FILED

STATE OF NORTH CAROLINA

IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION

COUNTY OF NEW HANOVER

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FILE NO. 06 CVS 4980

NEW HANOVER COUNTY, C.S.C.

PERLENE HERRING, an individual,

Plaintiff,

v.

JOHNSON & JOHNSON,
a corporation,

JOHNSON & JOHNSON HEALTH CARE SYSTEMS, INC.,
a corporation,

ETHICON, INC.,
a corporation,

NEW HANOVER REGIONAL MEDICAL CENTER,
a not-for-profit corporation,

Defendants.

BY

Plaintiff's Original Class Action Complaint
(Jury Trial Demanded)

A TRUE COPY
CLERK OF SUPERIOR COURT
NEW HANOVER COUNTY
BY
Assistant, Deputy, Clerk Superior Court

PLAINTIFF'S ORIGINAL CLASS ACTION COMPLAINT
(Products Liability, Negligence And Fraudulent Concealment)

COMES NOW Plaintiff Perlene Herring and for her Original Class Action Complaint against Defendants states:

PARTIES

1. Plaintiff Perlene Herring is a resident of the State of North Carolina.

2. Defendant Johnson & Johnson ("J&J") is a foreign corporation with its principal place of business located in New Brunswick, New Jersey, and at all times pertinent hereto was the owner and parent company of Defendant Johnson & Johnson Health Care Systems, Inc. ("JJHCS") and Defendant Ethicon, Inc. ("Ethicon") and was in control of, and responsible for, the acts and omissions of said Defendants. Defendant J&J has done and continues to do business in the State of North Carolina.

3. Defendant Johnson & Johnson Health Care Systems, Inc. ("JJHCS") is a foreign corporation with its principal place of business in Piscataway, New Jersey. Defendant JJHCS was at all times pertinent hereto acting through its agents, servants and employees, who were acting within the scope and course of their employment and/or agency. Defendant JJHCS is registered to do business and maintains an agent for service of process in the State of North Carolina.

4. Defendant Ethicon, Inc., ("Ethicon") is a foreign corporation owned in whole or in part by Defendants J&J and JJHCS with its principal place of business located in Somerville, New Jersey. Defendant Ethicon was at all pertinent times hereto the agent of and under the direction and control of Defendants J&J and JJHCS. Defendant Ethicon has done and continues to do business in the State of North Carolina.

5. Defendant New Hanover Regional Medical Center ("New Hanover") is a domestic not-for-profit corporation located in the County of New Hanover, State of North Carolina, and was at all times pertinent hereto engaged in the business of providing medical services and products to the general public, including Plaintiff, and to the North Carolina medical community, including Plaintiff's surgeon. At all times pertinent hereto, New Hanover was acting through its servants and employees who were acting in the scope and course of their employment and agency.

JURISDICTION AND VENUE

7. Jurisdiction is proper in this Court pursuant to Article 6A, Section 1-75.4 of the North Carolina General Statutes because Plaintiff's causes of action accrued in the State of North Carolina and all Defendants herein transacted and continue to transact business in the State of North Carolina by purveying medical products which injured Plaintiff Perlene Herring and contributed to the accrual of Plaintiff's causes of action herein.

8. Venue is proper in this Court because Defendant New Hanover maintains an office for the transaction of business in New Hanover County, JJHCS maintains an agent for services of process in New Hanover County and, furthermore, because Plaintiff's causes of action accrued in New Hanover County, State of North Carolina.

GENERAL ALLEGATIONS COMMON TO ALL COUNTS

9. Plaintiff Perlene Herring was admitted to New Hanover Regional Medical Center on January 22, 2002 for an exploratory laparotomy, a total abdominal hysterectomy, and a bilateral salpingo-oophorectomy.

10. The aforesaid procedure was performed by John L. Powell, M.D., who followed and attended to the care of Perlene Herring at all times thereafter and during the entire post-operative medical period set forth in this Complaint. During the operative procedure described above, Dr. Powell performed fascial closure on Plaintiff's operative site in layers using size #1 Panacryl sutures for the peritoneum and fascia.

11. Almost immediately thereafter, Plaintiff began experiencing problems. On January 28, 2002, Plaintiff reported to Dr. Powell drainage from her wound and a low grade fever. Dr. Powell started Plaintiff on daily dosages of Keflex 500mg and Premarin 0.625mg.

12. On February 1, 2002, Plaintiff reported that her incision was itching. However, Dr. Powell noted that her incision appeared to be healing well with only a minimal amount of dehiscence. Dr. Powell instructed Plaintiff on local wound care and prescribed Darvocet for pain relief.

13. On February 27, 2002, Dr. Powell noted a small amount of purulent drainage from Plaintiff's incision. Dr. Powell applied pressure to evacuate pus in this area and noted that Plaintiff was suffering from a vaginal infection. Dr. Powell prescribed MetroGel for Plaintiff to apply nightly for two weeks.

14. On March 22, 2002, Dr. Powell noted that Plaintiff's wound was continuing to drain. Dr. Powell cleaned this area with hydrogen peroxide and advised Plaintiff not to return to work until after April 1, 2002.

15. On April 24, 2002, Dr. Powell noted that Plaintiff's abdominal incision appeared to be well healed and that her vaginal cuff also appeared to be well healed.

16. On September 20, 2002, Dr. Powell noted that Plaintiff was suffering and had been suffering from a draining sinus at her umbilicus since surgery. Dr. Powell probed

Plaintiff's sinus tract with a hemostat but was unable to locate any suture material. Dr. Powell further treated Plaintiff's wound with Bacitracin ointment and instructed Plaintiff to cleanse her wound daily with hydrogen peroxide and to apply an antibiotic ointment. Dr. Powell further noted that a silver nitrate cautery had been attempted on three occasions by Dr. Joseph Cooper, M.D., but that this procedure had failed to clear up the drainage from Plaintiff's sinus tract.

17. On September 30, 2002, Dr. Powell again noted that Plaintiff had developed a chronic draining sinus tract from her abdominal incision following her surgery on January 22, 2002. Dr. Powell recommended that Plaintiff be considered disabled from and after January 22, 2002 and noted that it was questionable whether Plaintiff would be able to go off disability in the future.

18. On October 29, 2002, Dr. Powell excised Plaintiff's sinus tract, infected skin, and subcutaneous tissue and removed Panacryl sutures from Plaintiff's abdomen. Plaintiff's wound was cauterized with Monsels solution and Plaintiff was further instructed in local wound care.

19. On November 13, 2002, Dr. Powell noted that Plaintiff was experiencing continuing drainage from her umbilicus, but that her wound appeared to be gradually closing. Dr. Powell removed another Panacryl subcutaneous suture that had broken through Plaintiff's skin.

20. On December 2, 2002, Dr. Powell noted that Plaintiff had suffered from a draining sinus that was excised on October 29, 2002, but that her wound appeared to be almost completely healed. Dr. Powell further noted punctuation of granulation tissue which he cauterized with silver nitrate.

21. On March 3, 2003, Dr. Powell noted that Plaintiff had again developed a draining sinus related to Panacryl sutures. Dr. Powell further noted that since removal of her Panacryl

sutures in November, 2002, Plaintiff had experienced gradually diminishing drainage from her umbilicus and that there appeared to be no visible granulation tissue. Plaintiff was advised to do follow up with Dr. Cooper.

22. On September 12, 2003, Dr. Powell conducted another local excision of Plaintiff's wound and cauterized the wound with Monsels solution.

23. On October 13, 2003, Dr. Powell again noted that Plaintiff had developed granulation tissue in her umbilicus, notwithstanding the removal of Panacryl suture material from her draining sinus tract. Dr. Powell cauterized Plaintiff's wound with silver nitrate.

24. On November 17, 2003, Dr. Powell noted that Plaintiff had been suffering from a draining sinus tract since her surgery in January, 2002 and noted that notwithstanding his excisions that Plaintiff had suffered from persistent drainage and had redeveloped granulation tissue at the umbilicus. Dr. Powell scheduled Plaintiff for additional surgery.

25. On December 2, 2003, Dr. Powell operated on Plaintiff, who was placed under a general endotracheal anesthesia, for excision of an infected sinus tract. Dr. Powell removed an eight inch long infected sinus tract involving the skin, subcutaneous tissues and fascia and noted granulation tissue and infected tissues extending along Plaintiff's entire previous incision. Further, Dr. Powell removed old retained Panacryl sutures still in place and a large amount of granulation tissue around the sinus tract. According to the histology report, Dr. Powell removed suture granulomas from Plaintiff's sinus tract including multiple fragments of tan pink soft tissue with marked hemorrhage, fibrosis and necrosis.

26. On January 19, 2004, Dr. Powell wrote to Judge Alexander Hild, Charleston Office of Hearings, North Charleston, South Carolina, stating that Plaintiff's post-operative course had been complicated by depression and the development of a draining sinus with

infected skin and subcutaneous tissues throughout her abdominal wound, which had been unresponsive to topical treatment. Dr. Powell further stated that Panacryl sutures, which he had utilized in January, 2002, had contributed to the wound infection and sinus tract. Dr. Powell noted that during the entire time preceding Plaintiff's final surgery for removal of Panacryl sutures in December, 2003, that Plaintiff had suffered from continuous drainage from the sinus tract in her abdominal wound. Finally, Dr. Powell stated that: "all of the surgeries and post-operative complications caused the patient to be disabled."

27. On March 12, 2004, Dr. Powell noted that Plaintiff's post-operative course had been complicated by a draining sinus secondary to Panacryl suture material. Dr. Powell noted that Plaintiff had undergone several operative procedures to remove all of the infected skin, subcutaneous tissue, and Panacryl sutures. Finally, Dr. Powell noted that Plaintiff's abdominal incision finally appeared to be completely healed and that her vaginal cuff also appeared to be well healed.

28. The offending Panacryl sutures were provided to Dr. Powell by Defendants J&J, JJHCS, and Ethicon and were distributed by Defendant New Hanover.

29. Defendants J&J, JJHCS and Ethicon initially launched Panacryl sutures (including size #1) on the American market in October, 1999, having purportedly conducted adequate testing to insure that said product was safe as a generally used suture within the human body.

30. These Defendants received authorization from the United States Food and Drug Administration ("FDA") on February 13, 1998, to market Panacryl Absorbable Poly Surgical Suture, Undyed, under the 510(k) registration number K974299.

31. The original product warnings, as contained on the product insert for Panacryl sutures, contained language under the sub-section entitled "Adverse Reactions," a portion of which reads as follows:

> **ADVERSE REACTIONS**: Adverse effects associated with the use of Panacryl suture include wound dehiscence, infection, minimal acute inflammatory tissue reaction, suture extrusion and delayed absorption with poor blood supply . . . (emphasis added)

At the time that said warnings were formulated and published, upon information and belief, Defendants J&J, JJHCS, and Ethicon had not completed or finalized various tissue reaction studies that were being performed on animals at their testing facilities. Further, upon information and belief, no human studies were performed prior to the product launch of the Panacryl sutures in relation to the use of said product in abdominal fascia closure.

32. Following the introduction of Panacryl sutures, product complaints began to emerge almost immediately involving risks of "inflammation/suture spitting (substantive tissue reaction)" or "post-operative infection." These complaints from the general American medical community alerted Defendants J&J, JJHCS, and Ethicon to the impending severity of the problems they would encounter with Panacryl sutures. These Defendants took no remedial actions regarding the design, marketing or warnings for Panacryl sutures based on these complaints.

33. By 2001, the volume of sales of Panacryl sutures had increased significantly, as had the cumulative product complaints. Notwithstanding the increased number of complaints concerning Panacryl sutures from healthcare providers, J&J, JJHCS, and Ethicon did not reposition Panacryl sutures in the medical products market, did not issue any information to the medical community to discuss the various problems with Panacryl sutures, did not educate or

retrain their sales force with regard to Panacryl products, and did not modify the warning section of the package insert included with all Panacryl suture products.

34. One of the product complaints was made by Plaintiff's surgeon, Dr. John L. Powell, M.D., who wrote a letter to the president of Defendant J&J describing the problems that he had experienced with Panacryl sutures, including a list of approximately twelve patients who had experienced suture spitting, suture granulation, and infected tissue following wound closures utilizing Panacryl sutures. These Defendants responded to Dr. Powell's letter stating that they could not investigate his complaint without additional information. At the time of their response, these Defendants were already well aware of the problems caused by Panacryl sutures, but deliberately withheld this information from Dr. Powell and his patients.

35. During 2000, 2001 and 2002, the FDA received numerous complaints about Panacryl sutures from surgeons and healthcare providers noting that the sutures were creating substantive tissue reaction risks, including suture granulomas, post-operative infections, suture spitting, sinus tract drainage, and related problems.

36. Not withstanding these complaints, Defendants, J&J, JJHCS, and Ethicon did nothing to either correct the problems caused by Panacryl sutures or to warn surgeons and patients of the risks, particularly in abdominal fascia closure, that were now obvious to these Defendants. Specifically, these Defendants failed to reposition Panacryl sutures in the marketplace, failed to produce or distribute any literature to the American medical field and to their own sales representatives to warn of the risks from using Panacryl sutures, failed to alter or supplement written warnings in the package inserts, boxes, or labeling for Panacryl sutures, failed to retrain their own sales force on the risks of Panacryl sutures, failed to institute any programs to enhance surgeon or customer education on the risks of Panacryl sutures, failed to

alert the American healthcare community that Panacryl was not an all purpose, general closure suture, as its sales literature had previously stated, and generally failed to react to the increasing number of complaints to the FDA and to these Defendants concerning the problems with Panacryl sutures.

37. During this period of corporate paralysis, in January, 2002, Plaintiff Perlene Herring would be operated upon by Dr. Powell using Panacryl sutures with neither surgeon nor patient having any knowledge of the known risks of using Panacryl sutures. Plaintiff's post-operative complications and sequelae, as set forth herein above, would begin to develop during this period of inaction by Defendants J&J, JJHCS and Ethicon, as would the frustration of Dr. Powell about the underlying cause of these complications in Plaintiff Perlene Herring and other patients.

38. Effective July 1, 2002, J&J, JJHCS, and Ethicon instituted a world wide withdrawal of Panacryl sutures under false pretenses by claiming that the product had suffered only from financial difficulties. Upon information and belief, the use of such a financial rationalization was, in fact, fraudulently offered by these Defendants to circumvent FDA scrutiny and to avoid litigation involving the use of Panacryl sutures.

39. Defendants J&J, JJHCS, and Ethicon were aware throughout 2001 and 2002, through and including July 1, 2002, the effective date of the withdrawal of Panacryl sutures, that these sutures were causing widespread post-operative wound infections in patients, particularly where the sutures were used for abdominal wound closures. These Defendants deliberately, knowingly, and fraudulently failed to advise the American medical community of these problems in an effort to conceal these defects from the American public in a calculated effort to avoid FDA scrutiny and to limit their exposure to litigation for damages caused by Panacryl sutures by

making it literally impossible for patients or their surgeons to learn the true facts about these sutures.

40. At the time of the product withdrawal, Plaintiff Perlene Herring had developed severe post-operative infection and granuloma and was being treated for these conditions by Dr. Powell and Dr. Cooper and by home care performed by herself and her friends and family. Neither she nor her surgeon had ever been warned of the multiplicity of Panacryl problems and complaints that led J&J, JJHCS, and Ethicon to discontinue worldwide distribution of this product, nor had either been warned of the serious health risks caused by Panacryl and from which Perlene Herring was suffering at that time.

41. In a disingenuous attempt to conceal the Panacryl problems, and further frustrate healthcare providers, J&J, JJHCS, and Ethicon blamed the product discontinuance on low sales and surgeon product preference. Such efforts were intended to avoid the appearance of the self-imposed recall of the Panacryl sutures at issue. Effective July 1, 2002, Ethicon abandoned its advertising and marketing of Panacryl as a general soft-tissue closure suture appropriate for abdominal fascia closure.

42. Plaintiff Perlene Herring underwent the aforesaid surgical procedures in which Panacryl was inserted in her body in January, 2002. At said time, J&J, JJHCS, and Ethicon knew of the aforesaid defects of Panacryl products, but failed to warn Plaintiff and her surgeon of what had now become apparent and dangerous risks associated with Panacryl sutures when used in precisely the surgical procedures that Plaintiff Perlene Herring underwent.

43. Plaintiff and her surgeon, as well as thousands of patients and their surgeons worldwide, were never informed or warned of the identified risks of using Panacryl sutures.

44. As a direct and proximate result of Defendants J&J, JJHCS, and Ethicon's acts, omissions and/or concealment, the offending Panacryl sutures have had and will continue to have an injurious effect on Plaintiff's health and general well-being. In particular, as a direct and proximate result of these Defendants' conduct, Plaintiff has been injured or damaged in one or more of the following respects:

a. By enduring serious adverse tissue reaction in her abdominal area, Plaintiff has undergone numerous unnecessary surgeries and/or procedures to arrest the resultant infection and granuloma;

b. By causing pain, suffering, and disfigurement of Plaintiff in the site of her operative incisions;

c. By causing Plaintiff to suffer severe pain and suffering and emotional distress as a result of the continuous adverse tissue reaction of the Panacryl sutures and the numerous, repetitive, and unnecessary procedures she was forced to undergo;

d. By causing Plaintiff, by herself and through the help of friends and family, to endure almost two years of debilitating and degrading self-administered homecare in an effort to arrest the infection, tissue reaction and other complications caused by use of Panacryl sutures that continued to have a toxic effect on her bodily tissues.

e. By causing Plaintiff to become depressed, disabled, and unable to work to support herself and her family.

45. All of the aforesaid conditions exhibited by Plaintiff Perlene Herring directly mirror common symptoms about which Defendants J&J, JJHCS, and Ethicon received a torrent of Panacryl complaints for more than two (2) years including:

- Pain in varying degrees to the patient;
- Recurrent or prolonged treatment with re-intervention to remove suture material and re-close the wound;
- Risks related to deep wound infection; and

- Need to remove un-absorbed fascia closure sutures.

46. Plaintiff has been further damaged by incurring medical expenses and will continue to incur future medical expenses for her treatment and care, in addition to incurring severe pain, suffering and disfigurement in the future.

47. Defendants' entire course of conduct in failing to warn Plaintiff and her surgeon of the dangers known to Defendants regarding the use of Panacryl sutures in abdominal surgery showed a complete indifference to or conscious disregard for the health and safety of Plaintiff Perlene Herring and all other patients similarly situated in the period October, 1999 through March, 2006. Such behavior by Defendants, as manufacturers and distributors of healthcare products that have the potential to cause serious and devastating injuries, justifies and demands an award of punitive damages in such sum as will serve to punish Defendants and deter them and others from such callous conduct.

48. On March 28, 2006, Defendants J&J, JJHCS and Ethicon issued a general recall of Panacryl sutures. The reason given for the recall was: "The unique absorption profile of Panacryl in the suture could act as a foreign body so that surgeons should consider its use in specific situations." Thus, for the first time since the introduction of Panacryl as a general soft-tissue closure suture appropriate for abdominal fascia closure, and almost four years after withdrawing this product from the market, these Defendants publicly admitted to the FDA and to the American medical community that Panacryl sutures created the risk of post-operative complications such as those suffered by Plaintiff Perlene Herring.

COUNT I

(Strict Product Liability – Failure to Warn)

Comes now Plaintiff Perlene Herring and for Count I of her Original Class Action Complaint against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc. and Ethicon, Inc., states:

49. Plaintiff re-alleges and incorporates herein the allegations contained in Paragraphs 1 through 48 as if said paragraphs were fully set forth in this Count.

50. Defendants J&J, JJHCS and Ethicon sold Panacryl sutures in the course of their busiess as manufacturers and distributors of healthcare products.

51. At the time of the sale of these sutures to New Hanover Regional Medical Center, and for subsequent use by Dr. Powell in the aforesaid surgery upon Plaintiff Perlene Herring, Panacryl sutures were unreasonably dangerous when put to a reasonably anticipated use without the user having knowledge of its characteristics. The use of Panacryl sutures for abdominal fascia closure on Plaintiff Perlene Herring was a reasonably anticipated use of the product and, at the time of said use, Dr. Powell had no knowledge whatsoever that said sutures could cause a significant risk of substantive tissue reaction and post-operative infection when used for such procedures.

52. Defendants J&J, JJHCS and Ethicon did not provide an adequate warning of the risks of substantive tissue reaction and post-operative infection to Plaintiff Perlene Herring or Dr. Powell when they knew clearly that such risks existed. In fact, these Defendants failed to provide said warning at a time when they had not only realized these risks, but had failed to remediate such risks.

53. Panacryl sutures were used by Dr. Powell in the surgeries upon Plaintiff Perlene Herring in a manner reasonably anticipated and even encouraged by Defendants J&J, JJHCS and Ethicon, through their own published literature and advertising.

54. Plaintiff Perlene Herring was damaged as a direct and proximate result of the use of Panacryl sutures being sold by J&J, JJHCS, and Ethicon without an adequate warning.

55. Defendants' entire course of conduct in failing to warn Plaintiff and her surgeon of the dangers known to Defendants regarding the use of Panacryl sutures in abdominal surgery showed a complete indifference to or conscious disregard for the health and safety of Plaintiff Perlene Herring and all other patients similarly situated in the period between Octoober, 1999 and March, 2006. Such behavior by these Defendants, as manufacturers and distributors of healthcare products that have the potential to cause serious and devastating injuries, justifies and demands an award of punitive damages in such sum as will serve to punish these Defendants and deter them and other from such callous conduct.

WHEREFORE, Plaintiff Perlene Herring prays for judgment against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc., and Ethicon, Inc., jointly and severally for herself and all persons similarly situated:

A) For actual damages in excess of $10,000.00;

B) For a fair and just amount of punitive damages;

C) For pre-judgment interest;

D) For her costs herein incurred; and

E) For such other and further relief which may in the premises be just and proper.

COUNT II

(Products Liability – Negligent Failure to Warn)

Comes now Plaintiff Perlene Herring and for Count II of her Original Class Action Complaint against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc. and Ethicon, Inc., states:

56. Plaintiff re-alleges and incorporates herein the allegations contained in Paragraphs 1 through 55 as if said paragraphs were fully set forth in this Count.

57. Defendants J&J, JJHCS, and Ethicon designed, manufactured and marketed the Panacryl sutures described herein.

58. Panacryl sutures, when used for abdominal fascia closure, created hazards and health risks to patients, as documented by the complaints received by said Defendants regarding this product. These risks were clearly known to these Defendants and a duty to warn Plaintiff and her surgeon of said risks was thereby created.

59. The duty of Defendants J&J, JJHCS, and Ethicon to warn users of Panacryl about said hazards and health care risks arose from their own ongoing analysis of the complaints received about Panacryl sutures and their own inexplicable failure to initiate any such warnings.

60. Defendants J&J, JJHCS, and Ethicon failed to use ordinary care to adequately warn Plaintiff Perlene Herring and her surgeon and all other similarly situated patients and surgeons of the risk of harm from the hazards and healthcare risks of Panacryl sutures of which they had clear and absolute knowledge, and thereby breached their duty to warn of said risks.

61. As a direct and proximate result of the failure of Defendants J&J, JJHCS, and Ethicon to warn Plaintiff and her surgeon of said hazards and health care risks of Panacryl sutures, Plaintiff Perlene Herring sustained damages as set forth herein above.

62. Defendant J&J, JJHCS, and Ethicon's entire course of conduct in failing to warn Plaintiff and her surgeon of the dangers known to Defendants regarding the use of Panacryl sutures in abdominal surgery showed a complete indifference to or conscious disregard for the health and safety of Plaintiff Perlene Herring and all other patients similarly situated in the period between October, 1999 and March, 2006. Such behavior by these Defendants, as

manufacturers and distributors of healthcare products that have the potential to cause serious and devastating injuries, justifies and demands an award of punitive damages in such sum as will serve to punish Defendants and deter them and others from such callous conduct.

WHEREFORE, Plaintiff Perlene Herring prays for judgment against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc., and Ethicon, Inc., jointly and severally for herself and all persons similarly situated:

A) For actual damages in excess of $10,000.00;

B) For a fair and just amount of punitive damages;

C) For pre-judgment interest;

D) For her costs herein incurred; and

E) For such other and further relief which may in the premises be just and proper.

COUNT III

(Negligent Supply of Dangerous Instrumentality)

Comes now Plaintiff Perlene Herring and for Count III of her Original Class Action Complaint against Defendant New Hanover Regional Medical Center, states:

63. Plaintiff re-alleges and incorporates herein the allegations contained in Paragraphs 1 through 62 as if said paragraphs were fully set forth in this Count.

64. Defendant New Hanover purchased Panacryl sutures from Defendants J&J, JJHCS, and/or Ethicon for sale of these products to surgeons and their patients.

65. At the time of the sale of the Panacryl sutures for use by Dr. Powell in the aforesaid surgery upon Plaintiff Perlene Herring, Panacryl sutures were unreasonably dangerous when put to a reasonably anticipated use without the user having knowledge of its characteristics. The use of Panacryl sutures for abdominal fascia closure on Plaintiff Perlene

Herring was a reasonably anticipated use of the product and, at the time of said use, Dr. Powell had no knowledge whatsoever that said sutures could cause a significant risk of substantive tissue reaction and post-operative infection when used for such procedures.

66. As distributors of Panacryl sutures, Defendant New Hanover became aware of, or should have become aware of, customer and patient complaints similar to those received by the FDA and Defendants J&J, JJHCS, and Ethicon. New Hanover had a duty to investigate said complaints, especially those regarding adverse tissue reaction in abdominal closure procedures, to confront Defendants J&J, JJHCS and Ethicon about said complaints, and to independently warn healthcare providers and patients, including Plaintiff Perlene Herring and her surgeon, Dr. Powell, of the hazards and health risks of which it had become aware, or should have become aware, regarding Panacryl sutures.

67. Defendant New Hanover failed to exercise ordinary care to investigate and adequately warn Plaintiff Perlene Herring and her surgeon of the hazards and health care risks of Panacryl sutures and were thereby negligent in supplying these products for use by Dr. Powell I Plaintiff's surgery.

68. As a direct and proximate result of such failure to investigate and warn Plaintiff or her surgeon of said hazards and health care risks of Panacryl, Plaintiff sustained damages as set forth herein.

WHEREFORE, Plaintiff Perlene Herring prays for judgment against Defendant New Hanover Medical Center for herself and all persons similarly situated:

A) For actual damages in excess of $10,000.00;

B) For a fair and just amount of punitive damages;

C) For pre-judgment interest;

D) For her costs herein incurred; and

E) For such other and further relief which may in the premises be just and proper.

COUNT IV

(Fraudulent Concealment)

Comes now Plaintiff Perlene Herring and for Count IV of her Original Class Action Complaint against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc. and Ethicon, Inc., states:

69. Plaintiff re-alleges and incorporates herein the allegations contained in Paragraphs 1 through 68 as if said paragraphs were fully set forth in this Count.

70. Defendants J&J, JJHCS, and Ethicon designed, manufactured and marketed the Panacryl sutures described herein.

71. Notwithstanding the numerous complaints received by the FDA and Defendants J&J, JJHCS and Ethicon concerning the problems associated with the use of Panacryl sutures in abdominal surgery and the dangers known to these Defendants that Panacryl sutures were causing post-operative wound infections, suture granulomas, sinus tract infection and draining, and related problems, these Defendants deliberately and fraudulently concealed this information from Plaintiff Perlene Herring, her surgeon Dr. John Powell, M.D., and the general American medical community.

72. Defendants J&J, JJHCS and Ethicon deliberately concealed material facts concerning the propensity of Panacryl sutures to cause the aforesaid post-operative problems when used by surgeons, such as Dr. Powell, on patients such as Plaintiff Perlene Herring, in the manner and in the surgical procedures recommended by these Defendants.

73. Specifically, these Defendants concealed the large volume of complaints about Panacryl sutures received by the FDA and by such Defendants describing with particularity post-operative wound complications involving sinus tract drainage, wound dehiscence, suture spitting, suture granulomas, the development of necrotic tissue, and other related post-operative complications, all of which problems with Panacryl sutures were known to these Defendants.

74. Defendants J&J, JJHCS and Ethicon further withheld these material facts to Plaintiff's surgeon, Dr. John Powell, M.D., who wrote to the president of Defendant J&J describing in detail the problems he was experiencing with the use of Panacryl sutures and seeking information from this Defendant about his continued use of Panacryl sutures. All of Defendants J&J, JJHCS, and Ethicon's behavior in concealing these material facts were reasonably calculated to deceive surgeons such as Dr. Powell, and patients such as Perlene Herring, and the concealment of these material facts were made with the intent to deceive such surgeons and their patients.

75. Defendants J&J, JJHCS and Ethicon's concealment of the aforesaid material facts concerning these problems with Panacryl sutures in fact deceived Plaintiff's surgeon and Plaintiff Perlene Herring and resulted in damages to Plaintiff as set forth hereinabove.

76. Defendants J&J, JJHCS and Ethicon's behavior in concealing those facts was designed and calculated to deceive the FDA and the general American medical community and to limit its exposure to litigation for damages resulting from the use of Panacryl sutures.

77. Defendants J&J, JJHCS and Ethicon's entire course of conduct in concealing material facts from Plaintiff and her surgeon of the dangers known to these Defendants regarding the use of Panacryl sutures showed a complete indifference or conscious disregard for the health and safety of Plaintiff Perlene Herring and all other potential patients similarly situated in the

period between October, 1999 through March, 2006. Such behavior by these Defendants, as manufacturers and distributors of healthcare products, has the potential to cause serious and devastating injuries, and justifies and demands an award of punitive damages in such sum as will serve to punish these Defendants and deter them and others from such callous conduct.

WHEREFORE, Plaintiff Perlene Herring prays for judgment against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc., and Ethicon, Inc., jointly and severally for herself and all persons similarly situated:

A) For actual damages in excess of $10,000.00;

B) For a fair and just amount of punitive damages;

C) For pre-judgment interest;

D) For her costs herein incurred; and

E) For such other and further relief which may in the premises be just and proper.

COUNT V
(Class Action Allegations)

Comes now Plaintiff Perlene Herring and for Count V of her Original Class Action Complaint against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc. and Ethicon, Inc., states:

78. Plaintiff re-alleges and incorporates herein the allegations contained in Paragraphs 1 through 77 as if said paragraphs were fully set forth in this Count.

79. This action is brought by Plaintiff Perlene Herring on behalf of a class of persons upon whom surgeries were performed throughout the State of North Carolina in which Panacryl sutures were used which thereafter caused post-operative complications including sinus tract

drainage, wound dehiscence, infections, suture granulomas, infected and necrotic tissue, and other such problems as set forth hereinabove. The class is specifically defined as follows:

> All persons currently or formerly resident in the State of North Carolina who underwent one or more surgical procedures in which Panacryl sutures were used during the period November 1, 1999 through March 28, 2006, and who thereafter experienced wound dehescience, granulated tissue, infection, sinus tract infection and/or suture spitting resulting in one or more additional surgical procedures to remove the Panacryl sutures.

Plaintiff believes that the class as defined above includes, at a minimum, hundreds of affected patients.

80. Plaintiff Perlene Herring is a member of the class she purports to represent and has interests typical and/or identical to the other members of the class.

81. The named Plaintiff Perlene Herring is an adequate representative of the class because she was treated in the same manner as other class members by Defendants and has been damaged by this treatment in the same manner as other class members.

82. There are questions of law and fact applicable to the entire class including without limitation:

a. Whether Defendants J&J, JJHCS and Ethicon are strictly liable for failure to warn class members and their surgeons of the known dangers of Panacryl sutures;

b. Whether Defendants J&J, JJHCS and Ethicon are liable for negligently failing to warn class members and their surgeons of the known dangers of Panacryl sutures;

c. Whether Defendants J&J, JJHCS and Ethicon fraudulently concealed material facts from class members and their surgeons, which concealment was reasonably calculated to deceive and was made with the intent to deceive and, in fact, deceived class members and their surgeons resulting in damage to the injured class members;

d. Whether Defendants J&J, JJHCS and Ethicon were negligent in designing, manufacturing and distributing Panacryl sutures;

e. Whether Defendants J&J, JJHCS and Ethicon knowingly or intentionally misrepresented to the FDA that Panacryl sutures were safe for use in abdominal or soft tissue surgeries;

f. Whether Panacryl sutures were unreasonably dangerous when used as directed;

g. Whether Defendants J&J, JJHCS and Ethicon breached the applicable standard of care by failing to implement a recall sooner than March 28, 2006;

h. Whether the conduct of Defendants J&J, JJHCS and Ethicon satisfies the applicable legal standard for imposition of punitive damages;

i. Whether Defendant New Hanover was negligent in distributing and selling Panacryl sutures when they knew or should have known of the propensity of such sutures to cause infections and related complications.

83. These and other questions of law and fact are central to this case and common to all members of the class and predominate over any questions affecting only individual members of the class.

84. The claims of Plaintiff Perlene Herring are identical to the claims of other members of the class. Such Plaintiff shares the same interests as other members of the class in this action because Plaintiff and all class members have been damaged by the use of Panacryl sutures in their surgeries. Further, Plaintiff and all class members have been further damaged by Defendants J&J, JJHCS and Ethicon's fraudulent concealment of material facts concerning the problems associated with Panacryl sutures. Given the significance of Plaintiff Perlene Herring's losses, she has the incentive and is committed to vigorously prosecuting this claim. Plaintiff Perlene Herring has retained competent counsel who are specifically experienced in class action and products liability litigation to represent her and the proposed class.

85. A class action is the only realistic method available for the fair and efficient adjudication of this controversy. The expense and burden of individual litigation makes it

impracticable for members of the class to seek redress individually for the wrongful conduct alleged herein. Were each individual member required to bring a separate lawsuit, the resulting multiplicity of proceedings would cause undue hardship and expense for the litigants and the Court and create the risk of inconsistent rulings which would be contrary to the interests of justice and equity.

86. Class certification is appropriate pursuant to North Carolina Civil Procedure Rule 23 because the prosecution of separate actions would create the risk of:

a. Inconsistent or varying adjudication with respect to individual members of the class that would establish incompatible standards of conduct for the Defendant;

b. Adjudications with respect to individual members of the class which may, as a practical matter, be dispositive of the interests of other members not parties to the adjudication or which may substantially impair or impede their ability to protect their interests; and

c. The persons constituting the class are so numerous as to make it impracticable to bring them all before the Court.

87. Class certification is also appropriate under North Carolina Civil Procedure Rule 23 because common issues of law and fact relative to all Defendants' conduct predominate over individual issues.

88. A class action is superior to individual litigation because hundreds of such lawsuits would magnify the delay and expense for the parties and the courts. By contrast, the class action device presents far fewer management difficulties and provides the benefits of unitary adjudication and comprehensive supervision in a single court of law.

WHEREFORE, Plaintiff Perlene Herring, on behalf of herself and other class members, requests that judgment be entered against Defendants Johnson & Johnson, Johnson & Johnson Health Care Systems, Inc., and Ethicon, Inc., for the following:

A) Certification of the proposed class;

B) For actual damages in excess of $10,000;

C) For a fair and just amount of punitive damages;

D) For pre-judgment interest;

E) For her costs herein incurred; and

F) For such other and further relief which may in the premises be just and proper.

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