UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

RICHARD K. MCINTIRE, Individually and as the Administrator of the Estate of SANDRA MCINTIRE	:	
Plaintiff,	:	**CIVIL ACTION NO.**
VS.	:	
	:	**JURY TRIAL DEMANDED**
BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION	:	
Defendants.	:	

COMPLAINT

COME NOW Plaintiff, RICHARD K. MCINTIRE, Individually and as the Administrator of the Estate of SANDRA MCINTIRE, deceased, by and through his undersigned attorneys, and, for his complaint against the Defendants, BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION ("Defendants"), alleges as follows:

I. INTRODUCTION

1. This is a wrongful death and survival action to recover damages for the personal injuries and wrongful death suffered by SANDRA MCINTIRE, deceased, which were the direct and proximate result of the wrongful conduct of BAXTER INTERNATIONAL INC. and BAXTER HEALTHCARE CORPORATION, in connection with the research, testing, design, development, manufacture, production, inspection, labeling, advertisement, marketing,

promotion, sale, and distribution of the Baxter MiniCap with Povidone-Iodine Solution product ("MiniCap").

II. PARTIES

2. Plaintiff RICHARD K. MCINTIRE ("Plaintiff") is and at all relevant times was a citizen of the State of Ohio and resides in Ostrander, Delaware County, Ohio. Kenneth L. McIntire, Richard B. McIntire, and Michael K. McIntire are the adult children of Richard and Sandra McIntire.

3. Plaintiff was appointed Administrator of the Estate of Sandra McIntire, deceased, in Delaware County, Ohio Probate No. 1505-0534-PES on May 18, 2015 [a copy of the Entry Appointing Fiduciary; Letters of Authority is attached hereto as "Exhibit A"].

4. Decedent SANDRA MCINTIRE ("Decedent") was at all relevant times a citizen of the State of Ohio and resided in Ostrander, Delaware County, Ohio.

5. At all relevant times herein mentioned, Plaintiff RICHARD K. MCINTIRE was the husband of SANDRA MCINTIRE, who died on January 18, 2015.

6. Plaintiff RICHARD K. MCINTIRE brings this wrongful death and survival action as personal representative for the Estate of Sandra McIntire, and for the surviving spouse, children and other next-of-kin of the Decedent, for the personal injuries and resulting wrongful death of Decedent as a result of her use of the MiniCap peritoneal dialysis accessory that Defendants manufactured, designed, marketed, supplied, labeled, distributed, sold and/or promoted.

7. Defendant BAXTER INTERNATIONAL, INC. is, and at all times relevant to this Complaint was, a Delaware corporation with its principal place of business at One Baxter Parkway, Deerfield, IL 60015. Defendant BAXTER INTERNATIONAL, INC. is and was at all

times relevant herein doing business in and/or having directed its activities at the state of Ohio, and specifically this judicial district.

8. At all relevant times to this Complaint, BAXTER INTERNATIONAL, INC, designed, manufactured, tested, marketed, distributed and sold the Baxter MiniCap with Povidone-Iodine Solution product, either directly or indirectly, to customers throughout the United States, including the Plaintiff and Decedent, in the County of Delaware, State of Ohio.

9. Defendant BAXTER HEALTHCARE CORPORATION is, and at all times relevant to this Complaint was, a Delaware Corporation with its principal place of business at One Baxter Parkway, Deerfield, IL 60015. Defendant BAXTER HEALTHCARE CORPORATION operates as a subsidiary of BAXTER INTERNATIONAL INC. Defendant BAXTER HEALTHCARE CORPORATION is and was at all times relevant herein doing business in and/or having directed its activities at the state of Ohio, and specifically this judicial district.

10. At all relevant times to this Complaint, BAXTER HEALTHCARE CORPORATION, designed, manufactured, tested, marketed, distributed and sold the Baxter MiniCap with Povidone-Iodine Solution product, either directly or indirectly, to customers throughout the United States, including the Plaintiff and Decedent, in the County of Delaware, State of Ohio.

III. JURISDICTION AND VENUE

11. This Court has diversity jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and no Defendant is a citizen of the same state as Plaintiff.

12. At all times relevant to this action, the Defendants have been engaged either directly or indirectly in the business of marketing and selling kidney dialysis products, including

the MiniCap product, within the State of Ohio, with a reasonable expectation that the product would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

13. Venue is proper in this Court under 28 U.S.C. § 1391(c) as a substantial part of the events giving rise to Plaintiff's claim occurred in this judicial district. In addition, both of the Defendants regularly conduct business in this district.

IV. FACTUAL ALLEGATIONS

A. The Baxter MiniCap

14. Plaintiff alleges on information and belief against BAXTER INTERNATIONAL, INC. and BAXTER HEALTHCARE CORPORATION ("Defendants"), the following:

15. Defendants manufactured the Baxter MiniCap with Povidone-Iodine Solution product ("MiniCap"). The MiniCap was approved via the Food and Drug Administration's ("FDA") 510(k) premarket approval process on January 29, 1990.

16. The MiniCap was designed, developed, and sold for use as an accessory during peritoneal dialysis, a process which removes toxins and waste products from the bodies of people with kidney disease.

17. The MiniCap is a plastic cap containing a povidone-iodine soaked sponge, designed to isolate the connector of the solution transfer set used during peritoneal dialysis. The povidone-iodine sponge is used to disinfect the mating interface between the MiniCap and the solution transfer set. During peritoneal dialysis, blood vessels in the abdominal lining, or peritoneum, substitute for the kidneys with the help of a fluid, or dialysate, that flows into and out of the peritoneal space.

18. On information and belief, Plaintiff alleges that Defendants were and are aware that the use of their defectively manufactured MiniCap may result in peritonitis, an inflammation of the membrane lining the abdominal wall and covering the abdominal organs. Peritonitis is caused by an infection from bacteria or fungi. Peritonitis can rapidly spread into the blood (sepsis), and to other organs and can lead to a severe life-threatening infection throughout the entire body, as well as death.

B. <u>The Baxter MiniCap Recall</u>

19. On January 6, 2015, Defendants sent healthcare providers an "Important Product Information" letter warning them of the hazard associated with certain defective lots of MiniCaps. [A true and correct copy of the MiniCap "Important Product Information" letter is attached hereto as Exhibit "B"].

20. The January 6, 2015 letter stated that "Baxter received complaints indicating that the sponge of the MiniCap was fully separated from the cap, partially protruding from the cap, or missing."

Sponge is fully separated from the cap	Sponge is protruding from the cap	Missing sponge
		Sponge is neither present inside the cap nor inside the pouch.

21. On or about January 27, 2015, Defendants sent Plaintiff's Decedent a letter notifying her of the voluntary Urgent Product Recall involving certain lots of the MiniCap. The recall notice stated:

> Baxter received complaints indicating that the sponge of the MiniCap was fully separated from the cap, partially protruding from the cap, or missing.
>
> Use of MiniCaps with sponges fully separated or missing from the caps may compromise the ability of the MiniCap to provide a sterile barrier protection at the end of the transfer set when the transfer set is not connected to the patient line of the automated peritoneal dialysis (APD) cassette or continuous ambulatory peritoneal dialysis (CAPD) twin bag set-ups. This may increase the risk of peritonitis.
>
> Use of the MiniCaps with sponges protruding from the caps may encourage non-aseptic techniques, such as inadvertently touching the sponge to reposition it inside the cap. This may increase the risk of peritonitis. There have been no reported adverse events associated with these lots. [A true and correct copy of the Urgent Product Recall notice is attached hereto as Exhibit "C"].

22. In total, eight lots, or 4.4 million MiniCaps were subject to the recall[1].

23. Defendants admitted in their recall letter that the use of the recalled MiniCaps can increase the risk of peritonitis.

24. Defendants in their recall letter advised Plaintiff's Decedent that she received MiniCaps from one of the recalled lots.

25. On March 13, 2015, the FDA issued a Class 2 recall of the affected lots of the MiniCap.

26. The FDA informed the public at large that the manufacturers' reason for the recall was that the MiniCap may have separated or protruding sponges.

[1] The lots of MiniCaps subject to the recall are lot numbers: GD896845, Exp. 10/2015; GD897371, Exp. 01/2016; GD896936, Exp. 10/2015; GD897124, Exp. 11/2015; GD897165, Exp. 12/2015; GD897157, Exp. 12/2015; GD896944, Exp. 11/2015; GD896837, Exp. 10/2015.

27. The FDA recall incorrectly stated that "Baxter sent an Urgent Product Recall letter dated January 22, 2015, to all affected customers." The letter sent to Decedent was dated January 27, 2015.

C. Decedent Used the Defective MiniCaps and as a Result Suffered Severe Injuries and Death

28. As a result of being diagnosed with end-stage renal disease, on or about August 2014, Decedent began at home peritoneal dialysis.

29. Plaintiff was trained on how to perform the at home dialysis and subsequently performed all dialysis procedures for Decedent.

30. On information and belief, all dialysis products were supplied by Defendants.

31. On August 14, 2014, Plaintiff and Decedent placed an order with Defendants for certain peritoneal dialysis products. [A true and correct copy of the August 14, 2014 Baxter invoice is attached hereto as Exhibit "D"].

32. One of the products purchased on August 14, 2014, was an order of MiniCaps, which contained 60 MiniCaps.

33. The August 14, 2014 Baxter invoice confirms that the MiniCaps shipped to Plaintiff and Decedent were from Lot # GD897157.

34. The MiniCap lot number on the August 14, 2014 invoice is one of the lots that was subject to Baxter's voluntary recall and the FDA's Class 2 recall.

35. Decedent used the MiniCaps from the recalled lot according to their intended and directed use as part of her at home peritoneal dialysis treatment. The MiniCaps used by Decedent were manufactured, vended, sold, retailed, and wholesaled by Defendants.

36. At all times herein mentioned, the subject MiniCaps bore Product Code: 5C4466P, and Lot # GD897157.

37. Decedent had been consistently and continuously using the defective MiniCaps from the same lot recalled by Defendants, i.e. Lot # GD897157.

38. Decedent was hospitalized various times from November 24, 2014 through her death on January 18, 2015. Decedent's condition deteriorated throughout this time period until her death.

39. On November 24, 2014, Decedent presented to Grady Memorial Hospital with complaints of nausea, vomiting, chest pain, and shortness of breath. On exam, Decedent's abdomen was described as obese, protuberant, with the peritoneal dialysis catheter site intact and no apparent tenderness.

40. On December 7, 2014, Decedent returned to Grady Memorial Hospital. Emergency room notes refer to cellulitis at the peritoneal dialysis site. Decedent was discharged with diagnoses of acute exacerbation COPD, end stage renal disease, anemia due to ESRD, hypokalemia, atrial fibrillation, uncontrolled DM, OSA, decubitus ulcer buttock, and SIRS due to infectious process without acute organ dysfunction. The infectious process was blamed on pneumonia.

41. On December 14, 2014, Decedent presented to Riverside Methodist Hospital with shortness of breath and abdominal pain localized to her peritoneal dialysis site. Decedent was hospitalized at Riverside through December 19, 2014.

42. During her December 14, 2014 hospital admission, bacterial peritonitis was suspected. The records state that the antibiotics she was given for her pneumonia would "also cover her for, if the patient would have any peritonitis from the peritoneal dialysis, given she does have the abdominal wall pain and white count." The initial impression as listed on the emergency room report included "abdominal pain/rule out bacterial peritonitis related to peritoneal dialysis."

43. On December 15, 2014, Riverside Methodist Hospital records described Decedent's peritoneal dialysis catheter site as red, pink, and crusty and the records further state that she may have an infection.

44. On December 18, 2014, Riverside Methodist Hospital records described Decedent's PD catheter as intact, moist, oozing, pink, and her catheter site as tender.

45. Decedent was discharged to home healthcare on December 19, 2014.

46. On December 26, 2014, after being transferred from Grady Memorial Hospital, Decedent presented to Riverside Methodist Hospital for further management of acute on chronic respiratory failure, sepsis, and NSTEMI. The admission records note that she was suspected as having bacterial peritonitis with her peritoneal dialysis.

47. The initial assessment found that Decedent was suffering from abdominal pain with bacterial peritonitis with her peritoneal dialysis suspected as the cause.

48. On December 27, 2014, the nephrology assessment at Riverside Methodist Hospital stated that Decedent was suffering from septic shock of unclear source with concern for peritonitis due to abdominal pain. Peritoneal dialysis fluid was sent for testing and culture but the fluid was inadequate and no confirmed diagnosis of peritonitis was made at that time.

49. On December 27, 2014, Decedent had a pulmonary/critical care consultation. The consultation assessment included that she was suffering from septic shock presumably due to peritonitis and abdominal pain with concern for peritonitis. Decedent was to continue antibiotics while the peritoneal dialysis fluid analysis was pending.

50. On December 28, 2014, it was found that the white blood cell count in Decedent's peritoneal fluid was greater than 100/microliters, which was consistent with peritonitis.

51. On January 1, 2015, Decedent's assessment included septic shock due to peritonitis. Decedent's peritonitis was being treated as culture negative peritonitis due to the lack of a positive culture of her peritoneal dialysis fluid.

52. A person that has peritonitis may still have a culture come back negative due to the use of antibiotics, which Decedent had been using since at least December 14, 2014 for her suspected bacterial pneumonia.

53. On January 5, 2015, a nephrology note confirmed that Decedent was suffering from culture negative peritonitis.

54. On January 8, 2015, Decedent was discharged with a diagnosis of peritonitis, in addition to diagnoses of acute chronic respiratory failure, chronic obstructive lung disease, end stage renal disease, acute non ST segment elevation myocardial infarction, atrial fibrillation, diabetes mellitus type 2, hypertension, obstructive sleep apnea, anemia due to ESRD, and dysphagia.

55. On January 8, 2015, Decedent was admitted to Select Specialty Hospital with complaints of sepsis, respiratory failure, and renal failure. Decedent's initial assessment listed sepsis, suspected secondary to culture negative peritonitis.

56. On January 18, 2015, Decedent presented to Riverside Methodist Hospital with mental status changes and in moderate respiratory distress. Decedent was intubated, but shortly thereafter went into cardiac arrest. Decedent was unable to be revived.

57. On January 18, 2015, Decedent died from complications related to peritoneal dialysis induced peritonitis, caused by the Defendants' defectively manufactured MiniCaps. Decedent's cause of death as listed on her death certificate was myocardial infarction. Decedent was 70 years old.

58. Plaintiff alleges that the defective MiniCaps caused the Decedent to develop peritonitis, which led to sepsis and other complications, which ultimately caused the death of Decedent.

59. Decedent never saw or read the Baxter Urgent Product Recall letter that was sent on January 27, 2015 or the FDA Class 2 Recall notice that was posted on March 13, 2015, as Decedent had expired prior to the recall letter being sent and prior to the posting of the FDA Class 2 recall.

60. Plaintiff alleges that Defendants were aware that users of the affected lots of MiniCaps subject to their Urgent Product Recall had an increased risk of developing peritonitis and in fact, Plaintiff did develop peritonitis as a result of her use of Defendants' MiniCaps.

61. Decedent used MiniCaps that were subject to the Urgent Product Recall and Decedent has suffered substantial injuries and death as a result of her use of the Defendants' MiniCap product.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION
Strict Products Liability- Manufacturing Defect

62. Plaintiff re-alleges and incorporates by reference each of the allegations of paragraphs 1 through 61, above, as though fully set forth herein.

63. At all times herein mentioned, Defendants knew the MiniCap would be used by members of the public without inspection for defects.

64. At all times herein mentioned, Defendants knew the MiniCap was substantially in the same condition at the time of its use by Decedent as it left the possession of the Defendants' manufacture and/or that any changes to the MiniCap were reasonably foreseeable to Defendants.

65. At all times herein mentioned, the aforementioned MiniCap was defective in its manufacture in that the MiniCap was manufactured with a fully separated, partially protruding,

or missing sponge which resulted in compromised sterility protection at the connector of the solution transfer set thereby causing a failure of the MiniCap to disinfect the transfer connection, which in turn caused serious and deadly illnesses to patients (including Decedent) using the MiniCap including, but not limited to, peritonitis and death. At all times herein mentioned, the MiniCaps sold to and utilized by the Decedent were defective in their manufacture in that the MiniCaps deviated in a material way from the Defendants' designs and specifications and/or from other such typical said MiniCaps of the same product line.

66. At all times herein mentioned, including prior to the time the MiniCaps were purchased by and sold to the Decedent, the MiniCaps had potential risks and dangers, including the risks of serious illness and death that were known to the Defendants and/or knowable to them based on the industry and scientific knowledge available at the time of their manufacture and distribution by Defendants.

67. At all times herein mentioned, ordinary consumers, including Plaintiff and Decedent, utilizing home kidney dialysis, could not and would not have recognized the potential defects, risks, and dangers of the MiniCap.

68. At all times herein mentioned, despite their full knowledge of the defectiveness of the MiniCaps and their potential to cause serious injury and/or death to consumers using the MiniCaps in the manner intended and/or reasonably foreseeable to the Defendants, Defendants nevertheless failed and refused to warn Plaintiffs and other consumers in a timely manner of the MiniCap of the deadly dangers resulting from use of the defective MiniCaps.

69. At all time herein mentioned, the aforementioned MiniCaps were used by Plaintiff and Decedent in a manner which was reasonably foreseeable to the Defendants.

70. As a direct and proximate result of Decedent's use of the defective MiniCaps as manufactured, designed, sold, supplied and introduced into the stream of commerce by

Defendants, Decedent contracted peritonitis which was a substantial factor in bringing about her death on January 18, 2015, and Decedent and Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

71. As a direct and proximate result of the foregoing, Plaintiff is entitled to compensatory damages, as set forth below.

SECOND CAUSE OF ACTION
Strict Products Liability- Defective Due to Inadequate Warning

72. Plaintiff re-alleges and incorporates by reference each of the allegations of paragraphs 1 through 71, above, as though fully set forth herein.

73. The MiniCaps manufactured and supplied by Defendants were defective due to inadequate warnings or instructions because Defendants knew or should have known that the product created significant risks of serious bodily harm when the sponge inside the MiniCap was not in its proper placement, including but not limited to peritonitis and subsequent complications, and they failed to adequately warn consumers and/or their health care providers of such risks and failed to adequately warn consumers and/or health care providers that they should not use the MiniCap if the sponge inside the MiniCap was not in its proper placement.

74. In addition to, or in the alternative, the MiniCaps manufactured and supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm and death from the use of the defective MiniCaps, Defendants failed to provide a timely adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and death.

75. The risks of using the MiniCap were not open and obvious.

76. The warnings provided to consumers, like Decedent, who used the MiniCap, were

not adequate.

77. Had Plaintiff and Decedent been warned to not use the MiniCap if the sponge within the MiniCap was not in its proper placement, Decedent would not have used the MiniCaps with missing or improperly placed sponges and would not have developed peritonitis and would not have died on January 18, 2015.

78. As a direct and proximate result of Decedent's use of the MiniCaps as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Decedent and Plaintiff suffered harm, damages and economic loss and will continue to suffer such harm.

79. As a direct and proximate result of the foregoing, Plaintiff is entitled to compensatory damages, as set forth below.

THIRD CAUSE OF ACTION
Wrongful Death

80. Plaintiff re-alleges and incorporates by reference each of the allegations of paragraphs 1 through 79, above, as though fully set forth herein.

81. As a direct and proximate result of the conduct of the Defendants as described herein, and the resulting wrongful death of Decedent Sandra McIntire on January 18, 2015, Plaintiff, Decedent's Children, Kenny McIntire, Richard McIntire, and Michael McIntire, beneficiaries, and next of kin are entitled to all of those compensatory damages allowed by Ohio Revised Code Section 2125.02, including but not limited to:

(a) reasonable funeral and burial expenses;

(b) loss of services of Decedent;

(c) loss of the society of Decedent, including loss of companionship, consortium, care, assistance, attention, protection, advice, guidance, counsel, instruction, training, and education; and

(d) mental and physical anguish.

FOURTH CAUSE OF ACTION
Survivorship Action

82. Plaintiff re-alleges and incorporates by reference each of the allegations of paragraphs 1 through 81, above, as though fully set forth herein.

83. As a direct and proximate result of the Defendants' wrongful actions and sale of the defective MiniCap product, Decedent suffered profound pain and suffering until the time of her death.

84. As a further result of the care and treatment until the time of her death, Decedent incurred medical bills.

85. As a result of the death of Decedent, Plaintiff, her children, her beneficiaries, and her next of kin have suffered and will continue to suffer indefinitely, profound and serious damages and mental and physical anguish.

86. As a direct and proximate result of the wrongful acts and omissions of Defendants described herein, Decedent suffered mental anguish, emotional distress, loss of enjoyment of life, and incurred substantial, reasonable and necessary medical and other expenses.

.**FIFTH CAUSE OF ACTION**

Punitive Damages

87. Plaintiff re-alleges and incorporates by reference each of the allegations of paragraphs 1 through 86, above, as though fully set forth herein.

88. Plaintiff is further informed and believes, that Defendants' misconduct, as previously outlined herein, constituted a conscious disregard for rights and safety to other persons, including Decedent, that had a great probability of causing substantial harm including, but not limited to, exposing Decedent and other users of the MiniCap to deadly disease and death from peritonitis, the serious potential danger of which was known to the Defendants prior to their

mailing of warning letters to users of the MiniCap.

89. Plaintiff further alleges that prior to sending a voluntary recall letter to Decedent on January 27, 2015, Defendants had become fully aware of the defects in the MiniCap product which caused the death of Decedent on January 18, 2015, yet Defendants maliciously concealed the defects in the MiniCap product from the FDA, consumers such as Decedent and other members of the public.

90. Defendants maliciously failed and refused to warn Decedent and other members of the public of the deadly dangers of their unwitting continued use of the defective MiniCap, in order to advance the Defendants' pecuniary interests by avoiding a costly recall campaign, and/or replacement of defective products, and/or adverse publicity to Defendants, and/or a decline in purchases by the public of the MiniCap product, and/or personal injury and/or wrongful death litigation by consumers injured or killed by the defective MiniCap product, all for the purposes of reducing the costs and maximizing the profits on the continued sales of the MiniCap product by Defendants.

91. Defendants thereby acted with a conscious disregard for the rights and safety of Decedent and many other users of the MiniCap, thus warranting an award of punitive damages to Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, exclusive of interest and costs, and in an amount to fully compensate Plaintiff for all his wrongful death and survival damages, both past, present, and future;

b. Special damages, in excess of the amount required for federal diversity jurisdiction, exclusive of interest and costs, and in an amount to fully compensate Plaintiff for all

of his injuries and damages, both past and present, including but not limited to wrongful death damages provided by statute, and survival damages, including pain and suffering prior to the time of Decedent's death;

c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Decedent and Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;

d. Attorneys' fees, expenses, and costs of this action;

e. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

f. Such further relief as this Court deems necessary, just, and proper.

Dated: February 26, 2016

Respectfully submitted,

/s/ D. Andrew List
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JURY DEMAND

Plaintiff hereby demands a trial by jury as to all claims in this action.

/s/ D. Andrew List
D. Andrew List