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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SHARON SMITH,

Plaintiff,

vs.

JOHNSON & JOHNSON, a New Jersey Corporation, ETHICON, INC., a New Jersey Corporation, and DOES 1-40, inclusive,

Defendants.

CASE NO._____

COMPLAINT FOR:

1. **NEGLIGENCE;**
2. **STRICT LIABILITY – DESIGN DEFECT;**
3. **STRICT LIABILITY – MANUFACTURING DEFECT;**
4. **STRICT LIABILITY – FAILURE TO WARN**
5. **BREACH OF EXPRESS WARRANTY;**
6. **BREACH OF IMPLIED WARRANTY; AND**
7. **LOSS OF CONSORTIUM**

DEMAND FOR TRIAL BY JURY

COME NOW the Plaintiff, SHARON SMITH, who hereby files this Complaint AND JURY DEMAND, showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiff SHARON SMITH is a citizen of the State of California. Plaintiffs are seeking damages in excess of $75,000. Subject matter jurisdiction is proper

pursuant to 28 U.S.C. §1332. Defendants have significant contacts with the Central District of California, both generally and specific to the subject matter of this action such that they are subject to personal jurisdiction. A substantial part of the events and/or omissions giving rise to Plaintiffs' causes of action occurred in the Central District of California. Pursuant to 28 U.S.C. § 1391(a), venue is proper. This case is subject to transfer to the Northern District of Georgia for inclusion in In Re: Ethicon, Physiomesh Flexible Composite Hernia Mesh Products Liability Litigation, MDL No 2782, for coordinated and consolidated pretrial proceedings.

2. Defendant JOHNSON & JOHNSON ("Defendants" and/or "J&J") is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of Defendants as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

3. Defendant ETHICON, INC. ("Defendants") is a New Jersey corporation with its principal place of business in New Jersey. All acts and omissions of Ethicon, Inc. as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

4. Plaintiffs do not know the true names or identities of the Defendants sued herein as Does 1-40. Plaintiffs allege that each of these fictitiously named Defendants may be responsible in some manner for the occurrences herein alleged, whether as a manufacturer or distributor of pelvic mesh or in some other capacity, and caused the injuries and damages sustained by Plaintiffs herein alleged. At all times alleged herein, use of the collective term "Defendants" refers to the Defendants as well as Defendant Does 1-40. Plaintiffs will amend this Complaint when the true names and capacities of said fictitiously named defendants are ascertained.

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FACTUAL BACKGROUND

5. Plaintiff incorporates by reference paragraphs 1-4 of this Complaint as if fully set forth herein.

6. Defendants designed, manufactured, packaged, labeled, marketed, sold, and distributed the Ethicon Physiomesh Flexible Composite Mesh, including those which were implanted in Plaintiff giving rise to the claims asserted herein.

7. Plaintiff SHARON SMITH was implanted with the Ethicon Physiomesh Flexible Composite Mesh (the "Products") during surgery performed by Houlman Solomon, M.D. at Torrance Memorial Medical Center, Los Angeles California, on or about August 17, 2012. The Products were implanted in Plaintiff to treat her incisional hernia, the uses for which the Products were designed, marketed and sold. On October 9, 2017, after suffering from continued debilitating pain for years, her surgeon advised that the Products is the cause.

8. Due to the Products' defects, Defendants' negligence, and Defendants' breach of express and implied warranties as described herein, Plaintiff, SHARON SMITH, suffered severe and permanent bodily injuries and significant mental and physical pain and suffering, and economic losses.

9. Ethicon utilizes a light-weight polypropylene (plastic) to manufacture the base layer (middle) of the Physiomesh. Polypropylene is the same material that Ethicon makes their trans-vaginal mesh and bladder slings from. Ethicon has faced thousands of lawsuits over its trans-vaginal mesh and bladder slings made from polypropylene. Ethicon added an absorbable film coating to each side of a polypropylene sheet to create the Physiomesh. The coating on each side of the Physiomesh is made of polyglecaprone, which is intended to be absorbed by the body after implantation. The polyglecaprone coatings alone are not able to adhere to the polypropylene. A polydioxanone film is utilized on each side of the polypropylene to bond the polyglecaprone coatings to the polypropylene mesh. In total, there are 5 layers to the Physiomesh. Every layer except the polypropylene

in the middle of the Physiomesh is intended to be absorbed by the body after implantation.

10. Defendants sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to either of the Products.

11. On May 25, 2016, Ethicon announced the worldwide market withdrawal of Physiomesh Flexible Composite Mesh. In fact, Ethicon has issued statements that the recurrence and revision rates following laparoscopic ventral hernia pair were higher with the device than rates associated with the comparator.

12. The Physiomesh utilizes a lighter weight polypropylene than Ethicon previously used it its hernia mesh products. A "light-weight" polypropylene mesh simply means that less polypropylene is utilized to make the mesh. Manufacturers started using less polypropylene in hopes that there would be less complications associated with hernia mesh. The "light-weight" polypropylene is also significantly weaker than the old "heavy-weight" polypropylene. As a result, many patients have experienced the Physiomesh tear apart inside of them. Physicians frequently report patients experiencing their bowels blowing through the middle of the Physiomesh.

13. The Physiomesh has a thick coating on both sides of the polypropylene. If the Physiomesh is not coated on both sides, the coating easily slides off of the polypropylene. Utilizing a dual-sided coating enabled each coating to stick to the other coating and not just the polypropylene. The coating is intended to prevent the bowel from being exposed to the underlying polypropylene. Polypropylene will essentially stick or adhere to any tissue or organs in the human body. If the

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polypropylene sticks to the bowel, it can cause severe injuries such as a bowel obstruction. However, if a mesh is coated on both sides, the mesh will not properly incorporate into the abdominal wall. The inability of the Physiomesh to properly incorporate results in the mesh free floating and moving around in the patient's abdominal cavity. Hernia recurrence, severe pain, even bowel complications are common in patients in which the Physiomesh fails to incorporate, including Plaintiff SHARON SMITH.

14. Physiomesh takes less inflammation/irritation for adhesions to form between the mesh and the bowel than it does for the mesh to incorporate into the abdominal wall. Adhesions and incorporation are describing the same process, the development of internal scar tissue, occurring on opposite sides of the mesh. The bowel is much more sensitive than the abdominal wall, and as a result, scar tissue forms easier between the mesh and bowel than the mesh and abdominal wall.

15. The Physiomesh utilizes a foil package to keep the hernia mesh sterile. The foil packaging of the Physiomesh is prone to excessive wrinkling, which weakens the sterile packaging and allows micro perforations to form. The small holes that form in the sterile packaging of the Physiomesh are extremely hard to detect and greatly increase the risk that a surgeon implants a contaminated medical device. As a result, high rates of infection have been observed with the Physiomesh.

16. Defendants omitted the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries.

17. Contrary to Defendants' representations and marketing to the medical

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community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage, including Plaintiff, SHARON SMITH, making them defective under the law.

18. Defendants have underreported information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media.

19. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Products.

20. Defendants failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

21. Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

22. The Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained implanting physicians.

23. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

24. The Products implanted in Plaintiff, SHARON SMITH, was in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

25. In many cases, including Plaintiff, SHARON SMITH, patients have been

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forced to undergo and will inevitably undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt repair, and nerve damage, and the use of pain control and other medications.

26. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

27. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

28. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiffs, and the general public, on notice of the dangers and adverse effects caused by implantation of the Products.

29. The Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

30. As a result of having the Products implanted in her, Plaintiff, SHARON SMITH, has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and inevitably will undergo corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

FIRST CAUSE OF ACTION

FOR NEGLIGENCE

(By Plaintiff, SHARON SMITH, Against All Defendants)

31. Plaintiff incorporates by reference paragraphs 1-30 of this Complaint

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as if fully set forth herein.

32. Defendants had a duty to individuals, including Plaintiff, SHARON SMITH, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

33. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendants breached their aforementioned duty by:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to persons in whom the Products were implanted, including Plaintiff;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to persons in whom the Products were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to persons in whom the Products were implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to persons in whom the Products were implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

34. The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a. the dual-sided coating, preventing adequate incorporation inside the body and causing injuries;

b. the propensities for degradation, tear, or fragmentation;

c. the inability to properly incorporate into the abdominal wall; and

d. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

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35. Defendants also negligently failed to warn or instruct Plaintiff, and/or her health care providers, of subjects including, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, tear, or fragmentation;

c. the Products' inability to properly incorporate into the abdominal wall;

c. the rate and manner of mesh erosion or extrusion;

d. The risk of chronic inflammation resulting from the Products;

e. the risk of chronic infections resulting from the Products;

f. the risk of permanent scarring as a result of the Products;

g. the risk of recurrent and intractable pain resulting from the Products;

h. the need for corrective or revision surgery to adjust or remove the Products;

i. the severity of complications that could arise as a result of implantation of the Products;

j. the hazards associated with the Products;

k. the Products' defects described herein;

l. hernia repair using the Products is no more effective than feasible available alternatives;

m. treatment of hernias with the Products exposes patients to greater risk than feasible available alternatives;

n. treatment of hernias with the Products makes future surgical repair more difficult than feasible available alternatives;

o. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

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p. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

q. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

36. As a direct and proximate result of Defendants' negligence, Plaintiff, SHARON SMITH, has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will undergo inevitable corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

SECOND CAUSE OF ACTION

FOR STRICT LIABILITY – DESIGN DEFECT

(By Plaintiff, SHARON SMITH, Against All Defendants)

37. Plaintiffs incorporate by reference paragraphs 1-36 of this Complaint as if fully set forth herein.

38. The Products implanted in Plaintiff, SHARON SMITH, were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a. the design of the Products' dual-sided coating, preventing adequate incorporation inside the body and causing injuries;

b. the design of the Products' propensities for degradation, tear, or fragmentation;

c. the design of the Products' inability to properly incorporate into the abdominal wall; and

d. the design of the Products' wherein complete removal of the Products may not be possible and may not result in complete resolution of the

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complications, including pain.

39. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff, SHARON SMITH, has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will undergo inevitable corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

40. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

THIRD CAUSE OF ACTION

FOR STRICT LIABILITY – MANUFACTURING DEFECT

(By Plaintiff, SHARON SMITH, Against All Defendants)

41. Plaintiffs incorporate by reference paragraphs 1-40 of this Complaint as if fully set forth herein.

42. The Products implanted in Plaintiff, SHARON SMITH, were not reasonably safe for their intended uses and were defective as described herein as a matter of law with respect to their manufacture, in that they deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to said Plaintiff.

43. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

44. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

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FOURTH CAUSE OF ACTION

FOR STRICT LIABILITY – FAILURE TO WARN

(By Plaintiff, SHARON SMITH, Against All Defendants)

45. Plaintiff incorporates by reference paragraphs 1-44 of this Complaint as if fully set forth herein.

46. The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, tear, or fragmentation;

c. the Products' inability to properly incorporate into the abdominal wall;

c. the rate and manner of mesh erosion or extrusion;

d. The risk of chronic inflammation resulting from the Products;

e. the risk of chronic infections resulting from the Products;

f. the risk of permanent scarring as a result of the Products;

g. the risk of recurrent and intractable pain resulting from the Products;

h. the need for corrective or revision surgery to adjust or remove the Products;

i. the severity of complications that could arise as a result of implantation of the Products;

j. the hazards associated with the Products;

k. the Products' defects described herein;

l. hernia repair using the Products is no more effective than

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feasible available alternatives;

m. treatment of hernias with the Products exposes patients to greater risk than feasible available alternatives;

n. treatment of hernias with the Products makes future surgical repair more difficult than feasible available alternatives;

o. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

p. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

q. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

47. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff, has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

48. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

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FIFTH CAUSE OF ACTION

FOR BREACH OF EXPRESS WARRANTY

(By Plaintiff, SHARON SMITH, Against All Defendants)

49. Plaintiff incorporates by reference paragraphs 1-48 of this Complaint as if fully set forth herein.

50. Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

51. Plaintiff and/or her healthcare provider chose the Product based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Products.

52. Plaintiff, SHARON SMITH, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

53. Defendants breached these express warranties because the Products implanted in Plaintiff, SHARON SMITH, were unreasonably dangerous and defective as described herein and not as Defendants had represented.

54. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective product in Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

55. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

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SIXTH CAUSE OF ACTION

FOR BREACH OF IMPLIED WARRANTY

(By Plaintiff, SHARON SMITH, Against All Defendants)

56. Plaintiffs incorporate by reference paragraphs 1-55 of this Complaint as if fully set forth herein.

57. Defendants' impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

58. When the Products were implanted in Plaintiff to treat her incisional

hernia, the Products were being used for the ordinary purposes for which they were intended.

59. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Products implanted in her.

60. Defendants breached these implied warranties of merchantability because the Products implanted in Plaintiff were neither merchantable nor suited for their intended uses as warranted.

61. Defendants' breach of its implied warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

62. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

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ALLEGATIONS IN SUPPORT OF PUNITIVE DAMAGES

63. Plaintiffs incorporate by reference paragraphs 1-62 of this Complaint as if fully set forth herein.

64. Defendants sold the Products to Plaintiffs' healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the Product was reasonably safe.

65. Defendants sold the Products to Plaintiffs' health care providers and other health care providers throughout the United States in spite of their knowledge of the Products' propensity for tearing and fragmentation and the Products' inability to properly incorporate into the abdominal wall, thereby causing severe

and debilitating injuries suffered by Plaintiff and numerous other people.

66. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by Plaintiff and numerous other people. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Products as safe and effective.

67. Defendants knew the Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Products, as well as other severe and personal injuries which were permanent and lasting in nature.

68. Defendants withheld material information from the medical community and the public in general, including Plaintiffs, regarding the safety and efficacy of the Product.

69. Defendants knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat an incisional hernia.

70. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Products.

71. Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risks associated with the Products.

72. Defendants knew of the Products' defective and unreasonably dangerous nature, but continue to manufacture, market, distribute, and sell the

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Product so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs.

73. Defendants continue to conceal and/or fail to disclose to the public, including Plaintiffs, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

74. Defendants' conduct as described herein 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, Plaintiffs demand a trial by jury, judgment against Defendants for:

FIRST, SECOND, THIRD, FOURTH, FIFTH, AND SIXTH CAUSES OF ACTION:

1. Compensatory damages to Plaintiffs for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiffs, health and medical care costs, together with interest and costs as provided by law;

2. Restitution and disgorgement of profits;

3. Reasonable attorneys' fees;

4. The costs of these proceedings;

5. All ascertainable economic damages;

6. Punitive damages;

7. Such other and further relief as the Court deems just and proper.

PLAINTIFFS HEREBY DEMAND JURY TRIAL

DATED: December 28th, 2017

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