

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA**

NANCY MARIE GREGORY and, *
FRANCIS LEE GREGORY, *
Plaintiffs, *

Vs. * **CASE NO.: CV-2020-_____**

MEDTRONIC INC., *
MEDTRONIC USA, INC., *
COVIDIEN LP, *
COVIDIEN SALES, INC., *
Defendants. *

COMPLAINT

1. The Plaintiff, Nancy Gregory, is a resident of Tuscaloosa County, Alabama, and is over the age of nineteen (19) years.

2. The Plaintiff, Francis Lee Gregory, is a resident of Tuscaloosa County, Alabama, and is over the age of nineteen (19) years.

3. The Defendant Medtronic, Inc. is a duly registered corporation with the Secretary of State for the State of Alabama with Entity ID Number 854-606 and is believed to be the manufacturer and/or supplier of ProGrip mesh, and is a corporation incorporated in Minnesota, with its operational headquarters located in Minneapolis.

4. The Defendant Medtronic USA, Inc. is a duly registered corporation with the Secretary of State for the State of Alabama with Entity ID Number 910-412 and is believed to be the manufacturer and/or supplier of the ProGrip mesh, and is a corporation incorporated in Minnesota, with its principal place of business located in Minneapolis.

5. The Defendant Covidien LP is a duly registered corporation with the Secretary of State for the State of Alabama with Entity ID Number 815-635 and is believed to be the manufacturer and/or supplier of ProGrip mesh, and is a corporation incorporated in Massachusetts, with its operational headquarters located in Mansfield.

6. The Defendant Covidien Sales LLC is a duly registered corporation with the Secretary of State for the State of Alabama with Entity ID Number 050-409 and is believed to be the manufacturer and/or supplier of the ProGrip mesh, and is a corporation incorporated in Massachusetts, with its principal place of business located in Mansfield.

7. Defendant Medtronic organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its products, including but not limited to its hernia repair mesh products. According to MedTronic's website, there are four sectors of the company: Covidien products, Clinical Solutions, Clinical Education, and Support. The Covidien sector was charged by MedTronic with the design, development, promotion, marketing, testing, training, distribution and sale of the hernia repair mesh products at issue in this case so it is believed.

8. The Defendants Medtronic, Inc. and Medtronic USA, Inc. are believed to be sister corporations with joint operations, joint purposes and joint product development all of which are at issue herein and remain unknown to the Plaintiffs. The Defendants Covidien LP and Covidien Sales, Inc. are believed to be used as the sales and marketing arms and/or the sales and servicing arms of the parent corporations Medtronic, Inc. and Medtronic USA, Inc. notwithstanding which of the four (4) corporations have actual and direct corporate responsibility.

9. At all relevant times, each of the Defendants designed, developed, manufactured, licensed, marketed, distributed, sold and/or placed Hernia Mesh Products in the stream of commerce, including the ProGrip surgical mesh product that is at issue in this lawsuit.

10. Medtronics is believed to be owned and/or operated and/or managed by Sofradim Productions which located in Auvergne-Rhone-Alpes, France and is part of the Medical Equipment & Supplies Manufacturing Industry. Sofradim Production boasts that it has employees across all of its locations and that there are 669 companies in the corporate family.¹

¹ [SOFRADIM PRODUCTION Company Profile | TREVoux, AUVERGNE-RHONE-ALPES, France | Competitors, Financials & Contacts](#)

11. Notwithstanding same all corporations are believed to be responsible for the damages herein pled whether directly or indirectly and are named appropriately. Any reference herein to Medtronic is intended to refer to the responsible entity whose only discovery will reveal whether the same be Medtronic, Inc. and/or Medtronic USA, Inc. Any reference herein to simply "Covidien" is intended to refer to the responsible entity whose only discovery will reveal whether the same be Covidien LP and/or Covidien Sales LLC.

12. At all times hereinafter mentioned, upon information and belief, Defendants MedTronic and Covidien committed tortious acts inside and outside the State of Alabama, which caused injury to Plaintiff inside the State of Alabama.

13. At all times hereinafter mentioned, upon information and belief, Defendants expected or should have reasonably expected their acts to have consequences in the State of Alabama, and derives substantial revenue from interstate or international commerce.

14. Defendants MedTronic and Covidien have and continue to conduct substantial business in the State of Alabama, distribute Hernia Mesh Products in Alabama, receive substantial compensation and profits from sales of Hernia Mesh Products in this state, and made material omissions and misrepresentations and breaches of warranties in this state and are subject to jurisdiction in this state.

15. Defendants conducted business in the State of Alabama through sales representatives conducting business in the State of Alabama and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, and/or through third parties or related entities, Hernia Mesh Products in Alabama.

16. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has jurisdiction over Defendants, because Defendants are present in the State of Alabama

17. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

CLASS ACTION RESERVATION AND OPTION RIGHTS ASSERTED

18. At this time, the action is being filed as a single plaintiff claim. At some point in the litigation, the Undersigned may petition the Court for class certification and does notice the same herein. Upon ascertaining the same, the (i) full legal name, (ii) legal residency, (iii) legal status with regards to age of majority or minority, (iv) merits and basis of individual claims will be pled. Those claimants are the individuals not yet identified who have a claim under law and equity for certain tort and statutory claims.

FACTUAL BACKGROUND

19. The product implanted on October 19, 2018 was sold, purchased and implanted in the State of Alabama. The procedure was not required due to a life-threatening condition and was in fact performed at the election of the physician. Due to the allegations herein, the procedure and medical device implantation has caused more harm than effectuated medical good.

20. Defendants manufactured, sold, and/or distributed the ProGrip mesh product to Plaintiff Nancy Gregory, through her doctors, to be used for treatment of hernia repair.

21. At all times, the ProGrip product was utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use and created procedures for implanting the mesh.

22. The ProGrip mesh product implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of Defendants, and in the condition directed by and expected by Defendants.

23. On October 28, 2014 the Department of Health & Human Services issued a letter to Sofradim Productions as a global business unit of Covidien regarding the ProGrip and Paritex lines. In that letter the Department made clear that the "FDA's issuance of a substantial equivalence determination does not mean that the FDA has made a determination that your (Covidien) device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies." The letter went on to clarify, "You must comply with all the Act's requirements, including, but not limited to: registration and listing, labeling, medical device reporting, good manufacturing practice requirements as set for in the quality systems regulation, and if applicable the electronic product radiation control provisions."

24. The letter offered special advice if requested. The Defendants have

failed to properly list, label, receive adverse event reporting and otherwise followed the law to ensure consumer safety. The Department of Health and Human Services letter also included a Form FDA 3881 for each of the products which in the "Indications for Use" sets out the Defendants representations as to reinforce soft tissue, among other things, which the product woefully fails and failed to do safely.

25. Mary Mellows, Senior Regulatory Specialist at 60 Middletown Avenue, North Haven, CT 06473 is who the letter, Form FDA 3881 attachment and 501(k) Summary the letter on behalf of Sofradim Productions a global business unit of Covidien is addressed.

26. The Food and Drug Administration's Adverse Event Reporting system has received numerous patient reports. Those include, but are not limited to, the following:

- **Apr 2017:** Parietex FDA Adverse Event MDR# 6527113 "The doctor told the patient to cough after his surgery. When he coughed the mesh had torn, ripped, and frayed."
- **Jul 2016:** Parietex ProGrip FDA Adverse Event MDR# 5831296 "During a laparoscopic hernia repair, the mesh tore."
- **Sept 2015:** Parietex ProGrip FDA Adverse Event MDR# 5049541 "The mesh ripped while placing."
- **Sept 2015:** Parietex ProGrip FDA Adverse Event MDR# 5049526 "The patient presented with a recurrent hernia in less than 12 months after the initial repair. When the surgeon repaired the recurrent hernia, he noticed that the device had torn across its center. There were no sutures in the area of which had torn."
- **Dec 2014:** Parietex ProGrip FDA Adverse Event MDR# 4337643 "Device torn off while opening the package."
- **Mar 2014:** Parietex ProGrip FDA Adverse Event MDR# 3810085 "Product did not stand up to routine manipulation."
- **Jan 2014:** Parietex ProGrip FDA Adverse Event MDR# 3843549 "Mesh tore when inserting into patient."
- **Sept 2013:** Parietex ProGrip FDA Adverse Event MDR# 3556931 "Dr. was manipulating the piece of pro grip it tore in half."
- **Aug 2013:** Parietex ProGrip FDA Adverse Event MDR# 3330978 "The mesh started to fall apart during the case."
- **May 2013:** Parietex ProGrip FDA Adverse Event MDR# 3165306 "The surgeon was also using prolene sutures during the procedure. The pt bucked while under anesthesia and the surgeon noticed that the mesh had become torn 2cc x 2cm in the upper left hand corner of the mesh on the inside 1/2 cm from the edge."

- **Jul 2012:** Parietex ProGrip FDA Adverse Event MDR# 2661706 “Once he started the right side the mesh has torn when opening the gripping skirt. A 1 cm tear has been made very easily from the central hold of the mesh. The surgeon said he carefully handled the product as usual.”
- **Apr 2012:** Parietex ProGrip FDA Adverse Event MDR# 2557966 “As the mesh was being removed from the package to use in the procedure, it was noticed that the mesh was in two pieces.”
- **Apr 2012:** Parietex ProGrip FDA Adverse Event MDR# 2549687 “Mesh tore before being placed inside pt.”
- **Mar 2012:** Parietex ProGrip FDA Adverse Event MDR# 2502567 “The hernia mesh that the physician was going to put into the patient tore.”
- **Jan 2012:** Parietex ProGrip FDA Adverse Event MDR# 2436911 “4-5 patients required re-operation to reposition the band port. Upon second look, surgeons found no mesh attached to the port. All four suture locations still had suture attached but no mesh was present. Suture also pulled through the mesh very easily prior to placing port/mesh into patient.”
- **May 2011:** Parietex ProGrip FDA Adverse Event MDR# 2118706 “When they opened the device it was cut in half.”
- **Mar 2010:** Parietex ProGrip FDA Adverse Event MDR# 1646865 “The mesh was torn during manipulation (before implantation or contact with pt). It seemed the flap was fixed to the rest of the mesh. So by tearing, the flap gave loose.”
- **Mar 2010:** Parietex ProGrip FDA Adverse Event MDR# 1634365 ” Prior to application to the patient, the mesh shredded in his hands. Mesh fell apart when surgeon handled it.”
- **Mar 2009:** Parietex ProGrip FDA Adverse Event MDR# 1421993 “The flap was not attached to the mesh. The problem was identified when the mesh was taken out of the box and placed in the surgical field.”
- **Jan 2009:** Parietex ProGrip FDA Adverse Event MDR# 1355060 “The mesh tore while the surgeon was trying to reposition.”

27. These and other problems were not included properly into the consumer safety notices and were otherwise concealed by the Defendants.

28. Additionally studies have indicated the degree to which various synthetic materials resulted in mesh-induced chronic inflammation and scarring was evaluated and serious concern was expressed. It is held that because chronic inflammation and scarring can cause chronic pain and limited mobility the mesh in it's design is believed to deviate from the minimal safety standards without proper notice. Researchers have found that this type of “mesh induced the greatest FBR [Foreign Body Response] and lasting chronic inflammatory

response.”²³⁴ The tissue and inflammatory response caused by various meshes was compared. The researchers noted that “Mersilene showed an excellent and relatively inert tissue reaction of the interface compared to Prolene and Parietex”.⁵ Also, a retrospective study evaluated how various prosthetic materials and implantation techniques influenced long-term complications after hernia repair during the period of 1985 to 1994.

29. The researchers found that “polyester mesh had a significantly higher mean number of complications per patient, a higher incidence of fistula formation, a greater number of infections, and more recurrent hernias than the other materials used. The additional mean length of stay to treat complications was also significantly longer (30 vs 3-7 days) when polyester mesh was used. The deleterious effect of polyester mesh on long-term complications was confirmed on multiple logistic regression.”⁶ Additionally, the researchers concluded that “Polyester mesh should no longer be used for incisional hernia repair.”

30. Plaintiff Nancy Gregory and her physicians foreseeably used and implanted the ProGrip mesh, and did not misuse, or alter the ProGrip mesh in an unforeseeable manner.

31. Defendants advertised, promoted, marketed, sold, and distributed the ProGrip mesh product as a safe medical device when Defendants knew or should have known the ProGrip mesh was not safe for its intended purposes and that the mesh product could cause serious medical problems.

32. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects at the time of the design, marketing and sale.

33. In reliance on Defendants’ representations, Plaintiff’s doctor was induced to, and did use the ProGrip mesh products.

34. Defendants’ ProGrip products were marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily hernia repair and soft tissue repair, and as a safer and more effective as compared to the traditional products and procedures for

² <https://link.springer.com/article/10.1023/A%3A1004812410141>

³ <https://pubmed.ncbi.nlm.nih.gov/22099590/>

⁴ August 2012: Comparative Analysis of Histopathologic Effects of Synthetic Meshes Based on Material, Weight, and Pore Size in Mice.

⁵ October 2000: Polymers in Hernia Repair – Common Polyester vs. Polypropylene Surgical Meshes.

⁶ April 1998: Long-Term Complications Associated with Prosthetic Repair of Incisional Hernias.

treatment, and other competing hernia mesh products.

35. The Defendants have marketed and sold the Defendants' ProGrip mesh products 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 health care providers at medical conferences, hospitals, private offices, and/or group purchasing organizations, and include a provision of valuable consideration and benefits to the aforementioned.

36. Plaintiff, in the exercise of due diligence, could not have reasonably discovered the cause of her injuries-- including but not limited to the defective design the ProGrip mesh implanted inside of her until a date within the applicable statute of limitations.

37. On or about October 19, 2018, Plaintiff Nancy Gregory underwent diagnostic laparoscopy with appendectomy and right inguinal hernia repair with mesh at Surgery South, L.L.C., in Bessemer, Alabama by Dr. Matthew Reed. During this procedure, a ProGrip hernia mesh product was utilized for Plaintiff's hernia repair. The diagnostic laparoscopy revealed the presence of an inguinal hernia and as recommended by the Defendants Dr. Reed implanted the ProGrip mesh.

38. As a result of having the ProGrip mesh implanted, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent and substantial injury, permanent and substantial physical deformity, will have to undergo corrective surgery or surgeries or worse so will not be able to have the mesh surgically removed because of the cost-benefit analysis to removing the new permanently enmeshed tissues, to include muscle, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and present and future lost wages.

39. Due to the unsafe Mesh, the Plaintiff Nancy Gregory has suffered harms. These harms include: 1) suffered conscious pain and suffering both in the past and, it is expected by her physicians, the future, 2) incurred medical expenses in the past and will incur future medical expenses, 3) suffered mental and emotional sorrow and anguish, 4) suffered permanent physical injuries and disfigurement, and 5) will be required to undergo additional medical procedures and has sustained other damages or alternatively she will be forced to live in pain given it is more likely than not that the mesh has become so enmeshed with the Plaintiff's underlying body tissues to include muscle that removal is not prudent given a reasonable cost-benefit analysis.

40. All of the injuries and damages sustained by the Plaintiff were the direct and proximate result of the Defendants without any act or omission on the part of the Plaintiff directly thereunto contributing. The Plaintiff did not assume the risk of her injuries and it is believed the treating physician was not fully and transparently informed by the Defendants as to the risks of the Mesh to the patient(s).

41. At all times relevant the product at issue was placed in the “streams of commerce” as defined by Alabama law and the Defendants are thus responsible for damages caused thereby.⁷

COUNT #01 – PRODUCTS LIABILITY
ALABAMA EXTENDED MANUFACTURER'S LIABILITY DOCTRINE
**(As to Defendants MedTronic, Inc., Medtronic USA, Inc., Covidien LP,
and Covidien Sales LLC.)**

42. The Plaintiffs incorporate by reference all the above paragraphs as though fully set forth herein.

43. The Alabama Extended Manufacturers' Liability Doctrine (AEMDL) applies to the product at issue as the manufacturer, the supplier and the seller shall be subject to liability; the tort concept of fault is retained, where a defendant who markets a product that is not reasonably safe when applied to its intended use in the usual and customary manner is negligent as a matter of law.⁸

44. A product is defective when it is unreasonably dangerous and does not meet the reasonable expectations of an ordinary consumer with respect to its safety; that is, when the unreasonably dangerous product is in a condition not contemplated by the ultimate consumer.⁹ The mesh at issue ultimately cannot be removed without serious bodily harm or grave bodily harm therein in some situations making it practically unremovable.

45. To establish liability under the AEMLD, “(1) a plaintiff must prove he/she suffered injury or damages to himself/herself or property by one who sold a product in a defective condition unreasonably dangerous to the plaintiff as the ultimate user or consumer, if (a) the seller was engaged in the business of selling such a product, and (b) it was expected to, and did, reach the user or consumer without substantial change in the condition in which it was sold and

⁷ First National Bank of Mobile v. Cessna Aircraft, 365 So. 2d 966 (Ala. 1978)

⁸ See: Casrell v. Altec Industries, Inc., 335 So.2d 128 (Ala. 1976), Atkins v. American Motors Corp., 335 So 2d 134 (Ala. 1976)

⁹ Flemister v. General Motors Corp., 723 So. 2d 25, 27 (Ala. 1998)

(2) having established the above elements, the plaintiff has proved a *prima facie* case although (a) the seller had exercised possible care in the preparation and sale of his product and (b) the user or consumer had not bought the product from, or entered into any contractual relationship with, the seller.”¹⁰

46. This is a device tort action brought on behalf of the above-named Plaintiffs arising out of the failure of Defendants’ hernia mesh product. As a result, Plaintiff Nancy Gregory suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and a diminished quality of life.

47. Defendants MedTronic and Covidien market and sell ProGrip mesh products for the treatment of multiple medical conditions, primarily hernia repair.

48. Defendants’ Hernia Mesh Products were designed, patented, manufactured, labeled, marketed, sold, and distributed by the Defendants at all relevant times herein. Defendants’ Hernia Mesh Products are designed, intended, and utilized for permanent implantation into the human body. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the known severe and life-threatening risk associated with the implantation of said products.

49. Upon information and belief, when ProGrip mesh is implanted in a patient’s abdominal cavity, an inflammatory response occurs, causing complications including but not limited to pain, graft rejection, graft migration, organ damage, adhesions, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death. Upon information and belief, Defendants utilized non-conforming goods in the production of the ProGrip mesh products, including accepting goods without the required documentation to verify the source, quality, authenticity, or chain of custody of the goods. Upon information and belief, Defendants had actual knowledge of the inflammatory properties of the ProGrip product prior to introducing it into the stream of commerce and wantonly introduced the same notwithstanding. Upon information and belief, Defendants had actual knowledge of the substantial risk that ProGrip implants will fail to properly and safely incorporate into the abdominal walls of patients, requiring additional surgery.

50. At all relevant times the Defendants knew or should have known that ProGrip products demonstrated unacceptably high complication and failure

¹⁰ Atkins, 335 So. 2d at 141 cited in The Basics of Alabama’s Product Liability Law, Lee Hollis, Esquire & Benjamin Baker, Esquire of Beasley Allen. See also Sears, Roebuck & Co., Inc. v. Haven Hills Farms, Inc. 395 So. 2d 991, 993-96 (Ala. 1981)

rates. Defendants failed to adequately test the effects of the known inflammatory properties of the ProGrip in animals and humans, both before and after the product entered the stream of commerce. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the known inflammatory properties of the ProGrip product. Upon information and belief, Defendants paid doctors, surgeons, physicians, and/or clinicians to promote the ProGrip mesh products, but they did not readily disclose this information.

51. Defendants failed to implement adequate procedures and systems to report, track, and evaluate complaints and adverse events. Notice was never sent to ProGrip mesh patients to notify them of potentially unacceptably high rates of complication and failure. Defendants' did not advise surgeons to contact ProGrip mesh patients to notify them of potentially unacceptably high rates of complication and failure. Defendants failed to employ an adequate number of staff to receive, process, investigate, document, and report adverse events. Defendants marketed the ProGrip mesh products to the medical community and to patients as safe, effective, reliable, medical devices for the treatment of hernia repair, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing mesh products. Defendants have made claims that the ProGrip mesh is superior in a variety of ways, but have never conducted a single clinical study on the ProGrip mesh implanted in humans. Defendants' deception through false advertising resulted in more physicians utilizing the ProGrip products.

52. Defendants marketed and sold the ProGrip mesh products 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, aggressive marketing to health care providers at medical conferences, hospitals, and private offices, and include the provision of valuable benefits to health care providers. Also utilized were documents, patient brochures, and websites. Prior to the introduction of the ProGrip mesh products to the market, Defendants had been notified and warned about the risk of widespread and sometimes catastrophic complications associated with the ProGrip products by leading hernia repair specialists, surgeons, hospitals, patients, internal consultants, and employees. Instead of improving the design of ProGrip, Defendants chose to push ProGrip products to market while misrepresenting the efficacy and safety of the ProGrip through various means and media, actively and intentionally misleading the medical community, patients, and the public at large. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Defendants' ProGrip product.

53. Defendants failed to design and establish a safe, effective procedure

for removal of the Defendants' Parietex ProGrip product; therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove the Defendants' ProGrip product. Feasible and suitable alternative procedures and instruments, as well as suitable alternative designs for implantation and treatment of hernias and soft tissue repair have existed at all times relevant as compared to the Defendants' ProGrip. The Defendants' ProGrip mesh product was, at all times relevant to this Complaint, utilized and implanted in a manner foreseeable to the Defendants.

54. The Defendants have at all times provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Defendants' ProGrip mesh products, and thus increase the sales of the ProGrip, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff. The ProGrip mesh that was implanted into the Plaintiff was in the same or substantially similar condition as when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

55. As a direct, proximate, and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the ProGrip mesh products, the injuries, conditions, and complications suffered due to Defendants' ProGrip include but are not limited to: foreign body reaction, rashes, infection, adhesions, organ perforation, inflammation, fistula, mesh erosion, scar tissue, blood loss, dyspareunia, neuropathic and other acute and chronic nerve damage and pain, abdominal pain, nausea, vomiting, kidney failure, and-- in many cases-- the patients have been forced to undergo intensive medical treatment, including but not limited to operations to locate and remove the ProGrip, operations to attempt to repair abdominal organs, tissue, and nerve damage, the use of narcotics for pain control and other medications, and repeat operations to remove various tissues that are contaminated with the ProGrip mesh.

WHEREFORE, Plaintiffs demand judgment against Defendants, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT #02 -- STRICT LIABILITY – DESIGN DEFECT
(As to Defendants MedTronic, Inc., Medtronic USA, Inc., Covidien LP, and Covidien Sales LLC.)

56. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and

additionally or in the alternative, if same be necessary, allege as follows.

57. Defendants supplied, manufactured, sold, distributed and/or otherwise placed into the stream of commerce the ProGrip hernia mesh product that was implanted into Plaintiff. The mesh was defective in its design in that when it left the hands of Defendants, it was not safe for its anticipated use, and safer, more reasonable alternative designs existed that could have been utilized by Defendants. A reasonably prudent medical device manufacturer would not have placed the ProGrip product with its defective design into the stream of commerce.

58. The Alabama Extended Manufacturers' Liability Doctrine (AEMDL) is predicated on the strict liability doctrine promulgated by Section 402A of the Restatement (Second) of Torts.

59. AEMLD liability will arise where the product's design causes it to be unreasonably dangerous.¹¹ This liability will arise because a manufacturer has a duty to design and manufacture a product that is reasonably safe for its intended purpose and use. In this Count, Plaintiffs do not allege that the product is damaged, flawed or abnormal - the product was constructed as designed. Rather, Plaintiffs do herein allege that the design of the product renders the entire product line unreasonably dangerous.

60. The ProGrip mesh was defectively designed when supplied, sold, distributed and/or otherwise placed into the stream of commerce and when it was implanted in Plaintiff. The ProGrip product was unreasonably dangerous, taking into consideration the utility of said product and the risks involved in its use. The foreseeable risks associated with the design of the mesh were more dangerous than a reasonably prudent consumer such as Plaintiff and/or his physician would expect when the mesh was used for its normal and intended purpose.

61. The ProGrip product reached Plaintiff's implanting surgeon and was implanted in Plaintiff without any substantial change in the condition in which it was supplied, distributed, sold and/or otherwise placed into the stream of commerce. The ProGrip product failed to perform as safely as an ordinary consumer and/or her physician would expect when used as intended or when used in a manner reasonably foreseeable by the manufacturer, and the risks and dangers of the ProGrip mesh outweigh its benefits. The design defects in the ProGrip mesh were not known, knowable and/or reasonably visible to Plaintiff and/or her physician or discoverable upon any reasonable examination. The ProGrip product was used and implanted in the manner in which it was intended

¹¹ Banner Welders, Inc. v. Knighton, 524 So. 2d 441 (Ala. 1982)

to be used and implanted by Defendants, pursuant to the instructions for use and the product specifications provided by Defendants.

62. The defective and unreasonably dangerous condition of the ProGrip product was the proximate cause of the damages and injuries complained of by Plaintiff. As a direct and proximate result of the ProGrip product's aforementioned design defects, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

63. Defendants are strictly liable to Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against Defendants and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT #03 -- STRICT LIABILITY – FAILURE TO WARN

64. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows.

65. Where a manufacturer knows that the product might be dangerous when used in a reasonably foreseeable manner, then the manufacturer has a duty to issue adequate warnings.¹²

66. Defendants manufactured, designed, marketed, sold and/or otherwise placed into the stream of commerce their ProGrip surgical mesh product. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that ProGrip mesh was designed and/or manufactured in a way that could cause injuries and damages including lasting and permanent injuries. Defendants further failed to inform and further warn Plaintiff and her treating physician with respect to the most effective proper technique and methods of implantation and/or the selection of appropriate candidates to receive ProGrip mesh products.

¹² Richards v. Michelin Tire Corp., 21 F. 3d 1048, (11th Cir (Ala.) 1994)

67. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician as to the risks and benefits of the Defendants' ProGrip products. To the contrary, Defendants withheld information from Plaintiff and her treating physician regarding the true risks as relates to implantation of their ProGrip mesh.

68. The Defendants failed to properly and adequately warn and instruct Plaintiff and her treating physician that inadequate research and testing of the ProGrip products was done prior to ProGrip mesh being placed on the market and in the stream of commerce, and that Defendants lacked a safe, effective procedure for removal of the ProGrip mesh once complications from same arise.

69. The Defendants intentionally, recklessly, and maliciously misrepresented the efficacy, safety, risks, and benefits of ProGrip mesh, understating the risks and exaggerating the benefits in order to advance its own financial interest, with wanton and willful disregard for the rights, safety and health of Plaintiff.

70. As a direct and proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the ProGrip mesh, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

71. The Defendants are strictly liable in tort to the Plaintiffs for their wrongful conduct in failing to properly warn Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT #04 -- BREACH OF EXPRESS WARRANTY

72. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows.

73. At all relevant and material times, Defendants manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce ProGrip mesh products.

74. In advertising, marketing and otherwise promoting ProGrip products to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that their ProGrip mesh was safe for use. In advertising, marketing and otherwise promoting ProGrip mesh, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations in an effort to induce them to use ProGrip products for their patients.

75. The Plaintiff was a person whom the Defendants could reasonably have expected to use, consume, or be affected by the Defendants' hernia mesh products as the Defendants specifically designed the ProGrip mesh products for permanent implantation in patients exhibiting hernia such as Plaintiff.

76. With respect to Plaintiff, Defendants intended that ProGrip mesh be implanted in Plaintiff by her treating surgeon in the reasonable and foreseeable manner in which it was implanted and in accordance with the instructions for use and product specifications provided by Defendants. Plaintiff was in privity with Defendants.

77. Defendants expressly warranted to physicians, hospitals, other healthcare providers and the general public, including Plaintiff, that ProGrip mesh was safe and fit for use by consumers including Plaintiff, that it was of merchantable quality, that its risks, side effects and potential complications are minimal and are comparable to other hernia mesh products, that it was adequately researched and tested and was fit for its intended use. Plaintiff and her physicians and healthcare providers relied upon these express representations and warranties made by Defendants and consequently, Plaintiff was implanted with Defendants' ProGrip mesh product.

78. Defendants breached express representations and warranties made to Plaintiff and her physicians and healthcare providers with respect to the ProGrip mesh implanted in Plaintiff including the following particulars:

A. Defendants represented to Plaintiff and her physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions-- among other ways-- that the Defendants' ProGrip mesh was safe; meanwhile, Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ProGrip mesh;

B. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' ProGrip mesh was as safe and/or safer than other alternative procedures and devices then on the market; meanwhile, Defendants fraudulently concealed information that demonstrated that ProGrip mesh was not safer than alternative therapies and products available on the market; and

C. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' ProGrip mesh products were more efficacious than other alternative procedures, therapies and/or devices. Meanwhile, Defendants fraudulently concealed information, regarding the true efficacy of ProGrip products.

79. At the time of making such express warranties, Defendants knew or should have known that Defendants' ProGrip mesh does not conform to the express warranties. Defendants' acts were motivated by financial gain, while the adverse consequences of Defendants' conduct was outrageous, fraudulent, oppressive, done with malice or gross negligence and evidenced reckless indifference to Plaintiff's rights, health and safety.

80. As a direct and proximate result of Defendants' breaches of the aforementioned express warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendants and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

**COUNT #05 - BREACH OF IMPLIED WARRANTIES OF
MERCHANTABILITY AND FITNESS OF PURPOSE**

81. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows.

82. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' ProGrip hernia

mesh products. At all relevant times, Defendants intended that its ProGrip mesh product be implanted for the purposes and in the manner that Plaintiff's implanting surgeon did in fact implant it, in accordance with the instructions for use and product specifications provided by Defendants. Defendants impliedly warranted that their ProGrip mesh product was of merchantable quality, safe and fit for its intended use of implantation in Plaintiff and was properly and adequately tested prior to being placed in the stream of commerce.

83. The Plaintiff was a person whom the Defendants could reasonably have expected to use, consume, or be affected by the Defendants' hernia mesh products, as the Defendants specifically designed the ProGrip mesh for permanent implantation in patients exhibiting hernia such as Plaintiff.

84. Defendants were aware that consumers such as Plaintiff would be implanted with ProGrip mesh by their treating physicians in accordance with the instructions for use and product specifications provided by Defendants to Plaintiff's physicians. Plaintiff was a foreseeable user of Defendants' ProGrip mesh, and Plaintiff was in privity with Defendants.

85. Defendants breached implied warranties with respect to the ProGrip products including the following particulars:

A. Defendants represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' ProGrip mesh was of merchantable quality and safe when used for its intended purpose; meanwhile, Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using ProGrip mesh;

B. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' ProGrip mesh was safe, as safe as and/or safer than other alternative procedures and devices; meanwhile, Defendants fraudulently concealed information which demonstrated that the ProGrip mesh was not safe, as safe as or safer than alternatives and other products available on the market; and

C. Defendants represented to Plaintiff and her physicians and healthcare providers that the Defendants' ProGrip products were more efficacious than other alternative procedures and/or devices. Meanwhile, Defendants fraudulently concealed information, regarding the true efficacy of ProGrip products.

86. In reliance upon Defendants' implied warranties, Plaintiff's implanting surgeon used ProGrip mesh to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants, and in accordance with the instructions for use and product specification provided by Defendants.

87. Defendants breached their implied warranty to Plaintiff in that the Defendants' ProGrip mesh product was not of merchantable quality, safe and fit for its intended use, nor was it adequately tested prior to being placed in the stream of commerce.

88. Defendants acts were motivated by financial gain, while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

89. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff was caused and in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, impairment of personal relationships, and other damages.

WHEREFORE, Plaintiffs demands judgment against Defendants and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT #06 -- CONSUMER FRAUD

90. Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows.

91. The Defendant acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including Plaintiff and her prescriber, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of its said hernia mesh product, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe it for

patients/consumers such as the Plaintiff. By reason of the Defendant's unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff, were caused to suffer ascertainable loss of money and property and actual damages.

92. The Defendant engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

93. The Defendant misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

94. The Defendant's misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product.

95. The United States, as well as Alabama, has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. The Defendant violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendant knew it was defective and dangerous, and by other acts alleged herein.

96. The Defendant engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including Plaintiff.

97. As a direct and proximate result of the Defendants' violations, Plaintiffs have suffered damages, for which they are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

98. As a direct and proximate result of Defendants' conduct, Plaintiff used the said hernia mesh and suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

99. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT #07 -- WANTONNESS, GROSS NEGLIGENCE AND INTENTIONAL CONDUCT

100. Plaintiffs reallege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows.

101. The acts and omissions of Defendants as alleged herein are of a character and nature that is outrageous, fraudulent, oppressive, done with malice and evidenced reckless disregard for Plaintiff's rights, health and safety and constitute gross negligence and/or willful or intentional indifference or conduct.

102. The acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence or willful and/or intentional conduct that proximately caused injuries to Plaintiffs. The Plaintiffs are able to prove the same by clear and convincing evidence given, among other things, the Food & Drug Administrations (FDA) communications to the Defendant(s).

WHEREFORE, Plaintiffs demand judgment against Defendants and request punitive damages¹³, compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT #08 -- LOSS OF CONSORTIUM

103. The Plaintiffs incorporate by reference all the above paragraphs as though fully set forth herein. At the time of the acts and injuries complained of in the Plaintiffs' Complaint, the Plaintiffs were married, and the Plaintiffs continue to be married.

¹³ Ala. Code Section 6-11-20(a), *Richards v. Michelin Tire Corp.*, 21 F. 3d 1048 (11th Cir. (Ala) 1994).

104. As a result of the wrongful and negligent acts of the Defendants, and each of them, the Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, affection, assistance, and conjugal fellowship, all to the detriment of their marital relationship.

105. All the injuries and damages were caused solely and proximately by the negligence of the Defendants.

WHEREFORE, the Plaintiffs jointly as husband and wife, demand judgment and claim monetary damages against the Defendants, jointly and severally, in an amount to be determined at trial, plus costs, pre-judgment interest, post-judgment interest, and any other costs this court deems appropriate.

COUNT #09 -- UNJUST ENRICHMENT

106. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein and additionally or in the alternative, if same be necessary, allege as follows.

107. Defendants at all times were the manufacturers, sellers, and/or suppliers of ProGrip mesh products.

108. Plaintiff was implanted with Defendants' mesh product for the purpose of treatment for hernia repair, and Defendants were paid for Plaintiff's use of said product.

109. Defendants have accepted payment by Plaintiff and/or by others on Plaintiff's behalf for the purchase of the ProGrip mesh with which Plaintiff was implanted.

110. Plaintiff was not implanted with, nor did she receive, a medical device that was—despite Defendants' representations and warranties-- safe, effective and efficacious and for which Plaintiff paid.

111. Equity demands that Defendants be required to disgorge any and all moneys, profits and/or any other thing of value received by Defendants on account of Plaintiff receiving a product that was substantially different than that which was represented and/or warranted and because of Defendants' conduct, acts and omissions as set out herein.

WHEREFORE, Plaintiffs demand judgment against Defendants and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT #10 -- NEGLIGENCE

(As to Defendants MedTronic, Inc., Medtronic USA, Inc., Covidien LP, and Covidien Sales LLC.)

112. Plaintiffs re-allege and incorporate by reference every allegation of this Complaint as if each were set forth fully and completely herein. At all relevant times, Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' ProGrip mesh products, and recruitment and training of physicians to implant the ProGrip mesh.

113. Defendants breached the duty of care to the Plaintiff, as aforesaid, in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and recruitment and training of physicians to implant the ProGrip mesh.

114. Defendants knew or should have known that its failure to exercise ordinary care in the manufacture, design, labeling, warnings, instructions, sale, marketing, distribution and recruitment and training of physicians to implant the ProGrip products would cause foreseeable harm, injuries and damages to individuals such as Plaintiff who are implanted with ProGrip mesh. As a direct, proximate and foreseeable result of the Defendants' design, manufacture, labeling, marketing, sale, and distribution of the ProGrip mesh, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

115. Each act or omission of negligence was a proximate cause of the damages and injuries to Plaintiff.

WHEREFORE, Plaintiffs demand judgment against Defendants, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT #11 -- CONSPIRACY TO COMMIT TORTIOUS CONDUCT

116. In conspiracy with others and one another, the Defendants and agents of the Defendants have worked together systematically, both spoken and unspoken, in policy adopted, created, understood or otherwise accepted, all of which have worked to tortious damage to the Plaintiffs.

COUNT #12 -- VICARIOUS LIABILITY

117. Whenever in this Complaint it is alleged that Defendants did or omitted to do any act, it is meant that Defendants' officers, agents, servants, employees, or representatives did or omitted to do such act and that, at the time such act or omission was done, it was done with the full authorization or ratification of Defendants or was done in the normal and routine course and scope of employment of Defendants' officers, agents, servants, employees, and representatives.

WHEREFORE, Plaintiffs demand judgment against Defendants and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

In consideration of this Complaint, premises considered, Plaintiffs demand judgment against Defendants and pray for the following relief in accordance with applicable law and equity:

- i. 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 Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, past and future health and medical care costs and economic damages including past and future lost earnings and/or earning capacity together with interest and costs as provided by law;
- ii. Punitive damages for the wanton conduct and other actions herein pled;
- iii. Reasonable attorneys' fees as provided by law; the costs of these proceedings, including past and future costs of the suit incurred herein;
- iv. Prejudgment interest on all damages as is allowed by law; and
- v. Such other and further relief legal or equitable as this Court deems just and proper.

JURY TRIAL DEMANDED-- Plaintiffs hereby demand a trial by jury on all issues so triable.

Dated this the 19th day of October, 2020.

Respectfully submitted,



TRENTON R. GARMON (GAR093)
Attorney for Plaintiffs

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Respectfully submitted,

/s/ Erica K. Kemmer

Erica K. Kemmer (BOO038)
Attorney for Plaintiffs

OF COUNSEL:

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11 2nd Avenue/ P.O. Box 592

Moundville, Al 35474

Phone: (205) 450-9185

E-Mail: ericakemmer@gfile.legal

REQUEST FOR SERVICE BY CERTIFIED MAIL

Pursuant to ARCP 4.1 and 4.2, Plaintiff requests that the Clerk direct service of the foregoing "Summons and Complaint" by certified mail, addressed as follows:

DEFENDANT'S SERVICE ADDRESS:

MEDTRONIC, INC. c/o
CORPORATION SERVICE COMPANY INC.
641 SOUTH LAWRENCE STREET
MONTGOMERY, AL 36104

MEDTRONIC USA, INC. c/o
CORPORATION SERVICE COMPANY INC.
641 SOUTH LAWRENCE STREET
MONTGOMERY, AL 36104

COVIDIEN LP %
CORPORATION SERVICE COMPANY INC.
641 SOUTH LAWRENCE STREET
MONTGOMERY, AL 36104

COVIDIEN SALES, LLC %
CORPORATION SERVICE COMPANY INC.
641 SOUTH LAWRENCE STREET
MONTGOMERY, AL 36104

DATED this the 20 day of September, 2020.

Nancy Marie Gregory
NANCY MARIE GREGORY
Plaintiff

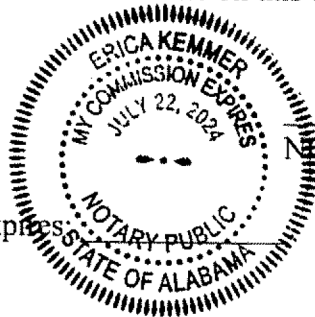
STATE OF ALABAMA)

TUSCALOOSA COUNTY)

Before me, the undersigned authority, a Notary Public in and for said State at large, personally appeared NANCY MARIE GREGORY, the Plaintiff in the above-styled cause, who is personally known to me and who, being first duly sworn, doth depose and says that she has read the foregoing statements and that said statements are true and correct to the best of her knowledge, information and belief.

Nancy Marie Gregory
NANCY MARIE GREGORY
Plaintiff

Sworn to and subscribed before me on this the 20 day of September, 2020.



Erica Kemmer
NOTARY PUBLIC

My commission expires

DATED this the 20 day of September, 2020.

Francis Lee Gregory
FRANCIS LEE GREGORY
Plaintiff

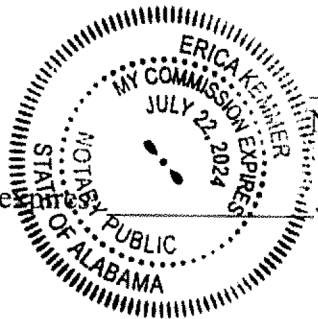
STATE OF ALABAMA)

TUSCALOOSA COUNTY)

Before me, the undersigned authority, a Notary Public in and for said State at large, personally appeared FRANCIS LEE GREGORY, the Plaintiff in the above-styled cause, who is personally known to me and who, being first duly sworn, doth depose and says that he has read the foregoing statements and that said statements are true and correct to the best of his knowledge, information and belief.

Francis Lee Gregory
FRANCIS LEE GREGORY
Plaintiff

Sworn to and subscribed before me on this the 20 day of September, 2020.



My commission expires

Erica Keener
NOTARY PUBLIC