendants.

68. Plaintiff William Mills and his physicians relied on Defendants' inadequate warnings in deciding to purchase and use the Medtronic Paradigm Pump, Medtronic insulin

reservoirs, and Medtronic insulin infusion sets. Plaintiff William Mills and his physician would not have purchased, used, and continued to use these devices, had they known of the true safety risks related to them.

69. As a direct and proximate result of one or more of the above-listed dangerous conditions and defects, and of Defendants' failure to provide adequate warnings about them, Plaintiff William Mills sustained serious injuries on or about June 26th, 2013.

WHEREFORE, Plaintiff prays judgment against Defendants as hereinafter set forth.

SECOND CAUSE OF ACTION
Strict Products Liability – Manufacturing Defect

70. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

71. At all times herein mentioned, Defendants designed, distributed, manufactured, sold, tested and marketed the Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets to consumers, such as Plaintiff William Mills, and to physicians and surgeons in the United States.

72. At all relevant times, Defendants designed, distributed, manufactured, marketed, and sold the Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets, which were being utilized by Plaintiff William Mills at the time of his injuries, such that these devices were dangerous, unsafe, and defective in manufacture.

73. At all relevant times, the Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets were expected to and did reach Plaintiff William Mills and his medical providers without substantial change in their condition as manufactured, distributed, and sold by Defendants.

74. At all relevant times, the Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets utilized by Plaintiff William Mills contained manufacturing defects, in that they differed from Defendants' design or specifications.

75. At all relevant times, the Medtronic Paradigm Pump, Medtronic insulin

reservoirs, and Medtronic insulin infusion sets utilized by Plaintiff William Mills contained manufacturing defects, in that they differed from other typical units of the same product lines, thereby rendering these products unreasonably dangerous to consumers such as Plaintiff William Mills.

76. At all relevant times, the Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets were used in a manner that was foreseeable and intended by Defendants.

77. As a direct and proximate result of the manufacturing defects herein described, Plaintiff was caused to suffer and sustain the injuries, damages, losses, and harms as set forth herein.

WHEREFORE, Plaintiff prays judgment against the Defendants as hereinafter set forth.

THIRD CAUSE OF ACTION
Strict Products Liability – Design Defect

78. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows.

79. At all relevant times herein mentioned, Defendants designed, fabricated, manufactured, distributed and marketed to American consumers the above-described Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets.

80. Until the time of Plaintiff William Mills's injuries, the subject Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets were in substantially the same condition as when they left the possession of the Defendants.

81. On and prior to Plaintiff William Mills's injury, the subject Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets were defective in their design in that, among other things, they would not, could not and did not perform in a manner as safely as an ordinary consumer would expect in that they caused injury to Plaintiff William Mills by failing to inject insulin as intended and/or programmed.

82. On and prior to Plaintiff William Mills's injury, the subject Medtronic Paradigm

Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets were further defective in design because the benefits of their design were outweighed by the risks they posed to consumers such as Plaintiff William Mills when used in a foreseeable manner and because the defective design rendered the subject Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets unreasonably dangerous to consumers such as Plaintiff William Mills.

83. On and prior to Plaintiff William Mills's injuries, the subject Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets were further defective in design because there existed a reasonable alternative design that would have reduced the risk posed by the subject Medtronic Paradigm Pump, Medtronic insulin reservoirs, and Medtronic insulin infusion sets.

84. As a direct and proximate result of the design defects herein described, Plaintiffs were caused to suffer and sustain the injuries, damages, losses, and harms as set forth herein.

WHEREFORE, Plaintiffs pray judgment against the Defendants as hereinafter set forth.

FOURTH CAUSE OF ACTION
Negligence

85. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

86. At all relevant times, Defendants had a duty to ensure that those products that they placed or caused to be placed into the stream of commerce were free of defects and reasonably fit and suitable for their intended or foreseeable uses, that they contained adequate warnings and instructions for use, and that they conformed to federal regulations, and performed in accordance with the FDA-approved design and specifications.

87. At all relevant times, Defendants were under a duty to conform to and manufacture their products in accordance with federal law and, in particular, with applicable provisions of the FDCA, including with Current Good Manufacturing Practice requirements of the Quality System regulations (21 C.F.R. § 820, et seq., which "govern the methods used in, and

the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use," and which are "intended to ensure that all finished devices will be unsafe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act." 21 C.F.R. § 820.1. These laws were enacted for the protection of consumers who would use such devices, including Plaintiff William Mills.

88. At all times material hereto, Defendants were in violation of the CGMP requirements, and the Medtronic Defendants were specifically cited by the FDA for manufacturing "adulterated" and "misbranded" products as a result of their non-compliance and non-conformance with CGMPs.

89. At the time the pump and its associated equipment in this case were manufactured, packaged, labeled, and/or distributed, Defendants were not in compliance with CGMP requirements, and the pump and associated equipment did not comply with the FDCA and applicable regulations and were, therefore, not in conformance with federal law governing the manufacture and performance of the insulin pumps.

90. The failure to conform to CGMPs (and other applicable regulations) means that Defendants were unable to verify, in compliance with FDA regulations, that the pump and/or related equipment was (or were) safe and effective, fully conformed to specifications and was (or were) free of defects that could lead to malfunctions having the potential to cause or contribute to serious bodily injury or death.

91. Additionally, at all times material hereto, the pump at issue malfunctioned, delivering, without warning, an unexpected, un-programmed, unwarranted, and excessive dose of insulin and therefore did not perform in accordance with or conform to the specifications which formed the basis of the FDA's approval to market the devices.

92. Defendants had a confidential and special relationship with Plaintiff William Mills due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to the pump and its associated equipment, and (b) Defendants' sole and/or superior knowledge of

their dangerous and irresponsible practices of improperly manufacturing, marketing, selling, and distributing misbranded and adulterated devices.

93. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiff William Mills and his physicians of the true health and safety risks related to the use of the pump and its associated equipment, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly marketing and selling misbranded and adulterated products. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers associated with the pump and its associated equipment to Plaintiff William Mills and his physicians.

94. At all times material hereto, Defendants negligently and unreasonably placed, or caused to be placed into the stream of commerce, a product or products which malfunctioned and/or failed to operate as intended and which were therefore not safe and effective, were defective and/or not reasonably fit or suitable for their intended or foreseeable uses.

95. Defendants knew, or should have known in the exercise of reasonable care, that their product or products were dangerous when used in a reasonably foreseeable manner and that the products were prone to malfunction and cause injury.

96. Defendants knew or reasonably should have known that end users like Plaintiff William Mills, and their physicians, would not realize the danger of Defendants' products.

97. Defendants nevertheless negligently, recklessly, and willfully failed to provide adequate warnings of the danger of the pump and associated equipment, and negligently failed to provide adequate instructions regarding the safe use of the pump and associated equipment under the circumstances.

98. A reasonable manufacturer, seller, or distributor of the pump and associated equipment, under the same or similar circumstances, would have warned of the danger that the pump and associated equipment were capable of causing serious injury and/or death, including to but not limited to injury or death due to the products' failure to properly regulate insulin levels.

99. A reasonable manufacturer, seller, or distributor of the pump and associated

equipment, under the same or similar circumstances, would have provided additional instructions, which Defendants failed to provide, regarding the safe use of the pump and associated equipment.

100. Defendants negligently, recklessly, and willfully designed, manufactured, supplied, installed, inspected, and repaired the insulin pump and related equipment so as to cause defects in those products, and an unreasonable risk of harm to consumers when using the products in a foreseeable manner.

101. Although Defendants knew or should in the exercise of reasonable care have known of the dangerous and defective nature of their products, Defendants nevertheless negligently placed these non-conforming and defective products into the stream of commerce where Defendants expected them to be utilized by diabetics like Plaintiff William Mills.

102. Although Defendants knew or should in the exercise of reasonable care have known of the dangerous and defective nature of their products, Defendants nevertheless negligently failed to timely recall their products.

103. As a foreseeable, direct and proximate result of Defendants' negligence as set forth herein, Plaintiff William Mills was exposed to a substantial risk of harm from a defective product in a dangerous condition and did in fact suffer harm as a result of using such defective products in a dangerous condition, and Plaintiffs thereby sustained compensable damages.

104. As a direct and proximate result of the design defects herein described, Plaintiffs were caused to suffer and sustain the injuries, damages, losses, and harms as set forth hereinabove.

WHEREFORE, Plaintiff prays judgment against the Defendants as hereinafter set forth.

FIFTH CAUSE OF ACTION
Breach of Express Warranty

105. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

106. At all times material hereto, Defendants expressly warranted by way of written literature, including, but not limited to, product labeling, patient package inserts, articles in medical journals, advertising or other documents and/or promotional materials, directed Plaintiff William Mills's physicians and/or Plaintiff William Mills, by and through statements made by Defendants or their authorized agents or sales representatives, orally and/or in publications, package inserts, or other written materials intended for physicians and/or their patients, that their products were safe, effective, fit and proper for their intended use or foreseeable uses and conformed to FDA regulations and specifications.

107. Apart from any other representations alleged above, Medtronic specifically states in the Insulin Pump User Guide that is supplied with Plaintiff William Mills's Paradigm MiniMed pump and associated equipment that:

> For your protection the pump as undergone extensive testing to confirm appropriate operation when used with the Paradigm reservoirs and Paradigm compatible infusion sets manufactured or distributed by Medtronic Diabetes.

Additionally, the User's Guide represents that the "pump has a sophisticated network of safety checks and systems."

108. Plaintiff William Mills was prescribed, purchased, consumed, and/or otherwise utilized Defendants' devices for the purposes of controlling his blood glucose levels by way of an insulin pump with its associated equipment. In so doing, Plaintiff relied upon the skill, judgment, representation, and the foregoing written warranties of the Defendants. Said warranties and representations were false, misleading and inaccurate in that the aforementioned products were not in compliance with FDA regulations and/or did not conform to or perform in accordance with approved specifications and malfunctioned during use and were therefore not safe and effective and were unfit for the uses for which they were intended or put with the knowledge and/or encouragement and/or approval of Defendants.

109. As a direct and proximate result of the design defects herein described, Plaintiff was caused to suffer and sustain the injuries, damages, losses, and harms as set forth

hereinabove.

WHEREFORE, Plaintiff prays judgment against the Defendants as hereinafter set forth.

SIXTH CAUSE OF ACTION
Breach of Implied Warranty

110. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

111. Prior to the time that the aforementioned products were used by Plaintiff William Mills, Defendants impliedly warranted to Plaintiff and his physicians that said products were of merchantable quality, were manufactured, labeled, and/or packaged in accordance with FDA regulations, complied with applicable FDA regulations and approved specifications and were safe, effective and fit for the use for which they were intended or for other known or foreseeable uses.

112. Plaintiff William Mills was unskilled in the research, design, and manufacture of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranties of the Defendants in being prescribed, purchasing, consuming, and otherwise utilizing the aforementioned products.

113. The aforementioned products were not manufactured, packaged, or labeled in accordance with FDA regulations, did not conform to or perform in accordance with approved specifications and were therefore not safe nor effective for their intended, known or foreseeable uses, nor of merchantable quality, as warranted by Defendants in that they had the potential to malfunction and cause serious and permanent injuries, including death, when put to their intended, known, or foreseeable uses.

114. As a direct and proximate result of the design defects herein described, Plaintiff was caused to suffer and sustain the injuries, damages, losses, and harms as set forth hereinabove.

WHEREFORE, Plaintiff prays judgment against the Defendants as hereinafter set forth.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests of this Court the following relief:

A. For non-economic damages according to proof;

B. For economic damages, past loss of income, and future loss of earning capacity according to proof;

C. For exemplary or punitive damages against the Medtronic Defendants as provided by law;

D. For an award of pre-judgment and post-judgment interest as provided by law;

E. For an award providing for attorney's fees and payment of costs of suit;

F. For any other damages to which Plaintiffs may be entitled under all applicable laws;

G. For such other and further relief as this Court may deem just and proper.

VII. JURY DEMAND

Plaintiff requests this case be tried before a jury.

Dated: June 26, 2015

/s/ Shelly L. Friedland

Shelly L. Friedland
TRIEF & OLK
150 East 58th Street
New York, NY 10155
Telephone: (212) 486-6060

/s/ Charles R. Houssiere, III

Charles R. Houssiere III (*pro hac vice application anticipated*)
HOUSSIERE DURANT & HOUSSIERE LLP
Three Post Oak Central
1990 Post Oak Boulevard, Suite 800
Houston, TX 77056-3812
Telephone: (713) 626-3700

Attorneys for Plaintiff