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IN THE CIRCUIT COURT
FOR PRINCE GEORGE'S COUNTY, MARYLAND

RS

WANDA SWARTZ
31 Clay St., Unit 101
Easton, Maryland 21601

MARK SWARTZ
31 Clay St., Unit 101
Easton, Maryland 21601

Plaintiffs,

v.

ELUTIA INC. f/k/a Aziyo Biologics, Inc.
12510 Prosperity Drive, Suite 370
Silver Spring, Maryland 20904
Serve on: Corporation Service Company,
251 Little Falls Drive
Wilmington, Delaware 19808

MEDTRONIC SOFAMOR DANEK USA, INC.
2600 Sofamor Danek Drive
Memphis Tennessee 38132
Serve On: Corporation Service Company,
2908 Poston Ave.
Nashville, Tennessee 37203

SPINALGRAFT TECHNOLOGIES, LLC
4340 Swinnea Road
Memphis Tennessee 38118
Serve On: Corporation Service Company,
2908 Poston Ave.
Nashville, Tennessee 37203

DCI DONOR SERVICES, INC.
566 Mainstream Dr., Ste. 300
Nashville, Tennessee 47288
Serve On: Corporation Service Company
2908 Poston Ave.

C.A. No.: C-16-CV-24-001963

Nashville, Tennessee 19808 NEW MEXICO DONOR SERVICES 1609 University Blvd., NE Albuquerque, New Mexico 87012 Serve On: Corporation Service Company, MC-CSC 1726 E. Michigan Dr., Ste. 101 Hobbes, New Mexico 88240 Defendants.	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, WANDA SWARTZ and MARK SWARTZ, husband and wife, by and through their attorneys, as and for their complaint against Defendants, ELUTIA INC. f/k/a/ AZIYO BIOLOGICS, INC., MEDTRONIC SOFAMOR DANEK USA, INC., SPINALGRAFT TECHNOLOGIES, LLC, DCI DONOR SERVICES, INC. and NEW MEXICO DONOR SERVICES (collectively, "Defendants"), allege as follows:

I. INTRODUCTION

1. This action seeks to recover damages for the personal injuries suffered by WANDA SWARTZ and MARK SWARTZ and the loss of consortium claim of MARK SWARTZ, which were the direct and proximate result of the wrongful conduct of ELUTIA INC., f/k/a AZIYO BIOLOGICS, MEDTRONIC SOFAMOR DANEK USA, INC., SPINALGRAFT TECHNOLOGIES, LLC, DCI DONOR SERVICES, INC. and NEW MEXICO DONOR SERVICES in connection with the research, harvesting, testing, design, development, manufacture, production, tissue recovery, production, inspection,

labeling, advertisement, marketing, promotion, sale, and/or distribution of FiberCel Fiber Viable Bone Matrix ("FiberCel") and the human tissue used to make FiberCel.

II. PARTIES

2. Plaintiffs WANDA SWARTZ and MARK SWARTZ ("Plaintiffs"), are and at all relevant times were residents of the State of Maryland, residing in Easton, Maryland.

3. Defendant ELUTIA INC., f/k/a AZIYO BIOLOGICS, INC. ("Aziyo") is a Delaware corporation, whose registered agent for service of process is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Aziyo's principal place of business is located at 12510 Prosperity Drive, Suite 370, Silver Spring, Maryland 20904. Aziyo does business throughout the United States, including conducting regular business in Maryland.

4. Upon information and belief, Aziyo recently changed its corporate name to Elutia, Inc.

5. Upon information and belief, Aziyo developed, manufactured, marketed, promoted, distributed, supplied and/or sold FiberCel which was implanted into Plaintiff, Wanda Swartz, and which is the subject of this complaint.

6. Defendant, MEDTRONIC SOFAMOR DANEK USA, INC. ("Medtronic") is a Tennessee corporation with an office address of 2600 Sofamor Danek Drive, Memphis, TN 38132 and with a registered agent listed as Corporation Services Company, 2908 Poston Ave., Nashville, TN 37203-1312. Medtronic does business throughout the United States, including conducting regular business in Maryland.

7. Defendant, SPINALGRAFT TECHNOLOGIES, LLC ("Spinalgraft") is a Tennessee limited liability company with an office address at 4340 Swinnea Road, Memphis, TN 38118, and a registered agent listed as Corporation Services Company, 2908 Poston Ave., Nashville, TN 37203-1312. Spinalgraft does business throughout the United States, including conducting regular business in Maryland. Defendant Spinalgraft is affiliated with Defendant Medtronic (hereinafter, Medtronic and Spinalgraft Defendants will be collectively referred to as "Medtronic" or "Medtronic/Spinalgraft").

8. Medtronic/Spinalgraft develop therapeutic and diagnostic medical products and are along with their affiliates among the world's largest medical technology, services, and solutions companies. On information and belief, Medtronic/Spinalgraft were directly and pertinently involved in the development, marketing, sale, and distribution of the FiberCel product herein and the Medtronic and Spinalgraft Defendants are jointly and severally liable for all causes of action herein.

9. Upon information and belief, during the pertinent times, Medtronic/Spinalgraft were designated as the exclusive U.S. distributor of the FiberCel product manufactured by Defendant Aziyo.

10. At all times relevant, Medtronic/Spinalgraft developed, distributed, supplied, and sold the FiberCel product which was implanted into Plaintiff, and which is the subject of this complaint.

11. Defendant, DCI DONOR SERVICES, INC. ("DCI") is incorporated in Tennessee, having its principal place of business at 566 Mainstream Dr., Ste. 300, Nashville, TN 47288 with a registered agent located at Corporation Service Company,

2908 Poston Ave., Nashville, TN 19808. DCI DONOR SERVICES, INC. is the parent company of NEW MEXICO DONOR SERVICES and does business throughout the United States, including conducting regular business in the State of Maryland.

12. Defendant, NEW MEXICO DONOR SERVICES ("NMDS") is incorporated in New Mexico, having its principal place of business at 1609 University Blvd. NE, Albuquerque, NM 87012 with a registered agent for service located at Corporation Service Company, MC-CSC1726 E. Michigan Dr., Ste. 101, Hobbes, NM 88240. NEW MEXICO DONOR SERVICES does business throughout the United States, including conducting regular business in the State of Maryland.

13. DCI Donor Services, Inc., and New Mexico Donor Services (collectively, "Donor Services" or "Donor Defendants") are engaged in the business of, inter alia, locating, properly identifying and qualifying, and recovering parts of human cadavers that should at all times qualify for recovery, processing, distribution and ultimately for use in a wide variety of surgical procedures where human bone, tissue, etcetera, can be appropriately and safely utilized.

14. Upon information and belief, Donor Services harvested, recovered, processed, supplied and/or sold human tissue for use in FiberCel which was implanted into Plaintiff, and which is the subject of this complaint.

15. Defendants, at all times relevant to this lawsuit, manufactured, developed, designed, marketed, distributed, promoted, supplied, provided human tissue for and/or otherwise sold (directly or indirectly) FiberCel to various locations for use in surgeries requiring bone grafting, including to Anne Arundel Medical Center in Annapolis,

Maryland where it was surgically implanted into Plaintiff, Wanda Swartz, causing her to suffer harm as described herein.

16. When reference is made in this Complaint to any act or omission of any of the Defendants, it shall be deemed that the officers, directors, agents, employees, or representatives of the Defendants committed or authorized such act or omission, or failed to adequately supervise or properly control or direct their employees while engaged in the management, direction, operation, or control of the affairs of Defendants, and did so while acting within the scope of their duties, employment or agency.

III. JURISDICTION AND VENUE

17. This claim arises out of a cervical spine operation performed on Plaintiff, Wanda Swartz, at Anne Arundel Medical Center in Annapolis, Maryland on March 31, 2021, in which FiberCel was surgically implanted into her body.

18. This Court has jurisdiction over this dispute because the Complaint seeks damages in excess of $30,000.00, exclusive of interest and attorney's fees.

19. Personal Jurisdiction and Venue are appropriate in the State of Maryland pursuant to Md. Ct. & Ju. Proc. §6-102(a) and §6-103(b)(1)(2)(3) and (4) for at least the reasons that there are multiple defendants, that the cause of action arose in the State of Maryland and that the plaintiff resides in Prince George's County.

20. Personal jurisdiction is appropriate in the State of Maryland over all Defendants because they have engaged either directly or indirectly, in the business of acquiring, supplying, manufacturing, testifying, marketing, selling, and/or distributing FiberCel and/or the human tissue used in FiberCel within the State of Maryland, with a

reasonable expectation that the product would be used in the State of Maryland, and thus regularly solicited or transacted business in this State. Furthermore, the product at issue was implanted in the State of Maryland.

21. Venue is properly set in the State of Maryland pursuant to Md Cts. & Jud. Proc. §6-202(8) and §6-202(11), as this tort action is based on negligence with the implantation of the tainted FiberCel into a Maryland resident in the State of Maryland.

IV. FACTUAL ALLEGATIONS

A. FiberCel Fiber Viable Bone Matrix

22. The FiberCel Fiber Viable Bone Matrix product ("FiberCel") is made from human tissue consisting of cancellous bone particles with preserved cells, combined with demineralized cortical fiber. FiberCel is used as a bone void filler in various orthopedic and spinal procedures. The allografts contain the scaffold, growth factors and cells required for regeneration critical for successful bone formation.

23. FiberCel is classified by the FDA as a human cell, tissue, cellular or tissue-based product (HCT/P). HCT/Ps are regulated by the FDA as drugs, devices, and/or other biological products.

24. FiberCel is marketed for use in orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft.

25. The FiberCel package insert states that "THIS PRODUCT IS MANUFACTURED FROM DONATED HUMAN TISSUE," which consists of highly

processed donor tissue and growth factor cells. The exact formulation of FiberCel is closely held by Defendants and is not known to Plaintiff.

26. Because FiberCel uses human tissue from human donors, and includes preserved living cells, it is imperative that rigorous screening and quality control procedures be used to ensure that the resultant product is not contaminated. This is also so because the FiberCel product is meant to be used in surgeries and medical procedures involving patients already in a vulnerable medical status given their context as procedure recipients.

27. On June 20, 2019, Aziyo announced it had signed an exclusive, multi-year distribution agreement with defendant Medtronic/Spinalgraft in the U.S. orthopedic market. According to the agreement, Aziyo agreed to manufacture and supply FiberCel to Medtronic/Spinalgraft for distribution through the company's sales and marketing organization.

28. Medtronic/Spinalgraft along with their affiliates comprise a very large and sophisticated medical manufacturer and distributor. The enterprise holds itself out as having special knowledge and expertise regarding the medical products that it carries and distributes, and in fact even has training and instructional videos pertaining to the use of the FiberCel product on its Medtronic English language website.

29. Upon information and belief, in addition to distributing FiberCel, Medtronic/Spinalgraft developed FiberCel along with Defendant Aziyo Biologics, Inc.

30. The FiberCel used in Plaintiff's surgery was manufactured using human tissue recovered from a single donor by DCI Donor Services, Inc. and New Mexico Donor Services ("Donor Services").

31. Upon information and belief, the single donor whose tissue was recovered by Donor Services had a tuberculosis infection prior to his death and had clear signs and symptoms at the time of his death of an infectious etiology.

B. The FiberCel Product is Recalled

32. On June 2, 2021, the United States Food & Drug Administration (FDA) issued an urgent voluntary recall of FiberCel, specifically three products from Donor Lot Number NMDS210011: VMB9901, VBM9905, and VBM9910.

33. Aziyo initiated the voluntary recall in response to reports of patients testing positive for Tuberculosis and post-surgical infections following the surgical implantation of FiberCel as part of an orthopedic or spinal procedure.

34. Tuberculosis ("TB") is an infectious disease caused by bacteria known as *Mycobacterium tuberculosis*. TB is highly contagious, and mostly impacts the lungs, but can also spread through the lymph nodes to other parts of the body, including the kidneys, brain, and spine.

35. Once mycobacterium tuberculosis is introduced to the body, the bacteria must then proliferate within the new host for the host to develop disease. When this bacteria is introduced in a surgical wound, the patient is already in an immunocompromised

position, causing them to have an increased likelihood of developing TB, which can be fatal.

36. The recalled contaminated FiberCel lot contained 154 units delivered to 20 states, including Maryland.

37. Upon information and belief, Anne Arundel Medical Center received multiple units from the contaminated FiberCel Donor Lot No. NMDS210011, and the contaminated units were implanted into several patients, including Plaintiff, Wanda Swartz.

38. Multiple patients that have received FiberCel from this Donor Lot have tested positive for Tuberculosis, including Plaintiff, Wanda Swartz.

39. This recall acknowledged that viruses and bacteria, including Tuberculosis, can be transplanted into patients along with the FiberCel product.

C. Plaintiff Received the Contaminated FiberCel Product and as a Result, Suffered Severe Injury & Passed on the Infection to her Spouse

40. Plaintiff, Wanda Swartz, underwent cervical spine surgery on March 31, 2021, at Anne Arundel Medical Center in Annapolis, Maryland

41. Plaintiff, Wanda Swartz's surgery included bone grafting, utilizing FiberCel from Donor Lot Number NMDS210011.

42. Unbeknownst to Plaintiff, Wanda Swartz, or her physicians at the time of her surgery, the FiberCel implanted into Plaintiff was contaminated with tuberculosis.

43. Following her March 31, 2021, operation, Plaintiff, Wanda Swartz, tested positive for tuberculosis.

44. As a result of Plaintiff, Wanda Swartz's tuberculosis infection, she passed the infection on to her husband, Plaintiff, Mark Swartz.

45. Plaintiffs' tuberculosis was caused by the contaminated and recalled FiberCel used in her operation, which contained contaminated human tissue recovered by Donor Services and developed, manufactured, sold, and distributed by the Aziyo and Medtronic defendants.

46. The FiberCel product contained no adequate warning to Plaintiff, Wanda Swartz, or her physicians of the danger that she could contract tuberculosis if a FiberCel product was used during the surgery.

47. As a direct and proximate result of the implantation of contaminated FiberCel, Plaintiff, Wanda Swartz, was forced to undergo additional painful and complicated cervical spine reconstructive surgery.

48. Plaintiff, Wanda Swartz, continues to suffer from intermittent neck and joint pain, pain at her bone grafting site, weakness, fatigue, anxiety, and depression that, upon information and belief, are related to the tuberculosis infection and/or the treatment she received due to said infection.

49. Plaintiff, Wanda Swartz's diagnosis of tuberculosis has required extensive and invasive medical protocols to manage the manifestation of this disease.

50. As a direct and proximate result of the implantation of contaminated FiberCel into his wife, Plaintiff, Mark Swartz, contracted tuberculosis requiring him to undergo extensive and invasive medical protocols to manage the manifestation of the disease.

51. Plaintiffs will require continued medical monitoring now and into the future in order to monitor Plaintiffs' health related to the ongoing and serious nature of their tuberculosis diagnoses.

52. Plaintiffs would not have suffered from tuberculosis, as well as the need to undergo the treatment they have had and will in the future endure, had Defendants harvested, manufactured, sold, and distributed a product that was free from tuberculosis contamination.

53. As a direct and proximate result of Plaintiffs' exposure to Defendants' contaminated FiberCel product and human tissue recovered for use in FiberCel, which was used in Plaintiff, Wanda Swartz's cervical spine surgery, Plaintiffs have suffered and continues to suffer from severe pain and discomfort, emotional distress, the loss of daily functions, and economic loss, including, but not limited to, present and future medical expenses, all of which are a direct result of Defendants' liability producing conduct.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE
(Against Elutia Inc., f/k/a/ Aziyo Biologics, Inc., Medtronic Sofamor Danek, USA, Inc. and Spinalgraft Technologies, LLC)

54. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

55. Defendants owed a duty to Plaintiffs, Wanda Swartz and Mark Swartz to exercise reasonable care in designing, developing, researching, manufacturing, marketing, supplying, promoting, selling, testing, quality assurance, quality control, and distribution

of FiberCel into the stream of commerce, including a duty to assure that the FiberCel would not cause those who used it, including Wanda Swartz, to suffer adverse harmful effects.

56. Defendants failed to exercise reasonable care in the designing, developing, researching, manufacturing, marketing, supplying, promoting, selling, testing, quality assurance, quality control and distribution of FiberCel.

57. Defendants knew or should have known that those individuals who used the defective FiberCel and those exposed to them were at risk for suffering harmful effects from it, including but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

58. Defendants were negligent in designing, developing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of FiberCel. The negligence of Defendants, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

a. Designing, developing, manufacturing, producing, creating, and/or promoting FiberCel without adequately, sufficiently, or thoroughly testing the FiberCel units to ensure they were free from contamination of communicable diseases, including but not limited to, tuberculosis;

b. Negligently selling their FiberCel product which was contaminated with tuberculosis;

c. Not conducting a sufficient quality control testing program to determine whether or not the subject FiberCel was manufactured properly and was

free from contamination or other defects making it unsafe for users of the product;

d. Failing to have a sufficient quality control program to ensure that the donor whose tissue was used in the subject FiberCel was free from communicable disease;

e. Failing to adequately and properly obtain and review complete donor medical history of the donor whose tissue was used in the product;

f. Failing to adequately and properly review the entire donor chart for signs and symptoms of communicable disease;

g. Failing to recognize signs and symptoms of communicable disease in the donor whose tissue was used in the recalled FiberCel;

h. Negligently making a donor eligibility determination;

i. Failing to follow applicable statutes, regulations, FDA guidelines, AATB rules, and industry standards in determining that donor tissue used in the recalled FiberCel was eligible for use in the product;

j. Negligently failing to timely recall their dangerous and defective FiberCel lots at the earliest date that it became known that certain lots of FiberCel were, in fact, dangerous and defective;

k. Negligently manufacturing FiberCel in a manner that was dangerous to those individuals who had FiberCel implanted into their bodies;

l. Negligently producing FiberCel in a manner that was dangerous to those individuals who had it transplanted into their bodies;

m. Negligently and carelessly using human tissue from an unqualified and inadequately screened human donor;

n. Were grossly negligent by willfully ignoring factors that should have led the donor to be deemed ineligible for tissue recovery;

o. Failing to warn individuals who were using the product of the risks of contracting tuberculosis; and

p. Acting otherwise careless and negligently.

59. Defendants knew or should have known that consumers, such as Plaintiffs, Wanda Swartz and Mark Swartz , would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

60. Defendants' negligence was the proximate cause of and was a substantial contributing factor in causing Plaintiffs, Wanda and Mark Swartz's physical, mental, emotional injuries and harm, and economic loss.

61. By reason of the foregoing, Defendants are liable to Wanda Swartz and Mark Swartz for all of their injuries, harm, damages, and economic and non-economic losses in an amount to be determined in the future.

SECOND CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY
(Against Elutia Inc., f/k/a/ Aziyo Biologics, Inc., Medtronic Sofamor Danek, USA, Inc. and Spinalgraft Technologies, LLC)

62. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

63. Defendants are in the business of designing, developing, manufacturing, supplying, selling, and placing into the stream of commerce certain goods, including FiberCel.

64. By placing FiberCel into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

65. The FiberCel placed into the stream of commerce by Defendants and implanted into Plaintiff was contaminated, leading those persons who received FiberCel

implants and those exposed to them to develop tuberculosis, including Plaintiffs, Wanda Swartz and Mark Swartz, and accordingly, was not fit, safe, or merchantable for its intended use.

66. The contamination in the FiberCel developed, manufactured, supplied, sold, distributed, and placed into the stream of commerce by Defendants was present at the time the FiberCel units left Defendants' control and at the time it was implanted into Plaintiff, Wanda Swartz, as part of her spinal operation.

67. Defendants breached the implied warranty for FiberCel because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Wanda Swartz and Mark Swartz, including their development of tuberculosis.

68. Plaintiff, Wanda Swartz, was a foreseeable user of the FiberCel designed, manufactured, and placed into the stream of commerce by Defendants.

69. By reason of the foregoing, Defendants are liable to Plaintiff, Wanda Swartz and Mark Swartz, for their injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

THIRD CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY
(Against Elutia Inc., f/k/a Aziyo Biologics, Inc., Medtronic Sofamor Danek, USA and Spinalgraft Technologies, LLC)

70. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint as if they were set forth at length herein.

71. At all times mentioned, Defendants expressly represented and warranted to Plaintiff, Wanda Swartz, her agents and physicians, by and through statements made by Defendants and their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the public, that FiberCel is safe, effective, fit, and proper for its intended use. Plaintiff, Wanda Swartz and her physicians utilized FiberCel relying upon these warranties.

72. Defendants' own promotion states that FiberCel is processed in sterile conditions and is screened for bacteria and communicable disease.

73. In utilizing FiberCel, Plaintiff, Wanda Swartz, relied on the skill, judgment, representation, and foregoing express warranties of the Defendants. These warranties and representations were false in that FiberCel is unsafe and unfit for its intended uses as the FiberCel used by Plaintiff, Wanda Swartz, was contaminated with tuberculosis.

74. As a result of the abovementioned breach of express warranties by Defendants, Plaintiffs suffered injuries and damages as alleged herein.

75. By reason of the foregoing, Defendants are liable to Plaintiffs, Wanda Swartz and Mark Swartz, for their injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

GROSS NEGLIGENCE
(Against Elutia Inc., f/k/a Aziyo Biologics, Medtronic Sofamor Danek, USA and Spinalgraft Technologies, LLC)

76. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

77. Plaintiffs are further informed and believe that Defendants' misconduct, as previously outlined herein, constituted a conscious disregard for the rights and safety of other persons, including Plaintiffs, Wanda Swartz and Mark Swartz, that had a great probability of causing substantial harm including, but not limited to, exposing Plaintiffs, Wanda Swartz and Mark Swartz, and other recipients of FiberCel to tuberculosis, a potentially deadly infectious disease.

78. Plaintiffs are further informed and believe that Defendants engaged in conduct with respect to the contaminated FiberCel units alleged herein which was a legal cause of loss, damages, injuries, and harm to Plaintiffs, and which exposed Plaintiffs and other recipients of the contaminated FiberCel units to serious complications, including the diagnosis of tuberculosis in Plaintiff, Wanda Swartz's post-surgical wound.

79. Defendants' actions and inactions leading to the contamination of the FiberCel product were reckless, outrageous, willful and wanton, and done with reckless disregard for the safety of the Plaintiffs, Wanda Swartz and Mark Swartz.

80. The Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiffs was the direct proximate cause of Plaintiffs' injuries and damages.

81. Defendants' acts and/or omissions constitute gross negligence because they constitute a total lack of care and an extreme departure from what a reasonably careful actor would do in the same situation to prevent foreseeable harm to Plaintiffs.

82. As a direct and proximate result of the Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiffs, Wanda Swartz and Mark Swartz, the Plaintiffs have suffered and continue to suffer damages as set forth above.

83. Defendants thereby acted with a conscious disregard for the rights and safety of Plaintiffs, Wanda Swartz and Mark Swartz, and many other users of the contaminated FiberCel units, thus warranting an award of punitive damages to Plaintiffs.

FIFTH CAUSE OF ACTION

STRICT LIABILITY- DEFECT IN MANUFACTURE
(Against Elutia Inc., f/k/a Aziyo Biologics, Inc., Medtronic Sofamor Danek, USA and Spinalgraft Technologies, LLC)

84. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

85. At all times relevant, Defendants engaged in the design, development, manufacture, fabrication, testing, inspecting, marketing, advertising, sale, and distribution of the FiberCel product in a defective and unreasonably dangerous condition to consumers, including Plaintiffs, due to the fact that FiberCel was contaminated with tuberculosis.

86. At all times relevant hereto, Defendants knew or should have known of the foreseeable risk of injury caused by their tuberculosis contaminated product, including the injuries sustained by Wanda Swartz and her husband, Mark Swartz, inherent in the design and manufacture of FiberCel.

87. As such, Defendants owed a non-delegable duty to consumers and end-users of their products to provide them with products that are not unreasonably dangerous for their reasonably anticipated use and to exercise a degree of care in their plan or design so

as to avoid any unreasonable risk of harm to anyone who is likely to be exposed to the danger.

88. At all times relevant hereto, Defendants placed the subject FiberCel into the stream of commerce knowing that it would be used without any further inspection prior to implantation.

89. At all times relevant hereto, Defendants placed the subject FiberCel into the stream of commerce in a defective and unreasonably dangerous fashion such that it failed to perform reasonably, adequately, and safely when used in the manner for which the product was intended in that it was contaminated with tuberculosis and caused Plaintiffs to suffer from tuberculosis.

90. The subject FiberCel reached consumers, including Plaintiff, Wanda Swartz, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

91. Plaintiff, Wanda Swartz used FiberCel in a manner normally intended, recommended, promoted, and marketed by Defendants.

92. FiberCel failed to perform safely when used by Plaintiff, Wanda Swartz in a reasonably foreseeable manner; that is, the presence of tuberculosis rendered the FiberCel used by Plaintiff, Wanda Swartz, unreasonably dangerous, unfit, and unsafe for its intended and reasonably foreseeable use and exposed Plaintiffs to a dangerous and deadly bacterium that caused them to suffer the serious injuries described herein.

93. The FiberCel contained a manufacturing defect when it left the possession

of Defendants. Specifically, the FiberCel sold by Defendants and used by Plaintiff differ from Defendants' intended result or from (possibly) other lots of the same product line because the FiberCel was contaminated with tuberculosis, and Defendants failures, included, but were not limited to, inadequately screening the Donor whose tissued was used to make FiberCel and failing to test the Product for the presence of contamination prior to selling and distributing the product.

94. The FiberCel did not meet or perform to the expectations of consumers/patients and their health care providers;

95. As a proximate result of Defendants' design, manufacture, packaging, labeling, marketing, sale, and distribution of FiberCel, Plaintiffs were injured catastrophically and were caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

96. By reason of the foregoing, Defendants are strictly liable to Plaintiffs, Wanda Swartz and Mark Swartz, for their injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

SIXTH CAUSE OF ACTION

STRICT LIABILITY- FAILURE TO WARN
(Against Elutia Inc., f/k/a Aziyo Biologics, Medtronic Sofamor Danek, USA and Spinalgraft Technologies, LLC)

97. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

98. The Defendants directly advertised and marketed the FiberCel to consumers, hospitals, and healthcare providers.

99. At the time the Defendants designed, developed, manufactured, prepared, processed, marketed, labeled, distributed, and sold FiberCel into the stream of commerce, they knew or should have known that it presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

100. Specifically, the Defendants knew or should have known that the FiberCel posed a significant risk of exposure to communicable diseases, such as tuberculosis, and that their product was contaminated with tuberculosis.

101. At all pertinent times, Plaintiff, Wanda Swartz, used FiberCel in a reasonably foreseeable manner.

102. The Defendants had a duty to warn of the risk of harm associated with the use of the FiberCel and to provide adequate warnings concerning the risk associated with its implantation.

103. The Defendants failed to properly and adequately warn and instruct the Plaintiff, Wanda Swartz, and her health care providers with regard to the inadequate research, testing, inspecting, and manufacture of FiberCel and the fact that the use of FiberCel could lead to the development of communicable disease, including tuberculosis.

104. The Defendants further failed to warn Plaintiff, Wanda Swartz, of the fact that FiberCel was contaminated with tuberculosis and what the dangers were to Plaintiffs from being exposed to tuberculosis.

105. At all pertinent times, including the time(s) of sale and use, the FiberCel product used by Plaintiff, Wanda Swartz, when put to the aforementioned reasonably foreseeable use, were in an unreasonably dangerous and defective condition because they

failed to contain adequate and proper warnings and/or instructions regarding the presence of—and dangers of—tuberculosis bacteria within the product. Defendants themselves failed to properly test and adequately warn and instruct Plaintiffs as to the risks and benefits of FiberCel given their need for this information, thus breaching the duty owed by Defendants to Plaintiffs.

106. Defendants knew that the risk of exposure to tuberculosis from use of its products was not readily recognizable to an ordinary consumer and that consumers would not inspect the product for bacteria or other contaminants.

107. Had Plaintiffs received notice or a warning that FiberCel was contaminated with tuberculosis, Plaintiff, Wanda Swartz, would not have used it and Plaintiffs, Wanda Swartz and Mark Swartz would not have suffered catastrophic injury as described herein.

108. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiffs.

109. The Defendants' defective warnings and labeling and/or instructions were substantial contributing causes of Plaintiffs' injuries.

110. As a direct and proximate result of the Defendants design, manufacture, marketing, sale, and/or distribution of FiberCel, and specifically the failure to warn, Plaintiffs have incurred significant damages.

111. By reason of the foregoing, Defendants are strictly liable to Plaintiffs, Wanda Swartz and Mark Swartz, for their injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

SEVENTH CAUSE OF ACTION

NEGLIGENCE
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

112. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

113. Donor Services Defendants owed a duty to Plaintiffs, Wanda Swartz and Mark Swartz to exercise reasonable care in harvesting, processing, supplying, promoting, selling, testing, quality assurance, quality control, and distribution of human tissue for use in FiberCel into the stream of commerce, including a duty to assure that their human tissue, which was used in the subject FiberCel lot, would not cause those who used it, including Wanda Swartz, to suffer adverse harmful effect.

114. Donor Services defendants failed to exercise reasonable care in the harvesting, processing, supplying, testing, quality assurance, quality control, sale, and distribution of their human tissue product for use in FiberCel.

115. Donor Services defendants knew or should have known that those individuals who were exposed to their contaminated human tissue used in FiberCel were at risk for suffering harmful effects from it, including but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting in nature, physical pain, mental anguish, and diminished enjoyment of life.

116. Donor defendants were negligent in the harvesting, recovering, processing, supplying, testing, quality assurance, quality control sale, and distribution of their human tissue product for use in FiberCel. The negligence of the Donor Defendants, their agents,

servants, and employees, included, but was not limited, to the following acts and/or omissions:

a. Harvesting, recovering, processing, and selling human tissue for use in FiberCel without adequately, sufficiently, or thoroughly testing the human tissue to ensure that it was free from contamination of communicable diseases, including but not limited to, tuberculosis;

b. Not conducting a sufficient quality control testing program to determine whether or not the subject human tissue used in the aforementioned defective FiberCel lot was properly recovered and was free from contamination or other defects making it unsafe;

c. Failing to adequately and properly obtain and review complete donor medical history;

d. Failing to stop the tissue recovery process once signs and symptoms of infection were discovered;

e. Failing to have medical professionals review the subject donor's body, medical records, and donor chart;

f. Negligently failing to timely recall their dangerous and contaminated human tissue at the earliest date that it became known that its human tissue sold for use in FiberCel was in fact, dangerous and defective;

g. Negligently harvesting, recovering, and selling human tissue for use in FiberCel in a manner that was dangerous to those individuals who had FiberCel implanted into their bodies;

h. Negligently and carelessly recovering tissue from an unqualified and inadequately screened human donor;

i. Negligently failing to screen the human donor whose tissue was used in the subject lot of FiberCel for signs of infection or disease that would have led Defendants to stop the tissue recovery process;

j. Negligently failing to test the human donor tissue and/or bone;

k. Failing to warn individuals who were using their human tissue of the risks of contracting tuberculosis;

l. Were grossly negligent by willfully ignoring factors that should have led the donor to be deemed ineligible for tissue recovery;

m. Acting in bad faith by failing to recognize obvious signs and symptoms of communicable disease of the donor and instead selling contaminated human tissue from the donor to be used in products that would be implanted into living individuals; and

n. Were otherwise careless and negligent.

117. Donor defendants knew or should have known that consumers, such as Wanda Swartz and those that would be exposed to her, including her spouse, Plaintiff, Mark Swartz, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of donor defendants' failure to exercise ordinary care, as set forth above.

118. Donor defendants' negligence was the proximate cause of Plaintiffs, Wanda Swartz and Mark Swartz's physical, mental, and emotional injuries and harm, and economic loss.

119. By reason of the foregoing, Donor defendants are liable to plaintiffs for all of her injuries, harm, damages, and economic and non-economic losses in an amount to be determined in the future.

EIGHTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

120. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this Complaint as if they were set forth at length herein.

121. At all times mentioned, Donor Defendants expressly represented and warranted to Plaintiff, Wanda Swartz, and her agents and physicians, by and through

statements made by Defendants and their authorized agents or sales representatives, orally and in publications, package inserts, and other written materials intended for physicians, medical patients, and the public, that their human tissue sold for use in FiberCel is safe, effective, fit, and proper for its intended use. Plaintiff, Wanda Swartz, and her physicians utilized FiberCel and the human tissue used in FiberCel relying upon these warranties.

122. In utilizing FiberCel and the human tissue used in FiberCel, Plaintiff, Wanda Swartz, relied on the skill, judgment, representation, and foregoing express warranties of the Defendants. These warranties and representations were false in that FiberCel and its human tissue component are unsafe and unfit for its intended uses due to the fact that the human tissue used in FiberCel and the FiberCel product were contaminated with tuberculosis.

123. By reason of the foregoing, Defendants are liable to Plaintiffs, Wanda Swartz and Mark Swartz, for their injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

NINTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

124. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

125. Donor Defendants are in the business of harvesting, recovering, selling, and placing into the stream of commerce certain goods and/or services, including the sale of human tissue. By placing human tissue into the stream of commerce to be used in surgical

procedures, including the Plaintiff, Wanda Swartz's surgical procedure, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

126. The tuberculosis contaminated human tissue sold by Donor Defendants and placed into the stream of commerce by Defendants and implanted into Plaintiff, Wanda Swartz, was contaminated, leading persons who received FiberCel utilizing contaminated human tissue sold by Donor Defendants and those potentially exposed to them to develop tuberculosis, including Plaintiffs, Wanda Swartz and Mark Swartz, and accordingly, was not fit, safe, or merchantable for its intended use.

127. The contamination in the human tissue, harvested, recovered, supplied, sold, and placed into the stream of commerce by the Donor Defendants was present at the time the human tissue left Defendants' control and at the time it was implanted into Plaintiff, Wanda Swartz, as part of her spinal operation.

128. Defendants breached the implied warranty for its human tissue because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiffs, including their development of tuberculosis.

129. Established medical and technological procedures existed at the time Donor Defendants harvested, recovered, supplied, and sold the tuberculosis contaminated human tissue that could have been employed pursuant to the standards of local medical practice that would have detected the presence of an infection in the donor, including but not limited to, the detection of tuberculosis.

130. Had established medical and technological procedures been employed,

including but not limited to additional blood testing, Donor Services could have discovered that its tissue was contaminated with tuberculosis and could have prevented its human tissue from being disseminated for use in surgical procedures.

131. Plaintiff, Wanda Swartz, was a foreseeable user and/or recipient of the human tissue harvested, recovered, supplied, sold, and placed into the stream of commerce by Defendants.

132. By reason of the foregoing, Defendants are liable to Plaintiffs, Wanda Swartz and Mark Swartz, for their injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

TENTH CAUSE OF ACTION

GROSS NEGLIGENCE
(Against DCI Donor Services, Inc. and New Mexico Donor Services)

133. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

134. Plaintiffs are further informed and believe that Defendants' misconduct, as previously outlined herein, constituted a conscious disregard for the rights and safety of other persons, including Plaintiffs, Wanda Swartz and Mark Swartz, that had a great probability of causing substantial harm including, but not limited to, exposing Wanda Swartz and other recipients of FiberCel and those exposed to them, including Mark Swartz, to tuberculosis, a potentially deadly infectious disease.

135. Plaintiffs are further informed and believe that Defendants engaged in conduct, with respect to the contaminated FiberCel product and human tissue used in the

contaminated FiberCel product, as alleged herein, which was a legal cause of loss, damages, injuries, and harm to Plaintiff, and which exposed Plaintiffs and other recipients of the contaminated FiberCel units and those exposed to them to serious complications, including the diagnosis of tuberculosis in Plaintiff, Wanda Swartz's post-surgical wound and the passing of the infection to her husband, Plaintiff, Mark Swartz.

136. Defendants' actions and inactions leading to the contamination of the FiberCel product were outrageous, willful and wanton, and done with reckless disregard for the safety of the Plaintiffs, Wanda Swartz and Mark Swartz.

137. The Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiffs was the direct proximate cause of Plaintiffs' injuries and damages.

138. As a direct and proximate result of the Defendants' outrageous, willful and wanton, and reckless conduct in disregard of the safety of the Plaintiffs, Wanda Swartz and Mark Swartz, the Plaintiffs have suffered and continue to suffer damages as set forth above.

139. Defendants thereby acted with a conscious disregard for the rights and safety of Plaintiffs, Wanda Swartz and Mark Swartz, and many other users of the contaminated FiberCel units, thus warranting an award of punitive damages to Plaintiffs.

ELEVENTH CAUSE OF ACTION

LOSS OF CONSORTIUM
(Against All Defendants)

140. Plaintiffs incorporate the foregoing paragraphs as though the same were set forth at length herein.

141. As a direct and proximate result of the injuries sustained by Plaintiff Wanda Swartz, her husband, Plaintiff, Mark Swartz has in the past and will in the future be deprived of the comfort, society, companionship, services and consortium of his wife, Wanda Swartz.

142. Defendants' negligent, reckless and/or willful conduct as well as defendants' breaches of warranties set forth herein, and the resulting injuries sustained by Plaintiff, Wanda Swartz, have directly led to Plaintiff, Mark Swartz's loss of consortium.

143. Plaintiff, Mark Swartz, is entitled to recover for such loss of consortium.

144. By reason of the foregoing, Defendants are liable to Plaintiff, Mark Swartz, for his injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief against Defendants, jointly and severally, as follows:

a. Compensatory damages exclusive of interest and costs, and in an amount to fully compensate Plaintiffs for all past, present, and future pain and suffering;

b. Special damages, exclusive of interest and costs, and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present;

c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

d. Attorneys' fees, expenses, and costs of this action;

e. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

f. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted,

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DEMAND FOR JURY TRIAL

The Plaintiffs, pursuant to Maryland Rule 2-325(a), hereby demand a trial by jury on all counts and claims raised herein.

CATHERINE BERTAM
8912180052