IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
PINE BLUFF DIVISION

JENNIFER STONE,

Plaintiff,

vs.

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants.

CASE NO. 5:17-cv-197-JLH

This case assigned to District Judge Holmes
and to Magistrate Judge Volpe

COMPLAINT AND JURY DEMAND

COMPLAINT AND JURY DEMAND

COMES NOW the Plaintiff, Jennifer Stone, by and through undersigned counsel and submits this Complaint and Jury Demand against Johnson & Johnson ("J&J") and Ethicon, Inc. ("Ethicon") (collectively "Defendants") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff as a direct and proximate result of Defendants' designing, developing, testing, assembling, manufacturing, packaging, labeling, preparing, distributing, marketing, supplying, warranting and/or selling the defective device sold under the name "Physiomesh" (hereinafter "Physiomesh" or "Defective Device"). In support, Plaintiff alleges the following:

INTRODUCTION

1. Defendants, directly or through their agents, apparent agents, servants or employees, designed, developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, warranted and/or sold the Defective Device for the use as a hernia mesh.

2. Defendants concealed, and continue to conceal, their knowledge of the Defective Device's unreasonably dangerous risks from Plaintiff, Plaintiff's medical providers, other consumers, and the medical community at large.

3. As a result of the defective nature of the Physiomesh, persons who were implanted with a Defective Device, including Plaintiff, have suffered, and may continue to suffer, severe and permanent personal injuries, including hernia revision surgery or invasive medical treatment to remove or revise the Defective Device, continued rehabilitation, otherwise unnecessary additional medical care, and likely additional surgeries.

4. After being implanted with the Defective Device, and as a direct and proximate result of the Defendants' actions and inaction, Plaintiff suffered physical pain, emotional distress, additional medical treatment, bodily injury, and other complications. The Physiomesh was defective, unreasonably dangerous, and caused permanent injury and damages to Plaintiff.

5. This is a product liability action for failure to warn, negligence, fraud, misrepresentation, breach of warranties, and violation of Arkansas's Deceptive Trade Practices Act against Defendants.

6. Plaintiff brings this action for personal injuries suffered as a proximate result of being implanted with the Defective Device. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies provided to him under equity and law as a result of injuries caused by the implantation of the Defective Device and for Defendants' conduct.

PARTIES

7. At all times relevant hereto, Plaintiff Jennifer Stone was a resident and citizen of Star City, Lincoln County, Arkansas. As a result of the implantation of the Defective Device,

Plaintiff suffered personal and economic injuries and sought treatment for the effects of the injuries that were the direct and proximate result of the implantation of the Defective Device and Defendants' conduct.

8. Defendant Johnson & Johnson ("J&J") is a corporation incorporated in New Jersey, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. J&J has as its citizenship the State of New Jersey.

9. Defendant J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the Physiomesh products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc.

10. Defendant Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson. Defendant Ethicon is a corporation incorporated in the State of New Jersey with its principal place of business in Somerville, New Jersey. Ethicon is authorized and registered to transact business within this State. Ethicon has as its citizenship the State of New Jersey.

11. Ethicon is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical devices including Physiomesh.

12. J&J, directly and/or through the actions of Ethicon, has at all pertinent times been responsible for the research, development, testing, manufacture, production, marketing, promotion, distribution and/or sale of Physiomesh.

13. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from the Defendants' design, manufacture, marketing, labeling, distribution, sale and placement of its defective mesh products at issue in the instant action, effectuated directly and indirectly through their respective agents, servants, employees and/or owners, all acting within the course and scope of their representative agencies, services, employments and/or ownership.

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

JURISDICTION AND VENUE

15. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

16. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of designing, developing, testing, assembling, manufacturing, packaging, labeling,

preparing, distributing, marketing, supplying, warranting, selling, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the Defective Device, within this State, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

17. At all times relevant to this action, Defendants were engaged in disseminating inaccurate, false, and/or misleading information about the Defective Device to health care professionals in this State, including Plaintiff's health care professionals, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout this State.

18. Defendants engaged in substantial business activities in this State. At all relevant times, Defendants transacted, solicited, and conducted business in this State through their employees, agents, and/or sales representatives and derived substantial revenue from such business in this State. Said activities including for the promotion, sale, and use of the Defective Device.

19. Further, Defendants committed torts in whole or in part against Plaintiff in this State. As such, this Court has personal jurisdiction over all named defendants.

20. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

21. On or about June 29, 2011, Plaintiff had a Physiomesh Composite mesh, lot/serial #D88GFSA0, implanted to repair a hernia.

22. Defendants manufactured, sold, and/or distributed the Physiomesh device to Plaintiff, through her doctors, to be used for treatment of hernia repair.

23. Plaintiff was later forced to undergo an invasive medical treatments because of complications from Defendants' defective Physiomesh. Plaintiff has suffered and will continue to suffer physical pain and mental anguish as a result of this revision. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of Physiomesh, including providing the warnings and instructions concerning the Defective Device.

24. Among the intended purposes for which Defendants designed, manufactured, and sold Physiomesh was use by surgeons for hernia repair surgeries, the purpose for which the Physiomesh was implanted in Plaintiff.

25. Defendants represented to Plaintiff and Plaintiff's physicians that Physiomesh was a safe and effective product for hernia repair.

26. Defendants' Physiomesh was defectively designed and/or manufactured, was not reasonably safe for its intended use in hernia repair, and the risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the Physiomesh, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; inadequate or failure of incorporation/ingrowth; migration; scarification; deformation of mesh; improper wound healing; excessive and chronic inflammation; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage; other complications; and/or death.

27. Physiomesh has a unique design incorporating five (5) distinct layers: two layers of polyglecaprone-25 ("Monocryl") film covering two underlying layers of polydioxanone film ("PDS"), which in turn coat a polypropylene mesh. This design is not used in any other hernia

repair product sold in the United States. The multi-layer coating was represented and promoted by the Defendants to prevent or minimize adhesion and inflammation and to facilitate incorporation of the mesh into the body, but it did not. Instead, the multi-layer coating prevented adequate incorporation of the mesh into the body and caused or contributed to an intense inflammatory and chronic foreign body response resulting in an adverse tissue reaction including migration and damage to surrounding tissue in the form of sclerotic, granulomatous and/or fibrotic tissue, and improper healing.

28. When affixed to the body's tissue, the impermeable multi-layer coating of the Physiomesh prevents fluid escape, which leads to seroma formation, and which in turn can cause infection, abscess formation, and other complications.

29. The multi-layer coating provides a breeding ground for bacteria in which the bacteria cannot be eliminated by the body's immune response, which allows infection to proliferate.

30. The multi-layer coating of Defendants' Physiomesh is cytotoxic, immunogenic, and not biocompatible, which causes or contributes to complications such as delayed wound healing, inflammation, foreign body response, rejection, infection, and other complications.

31. Defendants knew or should have known of the cytotoxic and immunogenic properties of the multi-layer coating of the Physiomesh prior to introducing it into the stream of commerce.

32. When the multi-layer coating of the Physiomesh is disrupted and/or degrades, the "naked" polypropylene mesh is exposed to the adjoining tissue and viscera, and can become adhered to organs, and cause damage to organs, and potentiate fistula formation.

33. These manufacturing and design defects associated with the Physiomesh were directly and proximately related to the injuries suffered by Plaintiff.

34. Neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the defective and dangerous nature of Physiomesh. Moreover, neither Plaintiff nor Plaintiff's implanting physician were adequately warned or informed by Defendants of the risks associated with the Physiomesh or the frequency, severity, or duration of such risks.

35. The Physiomesh implanted in Plaintiff failed to reasonably perform as intended. The mesh caused serious injury and necessitated additional invasive medical treatment which would have been unnecessary had the Physiomesh performed as intended.

36. Plaintiff's severe adverse reaction, and the accompanying medical treatments which were required, directly and proximately resulted from the defective and dangerous condition of the Defective Device and Defendants' defective and inadequate warnings about the risks associated with the Defective Device, and the frequency, severity and duration of such risks. Plaintiff has suffered, and will continue to suffer, both physical injury and pain and mental anguish, permanent and severe scarring and disfigurement, lost wages and earning capacity, and has incurred substantial medical bills and other expenses, resulting from the defective and dangerous condition of the Defective Device and from Defendants' defective and inadequate warnings about the risks associated with Physiomesh.

37. In May of 2016, Defendants issued an "Urgent: Field Safety Notice" relating to its Physiomesh Flexible Composite Mesh, the same product implanted in Plaintiff, and sent such notification to hospitals and medical providers in various countries worldwide. In this safety notice, Defendants advise these providers of "a voluntary product recall", citing two international device registries which reported data reflecting recurrence/reoperation rates after laparoscopic

placement as being higher than that observed from a data set relating to patient outcomes after being implanted with other mesh. However, in the United States, Defendants failed to issue a nationwide recall, opting instead to simply remove the product from shelves and cease further sales within the United States.

FEDERAL REQUIREMENTS

38. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

39. Pursuant to federal law, a device is deemed misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health if used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

40. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device may have caused or contributed to a death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to a death or serious injury. Federal law also requires the FDA to establish regulations requiring a manufacturer of a medical device to promptly report to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation federal law which may present a risk to health. *See* 21 U.S.C. § 360i.

41. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation, packaging, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe, effective and otherwise in compliance with federal law. *See* 21 U.S.C. §360j(f).

42. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR § 820 *et seq*. The Federal Register explains that the Current Good Manufacturing Practice (CGMP) regulations do not prescribe the details of how a manufacturer must produce a device because the regulations must apply to a variety of medical devices. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing process employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

43. Pursuant to 21 CFR § 820.1(c), the failure to comply with any applicable provisions in section 820 renders a device adulterated under section 501(h) of the Act. *See* 21 U.S.C. § 351.

44. Pursuant to 21 CFR § 820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management. *See* 21 CFR § 820.3(v).

45. Pursuant to 21 CFR § 820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

46. Pursuant to 21 CFR § 820.30(a), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

47. Pursuant to 21 CFR § 820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

48. Pursuant to 21 CFR § 820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

49. Pursuant to 21 CFR § 820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, batches, or their equivalents. Design validations shall ensure that the devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

50. Pursuant to 21 CFR § 820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

51. Pursuant to 21 CFR § 820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation.

52. Pursuant to 21 CFR § 820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

53. Pursuant to 21 CFR § 820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification method, process, or procedure.

54. Pursuant to 21 CFR § 820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control systems to verify that the system, including necessary equipment, is adequate and functioning properly.

55. Pursuant to 21 CFR § 820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or products by substances that could reasonably be expected to have an adverse impact on quality.

56. Pursuant to 21 CFR § 820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

57. Pursuant to 21 CFR § 820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality in order to ensure that it is removed or limited to an amount that does not adversely affect the device's quality.

58. Pursuant to 21 CFR § 820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer is required to validate computer software for its intended use according to an established protocol.

59. Pursuant to 21 CFR § 820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer must establish and maintain procedures to ensure that equipment is calibrated, inspected, checked, and maintained.

60. Pursuant to 21 CFR § 820.75(a), where the results of a process cannot be fully verified by subsequent inspections and testing, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing, by objective evidence, that a process consistently produces a result or product meeting its predetermined specifications. 21 CFR § 820.3(z)(1).

61. Pursuant to 21 CFR § 820.75(b), each manufacturer shall establish and maintain procedures for monitoring internal processes and establish control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualifies persons.

62. Pursuant to 21 CFR § 820.90, each manufacturer also must establish and maintain procedures to control products that do not conform to specified requirements.

63. Pursuant to 21 CFR § 820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventative actions.

64. Based on information and belief, Defendants' Defective Devices are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established

performance standards, and/or methods, facilities, or controls used for their manufacture, packaging, storage, or installation and are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

65. Based on information and belief, Defendants' Defective Devices are misbranded because, among other things, they are dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

66. Based on information and belief, Defendants' Defective Devices are adulterated pursuant to 21 U.S.C. § 351 because Defendants failed to establish and maintain CGMP for its Physiomesh products in accordance with 21 CFR § 820 *et seq.*, as set forth above.

67. Based on information and belief, Defendants failed to establish and maintain CGMP with respect to quality audits, quality testing and process validation for its Physiomesh products.

68. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' Physiomesh products were defective and failed, resulting in injuries to Plaintiffs.

69. If Defendants had complied with the federal requirements regarding CGMP, Defendants' Physiomesh products would have been manufactured properly and would not have resulted in injuries to Plaintiffs.

FIRST CAUSE OF ACTION
NEGLIGENCE

70. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

71. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Defective Device into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events as well as a duty to comply with federal requirements.

72. Defendants had an obligation to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device, and otherwise distributing the Defective Device.

73. Defendants' acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendants to civil liability for all damages arising therefrom.

74. Plaintiff, as a purchaser of the Defective Device, is within the class of persons that the statutes and regulations previously described herein are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

75. The Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with the Defective Device.

76. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of the Defective Device.

77. Defendants breached their duty and failed to exercise ordinary care and/or were negligent and/or wanton in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotion and distribution of the Defective Device into interstate commerce because Defendants knew or should have known that these products caused significant bodily harm and were not safe for use by consumers.

78. Despite the fact that Defendants knew or should have known that the Defective Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Defective Device for implantation into consumers and/or continued to fail to comply with federal requirements.

79. The Defendants failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. Failing to properly and thoroughly test the Defective Device before releasing the device to market;

b. Failing to properly and thoroughly analyze the data resulting from the premarketing tests of the Defective Device;

c. Failing to conduct sufficient post-market testing and surveillance of the Defective Device;

d. Designing, manufacturing, marketing, advertising, distributing, and selling the Defective Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Defective Device;

e. Failing to provide warnings, instructions or other information that accurately reflected the high risks of failure of the Defective Device;

f. Failing to exercise due care when advertising and promoting Defective Device; and

g. Negligently continuing to manufacture, market, advertise, and distribute the Defective Device after the Defendants knew or should have known of its adverse effects.

80. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Defective Device, and otherwise distributing the Defective Device.

81. As a direct and proximate result of Defendants' negligence and/or wantonness, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

82. Plaintiff contends that the conduct of the Defendants as described above, including, but not limited to, their failure to adequately design and manufacture, as well as their continued marketing and distribution of the Defective Device when they knew or should have known of the serious health risks the device created and/or the failure to comply with federal requirements, is attended by circumstances of oppression, fraud, malice, willfulness, wantonness, and constitutes a conscious, reckless and flagrant disregard for human life, which warrants the imposition of exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred,

attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SECOND CAUSE OF ACTION
VIOLATION OF THE ARKANSAS DECEPTIVE TRADE PRACTICES ACT

83. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, excluding the previously named causes of action, with the same force and effect as if more fully set forth herein.

84. Defendants engaged in unfair and deceptive trade practices with Plaintiff in the following respects:

a. Defendants are merchants, who study, test, design, develop, manufacture, inspect, produce, market, promote, advertise, distribute and/or sell medical devices, including the Defective Device;

b. Defendants knowingly committed unfair and deceptive practices in their study, testing, design, development, manufacture, inspection, production, marketing, promotion, advertising, distribution, and/or sale of the Defective Device;

c. Defendants knowingly committed unfair and deceptive practices when they failed to safely design and construct a safe and effective hernia mesh for use by Plaintiff;

d. While Defendants knew or reasonably should have known that the Defective Device, when used as intended caused a significantly increased risk of injuries, including painful revision surgery or invasive medical treatment, while they were engaged in the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or selling the

Defective Device, Defendants did not inform the FDA, Plaintiff, and/or Plaintiff's physicians of their knowledge concerning the dangers posed to patients;

e. Defendants failed to give adequate warnings regarding the use and potential problems with the Defective Device;

f. Defendants' actions occurred while they were engaged in trade and commerce, and all of the conduct occurred during the course of their business.

85. The Defendants' conduct -- which the Plaintiff relied on -- in continuing to market, sell, and distribute the Defective Device without proper warnings after obtaining knowledge that the Defective Device caused the Plaintiff to suffer (1) an actual financial loss, and (2) suffer a significant increased risk of injuries, including painful revision surgery and/or invasive medical treatment shows complete indifference to or a conscious disregard for the safety of others and justifies an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

THIRD CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

86. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, excluding the previously named causes of action, with the same force and effect as if more fully set forth herein.

87. Defendants made fraudulent misrepresentations with respect to the Defective Device in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defective Device had been tested and found to be safe and effective for use in hernia repair surgeries;

b. Upon information and belief, Defendants represented that the Defective Device was safer than other alternative medical devices; and

c. Failed to dissemination information on known high failure rates of the Defective Device.

88. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risks associated with implantation of the Defective Device to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

89. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiff's physicians, rely upon them.

90. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of the Defective Device.

91. Plaintiff, Plaintiff's doctors, and others relied upon these representations.

92. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from painful invasive medical treatment and other related health complications. In addition, Plaintiff requires and will continue to require

healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

FOURTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

93. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, excluding the previously named causes of action, with the same force and effect as if more fully set forth herein.

94. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning the Defective Device, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

95. Defendants disseminated to health care professionals and consumers – through published labels, marketing materials, and otherwise – information that misrepresented the efficacy of the Defective Device with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to implant the Defective Device.

96. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, knew or reasonably should have known that health care professionals and

consumers of the Defective Device would rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of implanting Defective Device.

97. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the efficacy of the Defective Device was accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

98. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, knew or reasonably should have known that surgeons would implant the Defective Device in reliance on the information disseminated by Defendants, and that the patients implanted with the Defective Device would be placed in peril of suffering failure and require revision surgery or invasive medical treatment if the information disseminated by Defendants and relied upon by health care professionals and consumers, including Plaintiff, was materially inaccurate, misleading, or otherwise false.

99. From the time the Defective Device was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety and efficacy of the Defective Device. Defendants made material misrepresentations to Plaintiff, Plaintiff's health care professionals, the healthcare community, and the general public, including:

a. Stating that the Defective Device had been tested and found to be safe and effective implant for hernia repair surgeries;

b. Concealing, misrepresenting, and actively downplaying the severe and life threatening risks of harm related to the implantation of the Defective Device, when compared to comparable or superior alternative hernia mesh devices; and

c. Misrepresenting the Defective Device's risk of unreasonable and dangerous failure.

100. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

101. These representations were made directly by Defendants, their sales representatives, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

102. Defendants made these representations with the intent to induce reliance thereon, and to encourage purchase and implantation of the Defective Device.

103. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that the Defective Device had been tested and found to be a safe and effective hernia mesh option.

104. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

105. Defendants failed to exercise ordinary care in making their representations concerning the Defective Device and in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of the Defective Device.

106. Defendants engaged in a nationwide marketing campaign, over-promoting the Defective Device in written marketing literature and in written product packaging. Defendants' over-promotion was undertaken by touting the safety and efficacy of Defective Device while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening

risks of harm to patients implanted with the Defective Device, when compared to comparable or superior alternative hernia mesh options. Defendants negligently misrepresented the Defective Device's safety and efficacy.

107. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of the Defective Device, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions for years not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

108. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from painful invasive medical treatment and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

FIFTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

109. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, excluding the previously named causes of action, with the same force and effect as if more fully set forth herein.

110. Throughout the relevant time period, Defendants knew that the Defective Device was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the high risk of failure associated with implantation of the Defective Device.

111. Defendants fraudulently concealed information with respect to the Defective Device in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submission that the Defective Device was safe and fraudulently withheld and concealed information about the severity of the substantial risks failure of the Defective Device; and

b. Upon information and belief, Defendants represented that the Defective Device was safer than other alternative hernia mesh options and fraudulently concealed information which demonstrated that the Defective Device was not safer than alternatives available on the market.

112. Defendants were under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of the Defective Device because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of implantation of the Defective Device;

b. Defendants knowingly made false claims and omitted important information about the safety and efficacy of the Defective Device in the documents and marketing materials Defendants provided to physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of the Defective Device from Plaintiff.

113. As the designers, manufacturers, sellers, promoters, and/or distributors of the Defective Device, Defendants had unique knowledge and special expertise regarding the Defective Device. This placed them in a position of superiority and influence over Plaintiff and Plaintiff's healthcare providers. As such, Plaintiff and Plaintiff's health care providers reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

114. The facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or be implanted with the Defective Device.

115. The concealment and/or non-disclosure of information by Defendants about the severity of the high risks of failure after implantation of the Defective Device was intentional, and the representations made by Defendants were known by them to be false.

116. The concealment of information and the misrepresentations about the Defective Device were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase the Defective Device and Plaintiff's health care providers would recommend and implant the Defective Device.

117. Plaintiff, Plaintiff's doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk of failure after implantation of the Defective Device.

118. Had Defendants not concealed or suppressed information regarding the severity of the high risks of failure of the Defective Device, Plaintiff's physicians would not have used the Defective Device in Plaintiff's hernia repair surgery.

119. Defendants, by concealment or other action, intentionally prevented Plaintiff and Plaintiff's health care professionals from acquiring material information regarding the lack of safety and efficacy of the Defective Device, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

120. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from painful invasive medical treatment and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

121. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, excluding the previously named causes of action, with the same force and effect as if more fully set forth herein.

122. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing the Defective Device, which is unreasonably dangerous and defective, thereby placing the Defective Device into the stream of commerce.

123. Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that the Defective Device:

a. was safe and fit for its intended purposes;

b. was of merchantable quality; and

c. had been adequately tested and found to be safe and effective for implantation in hernia repair surgeries.

124. These express representations include incomplete marketing materials and labeling that purports, but fails, to include the true risks associated with high failure rates of the Defective Device. In fact, Defendants knew or should have known of the high failure rates associated with implantation of the Defective Device. Despite this, Defendants expressly warranted the Defective Device as safe and effective for implantation in hernia repair surgeries.

125. Defendants advertised, labeled, marketed, and promoted the Defective Device, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce the Defective Device's purchase or implantation, thereby making an express warranty that the Defective Device would conform to the representations. More specifically, the marketing materials and labeling of the Defective Device did not and does not contain adequate information about the true risks of high failure rate and the injuries complained of herein.

126. Despite this, Defendants expressly represented that the Defective Device was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective for implantation in hernia repair surgeries.

127. The representations about the Defective Device contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

128. The Defective Device does not conform to Defendants' express representations because it is not safe or effective. Therefore, Defendants breached the aforementioned warranties.

129. At all times relevant, the Defective Device did not perform as safely and as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

130. Neither Plaintiff nor Plaintiff's surgeon had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning the Defective Device.

131. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when recommending and implanting the Defective Device.

132. Had the marketing and labeling information for the Defective Device accurately set forth the true risks associated with the high failure rate of the Defective Device and potential injuries, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended purpose, Plaintiff could have avoided the injuries complained of herein.

133. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from painful invasive medical treatment and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

134. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, excluding the previously named causes of action, with the same force and effect as if more fully set forth herein.

135. Defendants manufactured, distributed, advertised, promoted, and sold the Defective Device.

136. At all relevant times, Defendants knew of the purpose for which the Defective Device was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

137. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device during hernia repair surgeries.

138. The Defective Device was neither safe for its intended purpose nor of merchantable quality, as impliedly warranted by Defendants, in that the Defective Device has dangerous propensities when used as intended and can cause serious injuries, including high failure rates resulting in additional painful revision surgeries or invasive medical treatments and the risks associated with these additional procedures.

139. At all relevant times, Defendants intended that the Defective Device be used in the manner used by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such purpose, despite the fact that the Defective Device was not adequately tested.

140. Defendants were aware that consumers, including Plaintiff, would be implanted with the Defective Device as marketed by Defendants. As such, Plaintiff was a foreseeable user of the Defective Device.

141. Upon information and belief, Plaintiff and/or Plaintiff's health care professionals were at all relevant times in privity with Defendants.

142. The Defective Device was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

143. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell the Defective Device only if it was indeed of merchantable quality and safe and fit for its intended purpose.

144. Defendants breached their implied warranty to consumers, including Plaintiff. The Defective Device was not of merchantable quality, nor was it safe and fit for its intended purpose.

145. Plaintiff and Plaintiff's physicians reasonably relied upon Defendants' implied warranty for the Defective Device when recommending and implanting the Defective Device.

146. Plaintiff's use of the Defective Device was as intended and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

147. The Defective Device was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

148. Defendants breached the warranties of merchantability and fitness for its particular purpose because the Defective Device was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

149. The harm caused by the Defective Device far outweighed its alleged benefit, rendering the Defective Device more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

150. Neither Plaintiff nor Plaintiff's health care professionals reasonably could have discovered or known of the high risk of failure associated with the Defective Device.

151. Defendants' breach of these implied warranties caused Plaintiff's injuries.

152. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from painful invasive medical treatments and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the

enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

EIGHTH CAUSE OF ACTION
FRAUD

153. Plaintiff repeats, reiterates, and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs, excluding the previously named causes of action, with the same force and effect as if more fully set forth herein.

154. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff, Plaintiff's health care professionals, the health care industry and consumers that the Defective Device had been adequately tested in clinical trials and was found to be safe and effective for implantation in hernia repair surgeries.

155. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risks associated with the implantation of the Defective Device. Defendants made their fraudulent misrepresentations willfully, wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of the Defective Device, such as Plaintiff.

156. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and Plaintiff's health care professionals, so as to induce them to recommend, purchase, and implant the Defective

Device, despite the risk of severe life threatening injuries, which Defendants knew were caused by the product.

157. The Defendants fraudulently and intentionally concealed material information, as aforesaid, Defendants knew that the Defective Device was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the Defective Device's risk.

158. Defendants fraudulently and intentionally failed to disclose and warn of the high failure rate and associated injuries described herein, which were known by Defendants to result from implantation of the Defective Device.

159. Defendants fraudulently and intentionally suppressed information about the severity of the risks of injuries associated with implantation of the Defective Device from physicians and patients, including Plaintiff and Plaintiff's surgeon, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of the Defective Device. For example:

a. The Defective Device was not as safe and effective as other hernia mesh implants given its intended purpose;

b. The Defective Device is not a safer and more effective method for hernia repair procedures than other available treatments;

c. The high risks of failure associated with the implantation of the Defective Device was greater than the risks of failure associated with other hernia mesh implants;

d. The high risk of failure with the Defective Device was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. Defendants knew that the high risk of failure associated with the implantation of the Defective Device was greater than the risks of harm associated with other hernia mesh implants, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff and Plaintiff's surgeon relied;

f. The limited clinical testing revealed that the Defective Device had an unreasonably high failure rate, above and beyond those associated with other hernia mesh implants;

g. Defendants intentionally and knowingly failed to disclose and concealed the high failure rate discovered in any clinical studies and trial results;

h. Defendants had knowledge of the dangers involved with the implantation of the Defective Device, which dangers were greater than those associated with other hernia mesh implants;

i. Defendants intentionally and knowingly failed to disclose that patients using the Defective Device could suffer failure and additional surgeries at a greater rate of occurrence that other, similar hernia mesh implants; and/or

j. The Defective Device was defective, and had an unreasonably high risk of failure and associated injuries, including the specific injuries described herein.

160. Defendants had access to material facts concerning the defective nature of the Defective Device and its substantial propensity to result in failure and cause serious and dangerous injuries and damages to persons who are implanted with the Defective Device and suffer additional

surgeries, including revision surgery or invasive medical treatment, information that was not publicly disseminated or made available, but instead was actively suppressed by Defendants.

161. Defendants' intentional concealment and omissions of material fact concerning the safety of the Defective Device was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Plaintiff, and with reckless intent to mislead, so as to cause Plaintiff's surgeon to purchase, recommend, and/or implant the Defective Device, and to cause Plaintiff to rely on Defendants' fraudulent misrepresentations that the Defective Device was a safe and effective medical device.

162. At the time Plaintiff purchased and was implanted with the Defective Device, Plaintiff was unaware that Defendants had made misrepresentations and omissions, and instead Plaintiff reasonably believed Defendants' representations to constitute a true, complete, and accurate portrayal of the Defective Device's safety and efficacy.

163. Defendants knew and had reason to know that Defective Device could and would cause serious personal injury to the users of the product, and that the product was inherently dangerous in a manner that exceeded any purported disclosures given by Defendants.

164. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff was induced to be implanted with, and in fact was implanted with, the Defective Device during a hernia repair surgery, thereby sustaining injuries and damages, including additional surgery and associated injuries. Defendants knew and had reason to know that Plaintiff and Plaintiff's health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and Plaintiff's health care professionals would not have recommended and implanted the Defective Device if the true facts regarding the Defective Device had not been concealed by Defendants. Additionally, Plaintiff and Plaintiff's health care

professionals would have medically monitored Plaintiff differently after the Defective Device was implanted in order to minimize and/or mitigate the damages which would result from the Defective Device.

165. During the marketing and promotion of the Defective Device to health care professionals, neither Defendants nor the co-promoters who were dealing the Defective Device on Defendants' behalf, warned health care professionals, including Plaintiff's surgeon, that the Defective Device had a high failure rate.

166. Plaintiff reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was crucial to understanding the true dangers inherent in the implantation of the Defective Device.

167. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Plaintiff, the public, Plaintiff's health care professionals, and the health care industry that the Defective Device was safe. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of any of Defendants' clinical tests and research.

168. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and patients implanted with the Defective Device, including Plaintiff. Defendants knew of the Defective Device's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

169. As foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered from painful invasive medical treatment and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the

enjoyment of life, a diminished quality of life, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper, Plaintiff also demands that the issues contained herein be tried by a jury.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the U.S. Constitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a) For general damages in a sum in excess of the jurisdictional minimum of this Court;

b) For medical, incidental and hospital expenses according to proof;

c) For pre-judgment and post-judgment interest as provided by law;

d) For consequential damages in excess of the jurisdictional minimum of this Court;

e) For compensatory damages in excess of the jurisdictional minimum of this Court;

f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendants for the conduct described herein;

g) For attorneys' fees, expenses and costs of this action; and

h) For such further and other relief as this Court deems necessary, just and proper.

Dated: July 31, 2017

John M. Rainwater, ABN: 2009137
Rainwater, Holt & Sexton, P.A.
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Little Rock, Arkansas 72222
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Facsimile: (501) 868-2505

JS 44 (Rev. 06/17)

CIVIL COVER SHEET 5:17-cv-197-JLH

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Jennifer Stone

(b) County of Residence of First Listed Plaintiff Lincoln
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

John M. Rainwater, Rainwater, Holt & Sexton, P.A.
P.O. Box 17250, Little Rock, AR 72222

DEFENDANTS

Johnson & Johnson and Ethicon, Inc.

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
21 USC 351, 21 USC 352, 21 USC 360, 21 CFR 820, 21 USC 331, 21 USC 333,

Brief description of cause:
Negligence; Violation of ADTPA; Fraudulent & Negligent Misrepresentation; Fraudulent concealment; Fraud; Etc

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE DOCKET NUMBER

DATE
07/31/2017

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE