IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COLLEEN K. COULTAS, Individually, as Next of Kin of and as Personal Representative of the Estate of SHANNON K. GILTNER, Deceased,	)	Case No. _____
Plaintiff,	)	
vs.	)	
FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS MEDICAL CARE NORTH AMERICA, INC., FRESENIUS USA SALES, INC., and FRESENIUS USA MARKETING, INC.	)	
Defendants.	)	

COMPLAINT AND JURY DEMAND

Plaintiff, by and through the undersigned counsel, hereby brings this Complaint for injuries and damages caused by the Defendants as alleged fully herein.

NATURE OF THE CASE

1. This is a product liability action for injuries and death caused by GranuFlo Dry Acid Concetrate (hereinafter "GranuFlo®") and/or NaturaLyte Liquid Acid Concentrate (hereinafter "NaturaLyte®") used during dialysis treatment administered to Decedent, Shannon K. Giltner.

2. Defendants above named (hereinafter "Fresenius," "Fresenius Defendants," and/or "Defendants"), designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed GranuFlo® and/or NaturaLyte® for use as acid concentrates during hemodialysis.

3. When warning of the safety, risks, and/or defects of GranuFlo® and/or NaturaLyte®, Defendants concealed their knowledge of GranuFlo® and/or NaturaLyte® safety, risks, and/or defects from Decedent, the United States Food and Drug Administration (hereinafter referred to as the "FDA"), the public in general and/or the medical community, specifically that GranuFlo® and/or NaturaLyte® could cause serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, stroke, and/or hypotension.\

4. Defendants negligently and/or fraudulently represented to the medical and healthcare community, the FDA, the Decedent, and the public in general that GranuFlo® and/or NaturaLyte® had been tested and were found to be safe and/or effective for their indicated use – as acid concentrates to be administered during hemodialysis.

5. When warning of the safety, risks, and/or defects of GranuFlo® and/or NaturaLyte®, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the FDA, the Decedent, and the public in general that GranuFlo® and/or NaturaLyte® had been tested and were found to be safe and/or effective for their indicated use – as acid concentrates to be administered during hemodialysis.

6. These representations and concealments were made by Defendants with the intent of defrauding and/or deceiving the Decedent, the public in general and the medical and healthcare community, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense, prescribe, administer, and/or otherwise use GranuFlo® and/or NaturaLyte® as acid concentrates during hemodialysis, all of which evinced a callous, reckless, willful, depraved indifference to health, safety, and welfare of the Decedent herein.

7. Defendants negligently and improperly failed to perform sufficient tests, if any, concerning GranuFlo® and/or NaturaLyte®'s potential to cause serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, and/or hypotension, during clinical trials.

8. As a result of the negligent, intentional, wanton, and/or otherwise culpable acts of the Defendants alleged herein, Decedent suffered severe and permanent personal injuries.

VENUE & JURISDICTION

9. This Court has personal jurisdiction over the Parties.

10. The amount in controversy exceeds $75,000.

11. There is complete diversity of citizenship between Plaintiff and Defendants.

12. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000, and because there is complete diversity of citizenship between Plaintiff and Defendants.

13. Venue is proper in this federal judicial district.

PARTY PLAINTIFFS

14. At all times relevant to this action, Decedent Shannon K. Giltner was an adult resident citizen of Portland in Multnomah County, Oregon.

15. Decedent suffered personal injuries and damages as a result of using GranuFlo® and/or NaturaLyte® during hemodialysis.

16. The use of GranuFlo® and/or NaturaLyte® caused Decedent to suffer severe injuries and damages including but not limited to the following: adverse cardiovascular event resulting in death on or about May 5, 2010.

17. Due to the negligent, intentional, willful, wanton, fraudulent, and/or otherwise culpable conduct of the Defendants alleged herein, the Decedent, Decedent's treating physicians and/or healthcare providers did not discover, nor did they have reason to discover, the serious and severe health risks associated with using GranuFlo® and/or NaturaLyte®, until the products were recalled by the FDA on July 12, 2012.

18. At all times relevant to this action, Plaintiff Colleen K. Coultas was an adult resident citizen of Portland in Multnomah County, Oregon. Plaintiff Coultas is the surviving daughter of Decedent and has been appointed Personal Representative of the estate of Shannon K. Giltner for purposes of prosecuting this lawsuit.

19. In addition to Plaintiff, Decedent was pre-deceased by her spouse, Clarence V. Giltner. There is no other known heir, surviving spouse, or devisee. d

PARTY DEFENDANTS

20. Defendant Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America ("FMCH") is a corporation organized and existing under the laws of New York with its principal place of business in at 920 Winter Street, Waltham, Massachusetts 02451. FMCH is the country's leading full-service provider of dialysis care. FMCH, through various affiliates, treats approximately 79,600 patients in its approximately 1,080 U.S. dialysis clinics, some of which are located in this district.

21. At all times relevant hereto, Defendant FMCH regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and distributing GranuFlo® and/or NaturaLyte® throughout the United States, including this judicial district.

22. Defendant FMCH has transacted and conducted business throughout the United States, including this judicial district.

23. Defendant FMCH has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States, including this judicial district.

24. Defendant FMCH derives substantial revenue from interstate commerce throughout the United States, including this judicial district.

25. Defendant Fresenius Medical Care North America, Inc. ("FMCNA") is a corporation organized and existing under the laws of the state of Massachusetts with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

26. At all times relevant hereto, Defendant FMCNA regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and distributing GranuFlo® and/or NaturaLyte® throughout the United States, including this judicial district.

27. Defendant FMCNA has transacted and conducted business throughout the United States, including this judicial district.

28. Defendant FMCNA has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States, including this judicial district.

29. Defendant FMCNA derives substantial revenue from interstate commerce throughout the United States, including this judicial district.

30. Defendant Fresenius USA, Inc. ("FUSA") is a corporation organized and existing under the laws of the state of Massachusetts with its principal place of business at 920 Winter

Street, Waltham, Massachusetts 02451. FUSA is a wholly owned subsidiary of Fresenius Medical Care AG & Co. KGaA.

31. At all times relevant hereto, Defendant FUSA regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and distributing GranuFlo® and/or NaturaLyte® throughout the United States, including this judicial district.

32. Defendant FUSA has transacted and conducted business throughout the United States, including this judicial district.

33. Defendant FUSA has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States, including this judicial district.

34. Defendant FUSA derives substantial revenue from interstate commerce throughout the United States, including this judicial district.

35. Defendant, Fresenius USA Manufacturing, Inc. ("Fresenius Manufacturing") is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

36. At all times relevant hereto, Defendant Fresenius Manufacturing regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and distributing GranuFlo® and/or NaturaLyte® throughout the United States, including this judicial district.

37. Defendant Fresenius Manufacturing has transacted and conducted business throughout the United States, including this judicial district.

38. Defendant Fresenius Manufacturing has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States, including this judicial district.

39. Defendant Fresenius Manufacturing derives substantial revenue from interstate commerce throughout the United States, including this judicial district.

40. Defendant, Fresenius USA Marketing, Inc. ("Fresenius Marketing") is a foreign corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

41. At all times relevant hereto, Defendant Fresenius Marketing regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and distributing GranuFlo® and/or NaturaLyte® throughout the United States, including this judicial district.

42. Defendant Fresenius Marketing has transacted and conducted business throughout the United States, including this judicial district.

43. Defendant Fresenius Marketing has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States, including this judicial district.

44. Defendant Fresenius Marketing derives substantial revenue from interstate commerce throughout the United States, including this judicial district.

45. Defendant Fresenius Marketing is a wholly-owned subsidiary of Fresenius Medical Care AG & Co. KGaA.

46. Defendant Fresenius USA Sales, Inc. ("FUSA Sales") is a corporation organized and existing under the laws of the state of Massachusetts with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451.

47. At all times relevant hereto, Defendant FUSA Sales regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and distributing GranuFlo® and/or NaturaLyte® throughout the United States, including this judicial district.

48. Defendant FUSA Sales has transacted and conducted business throughout the United States, including this judicial district.

49. Defendant FUSA Sales has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States, including this judicial district.

50. Defendant FUSA Sales derives substantial revenue from interstate commerce throughout the United States, including this judicial district.

51. Upon information and belief, each Defendant is a wholly-owned subsidiary of Fresenius Medical Care AG & Co. KGaA.

52. At all relevant times each Defendant acted in all aspects as agent and alter ego of for each corporate entity and as agent and alter ego of Fresenius Medical Care AG & Co. KGaA.

53. This Court has personal jurisdiction over the Defendants. At all times material hereto, Defendants maintained systematic and continuous contacts in this judicial district, regularly transact business within this judicial district, and regularly avails itself of the benefits of this judicial district. Defendants also employ people and receive substantial revenue in this judicial district.

54. Fresenius Medical Care is a publicly traded company. Fresenius is the world's largest integrated provider of products and services for individuals undergoing dialysis. "Through its network of 3,123 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 256,456 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products."[1]

55. At all relevant times, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of GranuFlo® and NaturaLyte®.

56. At all relevant times, Defendants intentionally, recklessly and/or negligently advertised, promoted, marketed, labeled, sold and distributed GranuFlo® and NaturaLyte® as being safe for use in dialysis when, in fact, Defendants had reason to know, and/or did know, that the products were not safe and caused serious medical problems, and in certain patients, catastrophic, life threatening, injuries that included death.

57. The combined acts and/or omissions of each Defendant resulted in the indivisible injury to Plaintiff/Decedent. Each above-named Defendant is a joint tortsfeasor and is jointly and severally liable to Plaintiff/Decedent for the negligent acts and omissions alleged herein.

58. Defendants are present and doing business in this state. Defendants are and were at all relevant times authorized to conduct business in this state and Defendant conducted such business within the state including the performance of acts that caused or contributed to the harm, giving rise to this action.

[1] http://www.fmc-ag.com/59.htm (last visited January 2, 2013).

59. Defendants marketed, advertised, distributed, and conducted such business within this judicial district; including the performance of acts that caused or contributed to the harm, giving rise to this action.

60. Defendants received substantial financial benefit and profits as a result of designing, manufacturing, marketing, advertising, promoting, labeling, selling and/or distributing GranuFlo® and NaturaLyte® in this district and throughout the United States.

FACTUAL BACKGROUND

61. This action arises from the injuries and damages caused by the use of GranuFlo® and NaturaLyte® in the dialysis treatment provided to Decedent.

A. Hemodialysis in General

62. Hemodialysis is a method of treating acute and chronic kidney disease, especially where conservative treatment has been judged inadequate.

63. Hemodialysis is a treatment that attempts to replace the function of a normal kidney by filtering waste and removing extra fluids and electrolytes form the body.

64. An individual undergoing hemodialysis is connected to a hemodialysis machine and then blood is removed from the body. A dialysate is utilized in the hemodialysis machine to remove the waste from the blood. Once the waste is removed, the blood is returned to the body.

65. Many patients who suffer from kidney disease also suffer from a condition known as metabolic acidosis, where there is too much acid in the body due to the impaired kidneys' inability to remove excess acid from the body.

66. Through hemodialysis, a patient's body acid levels can be brought into balance. This can be done through the use of a base—a bicarbonate dialysate—where the bicarbonate acts as a pH buffer to neutralize the metabolic acidosis.

67. Because kidney failure also affects the body's ability to product electrolytes, such as calcium and magnesium, these same electrolytes are introduced into the blood during hemodialysis. Yet, because the bicarbonates react to create an insoluble substance when combined with calcium and/or magnesium, an acid concentrate is added to the bicarbonate dialysate to prevent this from occurring.

68. Defendants' GranuFlo® and NaturaLyte® are acid concentrates.

69. When introduced into the body, the acid contained within acid concentrates is converted into bicarbonates by the liver, which increases bicarbonate levels in the blood.

70. As a result, a person undergoing hemodialysis receives bicarbonates from two sources: (1) the bicarbonate solution introduced during dialysis; and (2) the acid concentrate when it reaches the liver.

71. If an individual undergoing dialysis is administered and/or receives an excess of bicarbonates from one and/or both sources, metabolic alkalosis can occur.

72. Metabolic alkalosis is a medical condition in which there is too much bicarbonate or base in the blood. It is the converse of metabolic acidosis.

73. Metabolic alkalosis is a medical condition which, if left undiagnosed and/or untreated, can lead to serious adverse events, including but not limited to electrolyte imbalances, hypokalemia, hypercapnia, hypotension, hypoxemia, heart arrhythmias, heart attacks, coma, cardiac arrest, stroke, and/or death.

74. Given that a person undergoing hemodialysis receives bicarbonates from two sources (the bicarbonate solution and the acid concentrate), a prescribing physician and/or healthcare facility must ensure that the individual undergoing dialysis is receiving enough bicarbonates,

from both source, to address the individual's acid levels in the blood, but not excessive amounts of bicarbonates so as to cause metabolic alkalosis.

75. As such, it is imperative that the manufacturer, distributor, seller, and/or marketer of a product used in hemodialysis, such as an acid concentrate like GranuFlo® or NaturaLyte®, advise and/or warn prescribing physicians and healthcare facilities and their employees of any and all risks, concerns, defects, and other safety information regarding said product.

B. GranuFlo® and NaturaLyte® -- The Recall

76. GranuFlo® and NaturaLyte® are acid concentrates designed, manufactured, marketed, advertised, distributed, and sold by Defendants to be used in hemodialysis along with a bicarbonate concentrate to create a bicarbonate dialysate.

77. NaturaLyte® contains 4.0 mEq/L of acetate.

78. GranuFlo® contains 8.0 mEq/L of acetate.

79. GranuFlo® and NaturaLyte® are regulated as medical devices by the FDA.

80. GranuFlo® and NaturaLyte® are registered trademarks of Defendants.

81. GranuFlo® and NaturaLyte® were submitted for approval by the FDA through the 510(k) process as opposed to the FDA's more rigorous premarket approval process.

82. Upon information and belief, Defendants' submitted GranuFlo® and NaturaLyte® acid concentrates for FDA approval pursuant to the 510(k) approval process as opposed to the FDA's more rigorous premarket approval process so that they could save money and avoid certain safety procedures by bypassing the premarket approval process, which would have obligated them to design and implement a clinical investigation regarding the products and to submit the results of that investigation to the FDA for review.

83. Upon information and belief, on or about April 23, 1981, Defendants' NaturaLyte® 9000 Series was approved for marketing, sale, and use pursuant to the 510(k) approval process.

84. Upon information and belief, on or about December 3, 1982, Defendants' NaturaLyte® 4000 Series was approved for marketing, sale, and use pursuant to the 510(k) approval process.

85. Upon information and belief, on or about July 26, 1985, Defendants' NaturaLyte® 6000 Series was approved for marketing, sale, and use pursuant to the 510(k) approval process.

86. Upon information and belief, on or about January 18, 2007, Defendants' submitted to the FDA a premarket notification of their intent to market their previously approved NaturaLyte® acid concentrates with a modified formula ("NaturaLyte® January 510(k) submission") in the United States.

87. Upon information and belief, Defendants' NaturaLyte® January 510(k) submission to the FDA included Defendants' unilateral finding that NaturaLyte® was substantially equivalent to its previously approved NaturaLyte® acid concentrates.

88. Upon information and belief, based upon information provided to them by Defendants, the FDA approved NaturaLyte® with its modified formula for marketing, sale, and use on or about March 29, 2007.

89. Upon information and belief, on or about April 29, 1992, Defendants submitted to the FDA a premarket notification of their intent to market GranuFlo® in a granulated formula ("GranuFlo® April 510(k) submission") in the United States.

90. Upon information and belief, Defendants' GranuFlo® April 510(k) submission to the FDA included Defendants' unilateral finding that GranuFlo® in a granulated formula was substantially equivalent to other products on the market.

91. Upon information and belief, Defendants' GranuFlo® that was the subject of their GranuFlo® April 510(k) submission to the FDA did not contain diacetate.

92. Upon information and belief, based upon the information provided to them by Defendants, the FDA originally approved GranuFlo® in a granulated formula for marketing, sale, and use on or about March 30, 1994. Upon information and belief, in or about August 2002, Defendants altered the formula of their GranuFlo® by switching the acid use in said product to diacetate.

93. Upon information and belief, Defendants' goal in using diacetate in their GranuFlo® was to counter the negative effects of metabolic acidosis—use of diacetate would increase bicarbonate levels in the blood via an acid concentrate as opposed to and/or in addition to a bicarbonate solution.

94. Upon information and belief, Defendants' goal in using diacetate in their GranuFlo® was to improve pre-dialysis bicarbonate levels in the blood.

95. In or about August 2002, Defendants began administering their GranuFlo® with diacetate to dialysis patients.

96. Upon information and belief, in or about August 2002, Defendants began administering their GranuFlo® with diacetate to dialysis patients without FDA approval.

97. On or about January 14, 2003, Defendants submitted to the FDA a premarket notification of their intent to market GranuFlo® in a non-granulated formula in the United States ("GranuFlo® January 510(k) submission").

98. Defendants' GranuFlo® that was subject to the January 2003 submission contained diacetate.

99. Within their GranuFlo® January 510(k) submission, Defendants did not advise the FDA and/or concealed from the FDA that they had begun administering their GranuFlo® with diacetate to dialysis patients in or about August 2002.

100. Defendants' GranuFlo® January 510(k) submission to the FDA included Defendants' unilateral finding that GranuFlo®, in a non-granulated formula, was substantially equivalent to other products on the market, including their GranuFlo® that was approved by the FDA on or about March 30, 1994.

101. Within Defendants' GranuFlo® January 510(k) submission to the FDA, Defendants represented to the FDA that their GranuFlo®, in a non-granulated formula, would be used as a direct product replacement for their previously approved GranuFlo®.

102. Within Defendants' GranuFlo® January 510(k) submission to the FDA, Defendants represented to the FDA that their GranuFlo®, in a non-granulated formula, had the same chemical composition as their previously approved GranuFlo®.

103. Within Defendants' GranuFlo® January 510(k) submission to the FDA, Defendants failed to notify and/or inform the FDA that their GranuFlo®, in a non-granulated formula, contained diacetate.

104. Within Defendants' GranuFlo® January 510(k) submission to the FDA, Defendants intentionally, willfully, recklessly, and/or negligently hid, omitted, and concealed from the FDA that their GranuFlo®, in a non-granulated formula, contained diacetate.

105. Upon information and belief, Defendants intentionally drafted their January 510(k) submission in such a manner so as to mislead the FDA into believing that their GranuFlo®, in a non-granulated formula, contained the same type of acetate as their previously approved GranuFlo® so as to support a finding by the FDA that the products were substantially similar.

106. Upon information and belief, based upon information provided to them by Defendants, the FDA originally approved GranuFlo® in a non-granulated formula for marketing, sale, and use on or about May 20, 2003.

107. Upon information and belief, following FDA approval, Defendants only manufactured, marketed, promoted, advertised, distributed, and/or sold GranuFlo® containing dialysate.

108. Upon information and belief, following its approval by the FDA, Defendants only manufactured, marketed, promoted, advertised, distributed, and/or sold GranuFlo® containing 8 mEq/L, which is equivalent to 4mEq/L more acetate than any other acid concentrate on the market.

109. Upon information and belief, following its approval by the FDA, Defendants never communicated to all treating physicians and/or healthcare facilities administering and/or using GranuFlo® that bicarbonate levels needed to be adjusted to take into account the additional acetate provided by GranuFlo®.

110. In or about 2004, Defendants conducted a retrospective study of dialysis patents who had converted from previously approved acid concentrates to GranuFlo® containing diacetate between August 2002 and April 2003 ("Defendants' 2004 Retrospective Study").

111. Upon information and belief, the goal of Defendants' 2004 Retrospective Study was to determine the efficacy of acid concentrate containing diacetate (i.e. GranuFlo®) in improving pre-dialysis bicarbonate levels in the blood.

112. In or about 2004, Defendants evaluated the results of Defendants' 2004 Retrospective Study which revealed, among other things, higher than normal post-dialysis bicarbonate levels as a result of the administration of GranuFlo® containing diacetate.

113. In or about 2004, Defendants evaluated the results of Defendants' 2004 Retrospective Study which revealed, among other things, higher than normal pre-dialysis bicarbonate levels as a result of the administration of GranuFlo® containing diacetate.

114. In or about 2004, Defendants evaluated the results of Defendants' 2004 Retrospective Study which revealed, among other things, an increase in cases of metabolic alkalosis as a result of the administration of GranuFlo® containing diacetate.

115. In or about 2004, Defendants evaluated the results of Defendants' 2004 Retrospective Study which revealed, among other things, a significant increase in cases of metabolic alkalosis as a result of the administration of GranuFlo® containing diacetate.

116. As a result of Defendants' 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that the administration of GranuFlo® containing diacetate resulted in higher than normal post-dialysis bicarbonate levels.

117. As a result of Defendants' 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that the administration of GranuFlo® containing diacetate resulted in higher than normal pre-dialysis bicarbonate levels.

118. As a result of Defendants' 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that the administration of GranuFlo® containing diacetate resulted in an increase in metabolic alkalosis.

119. As a result of Defendants' 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that the administration of GranuFlo® containing diacetate resulted in a significant increase in metabolic alkalosis.

120. As a result of Defendants' 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that individuals not suffering from metabolic acidosis prior to

dialysis were at an increased risk of suffering from metabolic alkalosis as a result of administration of GranuFlo®.

121. As a result of Defendants' 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that dialysis patients may have been receiving too many bicarbonates during dialysis as a result of their receipt of GranuFlo®.

122. As a result of Defendants' 2004 Retrospective Study, Defendants were on notice and/or should have been on notice of the need to advise, instruct, and/or warn all prescribing physicians and/or healthcare facilities that dialysis patients may be receiving too many bicarbonates during dialysis as a result of their receipt of GranuFlo®.

123. Defendants were on notice and/or should have been on notice of their obligation to report the results of Defendants' 2004 Retrospective Study to the FDA, the medical community, the Decedent, Decedent's treating physicians and/or healthcare providers and the public.

124. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of the severe health risks associated with their GranuFlo®, Defendants intentionally and willfully concealed their knowledge of these results and/or the increased severe health risks associated with their GranuFlo® from the FDA, the medical community, the Decedent, Decedent's treating physicians and/or healthcare providers and the public.

125. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GranuFlo®, Defendants failed to adequately and timely inform the FDA, the medical community, the Decedent, Decedent's treating physicians and/or healthcare providers and the public, regarding these results and/or risks.

126. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GranuFlo®, Defendants failed to advise and/or warn all doctors and/or other healthcare providers treating patients with GranuFlo® to reduce the amount of bicarbonates being administered to and/or received by the patient during dialysis to take into account the additional bicarbonates that these individuals were receiving from GranuFlo®.

127. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GranuFlo®, Defendants failed to advise and/or warn all doctors and/or other healthcare providers treating patients with GranuFlo® to monitor more frequently the dialysis patient's post-dialysis bicarbonate levels.

128. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GranuFlo®, Defendants failed to advise and/or warn all doctors and/or other healthcare providers treating patients with GranuFlo® to monitor more frequently the dialysis patient's pre-dialysis bicarbonate levels.

129. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of these results and/or the increased severe health risks associated with their GranuFlo®, Defendants failed to advise and/or warn doctors, the FDA, the medical community, the Decedent, Decedent's treating physicians and healthcare providers and the public that individuals not suffering from metabolic acidosis prior to dialysis were at an increased risk of suffering from metabolic alkalosis as a result of the administration of GranuFlo®.

130. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of the severe health risks associated with their GranuFlo®, Defendants failed to conduct additional testing regarding the safety of their GranuFlo®.

131. Upon information and belief, despite the results of Defendants' 2004 Retrospective Study and their knowledge of the severe health risks associated with their GranuFlo®, Defendants failed to advise, instruct, and/or warn all prescribing physicians and/or healthcare facilities that dialysis patients may be receiving too many bicarbonates during dialysis as a result of their receipt of GranuFlo®.

132. On or about November 4, 2011, Fresenius Defendants supposedly sent an Internal Memo ("Fresenius' Internal Memo") to Fresenius medical directors and attending physicians regarding the severe health risks associated with their GranuFlo® and NaturaLyte®.

133. Within Fresenius' Internal Memo, Defendants identified a case-control study they performed to evaluate risk factors in hemodialysis patients who had suffered from cardiopulmonary arrest compared to other hemodialysis patients between January 1, 2010, and December 31, 2010.

134. Defendants did not notify the FDA of the case-control study identified within Fresenius' Internal Memo.

135. Upon information and belief, Defendants conducted the case-control study identified within Fresenius' Internal Memo because of increased reports of cardiac adverse events being associated with their GranuFlo®.

136. According to Fresenius' Internal Memo, the results of the case-control study identified within Fresenius' Internal Memo revealed that for the patients receiving Defendants' GranuFlo® and NaturaLyte®, there was a progressive shift towards higher pre-dialysis serum

bicarbonate levels, implying that more patients were experiencing alkalosis prior to dialysis and an even higher percentage of patients were experiencing alkalosis post-dialysis.

137. According to Fresenius' Internal Memo, the results of the case-control study identified within Fresenius' Internal Memo revealed that borderline elevated pre-dialysis bicarbonate levels and overt alkalosis were associated with six to eight fold greater risk of cardiopulmonary arrest and sudden cardiac death in the dialysis facility.

138. According to Fresenius' Internal Memo, Defendants stated "[i]n light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate levels of >24 mEq/L."

139. Fresenius' Internal Memo was only sent to medical directors and attending physicians employed by Fresenius Defendants.

140. Upon information and belief, Fresenius' Internal Memo was not sent to the medical facilities at which Decedent was administered and/or received GranuFlo® and NaturaLyte®.

141. Upon information and belief, Fresenius' Internal Memo was not sent to the Decedent's treating physicians who ordered and/or prescribed her dialysis treatments.

142. Fresenius' Internal Memo references previous internal memos that were supposedly sent to medical directors and attending physicians employed by Fresenius Defendants regarding the severe health risks associated with GranuFlo® and NaturaLyte®, which at all relevant times, remained in the custody, control, and possession of Defendants.

143. Upon information and belief, these previous internal memos were not sent to the medical facilities at which the Decedent was administered and/or received GranuFlo® and NaturaLyte®.

144. Upon information and belief, these previous internal memos were not sent to the Decedent's treating physicians who ordered and/or prescribed Decedent's dialysis treatments.

145. Fresenius' Internal Memo references a Medical Staff Newsletter dated January 2010 that was supposedly made available to medical directors and attending physicians employed by Fresenius Defendants and that discussed the severe health risks associated with GranuFlo® and NaturaLyte®, which, at all relevant times, remained in the custody, control, and possession of Defendants.

146. Upon information and belief, the Medical Staff Newsletter dated January 2010 was not sent to the medical facilities at which Decedent was administered and/or received GranuFlo® and NaturaLyte®.

147. Upon information and belief, the Medical Staff Newsletter dated January 2010 was not sent to Decedent's treating physicians who ordered and/or prescribed Decedent's dialysis treatments.

148. After Defendants learned and/or should have learned of these health risks associated with their GranuFlo® and NaturaLyte®, Defendants intentionally and affirmatively elected not to report these risks to the FDA as required by law.

149. After Defendants learned and/or should have learned of these health risks associated with their GranuFlo® and NaturaLyte®, Defendants intentionally and affirmatively elected not to report these risks to the entire medical community, the Decedent, Decedent's treating physicians and healthcare providers and the public at large.

150. Upon information and belief, Defendants colluded to hide, conceal, and obscure information about the severe health risks associated with their GranuFlo® and NaturaLyte® so that dialysis patients, such as Decedent, and Decedent's treating physicians and/or healthcare

facilities would rely on and/or continue to use their GranuFlo® and NaturaLyte® in dialysis treatments.

151. Upon information and belief, Defendants colluded to misrepresent information regarding the safety of their GranuFlo® and NaturaLyte® so that dialysis patients, such as Decedent, and Decedent's treating physicians and/or healthcare facilities would rely on and/or continue to use their GranuFlo® and NaturaLyte® in dialysis treatments.

152. Upon information and belief, Defendants colluded to hide, conceal, and obscure information about the severe health risks associated with their GranuFlo® and NaturaLyte® in order to maintain their market share and to minimize and diffuse the legal risks for Defendants.

153. Upon information and belief, Defendants colluded to misrepresent information regarding the safety to their GranuFlo® and NaturaLyte® in order to maintain their market share and to minimize and diffuse the legal risks to Defendants.

154. Upon information and belief, rather than informing the FDA, the medical community, the Decedent, Decedent's treating physicians and healthcare providers and the public at large of the severe health risks associated with their GranuFlo® and NaturaLyte®, Defendants decided to manufacture, market, promote, distribute, and/or sell a new acid concentrate, Citrasate, to replace their GranuFlo® and NaturaLyte®.

155. Upon information and belief, Defendants intended to advertise, market, and promote the benefits of their new acid concentrate, Citrasate, so that treating physicians and medical facilities would switch to Citrasate from GranuFlo® and NaturaLyte® and, thus, Defendants could justify a discontinuance of their GranuFlo® and NaturaLyte® for reasons other than product safety.

156. In reliance upon Defendants' misrepresentations, omissions and/or concealments as set forth herein, the Decedent, Decedent's treating physicians and/or healthcare facilities used GranuFlo® and NaturaLyte®.

157. Had the severe health risks associated with Defendants' GranuFlo® and NaturaLyte® been properly and/or adequately disclosed, the Decedent, Decedent's treating physicians and/or healthcare facilities would not have purchased and/or used GranuFlo® and NaturaLyte®.

158. In or about March 2012, Fresenius' Internal Memo was anonymously submitted to the FDA.

159. In or about March 2012, the FDA discovered Defendants' knowledge and unlawful concealment of the severe health risks associated with their GranuFlo® and NaturaLyte®.

160. In or about March 2012, the FDA discovered that Defendants had violated federal law by failing to report their knowledge of the severe health risks associated with their GranuFlo® and NaturaLyte®.

161. As a result of the FDA's discovery of Defendants' knowledge and unlawful concealment of the severe health risks associated with their GranuFlo® and NaturaLyte®, on or about March 27, 2012, Defendants received an inquiry from the FDA regarding the severe health risks associated with their GranuFlo® and NaturaLyte®.

162. Following the FDA's inquiry, on or about March 29, 2012, Defendants supposedly sent a vague and ambiguous two page memorandum entitled "Urgent Product Notification Letter" to non-Fresenius dialysis clinics, hospitals, and other customers notifying them of the risk of metabolic alkalosis associated with their GranuFlo® and NaturaLyte®.

163. Upon information and belief, after further investigation conducted by the FDA into the severe health risks associated with their GranuFlo® and NaturaLyte®, including Defendants'

knowledge and unlawful concealment thereof, on July 10, 2012, the FDA issued a Class I recall of Defendants' GranuFlo® and NaturaLyte®.

164. A Class I recall is a recall of dangerous or defective products that predictably could cause serious health problems or death.

165. A Class I recall is the most serious recall that can be issued by the FDA.

166. Decedent, Decedent's treating physicians, healthcare providers, and/or healthcare facilities did not discover, nor did they have reason to discover, the serious and severe health risks associated with Defendants' GranuFlo® and NaturaLyte®, until the products were recalled by the FDA on July 12, 2012.

C. Fresenius Defendants

167. Fresenius Defendants are the world's largest integrated providers of products and services for individuals undergoing dialysis because of chronic kidney failure.

168. As vertically integrated companies, Defendants offer both dialysis clinics and products used in dialysis case, such as dialysis machines and acid concentrates.

169. Defendants sell their products, including GranuFlo® and NaturaLyte®, not only to their own dialysis clinics, but also to their "competitors."

170. Defendants are, and at all relevant times were, responsible for ensuring, through adequate warnings, training, instruction, and monitoring, that their GranuFlo® and NaturaLyte® were being properly used and/or administered by treating physicians, technicians, and/or healthcare facilities and providers.

171. In 2011, Defendants reported net revenue of $12,795 million related to their dialysis services and products, with $8,150 million in revenue attributed to North America (64%).

172. In 2010, Defendants reported net revenue of $12,053 million related to their dialysis services and products, with $8,130 million in revenue attributed to North America (67%).

173. Defendants have represented that they are committed to conducting their business activities in compliance with local laws and regulations, and that they seek to demonstrate professionalism, honesty, and integrity in their business relationships with patients, customers, suppliers, the government, other payors, fellow employees, stockholders, and the general public.

174. Despite Defendants' representations, upon discovering the serious health consequences and risks associated with their GranuFlo® and NaturaLyte®, Defendants intentionally, willfully, recklessly, and/or negligently failed to advise and/or warn dialysis patients, including Decedent, their customers (i.e. treating physicians, healthcare facilities, providers, distributors), their suppliers, the government, other payers, and/or the general public of said serious consequences and risks.

175. Despite Defendants' representations, upon discovering the serious health consequences and risks associated with their GranuFlo® and NaturaLyte®, Defendants permitted their GranuFlo® and NaturaLyte® to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged, and/or sold without adequate warnings of the serious health consequences and risks associated with their GranuFlo® and NaturaLyte®.

176. Despite Defendants' representations, upon discovering the serious health consequences and risks associated with their GranuFlo® and NaturaLyte®, Defendants permitted their GranuFlo® and NaturaLyte® to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged, and/or sold

without adequate instructions regarding the safe and proper use of their GranuFlo® and NaturaLyte®.

177. Despite Defendants' representations, upon discovering the serious health consequences and risks associated with their GranuFlo® and NaturaLyte®, Defendants engaged in a marketing campaign to promote the purchase and/or sales of their GranuFlo® and NaturaLyte®.

178. Based upon the results of Defendants' 2004 Retrospective Study, at all relevant times, Defendants advertised and/or marketed that the use of GranuFlo® resulted in a 33% reduction in the prevalence of acidosis.

179. Defendants advertised and/or marketed GranuFlo® as less costly to transport to and/or store at healthcare facilities than other acid concentrates on the market.

180. Defendants marketed their GranuFlo® and NaturaLyte® throughout the United States by, among other things, conducting promotional campaigns that misrepresented the risks and benefits associated with their GranuFlo® and NaturaLyte® in order to induce widespread use and consumption.

181. Defendants' misrepresentations regarding and/or promotions about their GranuFlo® and NaturaLyte® were made by means of media advertisement, internet advertisements, press releases, sales literature, presentations, advertising campaigns, print ads, magazine ads, and/or additional commercial media.

182. Upon information and belief, Defendants did not disclose the serious health consequences and risks associated with their GranuFlo® and NaturaLyte® because they knew that physicians and/or healthcare facilities and providers would not purchase their GranuFlo® and NaturaLyte®, and, as a result, their sales would decline.

183. Upon information and belief, as a result of Defendants' advertising and/or marketing campaign, GranuFlo® experienced a steady increase in its market share since it was first approved in 2003 and, as of 2012, was used by the majority of hemodialysis patients in the United States.

184. Defendants' wanton, willful, fraudulent, and/or reckless conduct, as set forth herein, demonstrates a complete disregard and reckless indifference for the health, safety, and welfare of consumers and dialysis patients, including the Decedent, thus entitling Plaintiff/Decedent to punitive damages so as to punish and deter such similar conduct in the future.

D. Injuries and Damages

185. As a result of Defendants' concealment and/or failure to properly advise, instruct and/or warn all doctors and/or other healthcare providers and facilities of the defective nature and/or serious adverse health risks associated with GranuFlo® and NaturaLyte® as set forth hererin, dialysis patients, including Decedent, who received Defendants' GranuFlo® and NaturaLyte® experienced higher than normal post-dialysate bicarbonate levels.

186. As a result of Defendants' concealment and/or failure to properly advise, instruct and/or warn all doctors and/or other healthcare providers and facilities of the defective nature and/or serious adverse health risks associated with GranuFlo® and NaturaLyte® as set forth hererin, dialysis patients, including Decedent, who received Defendants' GranuFlo® and NaturaLyte® experienced higher than normal pre-dialysate bicarbonate levels.

187. As a result of Defendants' concealment and/or failure to properly advise, instruct and/or warn all doctors and/or other healthcare providers and facilities of the defective nature and/or serious adverse health risks associated with GranuFlo® and NaturaLyte® as set forth

hererin, dialysis patients, including Decedent, who received Defendants' GranuFlo® and NaturaLyte® have suffered and/or are suffering from metabolic alkalosis.

188. As a result of Defendants' concealment and/or failure to properly advise, instruct and/or warn all doctors and/or other healthcare providers and facilities of the defective nature and/or serious adverse health risks associated with GranuFlo® and NaturaLyte® as set forth hererin, dialysis patients, including Decedent, who received Defendants' GranuFlo® and NaturaLyte® have suffered from and/or will suffer from serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, stroke, coma, and hypotension.

189. As a result of the defective nature of GranuFlo® and NaturaLyte®, which was known and/or should have been known by Defendants at all relevant times, those persons who were administered, prescribed, and/or ingested and/or were exposed to GranuFlo® and NaturaLyte®, including Decedent, have suffered from, are suffering from, and/or will suffer from serious and grave health consequences, including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, stroke, coma, and hypotension.

190. Decedent, after using GranuFlo® and NaturaLyte®, suffered an adverse cardiovascular event and died on or about Mary 5, 2010.

191. Decedent died as a proximate result of being administered and having ingested GranuFlo® and NaturaLyte® during dialysis treatment during the days leading up to her death on or about May 5, 2010.

COUNT I
STRICT PRODUCTS LIABILITY

192. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

193. At all times relevant and material to this action, Defendants designed, tested, manufactured, packaged, labeled, marketed, advertised, distributed, promoted, and sold GranuFlo® and NaturaLyte®, placing the products into the stream of commerce, such products having been administered and/or used by Decedent.

194. At all times relevant and material, Defendants designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed GranuFlo® and NaturaLyte® in a defective and/or unreasonably dangerous condition.

195. GranuFlo® and NaturaLyte® were expected to reach, and did reach, the usual consumers, handlers, and persons coming into contact with said products, including Decedent, without substantial change in the conditions in which they were produced, manufactured, sold, distributed, and marketed by Defendants.

196. At those times, GranuFlo® and NaturaLyte® were in an unsafe, defective, and inherently dangerous condition, which were dangerous to users, and in particular, the Decedent.

197. The acid concentrates, GranuFlo® and NaturaLyte®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and disturbed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of GranuFlo® and NaturaLyte®.

198. The acid concentrates, GranuFlo® and NaturaLyte®, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and disturbed by Defendants were

defective in design or formulation in that, when they left the hands of Defendants' manufacturers and/or suppliers, were unreasonably dangerous, and they were more dangerous than an ordinary consumer would expect.

199. At all times herein mentioned, GranuFlo® and/or NaturaLyte® were in a defective condition and unsafe, and Defendants knew or had reason to know that said products were defective and unsafe, especially when used in the form and manner as provided by Defendants.

200. Defendants knew or should have known that GranuFlo® and/or NaturaLyte® were unreasonably dangerous when each product entered the stream of commerce in one or more of the following particulars:

a. GranuFlo® and NaturaLyte® contained manufacturing defects in that the each product caused and/or increased the risk of experiencing an adverse cardiovascular event, including but not limited to death, sudden cardiac death, heart attack, cardiac arrest, and/or congestive heart failure.

b. GranuFlo® and NaturaLyte® were not safe because the health risks associated with each product outweighed the benefits.

c. GranuFlo® and NaturaLyte® were marketed and promoted for use in hemodialysis treatment, when they carried an unreasonable and unnecessary risk of serious injury and death.

d. GranuFlo® and NaturaLyte® were insufficiently and/or inadequately tested by Defendants.

e. GranuFlo® and NaturaLyte® were not safe due, in part, to inadequate and/or defective instructions provided by Defendants.

f. GranuFlo® and NaturaLyte® were not safe due, in part, to inadequate and/or defective warnings provided by Defendants.

g. GranuFlo® and NaturaLyte® were marketed and promoted for use as safe treatment in hemodialysis treatment, when they were not.

h. GranuFlo® and NaturaLyte® were unreasonably dangerous in that, as designed, each product failed to perform safely when used in dialysis treatment provided to ordinary consumers, including Decedent.

i. GranuFlo® and NaturaLyte® were unreasonably dangerous in that, as designed, the risks serious injury and/or death, posed by using the products exceeded any benefits the products were designed to or might in fact bestow.

j. GranuFlo® and NaturaLyte® were unreasonably dangerous in that, as designed, the products were dangerous to an extent beyond that contemplated by foreseeable users, consumers, and patients, including Decedent.

k. GranuFlo® and NaturaLyte® were defective in design in that the products neither bore, nor were packaged with, nor accompanied by warnings adequate to alert users and dialysis patients, including Decedent, of the increased risks associated with using the products including, but not limited to, the risk of serious injury and/or death.

l. GranuFlo® and NaturaLyte® were not accompanied by adequate warnings and/or instructions for use that included inadequate information to fully apprise the medical, pharmaceutical and/or scientific communities, and users and/or consumers of the potential risks and serious side effects associated with using the products.

m. GranuFlo® and NaturaLyte® were unsafe for normal or reasonably anticipated use.

n. GranuFlo® and NaturaLyte® were defective and/or unreasonably dangerous in construction and/or composition.

o. GranuFlo® and NaturaLyte® were defective and/or unreasonably dangerous in design.

p. GranuFlo® and NaturaLyte® were defective and/or unreasonably dangerous because the products did not conform to an express warranty of the manufacturer about the product.

q. GranuFlo® and NaturaLyte® were defective and/or unreasonably dangerous due to inadequate warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and/or study.

201. GranuFlo® and NaturaLyte® as 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 injuries from use, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom it was directly

marketing and advertising; and, further, it continued to affirmatively promote GranuFlo® and NaturaLyte® as safe and effective.

202. A reasonable person who had actual knowledge of the increased risks associated with using GranuFlo® and NaturaLyte® would have concluded that GranuFlo® and NaturaLyte® should not have been marketed and/or used in dialysis treatment.

203. Despite the fact that Defendants knew or should have known of the defective nature of GranuFlo® and NaturaLyte®, Defendants continued to design, manufacture, market, and sell GranuFlo® and NaturaLyte® so as to maximize sales and profits at the expense of the public health and safety. Defendants thus acted with conscious and deliberate disregard of the foreseeable harm caused by GranuFlo® and NaturaLyte®.

204. Decedent could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by GranuFlo® and NaturaLyte®.

205. The non-defendant healthcare professionals involved in the dialysis treatment provided to Decedent could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by GranuFlo® and NaturaLyte®.

206. As a direct and proximate cause of the defective and/or unreasonably dangerous condition of GranuFlo® and NaturaLyte®, the products were used during the dialysis treatment provided to Decedent. As a result, Decedent suffered the injuries and damages alleged herein.

207. Information given by Defendants to the medical community and to the consumers concerning the safety and efficacy of GranuFlo® and NaturaLyte®, especially the information contained in the advertising and promotional material, did not accurately reflect the risks associated with using the products.

208. Had adequate information regarding the safety of the products been provided to Decedent and/or the non-defendant healthcare providers involved in the dialysis provided to Decedent, GranuFlo® and NaturaLyte® would not have been used in the dialysis treatment provided to Decedent. Had adequate warnings and/or instructions been provided, GranuFlo® and NaturaLyte® would not have been used in the dialysis treatment provided to Decedent.

209. Defendants acted with conscious and/or deliberate disregard of the foreseeable harm caused by use of their products.

210. Neither Decedent, nor the non-defendant healthcare professionals involved in the dialysis treatment provided to Decedent, knew about, nor could they have learned through the exercise of reasonable care, the risks of serious of serious injury and/or death associated with and/or caused by GranuFlo® and NaturaLyte®.

211. The injuries and damages alleged herein were caused by Defendants.

212. As a direct and proximate consequence of Defendants negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts Decedent suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT II
NEGLIGENCE AND NEGLIGENCE *PER SE*

213. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

214. Defendants negligently manufactured, designed, tested, researched, developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold GranuFlo® and NaturaLyte® in this district and throughout the United States.

215. At all times relevant and material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, research and development, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of GranuFlo® and NaturaLyte®.

216. Defendants breached their duty and were negligent in their actions, misrepresentations, and omissions in numerous ways including the following:

a. failing to test GranuFlo® and NaturaLyte® properly and thoroughly before releasing the products on the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of GranuFlo® and NaturaLyte®;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of GranuFlo® and NaturaLyte® which indicated risks associated with using the products;

d. failing to conduct adequate post-market monitoring and surveillance of GranuFlo® and NaturaLyte®;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing, and selling GranuFlo® and NaturaLyte® to consumers, including Decedent, without an adequate warning of risks associated with using the products;

g. designing, manufacturing, marketing, advertising, distributing, and selling GranuFlo® and NaturaLyte® to consumers, including Decedent, without proper and/or adequate instructions to avoid the harm which could foresee ably occur as a result of using the products;

h. failing to exercise due care when advertising and promoting GranuFlo® and NaturaLyte®;

i. negligently continuing to manufacture, market, advertise, and distribute GranuFlo® and NaturaLyte® after Defendants knew or should have known of the risks of serious injury and/or death associated with using the products;

j. failing to use due care in the preparation and development of GranuFlo® and NaturaLyte® to prevent and/or avoid and/or minimize the risk of injury and/or death to individuals when the products were used;

k. failing to use due care in the design of GranuFlo® and NaturaLyte® to prevent and/or avoid and/or minimize the risk of injury and/or death to individuals when the products were used;

l. failing to conduct adequate pre-clinical testing and research to determine the safety of GranuFlo® and NaturaLyte®;

m. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of GranuFlo® and NaturaLyte®;

n. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Decedent, consumers, the medical community, and the FDA;

o. failing to accompany GranuFlo® and NaturaLyte® with proper warnings regarding all possible risks associated with using the products;

p. failing to use due care in the manufacture, inspection, and labeling of GranuFlo® and NaturaLyte® to prevent risk of injuries to individuals who used the products;

q. failing to use due care in the promotion of GranuFlo® and NaturaLyte® to prevent the risk of injuries to individuals when the products were used in dialysis;

r. failing to use due care in the selling of GranuFlo® and NaturaLyte® to prevent the risk of injuries to individuals when the products were used;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the products;

t. failing to provide adequate and accurate training and information to non-defendant healthcare providers that used GranuFlo® and NaturaLyte®;

t. failing to educate non-defendant healthcare providers and the public about the safest use of the products;

u. failing to give non-defendant healthcare providers adequate information to weigh the risks of serious injury and/or death associated with the products;

v. failing to test and inspect GranuFlo® and NaturaLyte® in a reasonable manner in order to ascertain whether or not they were safe and proper for the purpose for which they were designed, manufactured, and sold;

w. failing to utilize and implement a reasonably safe design in the manufacture of GranuFlo® and NaturaLyte® ;

x. failing to manufacture GranuFlo® and NaturaLyte® in a reasonably safe condition;

y. failing to warn Decedent of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of GranuFlo® and NaturaLyte® ;

z. failing to label GranuFlo® and NaturaLyte® to adequately warn Decedent of the increased risk of death and/or injury associated with the products including the increased risk of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions;

aa. failing (through adequate training, instruction, monitoring, and hiring principles) to ensure that clinicians, nurses, contractors, employees, physicians, and other users of GranuFlo® and NaturaLyte® knew how to properly use all hemodialysis products in a manner that was safe and effective for the recipients, including the individuals who administered GranuFlo® and NaturaLyte® to Decedent;

bb. being otherwise reckless, careless and/or negligent.

217. Defendants knew or should have known that GranuFlo® and NaturaLyte® had unreasonably dangerous risks and caused serious side effects of which Decedent would not be aware.

218. Defendants advertised, marketed, sold and distributed GranuFlo® and NaturaLyte® despite the fact that the Defendants knew or should have known of the increased risks associated with using the products.

219. Defendants knew or should have known that GranuFlo® and NaturaLyte® had unreasonably dangerous risks and caused serious side effects of which the non-defendant

healthcare providers involved in the dialysis treatment provided to Decedent would not be aware. Defendants nevertheless advertised, marketed, sold and distributed GranuFlo® and NaturaLyte®.

220. Defendants have committed negligence *per se* in that Defendants' actions and omissions violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.,* and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations.

221. Defendants' acts and omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 331. As such, Defendants have committed negligence *per se.*

222. Despite the fact that Defendants knew or should have known that GranuFlo® and NaturaLyte® increased the risk of serious injury and/or death, Defendants continued to manufacture, market, advertise, promote, sale and distribute GranuFlo® and NaturaLyte® to healthcare professionals and consumers, including Decedent.

223. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations, and/or other culpable acts described herein, Decedent sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT III
BREACH OF EXPRESS WARRANTIES

224. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action, and further alleges:

225. Defendants knew and intended that GranuFlo® and NaturaLyte® be used in dialysis treatment when the products were placed into the stream of commerce.

226. Defendants knew and intended that GranuFlo® and NaturaLyte® be used in dialysis treatment as the products were used during the dialysis treatment provided to Decedent.

227. Defendants expressly warranted that use of GranuFlo® and NaturaLyte® was safe for use and well accepted by users during dialysis treatment.

228. The acid concentrates GranuFlo® and NaturaLyte® do not conform to these express representations because GranuFlo® and NaturaLyte® are not safe and have numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximately result of the breach of said warranties, Decedent suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

229. Decedent, Decedent's treating physicians and/or healthcare providers reasonably relied upon the representations, warranties, expertise, skill, judgment, and knowledge of Defendants and upon the express warranty that GranuFlo® and NaturaLyte® were safe, of merchantable quality, and fit for use during dialysis treatment.

230. The GranuFlo® and/or NaturaLyte® used during the dialysis treatment provided to Decedent were not safe, of merchantable quality, and/or not fit for use during dialysis treatment.

231. As a direct and proximate result of the breach of warranties by Defendants, Decedent sustained injuries and damages alleged herein.

232. As a direct and proximate result of Defendants' willful, wanton, and/or intentional acts, omissions, misrepresentations, and/or otherwise culpable acts described herein, Decedent sustained injuries and damages alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT IV
BREACH OF IMPLIED WARRANTIES

233. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

234. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold GranuFlo® and NaturaLyte®.

235. Defendants knew and intended that GranuFlo® and NaturaLyte® be used in dialysis treatment when the products were placed into the stream of commerce.

236. Defendants knew and intended that GranuFlo® and NaturaLyte® be used in dialysis treatment as the products were used during the dialysis treatment provided to Decedent.

237. Defendants impliedly warranted to Decedent that use of GranuFlo® and NaturaLyte® was of merchantable quality and safe for use during dialysis treatment.

238. Decedent, and non-defendant healthcare providers providing dialysis treatment to Decedent, reasonably relied upon the expertise, skill, judgment and knowledge of Defendants and upon Defendants' implied warranty that GranuFlo® and NaturaLyte® were safe, of merchantable quality, and fit for use during dialysis treatment.

239. The GranuFlo® and/or NaturaLyte® used during the dialysis treatment provided to Decedent were not safe, of merchantable quality, nor fit for use during dialysis treatment.

240. The GranuFlo® and/or NaturaLyte® used during the dialysis treatment provided to Decedent were neither safe nor fit for use in dialysis.

241. As a direct and proximate result of the breach of warranties by Defendants, Decedent sustained injuries and damages alleged herein.

242. Defendants were aware that consumers, including Decedent, would use GranuFlo® and NaturaLyte® in dialysis treatment; which is to say that Decedent was a foreseeable user of Defendants' products, GranuFlo® and NaturaLyte®.

243. Decedent was at all relevant times in privity with Defendants.

244. GranuFlo® and NaturaLyte® were expected to reach and did in fact reach consumers, including Decedent, without substantial change in the condition in which the products were manufactured and sold by Defendant.

245. Defendants breached various implied warranties with respect to GranuFlo® and NaturaLyte® including the following particulars:

246. Defendants impliedly represented to Decedent, consumers, and the medical community that GranuFlo® and NaturaLyte® were:

a. safe;
b. efficacious;
c. fit for use in dialysis treatment;
d. of merchantable quality;
e. adequately tested;
f. did not increase the risk of death;
g. did not increase the risk of experiencing any adverse cardiovascular event.

247. Defendants breached the implied warranties as follows:

a. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;

b. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.

c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;

d. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment

e. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market; and

f. Defendants misrepresented information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®.

248. GranuFlo® and NaturaLyte® did not conform to Defendants' representations and warranties.

249. Decedent, and non-defendant healthcare providers providing dialysis treatment to Decedent, reasonably relied upon one and/or several of the Defendants' implied warranties.

250. Decedent, and non-defendant healthcare providers providing dialysis treatment to Decedent, used GranuFlo® and/or NaturaLyte® in as intended and directed by Defendants and in a foreseeable manner as intended, recommended, promoted, and/or marketed by Defendants.

251. Defendants breached one or several of the implied warranties provided to and relied on by Decedent.

252. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Decedent sustained injuries, damages, and death alleged.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT V
FRAUDULENT MISREPRESENTATION

253. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

254. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of GranuFlo® and NaturaLyte®, and their intentional dissemination of promotional and marketing information about GranuFlo® and NaturaLyte® for the purpose of maximizing their sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the products.

255. Defendants fraudulently represented to Decedent, physicians, and other persons and professionals on whom it was known by Defendants that Decedent would rely, as well as the public at large, that GranuFlo® and NaturaLyte® were safe for use in dialysis treatment and that the utility of each product outweighed any risk associated with using the products.

256. Defendants failed to disclose to Decedent, and others for the benefit of Decedent, important safety and injury information, thereby suppressing material facts about the products, while having a duty to disclose such information, which duty arose, in part, from Defendants designing, manufacturing, making, marketing, advertising, promoting, distributing and selling such products.

257. The false representations of Defendants were fraudulently made, in that the subject products in fact caused injury, were unsafe, and the benefits of the products were far outweighed by the risk associated with use thereof.

258. Defendants committed acts of intentional misrepresentation and intentional concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of GranuFlo® and NaturaLyte®.

259. Defendants knew or should have known that its representations and/or omissions were false.

260. Defendants made false representations regarding the safety of GranuFlo® and NaturaLyte® with the intent or purpose that Decedent and/or the non-defendant healthcare providers involved in providing dialysis treatment to Decedent, would rely upon such representations, leading to the use of GranuFlo® and NaturaLyte®.

261. Defendants made fraudulent misrepresentations with respect to GranuFlo® and NaturaLyte® in the following particulars:

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;

b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;

c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;

d. Failed to inform Decedent that GranuFlo® and NaturaLyte® had not been adequately tested to determine the safety and risks associated with using the products.

e. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;

f. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.

g. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;

h. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment;

i. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market;

j. Defendants misrepresented information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®; and

k. Defendants misrepresented to Decedent that the clinicians, nurses, and/or physicians were adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

262. Defendants knew that these representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of GranuFlo® and NaturaLyte® to consumers, including Decedent, and to the medical community.

263. Defendants made these misrepresentations with the intent that non-defendant doctors and patients, including Decedent, rely upon them.

264. Defendants' misrepresentations were made with the intent of defrauding and deceiving Decedent, other consumers, and the medical community to induce and encourage the sale of GranuFlo® and NaturaLyte®.

265. Decedent and non-defendant healthcare providers involved in the dialysis treatment provided to Decedent relied upon the misrepresentations of Defendants.

266. Defendants' fraudulent representations evidence their callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Decedent.

267. Defendants made affirmative misrepresentations; and fraudulently concealed material adverse information regarding the safety and effectiveness of GranuFlo® and NaturaLyte®.

268. Defendants misrepresented and/or actively concealed adverse information at a time when Defendants knew or had reason to know that GranuFlo® and NaturaLyte® had defects and were unreasonably dangerous.

269. Defendants misrepresented and/or actively concealed adverse information at a time when Defendants knew or had reason to know that GranuFlo® and NaturaLyte® were not as safe as what Defendants had represented to the medical community, the FDA, and the consuming public, including Decedent.

270. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of GranuFlo® and NaturaLyte® including the increased risk of serious injury and/or death.

271. Defendants were willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of GranuFlo® and NaturaLyte® in order to increase sales.

272. The false and/or misleading representations and concealment were undertaken by Defendants with an intent that doctors and patients, including Decedent, rely upon them.

273. Defendants' false and/or misleading representations and concealments were undertaken with the intent of defrauding and deceiving Decedent, other consumers, and the medical community to induce and encourage the sale and purchase of GranuFlo® and NaturaLyte®.

274. Defendants' false and/or misleading representations and concealment evince a callous, reckless, willful, and/or depraved indifference to the health, safety, and welfare of consumers, including Decedent.

275. Decedent, and the healthcare professionals involved in providing dialysis treatment to Decedent, relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of GranuFlo® and NaturaLyte®.

276. Decedent and the treating medical community did not know that the representations made by Defendants were false and/or misleading and were justified in relying upon Defendants' representations.

277. Had Decedent been aware of the increased risks of serious injury and/or death associated with GranuFlo® and NaturaLyte®, Decedent would not have used GranuFlo® and NaturaLyte® during dialysis.

278. Had any non-defendant healthcare professionals involved in providing dialysis treatment to Decedent been aware of the increased risks of serious injury and/or death associated with GranuFlo® and NaturaLyte®, they would not have used GranuFlo® and NaturaLyte® during dialysis.

279. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which Decedent reasonably relied, Decedent suffered injuries and damages as alleged herein.

280. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Decedent sustained injuries and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT VI
FRAUDULENT CONCEALMENT

281. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

282. Defendants fraudulently concealed information with respect to GranuFlo® and NaturaLyte® in the following particulars:

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;

b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;

c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;

d. Failed to inform Decedent that GranuFlo® and NaturaLyte® had not been adequately tested to determine the safety and risks associated with using the products.

e. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;

f. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.

g. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;

h. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment

i. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market;

j. Defendants concealed from Decedent information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®; and

k. Defendants concealed from Decedent that the clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared

for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

283. Defendants had sole access to material facts concerning the dangers and unreasonable risks of GranuFlo® and NaturaLyte®.

284. The concealment of information by Defendants about the substantial risks of serious injury and/or death associated with GranuFlo® and NaturaLyte® were intentional, and the representations made by Defendants were known by Defendants to be false.

285. Defendants made the concealment of information and the misrepresentations about GranuFlo® and NaturaLyte® with the intent that doctors and patients, including Decedent, rely upon them.

286. Decedent and the non-defendant healthcare providers involved in providing dialysis to Decedent, detrimentally relied upon the misrepresentations and material omission of Defendants and were unaware of the substantial increased risk of serious injury and/or death associated with and/or caused by GranuFlo® and NaturaLyte®, which Defendants concealed from Decedent and any non-defendant healthcare providers.

287. Had Defendants not fraudulently concealed such information, GranuFlo® and/or NaturaLyte® would not have been used during the dialysis treatment provided to Decedent.

288. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Plaintiff sustained injuries and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT VII

NEGLIGENT MISREPRESENTATION

289. Plaintiff incorporates by reference all of the paragraphs of this Complaint as if fully set forth herein.

290. At all relevant times, Defendants designed, tested, manufactured, packaged, marketed, distributed, promoted, and sold GranuFlo® and NaturaLyte®.

291. At all relevant times, Defendants knew of the use for which GranuFlo® and NaturaLyte® were intended and expressly and/or impliedly warranted its products were of merchantable quality and safe and fit for such use.

292. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and the public, their specific knowledge regarding the risks and dangers of GranuFlo® and NaturaLyte®, and their intentional dissemination of promotional and marketing information about GranuFlo® and NaturaLyte® for the purpose of maximizing their sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the products.

293. Defendants recklessly, and/or negligently represented to Decedent, any non-defendant physicians, and other persons and professionals on whom it was known by Defendants that Decedent would rely, as well as the public at large, that the GranuFlo® and NaturaLyte® were safe to use and that the utility of the products outweighed any risk in use for their intended purposes.

294. Defendants recklessly and/or negligently failed to disclose to Decedent, and others, important safety and efficacy information, thereby suppressing material facts about GranuFlo® and NaturaLyte®, while having a duty to disclose such information, which duty arose from their

actions of making, marketing, promoting, distributing and selling pharmaceutical products to Decedent and others.

295. Defendants led Decedent to rely upon the safety of GranuFlo® and NaturaLyte® in its use.

296. The false representations of Defendants were recklessly and/or negligently made in that GranuFlo® and NaturaLyte® in fact caused injury, were unsafe, and the benefits of their use were far outweighed by the risk associated with use thereof.

297. Defendants committed acts of reckless and/or negligent misrepresentation and reckless and/or negligent concealment by suppressing material facts relating to the dangers and injuries associated with, and caused by, the use of GranuFlo® and NaturaLyte®.

298. Defendants knew or should have known that its representations and/or omissions were false. Defendants made such false, negligent and/or reckless representations with the intent or purpose that Decedent and any non-defendant physicians would rely upon such representations, leading to the use of GranuFlo® and NaturaLyte® by Decedent.

299. Defendants recklessly and/or negligently misrepresented and/or omitted information with respect to GranuFlo® and NaturaLyte® in the following particulars:

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;

b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;

c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;

d. Failed to inform Decedent that GranuFlo® and NaturaLyte® had not been adequately tested to determine the safety and risks associated with using the products,

e. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;

f. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.

g. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;

h. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment

i. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market;

j. Defendants misrepresented information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®;

k. Defendants misrepresented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that GranuFlo® and NaturaLyte® were safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using GranuFlo® and NaturaLyte®;

1. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe and/or safer than other similar products and fraudulently concealed information, which demonstrated that GranuFlo® and NaturaLyte® were not safer than alternatives available on the market;

m. Defendants misrepresented that GranuFlo® and NaturaLyte® were safer and more efficacious than other similar products and fraudulently concealed information, regarding the true safety and efficacy of the products; and

n. Defendants misrepresented to Decedent that the clinicians, nurses, and/or physicians were adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

300. Defendants made affirmative misrepresentations and recklessly and/or negligently omitted material adverse information regarding the safety and effectiveness of GranuFlo® and NaturaLyte®.

301. Defendants made these misrepresentations and/or omissions at a time when Defendants knew or had reason to know that GranuFlo® and NaturaLyte® had defects and were unreasonably dangerous and was not what Defendants had represented to the medical community, the FDA, and the consuming public, including Decedent.

302. Defendants omitted, suppressed and/or concealed material facts concerning the dangers and risk of injuries associated with the use of GranuFlo® and NaturaLyte® including, serious injury and death. Furthermore, Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of GranuFlo® and NaturaLyte® in order to increase sales.

303. Defendants' misrepresentations and/or omissions were undertaken by Defendants with an intent that doctors and patients, including Decedent, rely upon them.

304. Defendants' misrepresentations and/or omissions were undertaken with the intent of defrauding and/or deceiving Decedent, other consumers, and the medical community to induce and encourage the sale of GranuFlo® and NaturaLyte®.

305. Defendants' misrepresentations and/or omissions evinced Defendants' callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Decedent.

306. Decedent and any non-defendant physicians relied on and were induced by Defendants' misrepresentations, omissions, and/or active concealment of the dangers of GranuFlo® and NaturaLyte® in selecting treatment.

307. Decedent and the treating medical community did not know that the representations made by Defendants were false and were justified in relying upon Defendants' representations.

308. Had Decedent been aware of the increased risks associated with GranuFlo® and NaturaLyte® and the relative efficacy of GranuFlo® and NaturaLyte® compared with other readily available products, Decedent would not have been exposed to GranuFlo® and NaturaLyte®.

309. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Decedent sustained injuries, damages and alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT VIII
FRAUD AND DECEIT

310. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

311. Defendants conducted research and/or had a duty to conduct research using GranuFlo® and/or NaturaLyte®

312. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Decedent, Decedent's doctors, hospitals, healthcare providers, and/or the FDA that GranuFlo® and/or NaturaLyte® were safe and effective for their intended use as acid concentrates.

313. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Decedent and Decedent's healthcare providers.

314. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, the Decedent, Decedent's healthcare providers, and/or the FDA.

315. The information distributed to the public, the FDA, and the Decedent by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, internet advertisements, and/or all other commercial media contained material representations of fact and/or omissions concerning the true safety profile of GranuFlo® and/or NaturaLyte®.

316. The information distributed to the public, the FDA, and Decedent by Defendants intentionally included representations that Defendants' GranuFlo® and/or NaturaLyte® were safe and effective for their intended use as acid concentrates in hemodialysis treatment.

317. The information distributed to the public, the FDA, and Decedent by Defendants intentionally included representations that Defendants' GranuFlo® and/or NaturaLyte® carried the same risks, hazards, and/or dangers as other acid concentrates on the market.

318. The information distributed to the public, the FDA, and Decedent by Defendants intentionally included representations that Defendants' GranuFlo® and/or NaturaLyte® were more effective for the treatment of kidney disease during hemodialysis, thereby encouraging the use of GranuFlo® and/or NaturaLyte® in circumstances other than those in which the drug had been approved, over-promises the benefits and minimizes the risks associated with GranuFlo® and/or NaturaLyte® .

319. The information distributed to the public, the FDA, and the Decedent by Defendants intentionally included false representations that exposure to GranuFlo® and/or NaturaLyte® was not injurious to the health and/or safety of its intended users.

320. The information distributed to the public, the FDA, and the Decedent by Defendants intentionally included false representations that exposure to GranuFlo® and/or NaturaLyte® was as potentially injurious to the health and/or safety of its intended users as other acid concentrates.

321. These representations were all false and misleading.

322. Upon information and belief, Defendants intentionally suppressed, ignored, and disregarded test results not favorable to Defendants and the safety profile of GranuFlo® and/or NaturaLyte®—results that demonstrated that GranuFlo® and/or NaturaLyte® were not as safe as other means of acid concentrates and included an increased risks including metabolic alkalosis and sudden death.

323. Defendants intentionally made material misrepresentations to the FDA and the public, including the medical profession, the Decedent, and/or Decedent's healthcare providers, regarding the safety of GranuFlo® and/or NaturaLyte®, specifically but not limited to exposure to GranuFlo® and/or NaturaLyte® not having dangerous side effects and serious health and safety concerns.

324. Defendants intentionally made material misrepresentations to the FDA and the public, including the medical profession, the Decedent, and/or Decedent's healthcare providers, regarding the safety of GranuFlo® and/or NaturaLyte®, specifically but not limited to GranuFlo® and/or NaturaLyte® being as safe a means of acid concentrate as other acid concentrates on the market.

325. It was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, the Decedent, and/or Decedent's healthcare providers, to gain the confidence of the public, healthcare providers, the FDA, and Decedent to falsely ensure the

quality and fitness for use of GranuFlo® and/or NaturaLyte® and to induce the public, and/or the Decedent to purchase, request, dispense, prescribe, recommend, and/or continue to use GranuFlo® and/or NaturaLyte®.

326. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare providers, the FDA, and the Decedent that GranuFlo® and/or NaturaLyte® were fit and safe for use as acid concentrates in hemodialysis.

327. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare providers, the FDA, and the Decedent that GranuFlo® and/or NaturaLyte® were fit and safe for use as acid concentrates and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other acid concentrates on the market.

328. Defendants made claims and representations in its documents submitted to the FDA, the public, healthcare providers, the Decedent, and/or Decedent's healthcare providers that exposure to GranuFlo® and/or NaturaLyte® did not present health and/or safety risks.

329. Defendants made claims and representations in its documents submitted to the FDA, the public, healthcare providers, the Decedent, and/or Decedent's healthcare providers that exposure to GranuFlo® and/or NaturaLyte® did not present health and/or safety risks greater than other acid concentrates on the market.

330. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

331. That these representations and others made by Defendants were made with the intention of deceiving and defrauding the Decedent, Decedent's healthcare providers, and/or the

FDA, and were made in order to induce the Decedent, Decedent's healthcare providers, and/or the FDA to rely upon misrepresentations and caused the Decedent and/or Decedent's healthcare providers to purchase, use, rely on, request, dispense, recommend, and/or prescribe GranuFlo® and/or NaturaLyte®.

332. That Defendants recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of exposure to GranuFlo® and/or NaturaLyte® to the public at large, the Decedent, and/or Decedent's healthcare providers in particular, for the purpose of influencing the marketing of products known to be dangerous and defective and/or not as safe as other alternatives, including other acid concentrates.

333. That Defendants recklessly and intentionally failed to disclose the dangerous and serious health and/or safety concerns of exposure to GranuFlo® and/or NaturaLyte® to the public at large, the Decedent, and/or Decedent's healthcare providers in particular, for the purpose of influencing the marketing of products known to be dangerous and defective and/or not as safe as other alternatives, including other acid concentrates.

334. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Decedent and/or Decedent's healthcare providers, would rely upon the information being disseminated.

335. Defendants utilized direct to consumer advertising to market, promote, and/or advertise GranuFlo® and/or NaturaLyte®.

336. Decedent and/or Decedent's healthcare providers did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of Defendants regarding their acid

concentrates and were thereby induced to purchase, use, and rely on Defendants' GranuFlo® and/or NaturaLyte®.

337. That at the time the representations were made, the Decedent and/or Decedent's healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of exposure to GranuFlo® and/or NaturaLyte®.

338. That the Decedent and/or Decedent's healthcare providers did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Decedent and/or Decedent's healthcare providers with reasonable diligence have discovered the true facts.

339. That had the Decedent and/or Decedent's healthcare providers known the true facts with respect to the dangerous and serious health and/or safety concerns of GranuFlo® and/or NaturaLyte®, they would not have purchased, used, and/or relied on Defendants' acid concentrates GranuFlo® and/or NaturaLyte®.

340. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly, and/or purposefully on the Decedent and/or Decedent's healthcare providers.

341. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Decedent sustained injuries and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT IX
UNJUST ENRICHMENT

342. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

343. At all times relevant to this action, Defendants designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold GranuFlo® and NaturaLyte®.

344. GranuFlo® and/or NaturaLyte® were used during dialysis treatment provided to Decedent.

345. Defendants received payment for the cost of NaturaLyte and/or GranuFlo purchased and used in the dialysis treatment provided to Decedent.

346. Decedent did not receive the safe and effective products intended.

347. It is inequitable and unjust for Defendants to retain this money because Decedent did not receive the products that Defendants represented GranuFlo® and NaturaLyte® to be.

WHEREFORE, Plaintiff demands judgment against each Defendant and seeks disgorgement of profits, equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT X
WRONGFUL DEATH

348. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

349. As a direct and proximate result of Defendants' negligence and otherwise culpable acts described herein, Decedent received GranuFlo® and/or NaturaLyte® which caused Decedent to sustain injuries and damages outlined herein, and caused death.

350. Decedent's injuries and death as alleged more fully herein directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and/or misrepresentations. In

particular, Defendants' gross negligence and malicious, willful, wanton, and reckless conduct, as described herein, caused Decedent's death.

351. Defendants' negligence and otherwise culpable acts described herein violate the wrongful death statutes of Florida and any other applicable state statute, regulation, law, and/or rule providing for a chose-in-action relating to the wrongful death of an individual such as Decedent.

WHEREFORE, Plaintiff demands judgment against Defendants on behalf of the survivors and beneficiaries of a recovery for the wrongful death of Decedent (COLLEE K. COULTAS, and the Estate of SHANNON K. GILTNER) and seeks statutory damages, compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT XI
SURVIVORSHIP

352. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

353. This Count is for the conscious pain and suffering being brought for the benefit of the estate of the Decedent.

354. As a direct and proximate result of Defendants' conduct, Plaintiff's Decedent was cause to suffer severe mental, emotional, and physical pain and suffering prior to Decedent's untimely death.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

COUNT XII

WANTONNESS

355. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

356. Defendants wantonly and recklessly designed, manufactured, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold GranuFlo® and NaturaLyte® in this district and through the United States.

357. At all times material hereto, Defendants had a duty to exercise reasonable care in the design, manufacture, testing, research and development, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of GranuFlo® and NaturaLyte®.

358. Defendants negligently mixed, distributed, promoted, marketed, advertised, and sold GranuFlo® and NaturaLyte® in this district and throughout the United States.

359. At all times material hereto, Defendants had a duty to exercise reasonable care in the mixing, distribution, promotion, marketing, advertising, and sale of and GranuFlo® and NaturaLyte®.

360. Defendants breached their duty and were wanton and reckless in their actions, misrepresentations, and omissions toward Plaintiff in the following ways:

a. Failing to test and inspect GranuFlo® and NaturaLyte® in a reasonable manner in order to ascertain whether or not they were safe and proper for the purpose for which they were designed, manufactured, delivered, and sold;

b. failing to utilize and implement a reasonably safe design in the manufacture of GranuFlo® and NaturaLyte® ;

c. failing to manufacture GranuFlo® and NaturaLyte® in a reasonably safe condition;

d. failing to warn Plaintiff/Decedent of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of GranuFlo® and NaturaLyte® ;

e. failing to label GranuFlo® and NaturaLyte® reasonably so as to warn Plaintiff/Decedent of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of GranuFlo® and NaturaLyte® ;

f. failing to comply with accepted industry standards and federal regulations when manufacturing GranuFlo® and NaturaLyte®; and

g. failing to ensure clinicians, nurses, and/or physicians were adequately trained, instructed, credentialed, and prepared for proper use of GranuFlo® and NaturaLyte®.

361. Defendants knew that GranuFlo® and NaturaLyte® had unreasonably dangerous risks and caused serious side effects of which Decedent would not be aware. Defendants nevertheless advertised, marketed, sold, labeled, distributed, and instructed/trained on the use of GranuFlo® and NaturaLyte® knowing that there were safer methods and products for dialysis treatment.

362. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants as set forth above, Decedent sustained injuries and damages as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

GLOBAL PRAYER FOR RELIEF

Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges:

WHEREFORE, as so far as the law and this Court allows, Plaintiff demands judgment against each Defendant on each count as follows:

a. compensatory damages for the described losses with respect to each cause of action;
b. past medical expenses and burial expenses;
c. past and future lost wages and loss of earning capacity;

d. pain and suffering;
e. past and future emotional distress;
f. loss of enjoyment of life;
g. wrongful death;
h. consequential damages;
i. disgorgement of profits;
j. restitution;
k. punitive damages with respect to each cause of action;
1. injunctive relief;
m. reasonable attorneys' fees where recoverable;
n. costs of this action;
o. prejudgment and all other interest recoverable; and
p, such other additional and further relief as Plaintiff may be entitled to in law or in equity.

TOLLING OF THE LIMITATIONS PERIOD

363. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Decedent and any non-defendant healthcare providers the true and significant risks associated with GranuFlo® and NaturaLyte®.

364. As a result of Defendants actions, Decedent and the non-defendant healthcare providers involved in the dialysis treatment provided to Decedent were unaware, and could not have reasonably known or have learned through reasonable diligence, that Decedent had been exposed to the risks identified in this Complaint, and that those risks were the result of acts, omissions, and misrepresentations of each Defendant.

365. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between the use of GranuFlo® and NaturaLyte® and the harm suffered as a result.

366. Additionally, the accrual and running of any applicable statute of limitations has been tolled by reason of Defendants' fraudulent concealment.

367. Additionally, each Defendant is equitably estopped from asserting any limitations defense by virtue of its fraudulent concealment and other misconduct as described in this Complaint.

368. Additionally, the limitations period is tolled under principles of equitable tolling.

PLAINTIFF DEMANDS A TRIAL OF ALL ISSUES BY A JURY.

Date: May 17, 2013

By: /s/ Seth D. Jacobs

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612-349-8500

ATTORNEYS FOR PLAINTIFF

ATTACHMENT 3

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** Colleen Coultas vs Fresenius USA, Inc.

2. **Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).**

☐ I. **410, 441, 470, 535, 830*, 891, 893, 894, 895, R.23, REGARDLESS OF NATURE OF SUIT.**

☐ II. **110, 130, 140, 160, 190, 196, 230, 240, 290,320,362, 370, 371, 380, 430, 440, 442-446, 710, 720, 730, 740, 790, 820*, 840*, 850, 870, 871.**

☑ III. **120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 368, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 610, 620, 625, 630, 640, 650, 660, 690, 791, 810, 861-865, 875, 890, 892, 900, 950.**

***Also complete AO 120 or AO 121. for patent, trademark or copyright cases.**

3. **Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.**
See Attached (Fresenius Cases)

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**
YES ☐ **NO** ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**
YES ☐ **NO** ☐
If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?
YES ☐ **NO** ☐

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**
YES ☐ **NO** ☐

7. **Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**
YES ☑ **NO** ☐

A. **If yes, in which division do all of the non-governmental parties reside?**
Eastern Division ☑ **Central Division** ☐ **Western Division** ☐

B. **If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?**
Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**
YES ☐ **NO** ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Timothy G Lynch
ADDRESS 45 School Street, 3rd Floor
TELEPHONE NO. 617-367-2882

ATTACHMENT 2

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

Colleen Coultas, individually, as next of kin, and Personal Representative of the Estate of Shannon K. Giltner

(b) County of Residence of First Listed Plaintiff Multnomah
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Timothy G Lynch, Swartz & Lynch LLP
45 School St 3rd Floor Boston, MA 02108 617-367-2882

DEFENDANTS Fresenius USA Marketing, Inc.
Fresenius USA Inc, Fresenius USA Manufacturing Inc., Fresenius Medical Care Holdings, Inc. Fresenius Medical Care North Am., Inc, Fresenius USA Sales, Inc. Fresenius Kidney Care Marketing, Inc.

County of Residence of First Listed Defendant Middlesex
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☒ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☒ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	☐ 840 Trademark	☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**):
28 USC 1332

Brief description of cause:
Personal Injury- wrongful death/product

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Woodlock DOCKET NUMBER Attached (Fresenius cases)

DATE
05/17/2013

SIGNATURE OF ATTORNEY OF RECORD
Timothy G. Lynch

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Fresenius Cases- District of Massachusetts

Jones v Fresenius 1:12cv-12022-JLT

Boone v Fresenius 1:12 cv 12296-JLT

Johnson v Fresenius 1:12 cv 12295-JLT

Dubose v Fresenius Defendants 1:12 cv 12306-JLT

Moore v Fresenius Defendants 1:13 cv 10010-JLT

Taylor v Fresenius 1L13cv 10062-JLT

Roberts v. Fresenius 1:13 cv 10061-JLT

Alford v Fresenius 1:13 cv 10060-JLT

Heard v Fresenius 1:13 cv 1—66-JLT

Hernandez v Fresenius 1:13 cv 10082-JLT

Sims v Fresenius 1:13 cv 10109-NMG

Salazar v Fresenius 1:13 cv 10108-JLT