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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

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| GARY NORTHRUP,<br><br>Plaintiff,<br><br>v.<br><br>COVIDIEN, LP., and MEDTRONIC, INC.,<br><br>Defendants. | Case No.:<br><br>COMPLAINT FOR MONEY DAMAGES<br><br>JURY TRIAL DEMANDED |

Plaintiff, by and through his undersigned counsel, brings this Complaint for damages against Defendants and in support thereof states the following:

1. This is a device tort action brought on behalf of the above-named Plaintiff arising out of the failure of Defendants' hernia mesh products, the Covidien Parietex Optimized Composite Mesh ("Parietex Composite Mesh") and the Covidien Parietex Hydrophilic Anatomical Mesh ("Parietex Hydrophilic Anatomical Mesh") (collectively referred to as "Parietex Products"). As a result, Plaintiff Gary Northrup ("Plaintiff") has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which he may be legally entitled.

## STATEMENT OF PARTIES

2. Plaintiff is, and was, at all relevant times, a citizen and resident of Phelan, California, San Bernardino County, and the United States.

3. Covidien, LP, ("Covidien") is a Delaware Limited Partnership and has its principal place of business in Mansfield, Massachusetts. Covidien manufactures, distributes, and services medical devices, including medical devices known as the Parietex Composite Mesh and Parietex Hydrophilic Anatomical Mesh, medical devices implanted to treat persons like Plaintiff for hernias.

4. Medtronic, Inc. ("Medtronic") is incorporated in Minnesota and has its principal place of business in Minneapolis, Minnesota. Medtronic is a medical device company involved in the design, manufacturing, marketing, packaging, labeling, and sale of medical devices.

5. In January 2015, Medtronic acquired Covidien. From that point forward, Medtronic has been responsible for the actions of Covidien, and exercised control over Covidien's functions specific to the oversight of and compliance with applicable safety standards relating to and including the Covidien Products sold in the United States. In such capacity, Medtronic committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Medtronic's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

6. Covidien and Medtronic (collectively referred to as "Defendants") are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from their design, manufacturing, marketing, labeling, distribution, sale, and placement of the defective Covidien Products at issue in this suit. All acts were effectuated directly and indirectly through Defendants' respective agents, servants, employees, and/or owners, acting within the course and scope of their representative agencies, services, employments, and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all times relevant acting on Defendants' behalf and within the scope of their employment or agency with Defendants.

## VENUE AND JURISDICTION

8. This Court has diversity subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a).

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiff's claims occurred in this district.

10. Defendants have conducted, and continue to conduct, substantial business in the State of California and in this District; distribute Covidien Products in this District; receive substantial compensation and profits from sales of Covidien Products in this District; and make material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to personal jurisdiction in this District.

11. Covidien and Medtronic are registered to transact business in California.

## FACTS COMMON TO ALL COUNTS

12. On or about September 9, 2013, Plaintiff underwent laparoscopic ventral hernia repair by Dr. Deron Jean Tessier at Kaiser Permanente Fontana Medical Center in Fontana, California. A piece of Parietex Composite Mesh, Cat. No. PCO2520X, Lot No. PNC0471, and a piece of Parietex Hydrophilic Anatomical Mesh, Cat. No. TECT1510AL, Lot No. SND0273, were implanted in Plaintiff during this repair.

13. Defendants manufactured, sold, and/or distributed the Parietex Products to Plaintiff, through Plaintiff's doctors, to be used for treatment of hernia repair.

14. Plaintiff continued to suffer from abdominal pain, nausea, vomiting, and constipation after his hernia repair in September 2013, which resulted in multiple visits to the Emergency Room, appointments with his primary care physician, surgery consultations, and the use of a substantial amount of narcotics in order to ease the symptoms.

15. On or about October 24, 2017, Plaintiff returned to Dr. Tessier with concerns about the residual pain he was experiencing from his hernia repair in September 2013. Dr. Tessier administered an abdominal local anesthetic injection in order to ease the pain.

16. Plaintiff returned to Dr. Tessier three more times in order to receive an abdominal local anesthetic injection for his abdominal pain. Dr. Tessier then suggested on or about November 29, 2017 that Plaintiff Gary Northrup undergo minor surgery to remove sutures and subcostal tacks in an effort to ease the pain.

17. On or about January 27, 2018, Plaintiff underwent surgery to remove the sutures and subcostal tacks that were used in the placement of the Parietex Products. Dr. Tessier was able to identify and remove four tacks but was not able to identify or remove any sutures. Despite the removal of the tacks, the pain continued, and Plaintiff had the Parietex Products removed per the suggestion of Dr. Tessier.

18. On or about March 24, 2018, Plaintiff underwent removal of the failed Parietex Products at Kaiser Permanente Fontana Medical Center in Fontana, California by Dr. Tessier. Upon removal of the Parietex Products, Dr. Tessier noted "the mesh [was] adherent to fascia, carefully dissected off and explanted. All visible previously placed tacks and sutures removed. Dense adhesions from mid-jejunum to terminal ileum. All identified adhesions lysed sharply. Fascial edges cleared…"

19. Plaintiff continues to suffer severe pain associated with the failed Parietex Products.

20. Defendants' Parietex Composite Mesh is a two-sided composite mesh with an absorbable collagen barrier on the visceral side and a hydrophilic three-dimensional polyester textile on the parietal side used in the treatment of hernias such as laparoscopic ventral hernia repair.

21. Defendants claim that the Parietex Composite Mesh is coated with a protective absorbable collagen barrier to help prevent tissue attachment. However, the absorbable collagen barrier on the visceral side of Parietex Composite Mesh fails to

protect the body from the hydrophilic three-dimensional polyester textile on the parietal side because the absorbable collagen barrier breaks down after coming in contact with moisture.

22. Defendants claim that the Parietex Composite Mesh incites true tissue integration rather than inflammatory encapsulation and is optimized to minimize shrinkage. The composition of polyester in the Parietex Composite Mesh is weak. It tears easily during handling and is known to unravel causing the polyester fiber to detach and travel to other parts of the body inciting an inflammatory response. Parietex Composite Mesh further contracts over time causing tension to increase where secured by tacks and sutures resulting in tearing.

23. Contrary to the representations of Defendants, Parietex Composite Mesh has a high rate of failure, injury, and complication; fails to perform as intended; and causes severe and irreversible injuries like those suffered by Plaintiff.

24. Defendants' Parietex Hydrophilic Anatomical Mesh combines Parietex 2D weave with Parietex 3D weave. The 2D weave is lightweight and macroporous with a design that is rigid, making it ideal for laparoscopic applications due to its handling properties. The 3D weave is also a lightweight, macroporous mesh but has a design that provides compliance and softness.

25. Defendants represent that Parietex Hydrophilic Anatomical Mesh provides a custom designed mesh for laparoscopic inguinal hernia repair. Additionally, they represent that the material's softness allows for gentle placement over sensitive nerve and vessel structures in the inguinal area.

26. Defendants applied for clearance from the United States Food and Drug Administration ("FDA") to market the Parietex Products pursuant to Section 510(k) of the Food, Drug, and Cosmetic Act. The Section 510(k) process allowed Defendants to skip pre-market clinical studies and research intended to ensure the safety of the Parietex Products. The approval of the Parietex Products was based on a substantial equivalence to legally marketed predicate devices.

27. The FDA maintains a database of adverse incidents related to medical implants and devices and there are numerous reports documenting serious adverse events associated with the Parietex Products. Defendants misrepresented the Parietex Products as a safe and effective treatment for hernias; wrongly marketed the Parietex Products as safer and more effective than other meshes or methods for hernia repair; and improperly minimized the adverse effects of the Parietex Products.

28. Defendants knew or should have known that the Parietex Products were not a safe and effective treatment for hernias. Defendants also knew or should have known that the Parietex Products were considerably more harmful and inadequate than other meshes or methods for hernia repair. Additionally, Defendants knew or should have known that the Parietex Products were unreasonably dangerous as well as defective and likely to cause severe complications.

29. Defendants knew or should have known of the defective nature of the Parietex Products but continued to research, design, develop, test, manufacture, label, package, promote, advertise, market, supply, sell, and/or distribute Parietex Products so as to maximize sales and profits at the expense of the health and safety of the general public and Plaintiff. Defendants acted in conscious disregard for the foreseeable harm caused by Parietex Products in not adequately warning the FDA, the general public, the medical community, or Plaintiff of the numerous side effects, complications, and contraindications of the Parietex Products.

30. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution, and sale of Parietex Products, including providing the warnings and instructions concerning the product.

31. Among the intended purposes for which Defendants designed, manufactured, and sold Parietex Products was use by surgeons for hernia repair surgeries. That is the purpose for which the Parietex Products were implanted in Plaintiff.

32. Defendants represented to Plaintiff and Plaintiff's physicians that the Parietex Products were a safe and effective product for hernia repair.

## ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

33. Plaintiff incorporates the allegations in all prior paragraphs.

34. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

35. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating his injury, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

36. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultations with Plaintiff's medical providers, the nature of the injuries and damages, and their relationship to the Parietex Products, it was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, the action was filed well within the applicable statutory limitations period.

37. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from asserting a limitations defense due to their fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the Parietex Products. As a result of Defendants' fraudulent concealment, Plaintiff and his physicians were unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint, and that those risks were the direct and proximate result of Defendants' wrongful acts and omissions.

## FIRST CAUSE OF ACTION

## STRICT LIABILITY – MANUFACTURING DEFECT

38. Plaintiff incorporates by reference the allegations in all prior paragraphs.

39. Defendants expected and intended the Parietex Products to reach users such as Plaintiff in the condition in which the products were sold.

40. The implantation of the Parietex Products in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the products.

41. The Parietex Products were defectively manufactured when they were implanted in Plaintiff's body.

42. Defendants knew or should have known that the polyester used in the Parietex Products is more likely to cause severe inflammation than polypropylene, despite the coatings that have been applied. Additionally, Defendants knew or should have known that polyester is also less sturdy than polypropylene, creating difficulty during surgery.

43. Defendants knew or should have known that the unsealed edges of the Parietex Products would cause the mesh to fray and disintegrate once it was implanted and that once this had happened, organ perforation could result.

44. Defendants' Parietex Products are defective in composition, material, physical properties, pore size, mechanical properties, biomechanical properties, elasticity, and engineering.

45. As a direct and proximate result of Defendants' defective manufacturing of the Parietex Products, Plaintiff suffered injuries and damages as summarized in this Complaint.

## SECOND CAUSE OF ACTION

## STRICT LIABILITY – FAILURE TO WARN

46. Plaintiff incorporates by reference the allegations in all prior paragraphs.

47. When the Parietex Products were implanted in Plaintiff's body, the warnings and instructions Defendants provided were inadequate and defective. As described above, there was an unreasonable risk that the products would not perform safely and effectively for the purposes for which they were intended, and Defendants failed to

design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

48. Defendants expected and intended the Parietex Products to reach users such as Plaintiff in the condition in which the products were sold.

49. Plaintiff and his physicians were unaware of the defects and dangers of the Parietex Products, and were unaware of the frequency, severity, and duration of the risks associated with the products.

50. Defendants provided no warning to physicians that the Parietex Composite Mesh's collagen barrier quickly disintegrates once implanted and then exposes bare polyester to any underlying organs. This results in infections and dense adhesions to the bowel resulting in bowel obstructions, which are common with the Parietex Composite Mesh.

51. Defendants failed to adequately warn physicians that after implantation the unsealed edges of the Parietex Products can begin to unravel causing polyester fibers to detach and travel to other parts of the body inciting an inflammatory response.

52. Defendants failed to adequately warn physicians that Covidien's Parietex Mesh shrinks and contracts to a significant degree after it is implanted. The polyester fibers that create the Parietex are weaker than the titanium tacks or polypropylene sutures used to secure the mesh. Because of this, the polyester fibers will tear on the securing tacks or sutures after tension increases due to the mesh contracting. Once the mesh tears, the patient can re-herniate, and the mesh can migrate or ball up.

53. Defendants failed to adequately warn physicians of the significant risk of complications associated with mesh migration if the Parietex Products are implanted in the abdomen or inguinal area to repair a hernia.

54. The Instructions for Use for the Parietex Products also failed to adequately warn Plaintiff's physicians of numerous risks that Defendants knew or should have known were associated with the Parietex Products, including: risks of the product's immunologic response, pain, encapsulation, rejection, migration, scarification,

contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, bowel resections, or hernia incarceration or strangulation.

55. Defendants failed as well to adequately warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications with the Parietex Products or train the physicians on the proper treatment of such complications when they occurred.

56. Defendants failed to adequately warn Plaintiff or his physicians that: the surgical removal of the Parietex Products in the event of complications would leave the hernia unrepaired; the resulting hernia would be much larger than the original; and further, more complicated medical treatment to attempt to repair the same hernia would be necessary.

57. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity, and duration of those complications, although the complications associated with the Parietex Products were more frequent, more severe, and longer lasting than those in safer feasible alternative hernia repair treatments.

58. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of the Parietex Products, and of the frequency, severity, and duration of the risks associated with the products, Plaintiff would not have consented to allow the Parietex Products to be implanted, and Plaintiff's physicians would not have implanted the products in Plaintiff.

59. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

## THIRD CAUSE OF ACTION

## NEGLIGENCE

60. Plaintiff incorporates by reference the allegations in all prior Paragraphs.

61. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Parietex Products, they failed to do so.

62. Defendants knew, or in the exercise of reasonable care should have known, that the Parietex Products were defectively and unreasonably designed and/or manufactured and were unreasonably dangerous and likely to injure patients in whom the products were implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the Parietex Products.

63. Defendants knew or should have known that polyester should not be used for incisional hernia repair.

64. Defendants knew or should have known that the polyester used in the Parietex Products is soft and flimsy compared to similar hernia products that are made of polypropylene.

65. Defendants knew or should have known that polyester incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

66. Defendants knew or should have known that polyester is more likely to cause a severe inflammatory response than polypropylene, despite the protective absorbable collagen barrier that has been applied to the Parietex Products in order to prevent tissue attachment.

67. Defendants knew or should have known that the protective absorbable collagen barrier that has been applied to the Parietex Products in order to prevent tissue attachment can cause an inflammatory response.

68. Defendants knew or should have known that the unsealed edges of the Parietex Products would cause the products to fray and disintegrate once they have been implanted and organ perforation can result.

69. Defendants knew or should have known of the significant risk of complications if the Parietex Products are implanted into the abdomen to repair a ventral hernia. Nonetheless, Defendants marketed the Parietex Products as being safe and effective for inguinal and abdominal incisional hernia repair.

70. Defendants knew or should have known that the Parietex Products are more dangerous and less effective than other meshes or methods for hernia repair and cause injury.

71. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the Parietex Products, Plaintiff suffered injuries and damages as summarized in this Complaint.

## FOURTH CAUSE OF ACTION

## BREACH OF EXPRESS WARRANTY

72. Plaintiff incorporates by reference the allegations in all prior paragraphs.

73. At all material times, Defendants manufactured, marketed, sold, distributed, and otherwise placed into the stream of commerce the Parietex Products.

74. In advertising, marketing, and otherwise promoting Parietex Products to physicians, hospitals, and other healthcare providers, Defendants expressly warranted that their products were safe for use and reasonably fit for its intended purposes. In advertising, marketing, and otherwise promoting Parietex Products, Defendants intended that physicians, hospitals, and other healthcare providers rely upon their representations regarding safety and fitness, to induce them to implant the Parietex Products in their patients.

75. With respect to Plaintiff Gary Northrup, Defendants intended that the Parietex Products be implanted by his treating surgeon in a reasonable and foreseeable manner, and in accordance with the instructions for use and product specifications provided by Defendants.

76. Defendants expressly warranted the following to physicians, hospitals, other healthcare providers, and the general public, including Plaintiff Gary Northrup: the Parietex Products were safe and fit for use by consumers; they were of merchantable quality; the risks, side effects and potential complications were minimal and comparable to other hernia mesh products; the Parietex Products were adequately researched and tested; and they were fit for their intended use. Plaintiff and Plaintiff's physicians and healthcare providers reasonably relied upon Defendants' express representations and warranties, and consequently, Plaintiff was implanted with Defendants' products.

77. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public, including Plaintiff, that the Parietex Products were safe and fit for use for the repair of both groin inguinal and abdominal hernias.

78. Defendants represented that the Parietex Products would prevent or minimize hernia recurrence and pain, and facilitate incorporation of the mesh into the body, but it did not. Instead, the Parietex Products caused infections and dense adhesions to the bowel resulting in bowel obstructions and bowel resections.

79. Defendants breached these express warranties because the Parietex Products implanted in Plaintiff were unreasonably dangerous, defective, and not as Defendants had represented.

80. Defendants breached express representations and warranties to Plaintiff, as well as his physicians and healthcare providers, with respect to the Parietex Products, by representing the following:

A. through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions, among other methods, that their product was safe; but they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Parietex Products.

B. the Parietex Products were as safe and/or safer than other alternative procedures and devices on the market; but they fraudulently concealed information

demonstrating that Parietex Products were not safer than alternative therapies and products available on the market; and

C. the Parietex Products were more efficacious than other alternative procedures, therapies and/or devices; but they fraudulently concealed information regarding the true efficacy of the product.

81. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products into Plaintiff, placing his health and safety in jeopardy.

82. When Defendants made such express warranties, they knew or should have known that the Parietex Products do not conform to the express warranties. Defendants' acts were motivated by financial gain, while the adverse consequences of their conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence, and evidenced reckless indifference to Plaintiff's rights, health, and safety, so as to warrant the imposition of punitive damages.

## FIFTH CAUSE OF ACTION

## VIOLATION OF FEDERAL & STATE CONSUMER PROTECTION LAWS

83. Plaintiff incorporates by reference the allegations in all prior paragraphs.

84. Plaintiff purchased and used the Parietex Products primarily for personal use, and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

85. Had Defendants not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased and/or paid for the Parietex Products and would not have incurred related medical costs and injury.

86. Defendants engaged in wrongful conduct, while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Parietex Products, which would not have been paid had Defendants not engaged in unfair and deceptive conduct.

87. Unfair methods of competition or deceptive acts or practices that were proscribed by law, include the following:

A. representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

B. advertising goods or services with the intent not to sell them as advertised; and,

C. engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

88. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians, and consumers was to create a demand for and sell the Parietex Products. Each aspect of Defendants' conduct combined to artificially create sales of the products.

89. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Parietex Products.

90. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Parietex Products and would not have incurred related medical costs.

91. Defendants' deceptive, unconscionable, or fraudulent representations, and material omissions to patients, physicians, and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the federal and state consumer protection statutes listed below.

92. Defendants' actions constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of federal and state consumer protection statutes listed below.

93. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or false advertising, or have made false representations in violation of:

- 15 U.S.C. §§ 2301-2312 (1982)
- Cal. Civ. Code §§1750, et seq.
- Del. Code Ann. tit. 6, § 2511, et seq.
- Mass. Gen. Laws Ann. ch. 93A, § 1, et seq.

- Minn. Stat. Ann. § 325F.68, et seq.

94. Under the statutes listed above Defendants are the suppliers, manufacturers, advertisers, and sellers subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

95. Defendants violated the statutes enacted in these states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Parietex Products are fit to be used for the purpose for which they were intended, when in fact they are defective and dangerous, and by other acts alleged in this Complaint. These representations were made in marketing and promotional materials.

96. Defendants' actions and omissions are uncured or incurable deceptive acts under the consumer protection laws.

97. Defendants had actual knowledge of the defective and dangerous condition of the Parietex Products and failed to take any action to cure such defective and dangerous conditions.

98. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform.

99. Defendants' deceptive, unconscionable, or fraudulent representations, and material omissions to patients, physicians, and consumers, constitute unfair and deceptive acts and practices.

100. By reason of the unlawful acts in which Defendants engaged, and as a direct and proximate result of those acts, Plaintiff has suffered ascertainable losses and damages.

101. As a direct and proximate result of Defendants' violations of the consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory damages in an amount to be proven at trial.

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## SIXTH CAUSE OF ACTION

## NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

102. Plaintiff incorporates by reference the allegations in all prior paragraphs.

103. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed, and sold Parietex Products to Plaintiff.

104. Defendants carelessly and negligently concealed the harmful effects of their products from Plaintiff, individually and/or Plaintiff's physician, on multiple occasions. They continue to do so to this day.

105. Defendants carelessly and negligently misrepresented the quality, safety, and efficacy of Parietex Products to Plaintiff, individually and/or Plaintiff's physician, on multiple occasions. They continue to do so to this day.

106. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that he has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase Parietex Products sold and distributed by Defendants.

107. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers, and contraindications of Parietex Products to Plaintiff, individually and/or Plaintiff's physician, after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

108. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers, and contraindications of Parietex Products to Plaintiff, individually and/or Plaintiff's physician, knowing that doing so would cause him to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

109. As a proximate result of Defendants' acts or omissions, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

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## SEVENTH CAUSE OF ACTION

## FRAUDULENT CONCEALMENT

110. Plaintiff incorporates by reference the allegations in all prior paragraphs.

111. At all material times, Defendants knew or should have known that Parietex Products caused large numbers of complications. Moreover, they also knew or should have known the following: the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices; the safety and efficacy of the Parietex Products had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion; the Parietex Products were not safe and effective. But, Defendants continued to represent that the Parietex Products were safe and effective.

112. Despite what Defendants knew or should have known about the lack of safety and efficacy of the Parietex Products, they failed to disclose this information to Plaintiff Gary Northrup, to Plaintiff's physicians, and to the public at large.

113. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning Parietex Products: that they are dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and the likelihood of the products causing serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff was implanted with their products.

114. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the Parietex Products because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of the Parietex Products;

B. Defendants knowingly made false claims in documents and marketing materials about the safety and quality of the Parietex Products; and

C. Defendants fraudulently and affirmatively concealed the defective nature of the Parietex Products from Plaintiff.

115. The facts concealed and/or not disclosed by Defendants to Plaintiff and his physician were material facts that a reasonable person would have considered to be important in deciding whether to purchase and/or use the Parietex Products.

116. At all material times, Defendants willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and his physicians, with the intent to defraud.

117. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Parietex Products so that Plaintiff would request and purchase the products, and his healthcare providers would dispense, prescribe, and recommend Parietex Products; and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to his detriment.

118. At all material times, neither Plaintiff nor Plaintiff's physicians were aware of the facts set forth above. Had they been aware of the facts, they would not have acted as they did, *i.e.*, would not have reasonably relied upon the representations of safety and efficacy and utilized Parietex Products in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' Parietex Products. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

119. As a direct and proximate result of Defendants' conduct, Plaintiff was injured.

## EIGHTH CAUSE OF ACTION

## NEGLIGENT MISREPRESENTATION

120. Plaintiff incorporates by reference the allegations in all prior paragraphs.

121. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Parietex Products had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

122. Defendants failed to exercise ordinary care in the representations concerning Parietex Products while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented or concealed the Parietex Products' high risk of unreasonable and dangerous adverse side effects.

123. Defendants breached their duty in representing to Plaintiff, Plaintiff's physicians, and the medical community, that Parietex Products had no serious side effects different from those of other similar products and/or procedures.

124. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentations, they knew or should have known that the Parietex Products had been insufficiently tested or had not been tested at all. As well, they knew or should have known that the products lacked adequate and accurate warnings, creating a high risk—or higher than acceptable or reported and represented risk—of adverse side effects. Those included immunologic response, pain, encapsulation, rejection, migration, scarification, contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, bowel resections, or hernia incarceration or strangulation.

125. As a direct and proximate result of Defendants' acts and omissions, Plaintiff Gary Northrup has been injured and sustained severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

**PUNITIVE DAMAGES**

126. Plaintiff incorporates the allegations in all prior paragraphs.

127. Defendants failed to adequately test and study the Parietex Products to determine and ensure that the products were safe and effective before releasing the products for sale for permanent human implantation; and Defendants continued to manufacture and sell the products after having obtained knowledge and information that it was defective and unreasonably unsafe.

128. At all material times, Defendants knew or should have known that the Parietex Products were inherently more dangerous with respect to the following risks: immunologic response, pain, encapsulation, rejection, migration, scarification, contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, bowel resections, or hernia incarceration or strangulation.

129. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the Parietex Products, thus depriving Plaintiff and his implanting physicians of vitally necessary information to make a fully informed decision about whether to use the products.

130. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the Parietex Products can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment. But they recklessly failed to advise the medical community and the general public, including Plaintiff, of the risks and side effects.

131. At all material times, Defendants intentionally misstated and misrepresented data, and continue to misrepresent data, so as to minimize the perceived risk of injuries and the rate of complications associated with the Parietex Products.

132. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Parietex Products' increased risk of side effects and serious complications, Defendants continued to aggressively market the product to the medical community and to consumers without disclosing the true risk of such complications.

133. When Plaintiff Gary Northrup was implanted with the Parietex Products and since then, Defendants have known that the Parietex Products are defective and unreasonably dangerous. Nonetheless, they have continued to manufacture, produce, assemble, market, distribute, and sell the products so as to maximize sales and profits at

the expense of the health and safety of the public, in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the Parietex Products to the public, including Plaintiff.

134. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the Parietex Products, to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff.

135. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants, individually, jointly, and severally; and requests compensatory damages and punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**PRAYER FOR RELIEF**

Plaintiff, Gary Northrup, demands judgment against Defendants, individually, jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. restitution and disgorgement of profits;

iii. punitive damages;

iv. reasonable attorneys' fees as provided by law;

v. costs of these proceedings, including past and future costs of suit;

vi. all ascertainable economic damages;

vii. prejudgment interest on all damages as allowed by law; and

viii. such other and further relief as this Court deems just and proper.

Respectfully submitted,

Date: February 16, 2019

**MCCUNE·WRIGHT·AREVALO, LLP**

By: _____
Kristy M. Arevalo
*Attorney for Plaintiff*

**DEMAND FOR JURY TRIAL**

Plaintiff, Gary Northrup, hereby demands a trial by jury on all issues so triable.

Date: February 16, 2019

**MCCUNE·WRIGHT·AREVALO, LLP**

By: _____
Kristy M. Arevalo
*Attorney for Plaintiff*