UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

MATTHEW OCHOA,

Plaintiff,

V.

JURY TRIAL DEMANDED

C.R. BARD, INC., BARD DAVOL, INC., JOHNSON & JOHNSON, ETHICON, INC., ETHICON US, LLC, AND ETHICON ENDO-SURGERY, INC.,

Defendants.

PLAINTIFF'S ORIGINAL COMPLAINT

COMES NOW, Plaintiff, MATTHEW OCHOA ("Mr. Ochoa" or "Plaintiff"), and files this, his Original Complaint against Defendants C.R. BARD, INC. ("C.R. BARD") and BARD DAVOL, INC. ("BD") (hereinafter, "C.R BARD" and "BD" are collectively referred to as the "Bard Defendants"), and JOHNSON AND JOHNSON ("J&J"), ETHICON, INC. ("Ethicon"), ETHICON US, LLC ("ETHICON US"), and ETHICON ENDO-SURGERY, INC. ("Ethicon Endo") (hereinafter "Ethicon", "Ethicon US", and "Ethicon Endo" are collectively referred to as the "Ethicon Defendants") (hereinafter, the "J&J Defendants" and "Ethicon Defendants" are collectively referred to as the "Defendants"), and respectfully submits as follows:

I.

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, MATTHEW OCHOA, was, and at all times relevant times, a citizen of the State of Texas, and a resident of Harris County, Texas. Mr. Ochoa is in his early thirties as was a recipient of two sets of defective hernia meshes, one manufactured by the Bard Defendants and one manufactured by the J&J Defendants, as more fully explained below.

2. Defendant C.R. BARD, INC. (hereinafter, "C.R. BARD") is a foreign for-profit New Jersey Corporation with its principal place of business in Murray Hill, New Jersey, and is a citizen of the State of New Jersey. All acts and omissions of C.R. BARD 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. Bard is a manufacturer of surgery products, surgery sutures, and medical device products and is a citizen of the State of New Jersey, with its corporate headquarters located at 730 Central Avenue, Murray Hill, New Jersey. C.R. BARD can be served with process by serving its Agent of Service, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136. Plaintiff will effectuate service upon said Defendant.

3. Defendant BARD DAVOL, INC. ("BD") is a foreign for-profit Corporation with its principal place of business in Rhode Island and is a citizen of the state of Rhode Island. All acts and omissions of BD 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. BD is a manufacturer of surgery products and is a citizen of the State of Rhode Island, with its corporate headquarters located at 100 Crossings Blvd, Warwick, RI 02886. BD can be served with process by serving its Registered Agent of Service, CT Corporation System, 1999

Bryan Street, Suite 900, Dallas, Texas 75201-3136. Plaintiff will effectuate service upon said Defendant.

4. Defendant JOHNSON & JOHNSON ("J&J") is a foreign for-profit Corporation with its principal place of business in New Brunswick, New Jersey, and is a citizen of the State of New Jersey. All acts and omissions of J&J 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. J&J is a manufacturer of surgery products, consumer products related to healthcare, health, beauty products, and medical devices, and is a citizen of the State of New Jersey, with its corporate headquarters located in New Brunswick, New Jersey. J&J can be served with process by serving its Registered Agent of Service, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136. Plaintiff will effectuate service upon said Defendant.

5. Defendant Ethicon, Inc. ("Ethicon") is a foreign for-profit Corporation with its principal place of business in Sommerville, New Jersey, and is a citizen of the State of New Jersey. It is a subsidiary of Johnson & Johnson, incorporated under the Johnson & Johnson umbrella in 1949 to expand and diversify the Johnson & Johnson product line. All acts and omissions of Ethicon 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. Ethicon is a manufacturer of surgery products and surgical sutures and is a citizen of the State of New Jersey, with its secondary corporate headquarters located in Cincinnati, Ohio. Ethicon can be served with process by serving its Registered Agent of Service, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136. Plaintiff will effectuate service upon said Defendant.

6. Defendant Ethicon US, LLC ("Ethicon US") is a foreign for-profit Corporation with its principal place of business in Cincinnati, Ohio, and is a citizen of the State of Ohio. It is a subsidiary of Johnson & Johnson, incorporated under the Johnson & Johnson umbrella in 1949 to expand and diversify the Johnson & Johnson product line. All acts and omissions of Ethicon US 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. Ethicon US is a manufacturer of surgery products and is a citizen of the State of Ohio, with its secondary corporate headquarters located in New Jersey. Ethicon US can be served with process by serving its Registered Agent of Service, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136. Plaintiff will effectuate service upon said Defendant.

7. Defendant Ethicon Endo-Surgery, Inc. ("Ethicon Endo") is a foreign for-profit Corporation with its principal place of business in Cincinnati, Ohio, and is a citizen of the State of Ohio. It is a subsidiary of Johnson & Johnson, incorporated under the Johnson & Johnson umbrella in 1949 to expand and diversify the extensive Johnson & Johnson product line. All acts and omissions of Ethicon Endo 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. Ethicon Endo is a manufacturer of surgery products and is a citizen of the State of Ohio, with its secondary corporate headquarters located in New Jersey. Ethicon can be served with process by serving its Registered Agent of Service, CT Corporation System, 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136. Plaintiff will effectuate service upon said Defendant.

8. "C.R. BARD" and "BD" are collectively hereinafter referred to as the "Bard Defendants".

9. "J&J", "Ethicon", "Ethicon US", and "Ethicon Endo" are collectively hereinafter referred to as the "J&J Defendants."

10. C.R. BARD, BD, J&J, Ethicon, Ethicon US, and Ethicon Endo are hereinafter collectively referred to as "Defendants".

11. The court has jurisdiction over the lawsuit under 28 U.S.C. §1332(a)(1). Defendant has conducted business in Texas and has placed products in the stream of commerce in Texas, including the devices implanted into the Plaintiff Matthew Ochoa in Texas. Complete diversity exists between the Plaintiff and the named Defendants. The amount in controversy Plaintiff seeks from the Defendants is in excess of the minimum jurisdictional requirements of this Court, or greater than $75,000.00.

12. Venue in this Court is proper pursuant to 28 U.S.C. § 1391 in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Defendants are subject to personal jurisdiction in this District. At all times material hereto, Defendants were foreign for-profit corporations authorized to and doing substantial business in this district. The Defendants conducted business in Austin and Houston, Texas, by marketing and selling the devices inserted into the Plaintiff as safe and effective for the medical ailments he suffered. The exercise of jurisdiction over the Defendants does not offend traditional notions of fair play or justice as the Defendants have conducted business and have availed themselves in the State of Texas.

THE BARD DEFENDANTS

13. At all times material hereto, the Bard Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the pelvic mesh products at issue in this matter. By said activities, Bard's Pelvic Mesh Products were placed into the stream of commerce throughout the United States, including the State of Texas.

14. At all times material to this action. The Bard Defendants designed, patented, manufactured, labeled, marketed, sold and distributed a line of pelvic mesh products. The products by the Bard Defendants were designed primarily for the purposes of treating hernias and pelvic organ prolapse. The Bard's Defendants products at issue in this case were cleared for sale in the U.S. after the Bard Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety of efficacy.

15. The Bard Defendants conducted substantial business in the State of Texas and in this District, distributes pelvic mesh products in this District, receives substantial compensation and profits from sales of pelvic mesh products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to in personam jurisdiction in this District.

16. The Bard Defendants conducted business in the State of Texas through sales representatives conducting business in the State of Texas and because the Bard Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, pelvic mesh products; thus, there exists a sufficient nexus between each Bard Defendant forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Texas.

17. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has in personam jurisdiction over the Bard Defendants, because they are present in the State of Texas such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

18. The Bard Defendants are subject to personal jurisdiction in this district as they systematically and continually conduct business in this district, and conduct business throughout the United States, including Texas.

THE J&J DEFENDANTS

19. At all times material hereto, the J&J Defendants developed, designed, manufactured, labeled, packaged, distributed, marketed, supplied, advertised, sold and otherwise engaged in all activities that are part and parcel of the sale and distribution of the pelvic mesh products at issue in this matter. By said activities, J&J Defendants' Prolene mesh products were placed into the stream of commerce throughout the United States, including the State of Texas.

20. At all times material to this action. The J&J Defendants designed, patented, manufactured, labeled, marketed, sold and distributed a line of prolene pelvic mesh products. The products by the J&J Defendants were designed primarily for the purposes of treating hernias and pelvic organ prolapse. The J&J Defendants products at issue in this case were cleared for sale in the U.S. after the J&J Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety of efficacy.

21. The J&J Defendants conducted substantial business in the State of Texas and in this District, distributes pelvic mesh products in this District, receives substantial compensation and profits from sales of prolene mesh products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to in personam jurisdiction in this District.

22. The J&J Defendants conducted business in the State of Texas through sales representatives conducting business in the State of Texas and because the J&J Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or

selling, either directly or indirectly, and/or through third parties or related entities, pelvic mesh products; thus, there exists a sufficient nexus between each J&J Defendants forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Texas.

23. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has in personam jurisdiction over the J&J Defendants, because they are present in the State of Texas such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

24. The J&J Defendants are subject to personal jurisdiction in this district as they systematically and continually conduct business in this district, and conduct business throughout the United States, including Texas.

25. The amount in damages that Plaintiff seeks from all the Defendants is in excess of the jurisdictional requirements of this Court, or in excess of $75,000.00.

II.

INTRODUCTION

THE BARD DEFENDANTS

26. At all times relevant to the Plaintiff's Petition, the Bard Defendants manufactured, promoted, distributed and sold for profit a product entitled BARD Perfix Plug Large-6/CTN Catalogue Number 0112970 GTIN 1080174106874 ("Bard Perfix Mesh"). Defendant promoted, distributed, and sold the Bard Perfix Mesh, as a product to repair hernia surgeries in the population. Defendant BARD describes the product as follows, "The Bard PerFix Plug is ideal for use in a tension-free preperitoneal repair technique. Since its introduction in 1993, it has been used in more than four million implants worldwide and has kept pace with new surgical techniques." The Company's website continues:

> For example, in the innovative Modified Technique, the outer cone of the Bard PerFix Plug is designed with pleated edges that conform readily to defects of various sizes and shapes. The inner petals allow the plug to maintain its fluted form and can be removed to customize the Bard PerFix Plug to each individual patient. The monofilament polypropylene design ensures health tissue ingrowth. Because surgery with the Bard PerFix Plug requires less operating and recovery time compared to conventional hernia repair methods, procedures can be exceptionally cost-effective.

27. BARD continued to advertise to the medical community and general public that the dynamic design conforms to the defect, each inner petal and onlay patch can be trimmed and customized to the patient, and the "tension-free" repair is achieved with Classic or Modified Techniques.

28. On October 8, 2014, Bard initiated a Class 2 Device Recall on the Bard Perfix Light Plug Recall No. Z-0191-2015, Recall Event Id. 69464. Per the Food and Drug Administration's Website, Davol, Inc. which is a subsidiary of C.R. Bard, Inc., sent Customer Notification letters on Friday, October 10, 2014, to customers affected by the recall. The letter identified the product as the problem and the action needed to be taken by the customer. The recommendation stated to examine the inventory and identify any product subject to the recall. The enclosure also depicted the supplied label as well as an image of the label with the correct information. It continued that the customer needed to complete and return the accompanying Effectiveness Check Form attached to the letter regardless of whether the customer had any remaining units of the affected product lot. If there was any further distributed product, the respective organizations needed to be notified of the product.

29. Defendants made public statements in the form of written product descriptions, product labels, promotional materials, marketing materials and other materials that asserted that implanting the pelvic mesh products in patients was safe and would not cause harm to patients, like Plaintiff. Defendants has also sold and marketing these meshes to the medical community at large and patients through carefully planned, multifaceted marketing campaigns and strategies.

These campaigns and strategies include, but are not limited to direct to consumer advertising, aggressive marketing to healthcare providers at medical conferences, hospitals, private offices and include the provision of valuable consideration and benefits to healthcare providers. Also utilized are documents, brochures, websites, telephone information lines, and training offering exaggerated and misleading expectations as to the safety and utility of the products.

30. At all times relevant hereto, the Defendant knew of the defective nature of its product and its labeling as herein set forth, yet continued to design, manufacture, market, distribute and sell its product to maximize sales and profits at the expense of the general public's health and safety in conscious disregard for the foreseeable harm caused by this product. Defendant's conduct exhibited such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, gross negligence or willful and intentional disregard to the Plaintiff's individual rights, health and well-being and hence punitive damages are appropriate.

THE J&J DEFENDANTS

31. At all times relevant to the Plaintiff's Petition, the Ethicon Defendants, as subsidiaries of J&J manufactured, promoted, distributed and sold for profit a product entitled The Johnson & Johnson/Ethicon Prolene Mesh ("J&J Prolene Mesh"). The J&J Defendants promoted, distributed, and sold the J&J Prolene Mesh, as a product to repair hernia surgeries in the population, as well as to repair pelvic organ prolapse and stress urinary incontinence.

32. J&J is an American multinational medical device, pharmaceutical and consumer packaged goods manufacturer founded in 1886. The corporation includes some 250 subsidiary companies with operations in 60 countries and products sold in over 175 countries. J&J had worldwide sales of $70.1 billion in calendar year 2015. The company's business is divided into three major segments: (1) Pharmaceuticals, (2) Medical Devices, and (3) Consumer Products.

33. Ethicon has manufactured surgical sutures and wound closure devices since 1887. After World War II, Ethicon's market share in surgical sutures rose from 15% to 70% worldwide. In the United States, the market share is approximately 80%. Ethicon conducts business in 52 countries. In 1992, Ethicon was restructured, and became a separate corporate entity. During the 1990s, Ethicon diversified into new and advanced products and technologies and formed four different companies under the Ethicon umbrella, each of which specialize in different products. In November 2008, the wound management business was sold to One Equity Partners and became Systagenix Wound Management Limited.

34. Ethicon describes the product as follows, "For Open Ventral and inguinal hernia repair. Potential for improved patient comfort and healing." The Company's website continues:

- Nonabsorbable, synthetic mesh for the repair of abdominal wall fascial defects.
- Unique design results in a mesh that is approximately 50% more flexible than standard PROLENE Polypropylene Mesh.

35. Ethicon Prolene Mesh is a synthetic monofilament suture used to treat hernias, pelvic organ prolapse (POP), and stress urinary incontinence (SUI). It is made of polypropylene (PP), a petroleum-based plastic. It is composed of isotactic crystalline stereoisomer of polypropylene. The name Prolene is a trademark of Ethicon and is produced in Cornelia, Georgia.

36. Unfortunately, despite originally being considered a revolutionary breakthrough in medical device technology, Prolene Mesh has recently been associated with complications including mesh erosion, infections, pain, dyspareunia, organ perforation, and the recurrence of urinary problems. Prolene Mesh is also extremely difficult to remove once it has been implanted, meaning many may lose organs or must have severely invasive surgeries for mesh removal. Even then, because the mesh incorporates itself into tissue, complete removal of mesh remnants is difficult, if not impossible.

37. Ethicon, as a subsidiary of J&J, continued to advertise to the medical community and public that the prolene mesh is a Nonabsorbable mesh that is flexible ideal for inguinal hernia surgery repair, such as that suffered by the Plaintiff.

38. The Ethicon Prolene mesh was approved by the FDA through a backdoor called 501(k). It means the product was not tested by the FDA as other new products would be because it is "substantially similar" to other surgical meshes such as Ethicon's UltraPro, Proceed, and Physiomesh. The Prolene mesh recalls have found that they are prone to break, leading to bowel perforations and chronic intestinal fistulae. Several lawsuits against Ethicon have found that the mesh disintegrate into victims' bodies, leading to infections and other serious complications. The FDA ordered Ethicon to cease production until extensive testing and research was conducted on some of Ethicon's product line, including its vaginal mesh devices, or its Prolift device. In June 2012, following the FDA's order for additional testing, Johnson & Johnson permanently removed all Prolift products from the market.

39. In fact, Ethicon has issues statements for the recalls of their hernia products, stating: "The recurrence/reoperation rates (respectively) after laparoscopic hernia repair using Ethicon Physiomesh Composite Mesh were higher than the average rates of the comparator set of meshes among patients in these registries."

40. The J&J Defendants currently have thousands of lawsuits pending against them for the mesh products lines, including the Prolene Mesh inserted into the Plaintiff, Matthew Ochoa. On July 13, 2011, the FDA issued a Safety Communication update citing the common side effects of using surgical mesh in the pelvic region: (1) mesh erosion, (2) pain, (3) infection, (4) urinary problems, (5) bleeding, and (6) organ perforation. There were also reports of organ prolapse, neuro-muscular problems, severe pain, mental anguish, and emotional trauma. Many of the medical device reports cited the need for additional intervention, including medical or surgical

treatment and hospitalization. All the Johnson & Johnson Pelvic Floor Repair System products have been implicated, including the Prolift, Prolene, Gynecare TVT Sling, and Gynecare TVT-O.

41. The FDA's literature review has found that erosion of mesh through tissue is the most common and consistently reported mesh-related complication from surgeries using mesh. The scientific evidence adduced thus far shows that the Ethicon Prolene mesh, which is made of polypropylene material, is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with it. The product becomes infected via bacterial contamination and cause chronic inflammation. Biomechanical issues that result include shrinkage, contacting, and deforming of the mesh.

42. At all times relevant hereto, the Defendant knew of the defective nature of its product and its labeling as herein set forth, yet continued to design, manufacture, market, distribute and sell its product so as to maximize sales and profits at the expense of the general public's health and safety in conscious disregard for the foreseeable harm caused by this product. Defendant's conduct exhibited such an entire want of care as to establish that its actions were a result of fraud, ill will, recklessness, gross negligence or willful and intentional disregard to the Plaintiff's individual rights, health and well-being and hence punitive damages are appropriate.

III.

BACKGROUND FACTS

MATTHEW OCHOA

43. Matthew Ochoa is a 32-year old male who was working for Davey Resource Group on or about February 26, 2015.

44. On that date, Matthew was at the job site he was asked to be at where his task was to visually inspect and map out the interior of an electrical concrete box as part of his work duties. Because it had rained earlier in the day, Matthew utilized a shower to find the concrete box which

housed electrical wiring. As Matthew lifted the top off of the electrical box, he felt a sharp burning sensation in his mid-section. At the time, the pain was tolerable but very uncomfortable. At that time, he thought that he had merely pulled a muscle.

45. On the next morning, or February 27, 2015, Matthew returned to work feeling uncomfortable in his groin area. The pain grew more intense throughout the day.

46. On February 28, 2015, Matthew took the day off because the pain began to become more unbearable. That day, he began coughing because of his allergies and noticed that a lump came out of his groin and then went back in when he coughed. He called his employer and informed them that he was in severe pain. His employer informed him to make an appointment with their Worker's Compensation Doctor at Concentra. Matthew contacted Concentra and schedule an appointment for March 2, 2015. Because of the intense pain that he was feeling, Matthew took sick time as he was unable to move during this time.

47. On March 3, 2014, Matthew traveled to Concentra. The doctor confirmed that Matthew had a hernia and instructed him to immediately go to the emergency room. The same day, Matthew immediately went to the hospital where he got a CAT scan of the groin area and an ultrasound of the right testicle because it was swollen. Afterwards, Matthew was diagnosed with having an inguinal hernia, which required immediate surgery. At that point, Matthew emailed the information to his employer and called his field boss. His boss scheduled a time for them to meet the next day to fill out a Workman's Compensation injury form.

48. On March 5, 2015, Matthew met with his field boss and filled out the paperwork. Afterward, he looked for general surgeons to expedite the search. He found Dr. William Mayer, who scheduled an evaluation on March 5, 2015. In the meantime, Matthew was restricted to bed rest.

49. On March 5, 2015, Matthew met with Dr. Mayer, who discussed the surgery with him. During that time, the surgery was scheduled for March 10, 2015. Matthew again returned to bed rest.

50. On March 8, 2015, Matthew's employer called and informed him that they would no longer pay for his hotel room, where he was staying during his bed rest. Matthew employer came by his room and took his work equipment, work computer, his hotel card, and work truck and asked Matthew to find other means of living accommodations. Since Matthew's job required him to stay in hotels every day, Matthew did not have rent elsewhere, and thus had to contact his mother to stay with her.

51. **On March 10, 2015, Matthew arrived at St. David's Medical Center**. Dr. Mayer went into further detail with Matthew about his surgery. He told him that he would install a Bard Prefix Light Plug Mesh in to fix the hernia using an open repair technique. The mesh would be held in place with four stiches, one on each corner. The surgery was performed and Matthew was released two hours after the surgery to go home and be on immediate bed rest. The doctor had injected Matthew with Novocain to attempt and numb the pain.

52. On March 11, 2015, at 2 a.m. in the morning, Matthew woke up in excruciating pain in his groin. His screaming woke his mother, and she took him to Seton NW Hospital in North Austin. The hospital treated Matthew with high does of pain mediation; however, these pain medications did not numb his pain. The hospital staff told Matthew that since they have not performed the surgery on him, they were not able to perform any procedures on him. So, they sent him home at 6 a.m. with a prescription for pain medication. After his mother drove him home, Matthew went to sleep. His mother called Dr. Mayer's office and Dr. Mayer called back and told Matthew that his pain was normal for that type of procedure. Matthew was in bed rest and only got out of bed to go to the bathroom. When he did, he was in excruciating pain.

53. On March 18, 2015, Matthew went to the bathroom to find that his right testicle was very swollen. He returned to Seton NM Hospital (because it was about 35 minutes closer than St. David's), where they performed an ultrasound in his right groin/testicle area. They found an accumulation of fluid and suggested for Matthew to see a urologist. Later that week, Matthew spoke with Dr. Mayer about the fluid buildup, and Dr. Mayer assured him that was normal.

54. On April 13, 2015, Matthew saw Dr. Mayer at his office, where Julie (Matthew's Worker's Compensation Nurse) asked Dr. Mayer to order an MRI for the mesh.

55. On April 23, 2015, Matthew went to get the MRI at River Ranch Radiology to find that the radiologist had changed the MRI order to an order for a CAT scan (without Dr. Mayer's permission) because he believed metal mesh was inside Matthew's groin and was concerned the MRI would not see the metal mesh. However, the mesh was made of polypropylene, which will decompose faster when in contact with gamma rays, which a CAT scan emits. Neither Matthew nor the radiologist knew that this could be an issue at the time, but after the CAT scan, Matthew began to feel very ill. A rash began to spread to Matthew's stomach, which moved to his chest, his neck, and eventually his face, where it remains.

56. On April 17, 2015, the CAT scan results revealed there was a mass in Matthew's groin area. During that time, Matthew asked Dr. Mayer to reorder the MRI and not CAT scan. Dr. Mayer told Matthew that he was unaware that the radiologist had changed the original order, so he reordered an MRI.

57. On May 3, 2015, Matthew went to River Ranch Radiology to get the actual MRI performed on his groin to see where the mesh was.

58. On May 18, 2015, Matthew went to pick up a copy of the MRI report. The results found the same mass that the CAT scan showed. However, it showed that the mass was folded on itself and the radiologist identified it as mesh.

59. On May 30, 2015, Matthew had a sneezing fit, which resulting in his hernia rupturing again. The mesh was no longer connected to his muscle.

60. On June 2, 2015, Matthew met with Dr. Christopher Shin, who would offer a second opinion on another surgery. Dr. Shin confirmed that Matthew had a second hernia in the same area. He then ordered surgery and told Matthew that he would be able to perform laparoscopic hernia repair, where he would use a robot to go underneath the muscle cavity to repair the hernia with a prolene mesh and staple the mesh all the way around. This mesh would be underneath the original mesh.

61. Matthew's Worker's Compensation provider approved a surgery for Dr. Shin to utilize the prolene mesh through the laparoscopic procedure, leaving the original mesh inside to determine if the rash went away on its own through time.

62. On June 15, 2015, Matthew went to Seton NW Hospital for his second hernia surgery repair surgery. Dr. Shin informed Matthew before the surgery that if he continued to have pain from the original mesh, he would have a consultation with Matthew at a later time to discuss removing it. After the surgery, Matthew felt a sharp, excruciating pain in his lower right abdomen, a new pain that remains to this day. Also, the rash did not go away after the second surgery.

63. On July 7, 2015, Matthew had a follow-up visit with Dr. Shin to go over the removal of the original mesh. In this visit, Dr. Shin warned Matthew of the complications that can follow the removal of the mesh, including nerve damage and the possibility of losing his right testicle. Matthew accepted the risks and asked Dr. Shin to move forward with removing the original mesh, which he believed caused the rash.

64. On August 10, 2015, Matthew went to Seton NW Hospital to prep for the removal of the original mesh. During the operation, Dr. Shin found that the original mesh had been tangled with the nerves and 2% of the mesh concreted onto Matthew's spermatic cord, which he was

unable to remove. The operation took 25% longer than anticipated due to the complications that arose from the entanglement.

65. On August 12, 2015, Matthew went back to see Dr. Shin to have his catheter removed. During this time, Dr. Shin noticed that Matthew's rash had disappeared, which indicated that Matthew had been allergic to the original mesh.

66. On September 8, 2015, Matthew saw Dr. Shin for an evaluation of the previous surgery. Dr Shin found that the defective mesh was causing severe adverse reactions in Matthew's body. Dr. Shin recommended pain management to deaden the nerves in the groin, an allergist to test or an allergy to the mesh, and ordered an ultrasound for the groin/testicle area to test the blood flow to the right testicle.

67. Matthew went to Steeplechase Diagnostic Center to perform ultrasound on the right groin/testicle area, where the report found that there was cut off blood flow to the right testicle area with possible torsion.

68. On October 19, 2015, Matthew went to a new Concentra location in Houston, Texas to get the results of the ultrasound and see the doctor for referrals to the allergist and urologist. The Concentra doctor was concerned about the ultrasound's results, since they indicated the possibility of torsion of the spermatic cord on the right testicle. He referred Matthew to an allergist and a urologist and ordered a second ultrasound to see if the results matched.

69. On October 20, 2015, a second ultrasound was performed, which also indicated that the mesh had caused his spermatic cord to torsion.

70. On November 11, 2015, Matthew went to Concentra again, and found out that the doctor he originally saw was no longer working there. Thus, he was issued another doctor, Dr. Tedla. Dr. Tedla referred Matthew to a urologist named Dr. John Bertini.

71. On December 10, 2015, Matthew went to a dermatologist, Dr. Sara Pinney, about his rash on his face. At first glance, Dr. Pinney suspected that the rash appeared to be an allergic reaction to something. As the conversation went on, she them recommended that Matthew have the mesh removed to see if that eliminated the issue of the rash. During this time, the pain Matthew felt in his right testicle was severe.

72. On December 16, 2015, Matthew went to see Dr. Bertini, as the pain in his right testicle was unbearable. Dr. Bertini is a urologist at TIRR Memorial Hermann Hospital in Houston, Texas. As Dr. Bertini evaluated the patient, he saw the discomfort in the patient and recommended to get the mesh removed as well. Bertini knew that the patient had meshed concreted on the spermatic cord. Thus, he recommended to have a general surgeon and a urologist take all the mesh out and try to save the right testicle. The original plan was to go to Austin and have Dr. Shin and a urologist do the surgery.

73. On January 2, 2016, Matthew went to Austin with his friend Donny to visit his dying grandfather. During that time, Matthew felt a shift in the mesh, which caused a lot of discomfort in his groin and testicle. The following day, Matthew was back in Houston. He felt very light headed and the pain increased in his right testicle and groin area. Matthew then asked Donny to take him to the hospital because something was wrong with him. At that point, they checked him in to Houston Methodist West Hospital. Upon check-in, his elevated body temperature indicated that Matthew was fighting an infection. Matthew was sent home that day after they determined that they couldn't figure out what was wrong with him. Defeated and in extreme pain, Matthew went home.

74. On January 4, 2016, Matthew started to lose his equilibrium and started to fall. Matthew was taken to St. Joseph's Hospital in downtown Houston where Dr. Bertini had hospital privileges. Upon arriving at the hospital, Matthew lost his ability to walk and needed a wheelchair

to take him to the emergency room. When he was waiting to be seen and get checked into the emergency room, Matthew started slurring his words and faded out of consciousness. There was evidently something wrong in his body, but the doctors had no idea how to test him, let alone treat him. Matthew was checked into the hospital and a slew of tests were performed. On this first day, they did a CAT scan of the groin area and an ultrasound of the right testicle. When the test came back, the doctors found could not figure out what was the source of the problems. That being the case, blood work was performed and the results indicated that Matthew's liver was being attacked. During this time in the hospital, Matthew lost all control of his legs. At this point, his surgeons became concerned and discussed removing the mesh from Matthew because they suspected the mesh was the cause of the problem. Later that day, Dr. Bertini made the determination that the mesh had to be removed. Dr. Bertini recommended for Dr. Cramer to remove the mesh.

75. The following morning, or on January 6, 2016, Matthew was released from the hospital without the surgery being performed. Matthew was severely distraught as he could not move his legs, but was being released from the hospital. Matthew was released but distraught he was paralyzed from the waist down, he was rushed to Memorial Hermann Katy Hospital, where they performed an MRI of the lower spine. The doctors found some swelling in the lower spinal cord and prescribed Matthew some muscle relaxers and steroids. As Matthew began the course of treatment prescribed by the doctors, he began to slowly get better. Within a month, he was able to ambulate with the use of a cane, but he remained in severe pain because of his groin and right testicle.

76. In early February 2016, Matthew was referred to Dr. William Owen Cramer to discuss surgery to remove the defected mesh.

77. On February 22, 2016, Matthew went to St. Joseph's to get both pieces of mesh removed from his body. Dr. Cramer and Dr. Bertini were going into the patient's groin by utilizing

a six (6) inch open incision and found that 40% of the original mesh was tangled around the spermatic cord.

78. The original mesh turned out to be the source of all of Matthew's pain in the groin and right testicle. Dr. Bertini did his best to remove the mesh tangled around the cord, as Dr. Cramer found that the Prolene mesh Dr. Shin put in place, because of its defectiveness, tangled around a lot of nerves and tissue near the groin and lower right belly area. Once the surgery was over, Dr. Bertini and Dr. Cramer came into the room to explain out of all their collective years of practice, they had never seen a case as bad as Matthew's.

79. On February 22, 2016, Matthew woke up with excruciating pain in his right testicle to find it swelled up to the size of an avocado. The doctors did an ultrasound of his right testicle and found that it had died. So, they sent Matthew into emergency surgery where they opened his original incision and removed his right testicle. Two days later and after the second surgery, Matthew found that the rash that previously was all over his face had gone away.

80. Matthew did a follow up visit with Dr. Bertini, where he told Matthew how serious the surgery had been. As they went through the discussion, Dr. Bertini told Matthew that he would feel ghost pain in his right testicle from time to time, and Matthew continued to be in excruciating pain.

81. On March 7, 2016, Matthew had a follow up visit with Dr. Cramer, who told Matthew that there would be a lot of pain in his groin area due to the type of surgery that he did, and that he cut out all the nerves in the groin and lower abdomen area, which would also create a lot of pain. During this time, Matthew was issued a walker from the hospital to get around the house and other places. Matthew asked the doctor how long it would take for him to heal from this type of surgery and Dr. Cramer replied that it could take six months. He then sent him to a pain management doctor.

82. On April 1, 2016, Matthew went to see Dr. Wu, a pain management doctor at TIRR Memorial Hermann. Through the evaluation, Dr. Wu said he would like to try a nerve block to see if that would take the pain away. During this time, Matthew's ash had started to come back on some areas near his face and cheeks. Matthew's pain was severe during this time which made Matthew very depressed about life. Dr. Wu prescribed Matthew some anti-depression pills and pain medication. Dr. Wu also recommended that Matthew seek psychiatric help because Matthew thought of taking his life at this point.

83. From April 6, 2016 through July 13, 2016, Matthew sought treatment from Dr. Williams, a psychologist at TIRR Memorial Hermann Hospital. Through time of treatment, he helped Matthew with his negative feelings and the pain he had to endure.

84. On April 15, 2016, Matthew went for a nerve block procedure that Dr. Wu performed. During this time, they had to watch Matthew's blood pressure and heart rate because the pain he was enduring was so great that it gave him high blood pressure. After the procedure was done, Matthew went home for bed rest. When the numbing medication wore off near his belly, the pain had increased tenfold because it was creating more pressure in his belly and groin areas. The nerve block failed and then Dr. Wu wrote a referral for physical therapy.

85. From April 15, 2016 through September 9, 2016, Matthew had his first session with Ms. Gail, a physical therapist at Baseball USA Sports Medicine Rehabilitation Center. Through the evaluation, she said she had never seen more scar tissue in all her years of practice. His physical therapist said it would take years to knead the scar tissue out. Throughout the six sessions, his physical therapist found that Matthew had a major nerve stuck in scar tissue in his lower belly which was creating a significant amount of pain. Throughout the total of 19 sessions, Matthew still had a lot of pain with little relief.

86. From May 13, 2016 through January 9, 2017, Dr. Wu prescribed multiple types of medication for pain to Matthew. However, none of these modalities ameliorated the pain. Dr. Wu then prescribed a new device that utilized electrodes to send signals through his nerves in his spine to help with the pain. Dr. Wu had to train for three (3) months before he could install the device. Unfortunately, Dr. Wu ended up moving and Matthew can no longer see him. Matthew is still, to this day, in extreme pain and trying to find another pain management doctor to help him with the pain he constantly feels.

87. On June 7, 2016, Matthew had a visit with Dr. Cramer to see what could be done about the constant pain. Dr. Cramer told Matthew it was so unusual to have pain like this, so he sent him to a neurologist.

88. On June 20, 2016, Matthew went to see Dr. Piney, a dermatologist, about the small amount of rash that came back. She sent him home with a prescription of cream for the face and said that if that didn't fix the flare ups, they would need to perform a biopsy.

89. From May 10, 2016 through July 19, 2016, Matthew was under the care of Dr. Fallon, at UT Physicians because he was told they needed to monitor his liver damage. Blood work and diagnostic scans were performed and they showed that his liver, since the removal of the mesh, were starting to heal. However, the blood work indicated that there were problems with his liver. As of today's date, Dr. Tedla put in two referrals in the system to see a liver doctor and an immunologist.

90. On August 19, 2016, Matthew had a follow-up appointment with Dr. Pinney, his dermatologist. Matthew's rash had not gone away, so they believe that part of the defective mesh was left in his body.

THE FDA AND HERNIA MESH RECALLS

91. The FDA has historically been quick to approve untested hernia mesh products, which benefits medical device manufacturers and hurts the public. When a product is then shown to be defective, severely injuring thousands or tens of thousands nationwide, the FDA is slow to take any action. The manufacturers of hernia mesh know of the life-threatening complications their products can cause, but they don't warn the public or surgeons.

92. There are over 100,000 hernia meshes implanted every year in the United States. Many of the most dangerous hernia meshes remain on the market and have not been recalled by the FDA. Bowel obstructions and severe infections are common complications related to hernia mesh.

93. What causes complications can vary depending on the hernia mesh product. Many hernia mesh products contain a type of plastic known as polypropylene, the same material that is used to make many types of pelvic mesh and bladder slings. The Polypropylene Material Data Safety Sheet (MSDS) notes: "Prohibited Uses: Applications involving permanent implantation into the body." However, manufacturers of these hernia products, including Defendant, continue to use polypropylene.

94. Hernia mesh frequently cause life-threating complications. Hernia mesh can erode through the bowel, requiring multiple additional surgeries, weeks of hospitalization, partial bowel removal, colostomies, and more. The mesh failure frequently causes patients to experience a systemic infection.

95. A hernia is a condition in which part of the intestine bulges through a weak area in muscles in the abdomen. An inguinal hernia occurs in the groin (the area between the abdomen and the thigh). It's called "inguinal" because the intestines push through a weak spot in the inguinal canal, which is a triangle-shaped opening between layers of abdominal muscles near the

groin. Obesity, pregnancy, heavy lifting, and straining can cause the intestine to push against the inguinal canal.

96. Although there are several techniques used by surgeons for hernia repair, physicians often favor a mesh plug. The mesh plugs have been under scrutiny for over a decade because of thousands of reports linking it with complications and devastating injuries. The plugs have shown a consistent propensity to shrink, detach, and migrate to other parts of the body where they can damage organs and nerves.

97. The hernia mesh manufactured by the Defendants are both made of woven polypropylene, which is a cheap plastic that degrades and erodes through tissue once implanted. The woven design of the mesh creates small pores or holes throughout the mesh. Nerves grow into these pores and attach to the mesh soon after the implant. As the mesh erodes and moved through the inguinal canal, it pulls and stretches the nerves attached to it. The nerves stretching is what causes the debilitating pain. Additionally, pain caused from nerves stretching is essentially untreatable. Opioids are not effective at treating nerve pain. Once the mesh has eroded into the spermatic cord, it becomes impossible to remove without also removing the testicle. This was precisely the case with the Plaintiff.

98. The scientific evidence shows that the polypropylene material from which the product is made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the products, including Plaintiff. The product can become infected via bacterial contamination and cause chronic inflammation. Biomechanical issues that result include shrinkage, contracting, creeping, and deforming of the mesh. The Defendants should have known that, yet they continued to promote the product as safe and effective, even as no long-term trials had been conducted to assure safety and efficacy.

99. Because of years of the manufacturer and implementation and insertion of these mesh products manufactured by both the Bard and J&J Defendants, thousands of Plaintiffs have come forward to sue the Bard and the J&J Defendants. Men have been shown to be ten times more likely than women to experience an inguinal hernia. Most men have reported severe, chronic groin and leg pain after being implanted. Many have also lost one or both of their testicles, as has the Plaintiff.

100. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendant's mesh products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions and damage to Plaintiff. These defects include, but are not limited to:

a. The material is not inert and therefore reacts to human tissues and/or other naturally occurring human bodily contents adversely affecting patient health.
b. The mesh material harbors infections that adversely affect human tissues and patient health.
c. The mesh products migrate from the location of their implantation, adversely affecting tissues and patient health.
d. If polypropylene, the mesh material abrades tissues adversely affecting patient health.
e. The pelvic mesh products regularly fail to perform the purpose of their implantation such that the patient requires removal of the device and repeated treatment and surgery.
f. Due to their various defects, the pelvic mesh products regularly cause significant injury to patients such that the mesh products must be removed, resulting in additional surgery.
g. The mesh products become embedded in human tissue over time such that if it needs to be removed due to its various defects, the removal causes damage to the organs and tissues, adversely affecting patient health.
h. The mesh products are defective in shape, composition, weight, physical, chemical and mechanical properties and are inappropriately engineered.
i. The mesh products erode into other pelvic organs, tissue, muscle, nerves, and bone adversely affecting tissues and patient health.
j. The Defendants designed and defected an unreasonable dangerous hernia mesh product.
k. Failed to adequately research the mesh.

l. The Defendants knew or should have known about the potential risk of infections, allergic reactions, bowel damage and other internal injuries but withheld his information from patients and doctors.
m. Defendants failed to properly investigate reports of problems after the hernia mesh was introduced.
n. Defendants failed to warn about the risk of injury.
o. Defendants failed to promptly issue a recall after the problems were discovered.

101. Because of their numerous defects, the mesh products create an unreasonable risk of injury and other adverse health consequences for patients, including, but not necessarily limited to, mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistulae, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathy, and other acute and chronic nerve damage and pain, pelvic pain, prolapse of organs, and in most cases forcing the need for intensive medical treatment, including but not limited to operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis and spine.

102. Defendants made, participated in, and/or contributed to filing with the Food and Drug Administration in conjunction with the clearance process and other filing requirements for Defendants' products.

103. Upon information and belief, Defendants were in control or designing, assembling, manufacturing, marketing, testing, distributing, packaging, labeling, processing, supplying, marketing, advertising, promoting, selling, and issuing of product warnings and related information with respect to its mesh products.

104. Defendants have consistently underreported and withheld information about the propensity of its mesh products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients and the public at large.

IV.

PRODUCT LIABILITY ALLEGATIONS – BARD AND J&J DEFENDANTS

105. Plaintiff incorporates by reference the foregoing paragraphs as though fully set forth herein**.**

BARD MESH SURGERY – MARCH 11, 2015

106. On March 11, 2015, a day after his surgery utilizing the Bard PerFix Plug Mesh, Matthew woke up in an excruciating amount of pain.

107. Within a matter of days, it became evident that the mesh used to repair Matthew's hernia was defective and reacted horribly in his body. These effects are consistent with the hundreds if not thousands of other lawsuits filed against the Bard Defendants for their defective products.

108. The mesh caused Plaintiff's injuries, damages and or losses by failing, in its design, material, formulation, manufacture, testing, packaging, labeling, advertising, marketing, promotion, supply, sale and/or distribution of and warnings about Bard, to do the following:

a. Accompany the product with adequate, complete and appropriate warnings regarding all the possible adverse side effects about which Bard knew or should have known, including the extent of renal injury and risks related to age, associated with the use of Bard PerFix Plug®.
b. Accompany the product with information accurately reflecting the nature, extent, symptoms, scope, or severity of such side effects;
c. Accompany the product with information accurately reflecting that alternative bowel cleansing products were safer and more effective, to include the failure to provide the same instructions it provides to foreign purchasers/consumers of its Bard PerFix Plug® product;
d. Provide intended consumers and health care professionals with adequate, complete and proper use instructions that accurately and fully identified the appropriate dosing interval and hydration required to use a Bard PerFix Plug® safely, and about which Bard knew or should have known;
e. Perform responsible, ethical, adequate and reliable pre-clinical, clinical and post-marketing testing of the safety of using Bard PerFix Plug® as a laxative or bowel cleanser in that responsible, ethical, adequate and reliable testing would have shown that the use of Bard PerFix Plug® for this purpose

presented the risk of serious injury to the intended consumers of the Product;

f. Adequately report on the results of testing regarding the safety of Bard PerFix Plug® as a laxative or bowel cleanser that had been or were in the process of being performed;

g. Comply with its post-manufacturing duty to warn, which arose when Bard knew, or with reasonable care should have known, that consumers, such as people of Plaintiff's age, were being directed to use Bard PerFix Plug® without being provided the complete information that was known to Bard or receiving adequate warnings of the true risks of side effects.

109. Bard knew or should have known that users of Bard PerFix Plug® to repair hernias could suffer foreseeable injuries as a result of these failures of these plugs. Bard has known about these problems for years and failed to timely recall these mesh devices before they would reach consumers and patients, such as Plaintiff Matthew Ochoa.

110. Plaintiff will show that the damages suffered were the result of Defendants' flagrant disregard to the safety of the end users of its mesh products used for hernia surgeries and needlessly endangered both the persons and property of such end users like plaintiff in this case and others in light of being aware that it was likely to cause serious harm from putting end users and others at serious risk of harm.

111. Bard PerFix Plug® as manufactured, sold, labeled and/or supplied by Bard was defective and unreasonably dangerous because, after Bard knew or should have known of the risk of injury from Bard PerFix Plug®, Bard failed to provide adequate warnings about and instructions on the use of the product and failed to adequately test the safety of the product and report on the results of tests regarding product safety that had been or were in the process of being performed.

112. The Bard PerFix Plug® manufactured, sold and supplied by Bard was defective at the time it was sold and/or left Bard's control. Further, the Bard PerFix Plug® was expected to reach the user of consumer without substantial change in the condition in which it was so manufactured, sold and/or supplied.

113. At the time of Plaintiff's surgery to repair his hernia, Bard expressly warranted that the Bard PerFix Plug® was safe, well-tolerated and provided gentle relief without pain or spasm.

114. At the time of Plaintiff's surgery, Bard impliedly warranted that Bard PerFix Plug® was of merchantable quality.

115. At the time of Plaintiff's surgery, Bard impliedly warranted that the Bard PerFix Plug® was fit for acting to repair hernias such as those suffered by the Plaintiff.

116. Mr. Ochoa did not receive a safe and effective product that was placed into him via surgery, but instead suffered a life-altering and permanent personal injury and damage because of the use of the Bard PerFix Plug®.

A. FIRST CAUSE OF ACTION – STRICT LIABILITY: FAILURE TO WARN

117. Plaintiff incorporates by reference the foregoing paragraphs as though fully set forth herein.

118. As set forth above, the mesh product placed in Plaintiff Matthew Ochoa used was unreasonably dangerous and defective and not reasonably safe for its intended or reasonably foreseeable purposes because it did not have correct, adequate and complete warnings and instructions issued in language that was direct, unequivocal and sufficiently forceful to adequately explain and warn of the hazards of the product or the way to use the product safely.

119. Bard's sale, marketing, distribution, and supplying of a defective, inadequately labeled product to Plaintiff's surgeon, and ultimately Plaintiff, were a substantial factor in causing Plaintiff to suffer injuries and damages.

120. Mr. Ochoa has suffered and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, as well as other general non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs

associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss.

121. Bard is strictly liable to Mr. Ochoa.

122. Plaintiff is also entitled to punitive damages because Bard's conduct was wanton, grossly reckless, grossly negligent, and/or in conscious disregard of Plaintiff's rights, health, and safety.

J&J MESH SURGERY – JULY 15, 2015

123. On July 15, 2015, a day after his surgery utilizing the Prolene Mesh, Matthew woke up in an excruciating amount of pain and began to run a fever with a massive infection.

124. Within a matter of days, it became evident that the mesh used to repair Matthew's hernia using the Prolene mesh was defective and reacted horribly in his body. These effects are consistent with the hundreds if not thousands of other lawsuits filed against the J&J Defendants for their defective products.

125. The mesh caused Plaintiff's injuries, damages and or losses by failing, in its design, material, formulation, manufacture, testing, packaging, labeling, advertising, marketing, promotion, supply, sale and/or distribution of and warnings about Bard, to do the following:

h. Accompany the product with adequate, complete and appropriate warnings regarding all the possible adverse side effects about which J&J/Ethicon knew or should have known, including the extent of injuries, damages, and pain associated with the use of the J&J/Ethicon Prolene Mesh®.

i. Accompany the product with information accurately reflecting the nature, extent, symptoms, scope, or severity of such side effects;

j. Accompany the product with information accurately reflecting that alternative hernia repair products were safer and more effective, to include the failure to provide the same instructions it provides to foreign purchasers/consumers of its J&J/Ethicon Prolene Mesh® product;

k. Provide intended consumers and health care professionals with adequate, complete and proper installation instructions required to use a J&J/Ethicon Prolene Mesh® safely, and about which Bard knew or should have known;

l. Perform responsible, ethical, adequate and reliable pre-clinical, clinical and post-marketing testing of the safety of using J&J/Ethicon Prolene Mesh®

as a hernia repair mesh in that responsible, ethical, adequate and reliable testing would have shown that the use of J&J/Ethicon Prolene Mesh® for this purpose presented the risk of serious injury to the intended consumers of the Product;

m. Adequately report on the results of testing regarding the safety of J&J/Ethicon Prolene Mesh® as a hernia repair mesh that had been or were in the process of being performed;

n. Comply with its post-manufacturing duty to warn, which arose when J&J/Ethicon knew, or with reasonable care should have known, that consumers, such as people of Plaintiff's age, were being directed to use J&J/Ethicon Prolene Mesh® without being provided the complete information that was known to J&J/Ethicon or receiving adequate warnings of the true risks of side effects.

126. J&J/Ethicon knew or should have known that users of J&J/Ethicon Prolene Mesh® to repair hernias could suffer foreseeable injuries because of these failures of these products. J&J/Ethicon has known about these problems for years and failed to timely recall these mesh devices before they would reach consumers and patients, such as Plaintiff Matthew Ochoa.

127. Plaintiff will show that the damages suffered were the result of Defendants' flagrant disregard to the safety of the end users of its mesh products used for hernia surgeries and needlessly endangered both the persons and property of such end users like plaintiff in this case and others considering being aware that it was likely to cause serious harm from putting end users and others at serious risk of harm.

128. J&J/Ethicon Prolene Mesh® as manufactured, sold, labeled and/or supplied by J&J/Ethicon was defective and unreasonably dangerous because, after J&J/Ethicon knew or should have known of the risk of injury from J&J/Ethicon Prolene Mesh®, Bard failed to provide adequate warnings about and instructions on the use of the product and failed to adequately test the safety of the product and report on the results of tests regarding product safety that had been or were in the process of being performed.

129. The J&J/Ethicon Prolene Mesh® manufactured, sold and supplied by J&J/Ethicon was defective at the time it was sold and/or left J&J/Ethicon's control. Further, the J&J/Ethicon

Prolene Mesh® was expected to reach the user of consumer without substantial change in the condition in which it was so manufactured, sold and/or supplied.

130. At the time of Plaintiff's surgery to repair his hernia, J&J/Ethicon expressly warranted that the J&J/Ethicon Prolene Mesh® was safe, well-tolerated and provided gentle relief without pain or spasm.

131. At the time of Plaintiff's surgery, J&J/Ethicon impliedly warranted that J&J/Ethicon Prolene Mesh® was of merchantable quality.

132. At the time of Plaintiff's surgery, J&J/Ethicon impliedly warranted that the J&J/Ethicon Prolene Mesh® was fit for acting as a means to repair hernias such as those suffered by the Plaintiff.

133. Mr. Ochoa did not receive a safe and effective product that was placed into him via surgery, but instead suffered a life-altering and permanent personal injury and damage as a result of the use of the J&J/Ethicon Prolene Mesh®.

A. FIRST CAUSE OF ACTION – STRICT LIABILITY: FAILURE TO WARN – BARD AND J&J DEFENDANTS

134. Plaintiff incorporates by reference the foregoing paragraphs as though fully set forth herein.

135. As set forth above, the mesh products placed in Plaintiff Matthew Ochoa were unreasonably dangerous and defective and not reasonably safe for their intended or reasonably foreseeable purposes because they did not have correct, adequate and complete warnings and instructions issued to them in language that was direct, unequivocal and sufficiently forceful to adequately explain and warn of the hazards of the products or the way to use the products safely.

136. The Defendants' sale, marketing, distribution, and supplying of a defective, inadequately labeled products to Plaintiff's surgeon, and ultimately Plaintiff, were a substantial factor in causing Plaintiff to suffer injuries and damages.

137. Mr. Ochoa has suffered and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, as well as other general non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss.

138. The Bard and J&J Defendants are strictly liable to Mr. Ochoa.

139. Plaintiff is also entitled to punitive damages because both the Bard and J&J Defendants' conduct were wanton, grossly reckless, grossly negligent, and/or in conscious disregard of Plaintiff's rights, health, and safety.

B. SECOND CAUSE OF ACTION – STRICT LIABILITY: DESIGN DEFECT – BARD & J&J DEFENDANTS

140. Plaintiff incorporates by reference the foregoing paragraphs as if set forth fully herein.

141. As set forth herein, the hernia meshes implanted into Plaintiff Matthew Ochoa used were defectively designed and labeled that were unreasonably dangerous to consumers when used in a reasonably foreseeable manner, including the manner that was directed on the package and recommended by Defendant.

142. There are other, available, safer alternative mesh utilized for hernia surgeries for people of Plaintiff's ailments.

143. Defendant manufacturers knew about these design defects and their propensity for them to cause damage to other organ, including organs such as Plaintiff's lower abdomen and testicular sac.

144. The design of the products is inconsistent with a consumer's reasonable expectations of safety when using the products as intended and directed by both the Bard and J&J Defendants.

145. It would have been feasible to design the Bard and J&J Defendants' products in a way that would have eliminated or substantially reduced the risk of permanent organ injury, such as Plaintiff's abdominal cavity, lower abdomen, testicle, and other dangers and health risks known to both the Bard and J&J Defendants.

146. Defendants breached their duty to design a hernia mesh plug in a reasonably safe manner and Defendants were otherwise at fault in the way they promoted, marketed, labeled and recommended the use of the mesh products.

147. As a direct and proximate consequence of the defective design and labeling of the mesh products by both the Bard and J&J Defendants, Mr. Ochoa suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss.

148. Plaintiff is also entitled to punitive damages because the Bard and J&J Defendants' conduct was wanton, grossly reckless, grossly negligent, and/or in conscious disregard of Plaintiff's rights, health, and safety.

C. THIRD CAUSE OF ACTION – NEGLIGENCE – BARD AND J&J DEFENDANTS

149. Plaintiff incorporates by reference the foregoing paragraphs as if set forth fully herein.

150. Defendants knew or should have known that the design of the Defendants' mesh products were reasonably certain to be dangerous when used installed in the human body, including the way it was installed into the Plaintiff's body.

151. Defendants breached their duty of reasonable care owed to Plaintiff as set forth above by the manner in which it designed the Bard and J&J Defendants' mesh products in failing to give adequate warning of the dangers known to it or which in the use of reasonable care the Defendants should have known and which a user of the Defendants' mesh products ordinarily would not discover, and the Defendants' breached their duties of reasonable care to provide adequate instructions so the products could be used safely when used as intended.

152. As a direct and proximate consequence of the defective design and labeling of the Bard and J&J Defendants' mesh products, Mr. Ochoa suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss.

153. Plaintiff is also entitled to punitive damages because the Defendants' conduct was wanton, grossly reckless, grossly negligent, and/or in conscious disregard of Plaintiff's rights, health, and safety.

D. FOURTH CAUSE OF ACTION – BREACH OF WARRANTY – BARD AND J&J DEFENDANTS

154. Plaintiff incorporates by reference the foregoing paragraphs as if set forth fully herein.

155. When the Defendants placed the meshes into the stream of commerce, they knew or should have known of the use for which it was intended and expressly and impliedly warranted to Plaintiff that the use of the meshes were safe and acceptable.

156. Plaintiff reasonably relied upon the expertise, skill, judgment, and knowledge of the Defendants and upon the expressly and/or implied warranty that the Defendants' mesh products were of merchantable quality and fit for use as intended.

157. As set forth above herein, the Defendants' mesh products were not merchantable nor reasonably fit to be used for its ordinary purposes for people in Plaintiff's age group and accordingly, Defendants breached the implied warranties owed to Plaintiff.

158. As a direct and proximate consequence of the defective design and labeling of the Defendants' mesh products, Mr. Ochoa suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss.

159. Plaintiff is also entitled to punitive damages because Defendants' conduct was wanton, grossly reckless, grossly negligent, and/or in conscious disregard of Plaintiff's rights, health, and safety.

E. FIFTH CAUSE OF ACTION – FRAUD AND DECEIT – BARD AND J&J DEFENDANTS

160. Plaintiff incorporates by reference the foregoing paragraphs as if set forth fully herein.

161. Defendants fraudulently represented to the public and the Plaintiff that the hernia mesh products placed into the stream of commerce and utilized on the Plaintiff Matthew Ochoa were safe for use as hernia mesh repair devices by members of the Plaintiff's age group.

162. Defendants fraudulently concealed and failed to advise the public and Plaintiff of needed information and facts regarding the use of the mesh products and of the health risks and hazards known by Defendants to be associated with and caused by the use of Defendants' mesh products as a mesh to aid in the repair of hernias in abdominal cavities.

163. Defendants' material misrepresentations and omissions were knowingly or recklessly false when made, or made with conscious disregard of their truth or falsity, and were made with the intent of inducing the public and Plaintiff into purchasing and using the Defendants' mesh products used to repair hernias in people.

164. Specifically, Defendants knew of the risk of injuries to members of the Plaintiff's age group who used the product and failed to disclose the nature and extent of those risks despite its knowledge.

165. Plaintiff believed and justifiably relied upon Defendants' fraudulent misrepresentations and omissions and was thereby induced into purchasing and using the Defendants' mesh product as a mesh to repair his torn hernia.

166. As a direct and proximate consequence of the defective design and labeling of the Defendants' mesh products, Mr. Ochoa suffered injuries and damages and will continue to suffer permanent pain and suffering, emotional distress, loss of enjoyment of life, as well as other general or non-economic damages, in addition to past and future special damages in the form of medical expenses and other costs associated with the care and treatment of these injuries, wage loss or loss of earning capacity, or other economic loss.

167. Plaintiff is also entitled to punitive damages because Defendants' conduct was wanton, grossly reckless, grossly negligent, and/or in conscious disregard of Plaintiff's rights, health, and safety.

VI.

DAMAGES

168. Plaintiff incorporates by reference the foregoing paragraphs as if set forth fully herein.

169. Because Plaintiff's bodily injuries were proximately caused by Defendants' conduct, Plaintiff is entitled to reasonable and proper compensation for the following legal damages:

a. past and future medical expenses and charges;

b. past and future physical pain and mental anguish;

c. past and future physical impairment;

d. past lost wages and future lost wage-earning capacity; and

e. past and future loss of household services and consortium.

170. Plaintiff seeks actual and punitive damages to be awarded by the jury in an amount more than the minimum jurisdictional limits of this Court.

VII.

GROSS NEGLIGENCE

171. Plaintiff incorporates by reference the foregoing paragraphs as if set forth fully herein.

172. Plaintiff would further show that the clear and convincing evidence in this case will show that Defendants acted with gross negligence in that when viewed objectively from the standpoint of these Defendants at the time of the occurrence, there was an extreme danger of risk considering the probability and magnitude of potential harm to others, and of which Defendants had actual, subjective awareness of the risk involved, but nevertheless proceeded with indifference

to the rights, safety, or welfare of others, including the Plaintiff. Therefore, punitive damages are sought and should be assessed against Defendants.

VIII.

JURY DEMAND

173. Plaintiff hereby demands a jury trial on all issues.

IX.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff MATTHEW OCHOA demands judgment against Defendants, for actual and punitive damages, costs and attorney fees, pre- and post-judgment interest, and for such other relief as is warranted in this matter.

Respectfully submitted,

LEGER KETCHUM & COHOON, PLLC

By:_____

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