IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

[redacted] **Plaintiff,** **vs.** **MEDTRONIC, INC.** Serve: CSC-LAWYERS INCORPORATING SERVICE COMPANY 221 BOLIVAR ST. JEFFERSON CITY, MO 65101 **Defendant.**	**Case No. 4:22-cv-00643** **PRODUCT LIABILITY** **(In excess of $75,000)** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff [redacted] ("Plaintiff") states the following for her Complaint against Medtronic, Inc. ("Defendant"):

I. INTRODUCTION

1. This is a wrongful death and products liability action for damages for personal injuries and death sustained by [redacted] ("[redacted] arising from a defective product designed, manufactured, labeled, distributed, and/or otherwise placed into the stream of commerce by Defendant. As set forth herein, [redacted] suffered severe injuries and death as a foreseeable, direct, and proximate result of defects in the HeartWare Ventricular Assist Device (HVAD). The defects in the HVAD causing [redacted] death were direct violations of FDA regulations and the HVAD's premarket approval ("PMA").

II. PARTIES

2. Plaintiff is and was at all relevant times a citizen of Missouri.

3. Plaintiff brings this action pursuant to MO. REV. STAT. § 537.080, commonly referred to as the "Missouri Wrongful Death Statute," on behalf of herself and all persons entitled to recover under said statute.

4. Plaintiff is the proper party to bring this action for the wrongful death of her husband, [redacted] as she is a member of Class I pursuant MO. REV. STAT. § 537.080.

5. Defendant is a corporation incorporated or organized under the laws of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

6. Defendant acquired HeartWare, Inc., the original designer of the HVAD, in 2016.

7. Defendant is the lawful successor of HeartWare, Inc.

8. Defendant assumed all liabilities of HeartWare, Inc. relating to the HVAD.

9. Defendant's acquisition of HeartWare, Inc. was a merger of the two companies.

10. Defendant continued to sell the HVAD after its merger with HeartWare, Inc.

III. JURISDICTION

11. This Court has personal jurisdiction over Defendant pursuant to MO. REV. STAT. § 506.500, under which a court in Missouri may exercise personal jurisdiction over any nonresident as to a cause of action arising from, among other things, the transaction of any business within Missouri; the making of any contract within Missouri; or the commission of a tortious act within Missouri.

12. Defendant meets one or more of these conditions as Defendant transacted business within Missouri; committed torts within Missouri as pled herein; and/or entered into a contract within Missouri.

13. At all relevant times, Defendant was involved in designing, assembling, manufacturing, testing, packaging, labeling, marketing, distributing, selling, promoting, and/or

otherwise placing into the stream of commerce the HVAD with the expectation that the device would be purchased and implanted in patients in Missouri.

14. 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 $75,000.00, exclusive of interests and costs, and is between citizens of different states.

IV. VENUE

15. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claim occurred in St. Louis, Missouri.

16. [redacted] had his Medtronic HVAD implanted at Barnes Jewish Hospital in the City of St. Louis.

V. ALLEGATIONS COMMON TO ALL COUNTS

A. Background on the HeartWare Ventricular Assist Device (HVAD)

17. A ventricular assist device is a mechanical pump. When one of the heart's natural pumps does not perform as it should, the mechanical pump is used to increase the amount of blood pumped through the body.

18. The HVAD consists of a pump that is attached to a ventricle inside the body, an external controller that monitors the pump, a driveline cable connecting the pump to the controller, and power sources that run the pump and controller.

19. The HVAD Pump is surgically implanted in a sac around a patient's heart known as the pericardial space.

20. The HVAD Pump is connected directly to the heart at the bottom of the left ventricle and pushes blood into the aorta.

21. The HVAD controller is a mini-computer that monitors the pump. The HVAD controller runs on two batteries, or one battery combined with electricity from a wall or car outlet.

B. Legal Requirements Following Premarket Approval of the HVAD

22. The Medical Device Amendments to the Food, Drug and Cosmetic Act classifies medical devices into three groups (Classes I, II, and III).

23. 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.

24. Class III devices require U.S. Food and Drug Administration (FDA) approval in the form of a premarket approval (PMA) application.

25. The HeartWare Ventricular Assist Device Pump Implant Kit is a Class III medical device.

26. The HVAD was originally approved by the FDA through the PMA process on November 20, 2012. Its PMA number is P100047.

27. Medtronic has sought and received FDA approval of nearly 200 supplements or changes to the originally approved HVAD.

28. Federal regulations require a PMA holder such as Medtronic to comply with many requirements, including:

a. A device may not be manufactured, packaged, stored, labeled, distributed, or advertised 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.

b. Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for

release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. 21 C.F.R. §820.160 (a).

c. Each manufacturer is required to report adverse events, known as Medical Device Reporting (MDR), no later than thirty calendar days after the day they received, or otherwise became aware of information, from any source, that reasonably suggests that one of their marketed devices: (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned and would be likely to cause or contribute to a death or serious injury. 21 C.F.R. § 803.50; 21 C.F.R. § 803.52.

C. Recalls of the HeartWare Ventricular Assist Device (HVAD)

29. The FDA uses the term "recall" when a manufacturer takes a correction or removal action to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

30. Recalls are classified as either Class I, Class II, or Class III.

31. Class I recalls are issued for a situation where there is a reasonable chance that a product will cause serious health problems or death. Class II recalls are issued for a situation where a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death. Class III recalls are issued for a situation where a product is not likely to cause any health problem or injury.

32. On or about November 19, 2020, Medtronic initiated a Class I recall of the HVAD Pump Implant Kits due to delayed or failed restart after the pump had stopped. This recall was posted by the FDA on or about February 04, 2021 and is ongoing.[1]

33. The FDA issued this recall because the HVAD Pumps manufactured with impellers from a subset of lots from a single supplier were failing to start, restart, or experiencing a delay in restarting within the maximum number of restart attempts at a rate substantially higher than pumps in the overall population.

34. [redacted] HVAD was recalled.

35. Defendant never notified Plaintiff or [redacted] of any recalls related to his HVAD.

36. On or about June 3, 2021, Defendant Medtronic stopped the distribution and sale of the HVAD System and notified physicians to cease new implants of the Medtronic HVAD System.

37. Defendant Medtronic initiated this stoppage after observational clinical comparisons found, "a higher frequency of neurological adverse events, including stroke, and mortality with the HVAD System as compared to other circulatory support devices available to patients."[2]

38. On or about June 3, 2021, Defendant Medtronic also issued an Urgent Medical Device Communication informing physicians to stop new implants of the Medtronic HVAD System. Defendant Medtronic's Communication stated that, "Pump restart failure can potentially worsen a patient's heart condition, lead to a heart attack, require hospitalization, and result in death."[3]

39. This is not Medtronic's first-time facing recall actions.

[1] Ex. 1, FDA Recall Number: Z-0946-2021
[2] Ex. 2, "Medtronic to Stop Distribution and Sale of HVAD™ System" FDA Press Release
[3] Ex. 3, Medtronic Urgent Medical Device Communication Notification Letter

40. HeartWare recalled 18,000 potentially faulty batteries produced between 2013 and 2015.

41. Medtronic received warning letters from the FDA attesting to the failure to establish and maintain procedures for implementing corrective and preventive action, in violation of 21 CFR 820.100(a).[4]

42. A 2014 inspection revealed that the HVAD device was adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h).[5]

43. Defendant has received multiple warnings from the FDA that the HVAD was adulterated specifically because the methods used in, or the facilities or controls used for, its 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 (CFR), Part 820.

44. As of 2020, roughly 3,000 death reports and 20,000 injury reports related to the HVAD had been filed with the FDA.

D. FDA Form-483 Issued to HeartWare, Inc.

45. In 2016, Medtronic acquired Heartware, Inc., the original manufacturer of the HVAD, and thereafter continued the manufacture, sale, and distribution of the HVAD.

46. On August 7, 2018, the FDA issued Heartware, Inc. a Form-483 at the conclusion of several investigations and inspections of the HVAD manufacturing facilities from May through July of 2018.[6]

[4] Ex. 4, Heartware Inc. 2014 Warning Letter
[5] Ex. 4, Heartware Inc. 2014 Warning Letter
[6] Ex. 5, FDA Form-483

47. The Form-483, directed to the HVAD's Senior Manufacturing Director, cites several "objectional conditions" that violate the aforementioned FDA regulations and statutes, including the following:

a. "Failure to adequately implement a Design Control Process, in that design inputs requirements have not always been translated into a final design output, following comprehensive verification/validation activities to ensure final system design performs and functions as described in applicable system requirements."[7]

b. Recurring failures to correct issues with the HVAD such as: cracks on the Controller housing, chemical reactions deteriorating the controller housing, bent/damaged power connector ports, and loose component rattling.[8]

c. Failure to implement corrective and preventative actions to address multiple known nonconformities or deficiencies, especially for an "investigation of increased trend in power loss events".[9]

d. Failure to implement proper Product Complaint Handling procedures, specifically, emails containing reports of adverse events and/or product performance failures (including HVAD stoppage) were not considered complaints even though commonly associated with adverse events. Specifically, "at the time of this inspection your firm has 644 complaints that have been opened for 100-199 days and 120 complaints opened for a period of 200-299 days."[10]

e. "Your firm has not ensured the contract manufacturer of the HVAD Controller 2.0 has implemented design systems/subsystems requirements, including testing

[7] Ex. 5, FDA Form-483, Observation 1
[8] Ex. 5, FDA Form-483, Observation 1
[9] Ex. 5, FDA Form-483, Observation 2
[10] Ex. 5, FDA Form-483, Observation 3

methods, that reflect appropriate useful life and reliability attributes which are aligned with the actual use and label claims to ensure compliance of the HVAD System to design outputs…"[11]

f. Failure to implement the required Medical Device Reporting (MDR) procedure, in that "the firm reported 677 MDRs beyond the 30-day timeframe: 358 late initial reports (17 deaths, 154 serious injuries, and 187 malfunctions)."[12]

E. The HVAD was Manufactured in Violation of its PMA

48. The HVAD's PMA Approval Order mandated "that device labeling must be truthful."[13] But the HVAD did not comply with the following assertions in its labeling:

a. "The pump should restart" after connecting a new controller.[14]

b. "Disconnecting and then reconnecting both power supplies will result in the controller starting the pump as soon as the driveline is connected."[15]

c. "WARNING! DO NOT disconnect the driveline or power sources from the controller while cleaning it or the pump will stop. ***If this happens, reconnect the drive line to the controller as soon as possible to restart the pump***."[16]

d. "WARNING! DO NOT disconnect the driveline from the controller or the pump will stop. ***If this happens, reconnect the driveline to the controller as soon as possible to restart the pump***."[17]

[11] Ex. 5, FDA Form-483, Observation 3
[12] Ex. 5, FDA Form-483, Observation 5
[13] Ex. 6, PMA Package, p. 6
[14] Ex. 6, PMA Package, pp. 97-98.
[15] Ex. 6, PMA Package, p. 50
[16] Ex. 6, PMA Package, p. 52
[17] Ex. 6, PMA Package, p. 87

49. The HVAD's PMA Package also includes a Summary of Safety and Effectiveness Data (SSED) outlining key performance and design characteristics of the HVAD that were violated in this case, including:

a. The HVAD's batteries, when fully charged, should power the HVAD pump for approximately 4 to 6 hours;[18]

b. The HVAD's batteries are expected to have a useful operating life of greater than 250 charge and discharge cycles;[19]

c. Pump start and stop testing was conducted adequately and patients are likely to experience no more than 93 start/stop cycles in the dual mode of pump operation;.[20]

d. The HVAD was to comply with FDA recognized standards for electrical safety, IEC 60601-1 and IEC 60601-1-1 and for electromagnetic compatibility, IEC 60601-1-2.[21]

F. Defendant's Violations of FDA Regulations and Statutes and the PMA Resulted in a Defective HVAD that Caused [redacted] Injuries and Death.

50. On or about July 16, 2018, [redacted] was implanted with an HVAD at Barnes Jewish Hospital.

51. On or about November 29, 2019, [redacted] received an HVAD replacement at Barnes Jewish Hospital.

52. On or about February 24, 2021, [redacted] was admitted to Barnes Jewish Hospital to replace his HVAD controller following a request from his device coordinator due to impending internal battery failure.

[18] Ex. 6, PMA Package, p. 12
[19] Ex. 6, PMA Package, p. 12
[20] Ex. 6, PMA Package, p. 14
[21] Ex. 6, PMA Package, p. 14

53. [redacted] doctors described Defendant's product as faulty and defective and stated in the medical record that his "HVAD was one of the models where there is a small chance of not restarting once it stops."

54. Plaintiff's HVAD did not restart as it was supposed to despite ten (10) attempts of cycling the power to the device.

55. On or about February 25, 2021, [redacted] was discharged into hospice care at his home.

56. On or about March 4, 2021, as a result of the pump malfunctioning and not restarting, [redacted] died.

57. As a result of the aforementioned defects, malfunctions, violations of federal regulations and the HVAD's PMA, [redacted] HVAD failed to pump as programmed, resulting in the continued hospitalization and death of [redacted]

58. As a foreseeable, direct, and proximate result of Medtronic's conduct described herein, [redacted] suffered damages, including pain and suffering, lasting injury, mental anxiety and anguish, death, and medical bills in amounts to be proven at trial.

VI. Causes of Action

Count I: Strict Liability

59. Plaintiff incorporates the above allegations as though fully set forth herein.

60. The HVAD implanted around [redacted] heart was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and federal regulations, and was manufactured in violation of Missouri law that parallels federal requirements, in one or more of the following ways:

a. The HVAD was manufactured, monitored, packed, stored, inspected, or installed in violation of Current Good Manufacturing Practices found in 21 C.F.R. Part 820

and is therefore 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 HVAD implanted in [redacted] was adulterated because it was manufactured in deviation from Current Good Manufacturing Practices found in 21 C.F.R. Part 820.

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

   ii. The HVAD 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; and/or

   iii. The HVAD 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.

c. As a consequence of its defective manufacture, the HVAD implanted in [redacted] was also adulterated in violation of Missouri law because its quality fell below that which Medtronic purported or represented it to possess under MO. REV. STAT.§ 196.095 (2018).

d. A manufacturer is prohibited by Missouri statute from manufacturing, selling, or delivering an adulterated device under MO. REV. STAT. § 196.015 (2018).

e. The HVAD was introduced, sold, and delivered for introduction into interstate commerce and was adulterated in violation of 21 U.S.C. §§ 331(a), 351(h); 21 C.F.R. § 820; and MO. REV. STAT. § 196.015(3) (2018).

61. The HVAD implanted around [redacted] heart was not reasonably safe for its intended use as a matter of law with respect to its manufacture.

62. As a foreseeable, direct, and proximate result of Defendant's violations of these federal and state statutes and regulations, the HVAD implanted around [redacted] heart failed to restart, causing [redacted] to suffer injury and damages, including pain and suffering, mental anxiety and anguish, death, and medical bills.

WHEREFORE, Plaintiff prays for judgment against Defendant for a fair and reasonable amount in excess of ($75,000.00), for punitive damages, costs herein incurred, prejudgment interest, post judgment interest, and for such other and further relief as may be just and proper.

Count II: Negligence

63. Plaintiff incorporates the above allegations as though fully set forth herein.

64. Under Missouri law, Defendant had a duty to individuals, including [redacted] to use reasonable care in designing, assembling, manufacturing, testing, packaging, labeling, marketing, distributing, selling, promoting, and/or otherwise placing into the stream of commerce the HVAD, which includes complying with federal regulations and the HVAD's PMA designed to ensure the safe manufacture, assembly, inspection, packaging, and testing of medical devices.

65. The HVAD implanted in [redacted] was adulterated in violation of Missouri law because, as a consequence of its defective manufacture, its quality fell below that which Medtronic purported or represented it to possess under MO. REV. STAT. § 196.095 (2018).

66. A manufacturer is prohibited by Missouri statute from manufacturing, selling, or delivering an adulterated device under MO. REV. STAT. § 196.015 (2018).

67. At all times relevant herein, Defendant knew or should have known, by the use of ordinary care, of the above-described dangerous conditions of the HVAD, and, at all relevant

times herein, [redacted] did not know, and by using ordinary care, could not have known, of such dangerous conditions.

68. As a foreseeable, direct, and proximate result of Defendant's violations of these federal and state statutes and regulations, the HVAD implanted around [redacted] heart failed to restart, causing [redacted] to suffer injury and damages, including pain and suffering, mental anxiety and anguish, death, and medical bills.

WHEREFORE, Plaintiff prays for judgment against Defendant for a fair and reasonable amount in excess of ($75,000.00), for punitive damages, costs herein incurred, prejudgment interest, post judgment interest, and for such other and further relief as may be just and proper.

Count III: Negligence Per Se

69. Plaintiff incorporates the above allegations as though fully set forth herein.

70. At all times relevant to the Complaint, Defendant owed to the general public, including Plaintiff, a duty to design, manufacture and market only such HVADs as were not defective and unreasonably dangerous to use.

71. The HVAD was dangerously defective and unsafe for normal and foreseeable use by and in the presence of the public because of its defective manufacture.

72. The HVAD implanted around [redacted] heart violated the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant thereto, and violated Missouri law that parallels federal requirements, in one or more of the following ways:

a. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of 21 C.F.R. Part 820 is deemed to be adulterated under 21 U.S.C. § 351(h).

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

c. The HVAD implanted around [redacted] heart 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 so that non-conforming products do not reach the market.

d. The HVAD implanted in [redacted] was also adulterated in violation of Missouri law because, as a consequence of its defective manufacture, its quality fell below that which Medtronic purported or represented it to possess under MO. REV. STAT. § 196.095 (2018).

e. A manufacturer is prohibited by Missouri statute from manufacturing, selling, or delivering an adulterated device under MO. REV. STAT. § 196.015 (2018).

f. The HVAD was introduced or delivered for introduction into interstate commerce and was adulterated in violation of 21 U.S.C. §§ 331(a), 351(h); 21 C.F.R. Part 820; and MO. REV. STAT. § 196.015(3) (2018).

g. The HVAD was adulterated in interstate commerce in violation of 21 U.S.C. §§ 331(b), 351(h); 21 C.F.R. Part 820; and MO. REV. STAT. §§ 196.015(1) - (3) (2018).

h. The HVAD 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); 21 C.F.R. 820; and MO. REV. STAT. § 196.015(3) (2018).

i. The HVAD was adulterated while held for sale after shipment in interstate commerce in violation of 21 U.S.C. §§ 331(k), 351(h); 21 C.F.R. Part 820; and MO. REV. STAT. § 196.015(4) (2018).

73. [redacted] was a member of the class of persons that the aforementioned statutes and regulations were intended to protect.

74. [redacted] injuries and death are the type that the aforementioned statutes and regulations were intended to prevent.

75. As a foreseeable, direct, and proximate result of Defendant's violations of these federal and state statutes and regulations, the HVAD implanted around [redacted] heart failed to restart, causing [redacted] to suffer injury and damages, including pain and suffering, mental anxiety and anguish, death, and medical bills.

WHEREFORE, Plaintiff prays for judgment against Defendant for a fair and reasonable amount in excess of ($75,000.00), costs herein incurred, prejudgment interest, post judgment interest, and for such other and further relief as may be just and proper.

Count IV: Breach of Implied Warranties of Merchantability and Fitness for Particular Purpose

76. Plaintiff incorporates the above allegations as though fully set forth herein.

77. At all times relevant hereto, Defendant, as a merchant and manufacturer of medical devices, including the HVAD, impliedly warranted to [redacted] that his HVAD was fit for the ordinary purposes for which it would be used.

78. At all times relevant hereto, [redacted] relied on Defendant's skill and/or judgment as a merchant and manufacturer of medical devices to select or furnish suitable goods, such as the HVAD.

79. Defendant breached its implied warranty of merchantability in violation of MO. REV. STAT. § 400.2-314 because Defendant's numerous violations of FDA regulations and the HVAD's PMA resulted in the manufacture, sale, and distribution of a defective and unmerchantable HVAD to [redacted]

80. Defendant breached its implied warranty of fitness for a particular purpose in violation of MO. REV. STAT § 400.2-315 because Defendant's numerous violations of FDA regulations and the HVAD's PMA resulted in the manufacture, sale, and distribution of a defective HVAD to [redacted] that rendered it unable to perform the ordinary purposes for which it would be used.

81. As a foreseeable, direct, and proximate result of Defendant's violations of these warranties and federal and state statutes and regulations, the HVAD implanted around [redacted] heart failed to restart, causing [redacted] to suffer injury and damages, including pain and suffering, mental anxiety and anguish, death, and medical bills.

WHEREFORE, Plaintiff prays for judgment against Defendant for a fair and reasonable amount in excess of ($75,000.00), costs herein incurred, prejudgment interest, post judgment interest, and for such other and further relief as may be just and proper.

[redacted]

Respectfully submitted,