IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

REGINA BARNES, AS NEXT FRIEND OF TIANA GIBSON, AN INCAPACITATED ADULT, Plaintiff, v. MEDTRONIC, INC.; MEDTRONIC USA, INC.; MEDTRONIC LOGISTICS, LLC; and MEDTRONIC PUERTO RICO OPERATIONS, CO., Defendants.	CIVIL ACTION FILE JURY TRIAL DEMANDED

ORIGINAL COMPLAINT

Plaintiff Regina Barnes, as Next Friend of Tiana Gibson, an Incapacitated Adult, by and through her attorneys, files this her Original Complaint against Medtronic, Inc.; Medtronic Puerto Rico Operations, Co.; and Medtronic Logistics, LLC (collectively "Defendants" or "Medtronic"), as follows:

I. Introduction

1. This is a products liability action seeking damages for personal injuries sustained by Tiana Gibson arising from her use of a defective product designed, manufactured, labeled, distributed, and/or otherwise placed into the stream of commerce by Defendants and/or each of them. As set forth herein, Ms. Gibson

suffered severe injuries and hospitalization as a foreseeable, direct, and proximate result of defects in her Medtronic SynchroMed II Programmable Implantable Infusion Pump System for intrathecal drug delivery, which was implanted in her abdomen. Ms. Barnes brings this action on behalf of Ms. Gibson to recover for the damages caused by Defendants' conduct.

II. Parties

2. Plaintiff is, and at all relevant times was, a citizen of Georgia and resident of Lithia Springs, Douglas County, Georgia.

3. Defendant Medtronic, Inc. is, and at all relevant times was, a corporation or other business entity and citizen of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Anoka County, Minnesota 55432.

4. Defendant Medtronic USA, Inc. is, and at all relevant times was, a corporation or other business entity and citizen of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Anoka County, Minnesota 55432.

5. Defendant Medtronic Logistics, LLC is, and at all relevant times was, a limited liability company organized under the laws of Minnesota with its principal place of business at 710 Medtronic Parkway, Minneapolis, Anoka County, Minnesota 55432. The sole member of Medtronic Logistics, LLC is, and at all

relevant times was, Medtronic USA, Inc., a corporation or other business entity and citizen of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Anoka County, Minnesota 55432.

6. Defendant Medtronic Puerto Rico Operations Co. is, and at all relevant times was, a corporation or other business entity and a wholly owned subsidiary of Defendant Medtronic, Inc., and citizen of the Cayman Islands, with its principal place of business at Ceiba Norte Industrial Park Road 31, Km. 24, HM 4 Call Box 4070, Juncos 00777-4070, Puerto Rico.

III. Jurisdiction and Venue

7. This Court has personal jurisdiction over all Defendants pursuant to Ga. Code Ann. § 9-10-91, under which a court in Georgia may exercise personal jurisdiction over any nonresident as to a cause of action arising from, among other things, the transaction of any business within Georgia; the commission of a tortious act or omission within Georgia; or the commission of a tortious act or omission outside of Georgia, if the tortfeasor regularly does or solicits business or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in Georgia.

8. Defendants meet one or more of these conditions, insofar as Defendants are, and all relevant times were, involved in the design, assembly, manufacture, testing, packaging, labeling, marketing, distribution, sale, and/or promotion of,

and/or were otherwise involved in the placing in the stream of commerce, medical devices including the SynchroMed II Programmable Implantable Infusion Pump System (hereinafter the "SynchroMed II Device" or "Device"), and thus transacted business within Georgia; committed torts within Georgia as pled herein; and/or committed torts outside of Georgia as pled herein while regularly doing and/or soliciting business in Georgia and/or deriving substantial revenue from interstate commerce within Georgia, through their substantial and purposeful transactions of business there, including but not limited to their sales of the SynchroMed II Device, for which Defendants should reasonably expect their acts to have consequences in Georgia.

9. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because it is a civil action in which the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between citizens of different states and a foreign state.

IV. Factual Allegations

A. Background of the SynchroMed II Device

10. The SynchroMed II Device is a programmable drug infusion system implanted in the body for drug delivery. The SynchroMed II Device includes an infusion pump connected to a thin, flexible catheter attached to the intrathecal space (spinal canal) of the patient, into which the pump delivers medication.

11. The entire SynchroMed II Device is implanted and remains under the skin. A clinician measures a precise amount of medication and injects the medication into the pump's reservoir fill port. The medication passes through a reservoir valve and into the pump reservoir. At normal body temperatures, pressurized gas, used as a propellant, is stored below the reservoir and it expands and exerts constant pressure on the reservoir. This pressure pushes the medication into the pump tubing. The battery-powered electronics and motor gears deliver a programmed dose of medication through the tubing out through a catheter port and into a catheter. Medication delivery then continues through the catheter tubing and into the intrathecal space of a patient.

12. The intrathecal catheters and sutureless revision kits of the SynchroMed II Device are designed to connect the pump with the patient's intrathecal space. Each catheter has a pre-attached strain relief sleeve, a connector pin, and a sutureless pump connector (also known as a revision kit) that connects to the SynchroMed II pump.

13. The SynchroMed II Device is a Class III medical device, approved by the U.S. Food and Drug Administration (FDA) through the Premarket Approval (PMA) process on March 14, 1988, PMA No. P860004.

14. Since the initial approval, Medtronic has sought FDA approval of at least 351 supplements or changes to the originally approved Device.

15. The pump of the SynchroMed II Device is supplied in 20- and 40-ml reservoir sizes, model nos. 8637-20 and 8637-40, respectively.

16. According to Medtronic's SynchroMed II "System Components Sheet," as well as information identified through the FDA's recall database, the catheter of the SynchroMed II Device is supplied as one of the following brands and models, which are connected to the pump using the following connector or revision kit models:

Brand	*Catheter Model No.*	*Connector / Revision Kit Model No.*
Indura	8709	8575, 8578
Indura	8709SC	8578
Indura	8711	Not specified
Not Specified	8731	8596, 8596SC, 8598, 8598A
Not Specified	8731SC	8596SC, 8598A
Ascenda	8780	8784
Ascenda	8781	8784

17. According to Medtronic's SynchroMed II "Indications, Drug Stability, and Emergency Procedures Reference Manual," the SynchroMed II Device is FDA-approved solely for the following uses:

a. The chronic intrathecal infusion of Infumorph (preservative-free morphine sulfate sterile solution) in the treatment of chronic intractable pain, with a maximum approved concentration of 25 mg/ml.

b. The chronic intrathecal infusion of Prialt (preservative-free ziconotide sterile solution) for the management of severe chronic pain, with a maximum approved concentration of 100 μg/ml.

18. The chronic intrathecal infusion of Lioresal Intrathecal (baclofen injection) in the management of severe spasticity, with a maximum approved concentration of 2 mg/ml.

B. Tiana Gibson's Experience with the SynchroMed II Device

19. Plaintiff is a 32-year-old woman with a history of spasticity of the bilateral upper extremities, lower extremity weakness and seizure disorder due to a traumatic brain injury from an automobile accident in 2011.

20. To reduce muscle spasticity associated with her condition, Plaintiff was persuaded to have a SynchroMed II Device implanted in her abdomen to administer baclofen into the intrathecal space of her spine.

21. Plaintiff had her first SynchroMed II Device implanted in June 2011 at Piedmont Hospital in Atlanta, Georgia. This pump was replaced in June of 2017 in accordance with the pump's ERI. Ms. Gibson's second SynchroMed II Device—a model no. 8637-40 pump—was implanted at Piedmont Hospital in Atlanta, Georgia. This pump was removed shortly thereafter, when it eroded through Ms. Gibson's skin. Thus, Ms. Gibson's third SynchroMed II Device—a model no. 8637-20

pump—was implanted at Holy Cross Hospital in Silver Springs, Maryland in January 2018.

22. The SynchroMed II Devices implanted in Plaintiff's body was intended to deliver a programmed amount of baclofen medication into her spine, reducing or eliminating the need for oral medications.

23. For several months after Ms. Gibson had her SynchroMed II Device implanted, her spasticity improved intermittently. But then, at the end of October 2018, Plaintiff suffered a series of six seizures in a handful of days.

24. Following her seizures, her family took her to Holy Cross Hospital in Silver Springs, Maryland, where they conducted an MRI.

25. From October 2018 to December 2018, Plaintiff's spasticity significantly worsened, and Plaintiff was suffering from dramatic changes in mood.

26. In November 2018, Ms. Gibson returned to Atlanta, Georgia and made an appointment with a pain management physician at Shepard Center (in Atlanta, Georgia) to discuss the problems she had been experiencing with her device for several weeks.

27. In December 2018, Plaintiff's physicians concluded that her SynchroMed II Device had malfunctioned and failed, based on her presentation of symptoms of significant baclofen withdrawal (e.g., return of spasticity) and a pump interrogation showing motor stall.

28. Given the pump's failure, physicians recommended the removal of Plaintiff's pump. She was immediately scheduled for surgery to remove the bad device and implant a new one. In January 2019, Plaintiff underwent surgery for pump removal.

29. The removal of a defective medical device is a serious, invasive, and dangerous procedure.

30. As a result of the aforementioned defects and malfunctions, Plaintiff's SynchroMed II Device failed to deliver the prescribed medication as programmed, resulting in withdrawal and hospitalization and necessitating pump removal.

31. As a foreseeable, direct, and proximate result of Medtronic's conduct described herein, Tiana Gibson has suffered damages, including pain and suffering, mental anxiety and anguish, and medical bills in amounts to be proven at trial.

C. Legal Requirements Following Premarket Approval of the SynchroMed II Device.

32. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III medical devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, these devices require a premarket approval (PMA) application under Section 515 of the Federal Food, Drug, and Cosmetic Act (FD&C

Act) before they can be sold in the United States. The SynchroMed II Device is a Class III medical device.

33. In a PMA application, the applicant is required to supply information to the FDA. The information required includes device description, clinical safety trials, methods of its product testing, design of the device and specific manufacturing controls, outcome evaluation, and proposed labeling. The FDA does not conduct independent testing on a medical device in a PMA application. The FDA reviews the documentation provided to them by the PMA applicant and relies on the veracity of the company. The PMA applicant is solely responsible for submitting all truthful and necessary documentation to the FDA.

34. Once an application for PMA is approved, the holder (here, Medtronic) must comply with any and all post-approval requirements established by statute, the FDA, and federal regulations.

35. In particular, federal regulations require a PMA holder such as Medtronic to comply with the following requirements:

a. Adverse Events. Review, evaluate, and report to the FDA adverse events associated with the medical device.

i. Report individual adverse events within 30 days after becoming aware of an adverse event or aware of a reportable death, serious injury or malfunction, 21 C.F.R. § 803.l0(c)(1); and

ii. Report individual adverse events no later than five work days after becoming aware of a "reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health," 21 C.F.R. § 803.10(c)(2)(i).

b. Quality System. Establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured and that meets the requirement of this part. 21 C.F.R. § 820.5.

c. Management Responsibility. Management with executive responsibility shall establish its policy and objectives for, and commitment to quality. 21 C.F.R. § 820.20.

d. Qualified Personnel. Have sufficient personnel with the necessary educational background, training, and experience to assure that all activities required by this part are correctly performed. 21 C.F.R. § 820.25.

e. Corrective and Preventative Action (CAPA). Establish and maintain procedures for implementing corrective and preventive action, and document all CAPA activities. 21 C.F.R. § 820.100.

f. Complaint Files. Maintain complaint files, processed in a uniform and timely manner, oral complaints must be documents and must be evaluated to determine whether the complaint represents a reportable event under Medical Device Reporting. 21 C.F.R. § 820.198.

g. Statistical Techniques. Establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability and product characteristics. 21 C.F.R.§ 820.250.

h. Misbranded Drugs and Devices Prohibited. A device shall be deemed to be "misbranded" if, among other things, there has been a failure or refusal to give required notification or to furnish required material or information to the FDA. 21 U.S.C. § 352(t).

i. Adulterated Products Prohibited. If the manufacturer fails to ensure that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with applicable requirements, including but not limited to the Current Good Manufacturing Practice (CGMP) requirement of the Quality System regulations found at Title 21 Code of Federal Regulations Section 820, then such products are considered "adulterated." 21 U.S.C. § 351(h).

j. Off-Label Promotion Prohibited. A product may not be manufactured packaged, stored, labeled, distributed, advertised, or promoted in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device. 21 C.F.R. § 814.80.

D. Violations of Federal Law Resulting in Plaintiff's Defective and Malfunctioning SynchroMed II Device

1. Overview of FDA Inspections and Defendants' Violations

36. To ensure compliance with these statutes and regulations, the FDA conducts inspections of medical device manufacturing and quality-control facilities. Following such inspections, FDA inspectors issue FDA Form 483 documents, also known as Inspectional Observations, which list conditions or practices that indicate potential violations of statutes or regulations. The FDA may also issue a formal Warning Letter if, upon further review of the Inspectional Observations, the FDA determines that serious statutory or regulatory violations exist at a medical device manufacturing or quality-control facility.

37. Medtronic, in their manufacture of the SynchroMed II Device (including not only the pump but also catheters), violated federal law governing manufacture and quality control of PMA medical devices, which was discovered during a series of inspections by the FDA at Medtronic's manufacturing and quality control plants in Minneapolis, Minnesota and Juncos, Puerto Rico.

38. The inspections were followed by a series of Warning Letters to Medtronic that identify federal manufacturing and quality control violations at the plants that ultimately led to an April 27, 2015 Complaint Requesting a Permanent Injunction filed against Medtronic by the U.S. Department of Justice and U.S. Department of Health and Human Services, and a Court- Ordered Consent Decree

imposing a moratorium on the manufacture, sale, and distribution of the SynchroMed II Device in violation of federal law.

39. In addition, since receiving PMA approval, the SynchroMed II Device and its components associated with PMA No. P860004 have been subject to no fewer than 72 recalls.

40. These Warning Letters, recalls, and injunction, which include specific references to the SynchroMed II pump as well as its affiliated intrathecal catheters, speak to the seriousness of Defendants' violations of federal law and negligence in the manufacture of the SynchroMed II Device.

2. FDA Inspections and Warning Letters

41. In 2006, 2007, 2008, 2009, 2012, and 2013, during the time Plaintiff's SynchroMed II Device was being manufactured by Medtronic, the FDA conducted numerous inspections of Medtronic's manufacturing and quality-control facilities in Minneapolis, Minnesota and Juncos, Puerto Rico, discovering a multitude of significant violations of federal law governing the manufacture and quality control of PMA medical devices including the SynchroMed II pump and associated intrathecal catheters, as recorded in FDA Form 483s and Warning Letters issued to Medtronic.

42. 2006 Inspection and 2006 Warning Letter.[1]

a. From May 18 to June 22, 2006, the FDA conducted an inspection of Medtronic's manufacturing plant located at 800 53rd Avenue NE, Minneapolis, Minnesota 55421, where Medtronic "manufacturers manufactures implantable drug infusion . . . products to treat pain [and] movement disorders."

b. On August 29, 2006, the FDA issued Medtronic a Warning Letter concerning this inspection.

c. This inspection revealed that the SynchroMed II Device was "adulterated under Section 501(h) of the Act [21 U.S.C. 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, found at Title 21, Code of Federal Regulations (CFR), Part 820."

d. The 2006 Warning Letter enumerated the following "significant deviations" from the CGMP regulations with respect to catheters and pumps:

[1] *See* Ex. 1, FDA Warning Letter (Aug. 29, 2006). All quotations in the subparagraphs of this paragraph are sourced from this 2006 Warning Letter.

i. Violation of 21 C.F.R. § 820.30(c): Failure to implement procedures to ensure that a device's design input requirements are appropriate and address its intended use, including user/patient needs, in that design input work for intrathecal catheters had not resulted in development of a complete design specification for the catheter tip bond.;

ii. Violation of 21 C.F.R. § 820.30(g): Failure to conduct design validation using production units or their equivalents, in that design validation testing of intrathecal catheters was conducted with catheters manufactured with a tip marker bonding process that was different than that used in production;

iii. Violation of 21 C.F.R. § 820.75(a): Failure to validate a process whose results cannot be fully verified by subsequent inspections and tests, in that the bonding process for the catheter has not been validated;

iv. Violation of 21 C.F.R. § 820.70(a): Failure to control production processes to ensure that a device conforms to its specification, in that the bonding manufacturing procedures contained nonconforming instructions.

v. Violation of 21 C.F.R. § 820.100(a)(2): Failure to implement CAPA procedures addressing the investigation of the cause of nonconformities, including closing CAPAs without proper root cause analyses, with incorrect conclusions, or without evidence to support conclusions.

vi. Violation of 21 C.F.R. § 820.100(a)(5): Failure to implement changes in methods and procedures needed to correct and prevent identified quality problems, in that although a CAPA called for a catheter tip redesign, product specification was not changed, the revised manufacturing process was not validated, and no process monitoring was conducted.

vii. Violation of 21 C.F.R. § 820.100(a)(3): Failure to identify all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems; and

viii. Violation of 21 C.F.R. § 820.184: Failure to implement procedures to ensure that device history records for each batch, or unit are maintained to demonstrate that the device is manufactured in accordance with regulations.

e. The Warning Letter concluded that these violations "may be symptomatic of serious underlying problems in your firm's manufacturing

quality assurance systems" and called for a follow-up inspection.

43. 2006–07 Inspection and 2007 Warning Letter.[2]

a. From November 21, 2006 to January 24, 2007, the FDA conducted a follow-up inspection of Medtronic's manufacturing plant located at 800 53rd Avenue NE, Minneapolis, Minnesota 55421, where Medtronic "manufacturers implantable drug infusion . . . products."

b. On July 3, 2007, the FDA issued Medtronic a Warning Letter concerning this inspection.

c. This inspection revealed that the SynchroMed II Device was "adulterated within the meaning of section 501(h) of the Act [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations, (21 CFR) Part 820."

d. Specifically with respect to adulteration, the FDA found that Medtronic violated 21 C.F.R. § 820.198(a)(3) through its "[f]ailure to implement complaint handling procedures to ensure that all complaints are

[2] *See* Ex. 2, FDA Warning Letter (July 3, 2007). All quotations in the subparagraphs of this paragraph are sourced from this 2007 Warning Letter. *See also* Ex. 3, FDA Form 483 (Jan. 24, 2007).

evaluated to determine whether the complaint represents an event that must be filed as a Medical Device Report under 21 CFR Part 803."

e. This inspection also revealed that the SynchroMed II Device was "misbranded under section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)], in that [Medtronic] failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act (21 U.S.C. § 360i), and 21 CFR Part 803—Medical Device Reporting (MDR) regulation."

f. Specifically with respect to this misbranding, the FDA found that Medtronic violated 21 C.F.R. § 803.50(a)(1) through its "[f]ailure to submit MDR reports within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury." Medtronic:

i. failed to report SynchroMed II Device's intrathecal catheters associated with granuloma or inflammatory masses at or near the distal tip, which the FDA considers "serious injuries";

ii. failed to report SynchroMed II Device's intrathecal catheter fractures;

iii. failed to report a malfunction MDR, required when a marketed device malfunction would likely cause or contribute to a reportable death or serious injury;

iv. failed to submit MDR reports within 30 days of learning of a problem (pump malfunctions, catheter fracture or separation, inflammatory masses and granulomas) with the SynchroMed II device in the medical literature; and

v. failed to report consumer self-reported adverse events.

g. The inspection further revealed that the SynchroMed II Device was also "misbranded under section 502(t)(2) of the Act [21 U.S.C. § 352(t)(2)], in that [Medtronic] failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 806—Reports of Corrections and Removals."

h. Specifically, with respect to this additional misbranding, the FDA found that Medtronic violated 21 C.F.R. § 806.10(a)(1) because a "correction or removal conducted to reduce a risk to health posed by a device was not reported in writing to FDA" concerning the risk of an inflammatory mass occluding intrathecal catheters.

i. The 2007 Warning Letter further warned Medtronic: "[Y]our firm has several procedures for Medical Device Reporting and Adverse Drug Experience Reporting. These procedures, in turn reference several other procedures. Your firm's current problems regarding MDR reporting, as

discussed above in this Warning Letter, may be exacerbated by the complexity of your procedures and might have contributed to your firm's deviations from the regulations regarding MDR reporting."

j. The 2007 Warning Letter concluded by also revealing several ongoing violations at Medtronic's Minneapolis Plant's Quality System that were noted in a Form 483, stating "[t]he specific violations noted in this letter and Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and Quality Assurance systems." Specifically, the FDA warned that Medtronic failed to achieve consistent compliance in areas such as design controls in violation of 21 C.F.R. § 820.30 and failed to achieve consistent CAPA compliance in violation of 21 C.F.R. § 820.100.

44. 2008 Inspection and 2009 Warning Letter.[3]

a. From November 12 to December 15, 2008, the FDA conducted an inspection of Medtronic's manufacturing plant located at Road 31, Km 24, Ceiba Norte Industrial Park, Juncos, Puerto Rico, where Medtronic "manufacturers SynchroMed II Pumps."

b. On June 1, 2009, the FDA issued Medtronic a Warning Letter concerning this inspection.

[3] *See* Ex. 4, FDA Warning Letter (June 1, 2009). All quotations in the subparagraphs of this paragraph are sourced from this 2009 Warning Letter. *See also* Ex. 5, FDA Form 483 (Dec. 15, 2008).

c. This inspection "revealed that the SynchroMed II Pumps are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. §351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820."

d. The FDA enumerated the following violations in the 2009 Warning Letter:

i. Violation of 21 C.F.R. § 820.70(a): "Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, which shall include monitoring and control of process parameters and component and device characteristics during production," in that pumps were manufactured without propellant; "did not show evidence of a perforated septum," which is "performed to detect obstruction . . . early in the manufacturing process"; and lacked "a safety mechanism that serves to ensure that the pump is never overfilled."

ii. Violation of 21 C.F.R. § 820.100(a): "Failure to establish and maintain procedures for implementing corrective and preventive

action that include identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems," in that a critical step was left out of the pump manufacturing process concerning "critical internal functions such as calculating drug reservoir levels and drug dispensing rates." Despite numerous complaints that Medtronic received regarding accuracy rates, Medtronic failed to conduct any type of investigation into this problem.

iii. Violation of 21 C.F.R. § 820.184: "Failure to establish and maintain procedures to ensure that Device History Records (DHR's) for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the Device Master Record (DMR)," in that pump sterilization processes were not performed in the order specified by Medtronic procedures; and

iv. Violation of 21 C.F.R. § 820.198(c): "Failure to review, evaluate, and investigate complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications," in that, for several complaints of infections from nonsterile pumps, "a copy of [Medtronic's] investigation was not included as part of the complaint record, there was no reference to a specific investigation report number, . . . there was no documentation whether the investigation was

successfully closed, . . . [and] there was no record in the complaint file that Medical Device Reports were filed by [Medtronic] with FDA."

e. The Warning Letter concluded that these violations "may be symptomatic of serious problems in your firm's manufacturing quality assurance systems."

45. 2012 Investigation and 2012 Warning Letter.[4]

a. From March 14 to May 9, 2012, the FDA conducted an inspection of Medtronic's manufacturing plant located at 7000 Central Avenue NE, Minneapolis, Minnesota 55432, where Medtronic "manufactures implantable drug infusion systems."

b. On July 17, 2012, the FDA issued Medtronic a Warning Letter concerning this inspection.

c. This inspection revealed that Medtronic's SynchroMed II Devices were "adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP)

[4] *See* Ex. 6, FDA Warning Letter (July 17, 2012). All quotations in the subparagraphs of this paragraph are sourced from this 2012 Warning Letter.

requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (21 CFR), Part 820."

d. The FDA enumerated the following violations in the 2012 Warning Letter:

i. Violation of 21 C.F.R. § 820.100(a): "Failure to establish adequate procedures for corrective and preventive action," in that Medtronic failed to identify "the actions to correct and prevent recurrence of nonconforming product" relating to pump motor stalls and relied on incomplete data when conducting CAPA activities;

ii. Violation of 21 C.F.R. § 820.198(a): "Failure to establish adequate procedures for receiving, reviewing, and evaluating complaints by a formally designated unit," in that "[c]omplaint information received during a call was not documented"; and

iii. Violation of 21 C.F.R. § 820.198(c): "Failure to review, evaluate and investigate, where necessary, complaints involving the possible failure of a device to meet any of its specifications," in that "Product Performance Specialists did not adequately evaluate complaints," "[c]oding of similar complaints is inconsistent," and "[t]rending of complaint data / coding for evaluation was not completed per procedures."

e. The FDA expressed its significant "concern[] that incomplete complaint data and incorrect coding decisions . . . may have compromised Medtronic's ability to detect and investigate [safety] signals," i.e., signs of safety problems.

f. The Warning Letter concluded that these violations "may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems."

46. 2013 Inspection.[5]

a. From February 14 to April 3, 2013, the FDA conducted another inspection of Medtronic's manufacturing plant located at 7000 Central Avenue NE, Minneapolis, Minnesota 55432.

b. On April 3, 2013, the FDA issued a Form 483 informing Medtronic that that the plant failed to manufacture devices that adequately conform to specifications and instead manufactured devices that are not adequately controlled. Specifically, Medtronic:

i. distributed nonconforming intrathecal catheters that were prone to occlusion and

ii. failed to establish adequate CAPA procedures, in that "[a]ctions needed to correct and prevent recurrence of a quality problem

[5] *See* Ex. 7, FDA Form 483 (Apr. 3, 2013).

were identified but not implemented" concerning electrical shorting leading to pump motor stalls and implementation of recommendations from the Risk Evaluation Board, "Health Hazard Assessments for high priority CAPAs with the highest patient severity of death were not completed in a timely fashion," and "Health Hazard Assessments have not been updated after CAPA effectiveness monitoring signaled an increase in the rate of occurrence" of hazards involving intrathecal catheter occlusion.

47. Throughout the history of the manufacture of the SynchroMed II Device, the FDA has repeatedly notified Medtronic that their manufacture of the SynchroMed II Device failed to conform to manufacturing requirements enumerated in federal regulations and statutes. These federal violations caused the aforementioned defects and malfunctions in Plaintiff's SynchroMed II pump and catheter, which caused her injuries and damages alleged herein.

3. Recalls of the SynchroMed II Pump and Catheters.

48. A recall is an action taken to address a problem with a medical device that violates federal law.

49. Recalls are classified as either Class I, Class II, or Class III. A Class I recall is issued for a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences

or death. A Class II recall is issued for a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. Finally, a Class III recall is issued for a situation in which use of or exposure to a violative product is less likely to cause adverse health consequences.

50. The FDA has issued at least 19 Class I and II recalls specifically for SynchroMed II pump models during the time the SynchroMed II Device has been on the market, as summarized in the following table:

Recall No.	*Recall Class*	*Date Initiated by Medtronic*	*Recall Reason*
Z-1040-04	2	May 11, 2004	Mislabeling of pump reservoir size
Z-2181-2008	2	May 1, 2008	Pumps manufactured without propellant
Z-2182-2008	2	May 1, 2008	Pumps manufactured without propellant
Z-0591-2009	2	August 25, 2008	MRI-related motor stall
Z-0592-2009	2	August 25, 2008	MRI-related motor stall
Z-2276-2009	2	July 1, 2009	Battery failure
Z-1060-2011	1	January 14, 2011	Inadequate instruction for filling/refilling of pumps, causing injection of some or all of the prescribed drug into the patient's subcutaneous issue (a pocket fill)

Recall No.	*Recall Class*	*Date Initiated by Medtronic*	*Recall Reason*
Z-1061-2011	1	January 14, 2011	Inadequate instruction for filling /refilling of pumps, causing injection of some or all of the prescribed drug into the patient's subcutaneous issue (a pocket fill)
Z-3043-2011	1	July 5, 2011	Battery failure
Z-1338-2012	2	March 12, 2012	Software failure resulting in incorrectly displayed scheduled pump replacement date
Z-0497-2013	1	November 9, 2012	Use of unapproved drugs in the pumps leading to permanent motor stall and cessation of therapy
Z-1570-2013	1	June 3, 2013	Unintended delivery of drugs during the priming bolus procedure, resulting in life-threatening overdose and corresponding drug withdrawal
Z-1571-2013	1	June 3, 2013	Unintended delivery of drugs during the priming bolus procedure, resulting in overdose followed by underdose
Z-1579-2013	1	June 3, 2013	Potential for internal electrical shorting, leading to a loss of or reduction in therapy
Z-1570-2014	2	February 26, 2014	Potential for overinfusion resulting in life-threatening overdose and corresponding drug withdrawal
Z-1681-2015	2	April 10, 2015	Alarm failure
Z-0788-2017	1	October 3, 2016	Unintended delivery of drugs during the priming bolus procedure, resulting in overdose followed by underdose
Z-0896-2018	2	August 9, 2017	Risk of permanent motor stall and cessation of therapy due to corrosive wear

Recall No.	*Recall Class*	*Date Initiated by Medtronic*	*Recall Reason*
Z-0508-2020	1	October 11, 2019	Risk of permanent motor stall and cessation of therapy due to presence of a foreign particle inside the pump motor assembly

51. The FDA has also issued at least 16 recalls specifically concerning SynchroMed II catheters during the time the SynchroMed II Device has been on the market, as summarized in the following table:

Recall No.	*Recall Class*	*Date Initiated by Medtronic*	*Catheter Model*	*Recall Reason*
Z-1414-06	1	July 21, 2006	8371	Tip dislodgement during implantation
Z-1150-2008	1	January 16, 2008	Not specified	Formation of inflammatory masses near the tip of intrathecal catheters
Z-1151-2008	1	January 16, 2008	Not specified	Formation of inflammatory masses near the tip of intrathecal catheters
Z-2173-2008	2	April 14, 2008	8709SC (Indura)	Failure to engage with catheter connector, resulting in leakage or disconnection of the catheter
Z-2174-2008	2	April 14, 2008	8731SC	Failure to engage with catheter connector, resulting in leakage or disconnection of the catheter

Recall No.	*Recall Class*	*Date Initiated by Medtronic*	*Catheter Model*	*Recall Reason*
Z-2380-2008	1	June 26, 2008	8709SC (Indura)	Disconnection of catheters from the pump, or occlusion between the sutureless pump connector and the catheter port on the pump.
Z-2381-2008	1	June 26, 2008	8731SC	Disconnection of catheters from the pump, or occlusion between the sutureless pump connector and the catheter port on the pump.
Z-2073-2009	1	August 27, 2009	8709SC (Indura)	Labeling error incorrectly stating catheter-pump compatibility
Z-2074-2009	1	August 27, 2009	8731SC	Labeling error incorrectly stating catheter-pump compatibility
Z-0334-2011	1	September 29, 2010	8731SC	Presence of endotoxin in excess of United States Pharmacopeial Convention (USP) limits
Z-1575-2013	1	June 3, 2013	8709SC (Indura)	Potential for catheter misalignment and occlusion at the catheter-to-pump interface.

Recall No.	*Recall Class*	*Date Initiated by Medtronic*	*Catheter Model*	*Recall Reason*
Z-1576-2013	1	June 3, 2013	8731SC	Potential for catheter misalignment and occlusion at the catheter-to-pump interface.
Z-1723-2014	2	May 2, 2014	8780 (Ascenda)	Presence of endotoxin in excess of USP limits
Z-2172-2014	2	July 11, 2014	8780 & 8781 (Ascenda)	Catheter retainer ring failed specification criteria, resulting in possible disconnection of the catheter from the pump
Z-1271-2016	2	February 9, 2016	8781 (Ascenda)	Incorrect package labeling and lack of all components necessary to complete the implant procedure
Z-0537-2018	3	September 21, 2017	8780 & 8781 (Ascenda)	Increased potential for kinking where the catheter connects to the pump

4. Violations of the Permanent Injunction Resulting in the Manufacture, Distribution, and Sale of Plaintiff's Defective and Malfunctioning SynchroMed II Device.

52. Throughout the history of the manufacture of the SynchroMed II Device, Medtronic has shown an indifference to federal manufacturing requirements. Further, Medtronic, with full knowledge that it was manufacturing the SynchroMed II Device in violation of law, nonetheless demonstrated a pattern of

delayed responses or complete failures to respond to reported and known safety issues with the SynchroMed II Device.

53. Because of Medtronic's years-long pattern of indifference to regulatory authority, noncompliance with federal manufacturing requirements, and violations of federal law, the U.S. Department of Justice and the U.S. Department of Health and Human Services on April 27, 2015 filed a Complaint against Medtronic requesting a Consent Decree for Permanent Injunction against the manufacture, distribution, and sale of the SynchroMed II Device.[6]

54. The Complaint alleges that Medtronic, S. Omar Ishrak (Medtronic's Chairman and CEO), and Thomas M. Tefft (Medtronic's Senior Vice President and President of Medtronic Neuromodulation) "are well aware that their practices violate the [FD&C] Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act."[7]

55. In addition to the cited Warning Letters, the Complaint alleges that representatives of Medtronic attended a meeting with FDA's Center for Devices and Radiological Health and Minneapolis District Office on January 31, 2013. At this

[6] Ex. 11, Complaint for Permanent Injunction, *United States v. Medtronic, Inc.*, No. 15-cv-2168 (D. Minn. Apr. 27, 2015), ECF No. 1.
[7] *Id.* ¶¶ 15–17.

meeting, "Defendants stated that they were aware of the violations at their facilities and were taking steps to correct them."[8]

56. The Complaint further alleges Medtronic made promises to correct their violations in written responses to each inspection; however, the Complaint alleged that none of the responses contained adequate evidence that Medtronic corrected their deviations.[9]

57. The United States Attorney stated in the Complaint that, "[b]ased upon Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 USC §§ 331(a) and (k)"—introducing into interstate commerce any article of device that is adulterated or misbranded, or causing any article of device to become adulterated or misbranded while such devices are held for sale after shipment in interstate commerce.[10]

58. The United States' Complaint requested a permanent injunction to restrain Medtronic in their manufacture, distribution, and sale of the SynchroMed II Device from their continued violation of federal regulations, and specifically:

> That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly and indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) SynchroMed II implantable infusion pumps at or from its Medtronic's Neuromodulation faculties, unless and until Defendants' methods,

[8] *Id.* ¶ 18.
[9] *Id.* ¶¶ 19–20.
[10] *Id.* ¶ 21.

> facilities, and controls used to manufacture, process, pack, label, hold and distribute the SynchroMed II implantable infusion pumps are established, operated, and administered in compliance with 21 USC 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA.[11]

59. On April 27, 2015, United States District Court Judge Joan N. Erickson signed a Consent Decree of Permanent Injunction against Medtronic preventing the manufacture, distribution, and sale of Medtronic SynchroMed Implantable Infusion Pump systems in violation of the terms of the Consent Decree.[12]

60. Under the Consent Decree, Medtronic is "permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, labeling, holding, storing, and distributing, importing into or exporting from the United States of America, at or from any Medtronic Neuromodulation facilities, any model of, or components or accessories for, its SynchroMed devices." Under the Consent Decree, the permanent injunction would be lifted only in the event that Medtronic complies with a series of enumerated requirements to ensure that it would cease violating federal law in the production of its SynchroMed II Device.

61. Although there is an exception to the permanent injunction in cases of medical necessity,[13] Plaintiff's SynchroMed II Device was not medically necessary

[11] *Id.* at 8.
[12] Ex. 12, Consent Decree of Permanent Injunction, *United States v. Medtronic, Inc.*, No. 15-cv-2168 (D. Minn. Apr. 27, 2015), ECF No. 3.
[13] *Id.* ¶ 9.A.

and/or did not satisfy the procedural requirements set forth in the Consent Decree for the medical-necessity exception to apply.

62. Medtronic continues to produce, distribute, and sell their SynchroMed II Device in violation of the Consent Decree, including Plaintiff's Device, which was implanted nearly one year after entry of the Consent Decree.

5. Warning Letters, Inspections, and Recalls Which Directly Apply to the Defects in Plaintiff's Pump

63. Based on Medtronic's series of inspections, warning letters, recalls, and associated documents, the specific violations of CGMP requirements which resulted in Plaintiff's specific defective device include, but are not limited to:

a. The 2006, 2007, 2008/2009, and 2012 inspections which revealed that Medtronic's SynchroMed II Devices were "adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (21 CFR), Part 820."

b. Violation of 21 C.F.R. § 820.100(a): "Failure to establish adequate procedures for corrective and preventive action," in that Medtronic failed to identify "the actions to correct and prevent recurrence of nonconforming product," specifically motor stalls due to corrosion.

Specifically, Medtronic did not address "GCAPA 1485, opened October 26, 2007, [which] relates to motor corrosion resulting in device field failure (motor stall). Within the Investigation Report for SynchroMed II Pump Corrosion (NDHF1119-88863), it states 'corrosion […] can result in partial or complete removal of gear teeth.' This can 'seize' the motor altogether or 'gear wheel […] will continue to rotate, but there may be no drug delivery in the region of missing teeth.' . . . This GCAPA includes 567 complaints and has not been closed;"

c. Violation of 21 C.F.R. § 820.198(c): "Failure to review, evaluate and investigate, where necessary, complaints involving the possible failure of a device to meet any of its specifications," in that "Product Performance Specialists did not adequately evaluate complaints," "[c]oding of similar complaints is inconsistent," and "[t]rending of complaint data / coding for evaluation was not completed per procedures."

64. The FDA repeatedly found SynchroMed II pumps were adulterated due to "significant deviations" from the CGMP regulations which the FDA felt were "symptomatic of serious underlying problems in [Medtronic's] quality assurance system." The same violation is repeated in the inspection and warning letters from 2006, 2007, 2008, and 2012, indicating an on-going issue with Medtronic's production of SynchroMed II pumps. This is further documented by Medtronic's

admittance at a meeting with FDA's Center for Devices and Radiological Health and Minneapolis District Office on January 31, 2013 that "they were aware of the violations at their facilities and were taking steps to correct them."

65. Medtronic's continuous failure to comply with Federal law resulted in SynchroMed II pumps that did not meet PMA specifications, as further documented by associated recalls.

66. Highlighting those FDA actions which most support Plaintiff's factual allegations, an FDA Corrective and Preventive Action (CAPA) 1485 was first opened on October 26, 2007, concerning Medtronic's production of SynchroMed II pumps with defects which caused motor corrosion resulting in motor stall and the failure of the pump to deliver medication as programmed. Within the Investigation Report for the SynchroMed II Pump Corrosion (NDHF1119-88863), it states "corrosion … can result in partial or complete removal of gear teeth." This can seize the motor altogether or the "gear wheel … will continue to rotate, but there may be no drug delivery in the region of missing teeth."

67. The FDA specifically stated in the 2012 Investigation and Warning Letter, which was based on an inspection that took place from March to May of 2012 that Medtronic was still producing adulterated SynchroMed II pumps in violation of 21 C.F.R. § 820.100 (a) for "failure to establish adequate procedures" including those "actions to correct and prevent recurrence of nonconforming product" in

response to the CAPA 1485. The inspection revealed that "the SynchroMed II Pumps are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. §351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820." In this same letter, the FDA stated that 567 complaints had not been closed, verifying the continuing issue with noncompliant pumps experiencing motor stalls.

68. Furthermore, as evidenced by the 2012 Warning Letter, when Medtronic became aware of motor stalls in its pumps due to corrosion, Medtronic failed to establish adequate procedures for CAPAs to resolve the problem. As a result, Plaintiff's SynchroMed II pump was manufactured without the benefit of proper procedures that could have identified and prevented a motor stall in her pump, which resulted in Plaintiff's pump's motor stalling, seizing, or otherwise failing to deliver medication as programmed, causing morphine withdrawal.

69. On December 13, 2012, the FDA issued a corresponding recall, No. Z-0497-2013, to address the increased risk of motor stall, the very problem that caused Ms. Gibson's pump to fail.

70. Again, on August 9, 2017, the FDA initiated recall No. Z-0896-2018 to address motor stalls due to corrosion. In August 2017, as part of the recall,

Medtronic issued a Medical Device Safety Notification to healthcare professionals, detailing the rates of pump survivability specific to non-recoverable motor stall over a period of six years. These figures are based on post market surveillance data in a long-term study. The letter states that shaft wear is the most common contributing factor to motor stall. This clearly documents Medtronic's awareness of the motor stall defect from at least 2011; Plaintiff's device was implanted in 2018. The non-recoverable motor stall and resulting withdrawal detailed in the Safety Notification and recall is the expected outcome of the corrosion malfunction and the injury that Plaintiff suffered.

71. Ms. Gibson's pump was implanted mere months after the FDA initiated recall No. Z-0896-2018, which was initiated to address motor stall issues. Ms. Gibson's medical records state the reason for the failure was due to motor stall, indicating that motor stall rendered the permanent failure of the device. This supports Plaintiff's allegations that his individual SynchroMed II pump did not meet PMA specifications. In particular, it shows that his pump experienced a specific defect known by Medtronic to occur in other SynchroMed II pumps that also did not comply with PMA specifications, as evidenced by frequent notifications by the FDA of the violations resulting in adulterated pumps defective due to motor stall.

V. Causes of Action

Count I: Strict Liability Manufacturing Defect

72. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

73. The SynchroMed II Device implanted in Plaintiff's abdomen was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant thereto, and was manufactured in violation of Georgia law (Ga. Code Ann § 51-1-11(b)(1)) that parallels federal requirements, in one or more of the following ways:

a. The SynchroMed II Device implanted in Plaintiff was adulterated because it was manufactured in deviation from the manufacturing specifications approved by the FDA in Medtronic's PMA application, in violation of Current Good Manufacturing Practices found in 21 C.F.R. Part 820. The quality-control requirements of the CGMPs are designed to ensure Medtronic's products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and reported. The CGMPs require Medtronic to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated under 21 U.S.C. § 351(h), and a manufacturer is prohibited from

introducing, delivering, or selling an adulterated device into interstate commerce under 21 U.S.C. § 331(a)–(c), (k).

b. The SynchroMed II Device was introduced or delivered for introduction into interstate commerce and was adulterated in violation of 21 U.S.C. §§ 331(a), 351(h) and 21 C.F.R. Part 820;

c. The SynchroMed II Device was adulterated in interstate commerce in violation of 21 U.S.C. §§ 331(b), 351(h) and 21 C.F.R. Part 820;

d. The SynchroMed II Device was received in interstate commerce, was adulterated, and was delivered for pay or otherwise in violation of 21 U.S.C. §§ 331(c), 351(h) and 21 C.F.R. Part 820; or

e. The SynchroMed II Device was adulterated while held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§ 331(k), 351(h) and 21 C.F.R. Part 820.

f. As a result of numerous FDA inspections from 2006 through 2013 of Medtronic's manufacturing plants in Minneapolis, Minnesota and Juncos, Puerto Rico, as alleged herein, the FDA determined that Medtronic violated specific CGMPs as previously pled (including 21 C.F.R.§§ 820.30(c), 820.30(g), 820.70(a), 820.75(a), 820.100(a), 820.100(a)(2), 820.100(a)(3), 820.100(a)(5), 820.184, 820.198(a), 820.198(a)(3), and

820.198(c)), rendering the SynchroMed II Device implanted in Plaintiff's body adulterated.

g. On August 9, 2017, Medtronic initiated a Class II recall of both models (8637-20 and 8637-40) of the SynchroMed II pump. This recall was posted by the FDA on March 3, 2018, which was initiated to address motor stall issues—the injury that Ms. Gibson suffered.[14]

74. The SynchroMed II Device implanted in Plaintiff's abdomen was not reasonably safe for its intended use as a matter of law with respect to its manufacture.

75. As a foreseeable, direct, and proximate result of the SynchroMed II Device's aforementioned defects, the SynchroMed II Device implanted in Plaintiff failed and required removal surgery, causing Plaintiff to suffer injury and damages, including pain and suffering, mental anxiety and anguish, and medical bills.

Count II: Negligent Manufacturing Defect

76. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

77. The SynchroMed II Device implanted in Plaintiff's abdomen was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant thereto, and was manufactured in violation of

[14] Ex. 8, FDA Recall No Z-0896-2018.

Georgia law that parallels federal requirements, in one or more of the following ways:

a. The SynchroMed II Device implanted in Plaintiff was adulterated because it was manufactured in deviation from the manufacturing specifications approved by the FDA in Medtronic's PMA application, in violation of Current Good Manufacturing Practices found in 21 C.F.R. Part 820. The quality-control requirements of the CGMPs are designed to ensure Medtronic's products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and reported. The CGMPs require Medtronic to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated under 21 U.S.C. § 351(h), and a manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce under 21 U.S.C. § 331(a)–(c), (k).

b. The SynchroMed II Device was introduced or delivered for introduction into interstate commerce and was adulterated in violation of 21 U.S.C. §§ 331(a), 351(h) and 21 C.F.R. Part 820;

c. The SynchroMed II Device was adulterated in interstate commerce in violation of 21 U.S.C. §§ 331(b), 351(h) and 21 C.F.R. Part 820;

d. The SynchroMed II Device was received in interstate commerce, was adulterated, and was delivered for pay or otherwise in violation of 21 U.S.C. §§ 331(c), 351(h) and 21 C.F.R. Part 820; or

e. The SynchroMed II Device was adulterated while held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§ 331(k), 351(h) and 21 C.F.R. Part 820.

f. As a result of numerous FDA inspections from 2006 through 2013 of Medtronic's manufacturing plants in Minneapolis, Minnesota and Juncos, Puerto Rico, as alleged herein, the FDA determined that Medtronic violated specific CGMPs as previously pled (including 21 C.F.R.§§ 820.30(c), 820.30(g), 820.70(a), 820.75(a), 820.100(a), 820.100(a)(2), 820.100(a)(3), 820.100(a)(5), 820.184, 820.198(a), 820.198(a)(3), and 820.198(c)), rendering the SynchroMed II Device implanted in Plaintiff's body adulterated.

g. Specifically, with respect to Plaintiff's third pump, as evidenced by Recall No. Z-0896-2018, Medtronic defectively manufactured Plaintiff's pump, which led to motor stalls, cessation of therapy, and withdrawal, and which necessitated surgical removal and replacement of the pump.

78. Under Georgia law, Defendants had a duty to individuals, including Plaintiff, to use reasonable care in manufacturing the SynchroMed II Device, which includes complying with federal regulations designed to ensure the safe manufacture, assembly, inspection, packaging, and testing of medical devices.

79. Defendants were negligent in failing to use reasonable care in manufacturing the SynchroMed II Device, in that they failed to use reasonable care to ensure that Plaintiff's SynchroMed II Device complied with federal requirements, manufactured Plaintiff's SynchroMed II Device in a way that did not comply with federal requirements, and failed to test and inspect Plaintiff's SynchroMed II Device before placing it into the stream of commerce and making it available for sale to Plaintiff. In so doing, Defendants failed to comply with manufacturing requirements imposed by the Device's PMA requirements and post-approval regulations.

80. As a foreseeable, direct, and proximate result of Defendants' negligence, the SynchroMed II Device implanted in Plaintiff's abdomen failed and required removal surgery, causing Plaintiff to suffer injury and damages, including pain and suffering, mental anxiety and anguish, and medical bills.

Count III: Breach of Implied Warranty of Merchantability

81. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

82. The SynchroMed II Device implanted in Plaintiff's abdomen violates the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant thereto, and violates Georgia law that parallels federal requirements, in one or more of the following ways:

a. The SynchroMed II Device implanted in Plaintiff was adulterated because it deviates from the specifications approved by the FDA in Medtronic's PMA application, in violation of Current Good Manufacturing Practices found in 21 C.F.R. Part 820. The quality-control requirements of the CGMPs are designed to ensure Medtronic's products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and reported. The CGMPs require Medtronic to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated under 21 U.S.C. § 351(h), and a manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce under 21 U.S.C. § 331(a)–(c), (k).

b. The SynchroMed II Device implanted in Plaintiff was misbranded because Medtronic failed to report adverse event information to the FDA as required by 21 U.S.C. § 360i and 21 C.F.R. Part 803, and a manufacturer is prohibited from introducing, delivering, or selling a misbranded device into interstate commerce under 21 U.S.C. § 331(a)–(c), (k).

c. The SynchroMed II Device was introduced or delivered for introduction into interstate commerce and was adulterated and misbranded in violation of 21 U.S.C. §§ 331(a), 351(h), and 352(t)(2), and 21 C.F.R. Parts 803 and 820.

d. The SynchroMed II Device was adulterated and misbranded in interstate commerce in violation of 21 U.S.C. §§ 331(b), 351(h), and 352(t)(2), and 21 C.F.R. Parts 803 and 820.

e. The SynchroMed II Device was received in interstate commerce, was adulterated and misbranded, and was delivered for pay or otherwise in violation of 21 U.S.C. §§ 331(c), 351(h), and 352(t)(2), and 21 C.F.R. Parts 803 and 820.

f. The SynchroMed II Device was adulterated and misbranded while held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§ 331(k), 351(h), and 352(t)(2), and 21 C.F.R. Parts 803 and 820.

g. As a result of numerous FDA inspections from 2006 through 2013 of Medtronic's manufacturing plants in Minneapolis, Minnesota and Juncos, Puerto Rico, as alleged herein, the FDA determined that Medtronic violated specific CGMPs as previously pled (including 21 C.F.R. §§ 820.30(c), 820.30(g), 820.70(a), 820.75(a), 820.100(a), 820.100(a)(2), 820.100(a)(3), 820.100(a)(5), 820.184, 820.198(a), 820.198(a)(3), and 820.198(c)), rendering the SynchroMed II Device implanted in Plaintiff's body adulterated, and 21 C.F.R. §§ 803.50(a)(1) and 806.10(a)(1), rendering the SynchroMed II Device implanted in Plaintiff's body misbranded.

h. With respect to Plaintiff's SynchroMed II Pump: Specifically, as evidenced by the 2009 Warning Letter, Medtronic skipped a step in the manufacturing process concerning "critical internal functions such as calculating drug reservoir levels and drug dispensing rates," resulting in the SynchroMed II pump being manufactured without necessary steps designed to prevent overinfusion and underinfusion and to ensure accurate delivery of baclofen medication, further resulting in Plaintiff's pump malfunction.

83. At all times relevant hereto, Medtronic, as a merchant of medical devices including the SynchroMed II Device, impliedly warranted to Plaintiff that her SynchroMed II device was fit for the ordinary purposes for which it would be used—the intrathecal administration of baclofen.

84. Defendants breached their implied warranty of merchantability in violation of Ga. Code Ann. § 11-2-314 and also breached their implied warranty of fitness for a particular purpose because the Defendants' numerous violations of FDA regulations resulted in the manufacture, sale, and distribution of a defective SynchroMed II device to Plaintiff.

85. As a foreseeable, direct, and proximate result of Defendants' breach of its implied warranty, the SynchroMed II Device implanted in Plaintiff's abdomen failed and required removal surgery, causing Plaintiff to suffer injury and damages, including pain and suffering, mental anxiety and anguish, and medical bills.

Count IV: Negligence Per Se

86. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

87. The SynchroMed II Devices implanted in Plaintiff's abdomen violate the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant thereto, and violate Georgia law that parallels federal requirements, in one or more of the following ways:

a. The SynchroMed II Devices implanted in Plaintiff were adulterated because it deviates from the specifications approved by the FDA in Medtronic's PMA application, in violation of Current Good Manufacturing Practices found in 21 C.F.R. Part 820. The quality-control requirements of the

CGMPs are designed to ensure Medtronic's products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and reported. The CGMPs require Medtronic to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated under 21 U.S.C. § 351(h), and a manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce under 21 U.S.C. § 331(a)–(c), (k).

b. The SynchroMed II Devices implanted in Plaintiff were also adulterated in violation of Georgia statute because, as a consequence of its defective manufacture, quality fell below that which Medtronic purported or represented it to possess under Ga. Code Ann. § 26-3-7(3), and a manufacturer is prohibited by Georgia statute from manufacturing, selling, or delivering an adulterated device under Ga. Code Ann. § 26-3-3.

c. The SynchroMed II Devices implanted in Plaintiff were misbranded because Medtronic failed to report adverse event information to the FDA as required by 21 U.S.C. § 360i and 21 C.F.R. Part 803, and a

manufacturer is prohibited from introducing, delivering, or selling a misbranded device into interstate commerce under 21 U.S.C. § 331(a)–(c), (k).

d. The SynchroMed II Device was introduced or delivered for introduction into interstate commerce and was adulterated and misbranded in violation of 21 U.S.C. §§ 331(a), 351(h), and 352(t)(2); 21 C.F.R. Parts 803 and 820; and Ga. Code Ann. § 26-3-3(1).

e. The SynchroMed II Device was adulterated and misbranded in interstate commerce in violation of 21 U.S.C. §§ 331(b), 351(h), and 352(t)(2); 21 C.F.R. Parts 803 and 820; and Ga. Code Ann. § 26-3-3(2).

f. The SynchroMed II Device was received in interstate commerce, was adulterated and misbranded, and was delivered for pay or otherwise in violation of 21 U.S.C. §§ 331(c), 351(h), and 352(t)(2); 21 C.F.R. Parts 803 and 820; and Ga. Code Ann. § 26-3-3(3).

g. The SynchroMed II Device was adulterated and misbranded while held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§ 331(k), 351(h), and 352(t)(2); 21 C.F.R. Parts 803 and 820; and Ga. Code Ann. § 26-3-3(9).

h. As a result of numerous FDA inspections from 2006 through 2013 of Medtronic's manufacturing plants in Minneapolis, Minnesota and

Juncos, Puerto Rico, as alleged herein, the FDA determined that Medtronic violated specific CGMPs as previously pled (including 21 C.F.R. §§ 820.30(c), 820.30(g), 820.70(a), 820.75(a), 820.100(a), 820.100(a)(2), 820.100(a)(3), 820.100(a)(5), 820.184, 820.198(a), 820.198(a)(3), and 820.198(c)), rendering the SynchroMed II Devices implanted in Plaintiff's body adulterated, and 21 C.F.R. §§ 803.50(a)(1) and 806.10(a)(1), rendering the SynchroMed II Devices implanted in Plaintiff's body misbranded.

i. Specifically, with respect to Plaintiff's third pump, as evidenced by Recall No. Z-0896-2018, Medtronic defectively manufactured Plaintiff's pump, which led to motor stalls, cessation of therapy, and withdrawal, and which necessitated surgical removal and replacement of the pump.

88. Under Georgia law, Defendants had a duty to individuals, including Plaintiff, to use reasonable care in manufacturing the SynchroMed II Device, which includes complying with federal regulations and state law designed to ensure the safe manufacture, assembly, inspection, packaging, and testing of medical devices; Plaintiff therefore falls within the class of persons these statutes and regulations were designed to protect, namely, consumers of medical devices.

89. Defendants were negligent in failing to use reasonable care in manufacturing the SynchroMed II Device, in that they failed to use reasonable care to ensure that Plaintiff's SynchroMed II Device complied with federal requirements,

manufactured Plaintiff's SynchroMed II Device in a way that did not comply with federal requirements or state statutes, and failed to test and inspect Plaintiff's SynchroMed II Device before placing it into the stream of commerce and making it available for sale to Plaintiff; in so doing, Defendants failed to comply with manufacturing requirements imposed by the Device's PMA requirements and postapproval regulations, as well as state statute; the harm complained of is therefore the same these statutes and regulations are intended to guard against.

90. As a foreseeable, direct, and proximate result of Defendants' violations of these federal and state statutes and regulations, the SynchroMed II Devices implanted in Plaintiff's abdomen failed and required removal and replacement surgeries, causing Plaintiff to suffer injury and damages, including pain and suffering, mental anxiety and anguish, and medical bills.

Count V: Breach of Express Warranty

91. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

92. At all times relevant hereto, Medtronic expressly warranted and promised to Plaintiff, by way of a written warranty provided to Plaintiff along with her SynchroMed II Device, that if Plaintiff's SynchroMed II pump "fail[s] to function within normal tolerances due to a defect in materials or workmanship within . . . two (2) years commencing with the date of implantation," or if Plaintiff's

SynchroMed II catheter or accessories "fail to function within normal tolerances due to a defect in materials or workmanship within . . . one (1) year commencing with the date of implantation," then "Medtronic will at its option: (a) issue a credit to the purchaser of the replacement Component equal to the Purchase Price, . . . or (b) provide a functionally comparable replacement Component at no charge."[15]

93. This express warranty plainly relates to the SynchroMed II Device and became the basis of the bargain because Plaintiff received and relied upon this warranty when deciding to have the SynchroMed II Device implanted.

94. Defendants breached this express warranty in violation of Ga. Code Ann. § 11-2-313 because:

a. Plaintiff's third pump failed fewer than one year after it was implanted, due to manufacturing defects as pled herein;

b. Plaintiff met the qualifying conditions set forth in Section B of the warranty; and

c. Medtronic has neither refunded nor replaced free of charge the defective third pump.

95. As a foreseeable, direct, and proximate result of this breach, Plaintiff has suffered damages including medical bills consisting of the value of her defective pump.

[15] Ex. 13, Medtronic Limited Warranty Special Notice for Medtronic Pump System ¶ A(1).

Count VI: Punitive Damages

96. Plaintiff incorporates by reference as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

97. Defendants knew or should have known that the SynchroMed II Device was defective and presented an unreasonable risk of harm to Plaintiff.

98. Defendants' conduct as described in this Complaint, for which Plaintiff is entitled to recover compensatory damages, manifested the entire want of care such that it demonstrated a conscious indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the SynchroMed II Device, including Plaintiff, justifying the imposition of punitive damages pursuant to Ga. Code Ann. § 51-12-5.1.

Count VII: Attorneys' Fees and Expenses of Litigation

99. Plaintiff incorporates by reference as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

100. Defendants have acted in bad faith, have been stubbornly litigious, and have caused the Plaintiffs unnecessary trouble and expense, allowing Plaintiff to recovery attorneys' fees and expenses of litigation pursuant to Ga. Code Ann. § 13-6-11.

WHEREFORE, Plaintiff prays for the following:

(a) That Plaintiff recover from Defendants, jointly and severally, general and special damages, all in an amount to be determined by a jury of Plaintiff's peers;

(b) That Plaintiff recover against Defendants for their wrongful conduct such punitive damages that will punish and deter similar conduct, all in an amount to be determined by a jury of Plaintiff's peers;

(c) That Plaintiff recover reasonable attorneys' fees and expenses of litigation; and

(d) That Plaintiff has such other and further relief as this Honorable Court deems just and proper under the circumstances.

Dated: October 20, 2020

Respectfully Submitted:

/s/ Ellen A. Presby
Ellen A. Presby
Texas Bar No. 16249600
Van Wey, Presby & Williams, PLLC
12720 Hillcrest Road, Suite 600
Dallas, TX 75230
Phone: (214) 329-1350
Email: ellen@vwpwlaw.com
Pro Hac Vice (pending application)

-and-

Robert M. Hammers, Jr.
Georgia Bar No. 337211
SCHNEIDER HAMMERS, LLC
5555 Glenridge Connector, Suite 975

Atlanta, GA 30342
Phone: (770) 394-0047
Fax: (678) 623-5271
E-mail: rob@schneiderhammers.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that the foregoing is being filed using the Court's CM/ECF system this 20th day of October, 2020, which will automatically serve a copy to all known counsel of record via electronic mail.

/s/ Ellen A. Presby
Ellen A. Presby
Texas Bar No. 16249600
Van Wey, Presby & Williams, PLLC
12720 Hillcrest Road, Suite 600
Dallas, TX 75230
Phone: (214) 329-1350
Email: ellen@vwpwlaw.com
Pro Hac Vice