IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

WILLIAM C. JONES, PLAINTIFF VERSUS FRESENIUS MEDICAL CARE HOLDINGS, INC.; FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA; FRESENIUS USA, INC.; FRESENIUS USA MANUFACTURING, INC.; FRESENIUS USA MARKETING, INC.; FRESENIUS USA SALES, INC.; FRESENIUS MEDICAL CARE AG & CO. KGAA; FRESENIUS MEDICAL CARE MANAGEMENT, AG; FRESENIUS SE & CO. KGAA; and FRESENIUS MANAGEMENT,SE. DEFENDANTS .	**CIVIL ACTION NO.:**_____

COMPLAINT AND JURY DEMAND

Plaintiff WILLIAM C. JONES, by and through the undersigned attorneys, 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 damages caused by NATURALYTE LIQUID ACID CONCENTRATE (hereinafter "NATURALYTE") and/or GRANUFLO DRY ACID CONCENTRATE (hereinafter "GRANUFLO") used during dialysis treatment administered to Plaintiff WILLIAM C. JONES.

2. Defendants, FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., FRESENIUS USA SALES, INC., FRESENIUS MEDICAL CARE AG & CO. KGAA, FRESENIUS MEDICAL CARE MANAGEMENT, AG, FRESENIUS SE & CO. KGAA, and FRESENIUS MANAGEMENT, SE (hereinafter referred to as "FRESENIUS," "FRESENIUS DEFENDANTS" and/or "DEFENDANTS"), designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed NATURALYTE and/or GRANUFLO for use as acid concentrates during hemodialysis.

3. When warning of the safety, risks and/or defects of NATURALYTE and/or GRANUFLO, Defendants concealed their knowledge of NATURALYTE's and/or GRANUFLO's safety, risks and/or defects from Plaintiff(s), the United States Food and Drug Administration (hereinafter referred to as the "FDA"), the public in general and/or the medical community, specifically that NATURALYTE and/or GRANUFLO 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 Plaintiff(s), and the public in general that NATURALYTE and/or GRANUFLO 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 NATURALYTE and/or GRANUFLO, Defendants negligently and/or fraudulently represented to the medical and healthcare community, the FDA, the Plaintiff(s), and the public in general that NATURALYTE

and/or GRANUFLO 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 Plaintiff(s), 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 NATURALYTE and/or GRANUFLO as acid concentrates during hemodialysis, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff(s) herein.

7. Defendants negligently and improperly failed to perform sufficient tests, if any, concerning NATURALYTE's and/or GRANUFLO'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, Plaintiff(s) 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(s) 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(s) and Defendants.

13. Venue is proper in this federal judicial district.

PARTY PLAINTIFFS

14. Plaintiff, WILLIAM C. JONES, at all times material hereto, was an adult citizen and resident of Atlantic County, New Jersey. Plaintiff, WILLIAM C. JONES, suffered personal injuries and damages as a result of using NATURALYTE and/or GRANUFLO during hemodialysis.

15. NATURALYTE and/or GRANUFLO were used in the dialysis treatment provided to the Plaintiff, WILLIAM C. JONES, in this judicial district.

16. The use of NATURALYTE and/or GRANUFLO in dialysis treatment, caused the Plaintiff, WILLIAM C. JONES to suffer severe injuries and damages including but not limited to the following: cardiopulmonary arrest on or about August 9, 2012.

17. Due to the negligent, intentional, willful, wanton, fraudulent, and/or otherwise culpable conduct of the Defendants alleged herein, the Plaintiff(s), Plaintiff'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 NATURALYTE and/or GRANUFLO, until the products were recalled by the FDA on July 12, 2012.

PARTY DEFENDANTS

18. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. is a corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

19. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

20. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. has transacted and conducted business throughout the United States, including this judicial district.

21. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. 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.

22. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. derives substantial revenue from interstate commerce throughout the United States, including this judicial district.

23. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA is a corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

24. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

25. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA has transacted and conducted business throughout the United States, including this judicial district.

26. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA 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.

27. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA derives substantial revenue from interstate commerce conducted throughout the United States, including this judicial district and expected or should have expected to be held accountable in this judicial district.

28. Defendant FRESENIUS USA, INC. is a corporation organized under the laws of the State of Massachusetts having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

29. Defendant FRESENIUS USA, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

30. Defendant FRESENIUS USA, INC. has transacted and conducted business throughout the United States, including this judicial district.

31. Defendant FRESENIUS USA, INC. 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.

32. Defendant FRESENIUS USA, INC. derives substantial revenue from interstate commerce conducted throughout the United States, including this judicial district and expected or should have expected to be held accountable in this judicial district.

33. Defendant FRESENIUS USA MANUFACTURING, INC. is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

34. Defendant FRESENIUS USA MANUFACTURING, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

35. Defendant FRESENIUS USA MANUFACTURING, INC. has transacted and conducted business throughout the United States, including this judicial district.

36. Defendant FRESENIUS USA MANUFACTURING, INC. 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.

37. Defendant FRESENIUS USA MANUFACTURING, INC. 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; and, expected or should have expected its acts to have consequences within this judicial district.

38. Defendant FRESENIUS USA MARKETING, INC. is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

39. Defendant FRESENIUS USA MARKETING, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

40. Defendant FRESENIUS USA MARKETING, INC. has transacted and conducted business throughout the United States, including this judicial district.

41. Defendant FRESENIUS USA MARKETING, INC. has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

42. Defendant FRESENIUS USA MARKETING, INC. expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

43. Defendant FRESENIUS USA SALES, INC. is a corporation organized under the laws of the State of Massachusetts having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

44. Defendant FRESENIUS USA SALES, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

45. Defendant FRESENIUS USA SALES, INC. has transacted and conducted business throughout the United States, including this judicial district.

46. Defendant FRESENIUS USA SALES, INC. has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

47. Defendant FRESENIUS USA SALES, INC. expected or should have expected its acts to have consequences within this judicial district; and, derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

48. Upon information and belief, Defendants FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC. and FRESENIUS

USA SALES, INC. are wholly owned subsidiaries of Defendants FRESENIUS MEDICAL CARE HOLDINGS, INC. and/or FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

49. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

50. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA, a partnership limited by shares, was formerly known as FRESENIUS MEDICAL CARE AG, a stock corporation. FRESENIUS MEDICAL CARE AG & CO. KGAA is the same legal business entity as FRESENIUS MEDICAL CARE AG.

51. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA is and was at all relevant times the parent company of Defendants FRESENIUS MEDICAL CARE HOLDING, INC. and/or FRESENIUS MEDICAL CARE HOLDING, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

52. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

53. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA has transacted and conducted business throughout the United States, including this judicial district.

54. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

55. Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA expected or should have expected its acts to have consequences within this judicial district; and, derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

56. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is a corporation organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

57. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is the general partner of Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA, and is responsible for the management of Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA.

58. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG was the majority voting shareholder of FRESENIUS MEDICAL CARE AG & CO. KGAA, when it was known as FRESENIUS MEDICAL CARE AG, and was responsible for the management of Defendant FRESENIUS MEDICAL CARE AG & CO. KGAA, when it was known as FRESENIUS MEDICAL CARE AG.

59. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

60. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG has transacted and conducted business throughout the United States, including this judicial district.

61. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

62. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

63. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is and was at all times relevant herein a wholly owned subsidiary of Defendant FRESENIUS SE & CO. KGAA.

64. Defendant FRESENIUS SE & CO. KGAA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

65. Defendant FRESENIUS SE & CO. KGAA was formerly known as FRESENIUS SE, which was formerly known as FRESENIUS AG. FRESENIUS SE & CO. KGAA is the same legal business entity as FRESENIUS SE and FRESENIUS AG.

66. Defendant FRESENIUS SE & CO. KGAA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

67. Defendant FRESENIUS SE & CO. KGAA has transacted and conducted business throughout the United States, including this judicial district.

68. Defendant FRESENIUS SE & CO. KGAA has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

69. Defendant FRESENIUS SE & CO. KGAA expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

70. Defendant FRESENIUS MANAGEMENT SE is a corporation organized under the laws of Germany having its headquarters and principal place of business at 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

71. Defendant FRESENIUS MANAGEMENT SE is the general partner of FRESENIUS SE & CO. KGAA, and is responsible for the management of Defendant FRESENIUS SE & CO. KGAA.

72. Defendant FRESENIUS MANAGEMENT SE was the majority voting shareholder of FRESENIUS SE & CO. KGAA, when it was known as FRESENIUS SE, and was responsible for the management of Defendant FRESENIUS SE& CO. KGAA, when it was known as FRESENIUS SE.

73. Defendant FRESENIUS MANAGEMENT SE was the majority voting shareholder of FRESENIUS SE & CO. KGAA, when it was known as FRESENIUS AG, and was responsible for the management of Defendant FRESENIUS SE& CO. KGAA, when it was known as FRESENIUS AG.

74. Defendant FRESENIUS MANAGEMENT SE at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting,

selling and/or distributing NATURALYTE and/or GRANUFLO in the stream of commerce for use by the public, including Plaintiff(s).

75. Defendant FRESENIUS MANAGEMENT SE has transacted and conducted business throughout the United States, including this judicial district.

76. Defendant FRESENIUS MANAGEMENT SE has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

77. Defendant FRESENIUS MANAGEMENT SE expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

JOINT & SEVERAL LIABILITY

78. Hereinafter the aforementioned Defendants may collectively be referred to as "the Defendants" or "Fresenius."

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

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

81. At all relevant times each Defendant acted in all aspects as agent and alter ego of for each named Defendant.

82. At all relevant times each Defendant acted in all aspects as agent and alter ego of Fresenius Medical Care AG & Co. KGAA.

83. At all relevant times, Defendants were engaged in the business of designing, testing, manufacturing, marketing, promoting, selling, labeling, packaging, and/or distributing

NATURALYTE AND/OR GRANUFLO in this judicial district and throughout the United States.

84. At all relevant times, Defendants intentionally, recklessly and/or negligently designed, manufactured, marketed, advertised, promoted, labeled, sold and/or distributed NATURALYTE AND/OR GRANUFLO as being safe for use in dialysis when, in fact, the Defendants had reason to know, and/or did know, that the products were not safe and associated with an increased risk of serious injury and death.

85. At all times material hereto, Defendants maintained systematic and continuous contacts in this judicial district, regularly transacted business within this judicial district, and regularly availed itself of the benefits of this judicial district.

86. Defendants employ people in this judicial district.

87. At all relevant times, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of NATURALYTE AND/OR GRANUFLO.

88. Defendants are present and doing business in this state. Defendants are and were at all relevant times authorized to conduct business within this judicial district.

89. At all relevant times, Defendants intentionally, recklessly and/or negligently designed, manufactured, marketed, advertised, promoted, labeled, sold and/or distributed NATURALYTE AND/OR GRANUFLO in this judicial district which caused and/or substantially contributed to causing the injuries and damages alleged herein.

90. Defendants received substantial financial benefit and profits as a result of designing, manufacturing, marketing, advertising, promoting, labeling, selling and/or distributing

NATURALYTE AND/OR GRANUFLO in this judicial district and throughout the United States.

FACTUAL BACKGROUND

A. Hemodialysis in General

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

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

93. A person 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.

94. Many patients who suffer from kidney disease also suffer from a condition known as metabolic acidosis (too much acid in the body) because the kidneys are failing to remove excess acid from the body.

95. One goal of hemodialysis is to attempt to bring the body's acid levels 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.

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

97. Defendants' NATURALYTE and GRANUFLO are acid concentrates.

98. 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.

99. 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.

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

101. 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.

102. 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.

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

104. As such, it is imperative that the manufacturer of a product used in hemodialysis, such as an acid concentrate, advise and/or warn prescribing physicians and/or healthcare facilities of any and all risks, concerns, defects and other safety information regarding said product.

B. Naturalyte and Granuflo – The Recall

105. NATURALYTE and/or GRANUFLO are acid concentrates designed, manufactured, marketed, advertised, distributed, and sold by Defendants to be used with a bicarbonate concentrate to create a bicarbonate dialysate for hemodialysis.

106. NATURALYTE contains 4.0 mEq/L of acetate.

107. GRANUFLO contains 8.0 mEq/L of acetate.

108. NATURALYTE and/or GRANUFLO are regulated as medical devices by the FDA.

109. NATURALYTE and/or GRANUFLO are registered trademarks of the Defendants.

110. NATURALYTE and/or GRANUFLO were submitted for approval by the FDA through the 510(k) process as opposed to the FDA's more rigorous premarket approval process.

111. Upon information and belief, Defendants submitted their NATURALYTE and/or GRANUFLO acid concentrates for approval pursuant to the 510(k) approval process as opposed to the FDA's more rigorous premarket approval process so that they could bypass 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.

112. 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.

113. 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.

114. 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.

115. Upon information and belief, on or about January 18, 2007, Defendants submitted 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 to the FDA.

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

117. 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.

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

119. 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.

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

121. Upon information and belief, based upon 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.

122. Upon information and belief, in or about August 2002, Defendants altered the formula of their GRANUFLO by switching the acid used in said product to diacetate.

123. Upon information and belief, Defendants' goal in using diacetate in their GRANUFLO was to counter the negative effects of metabolic acidosis by increasing bicarbonate levels in the blood via an acid concentrate as opposed to and/or in addition to a bicarbonate solution.

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

125. In or about August 2002, Defendants began administering their GRANUFLO with diacetate to dialysis patients.

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

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

128. Defendants' GRANUFLO that was subject to the January 510(k) submission contained diacetate.

129. 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.

130. 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.

131. Within Defendants' GRANUFLO's 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.

132. Within Defendants' GRANUFLO's 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.

133. Within Defendants' GRANUFLO's 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.

134. Within Defendants' GRANUFLO's 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.

135. 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.

136. 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.

137. Upon information and belief, following its approval by the FDA, Defendants only manufactured, marketed, promoted, advertised, marketed, distributed and/or sold GRANUFLO containing dialysate.

138. Upon information and belief, following its approval by the FDA, Defendants only manufactured, marketed, promoted, advertised, marketed, 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.

139. Upon information and belief, following its approval by the FDA, the 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.

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

141. 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 resolving and/or reducing metabolic acidosis when compared with a standard acid concentrate.

142. 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.

143. In or about 2004, Defendants evaluated the results of their 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.

144. In or about 2004, Defendants evaluated the results of their 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.

145. In or about 2004, Defendants evaluated the results of their 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.

146. In or about 2004, Defendants evaluated the results of their 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.

147. As a result of their 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.

148. As a result of their 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.

149. As a result of their 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.

150. As a result of their 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.

151. As a result of their 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 the administration of GRANUFLO.

152. As a result of their 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that additional testing was necessary regarding the safety of their GRANUFLO.

153. As a result of their 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.

154. As a result of their 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.

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

156. Upon information and belief, despite the results of their 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 Plaintiff(s), Plaintiff's treating physicians and/or healthcare providers and the public.

157. Upon information and belief, despite the results of their 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 Plaintiff(s), Plaintiff's treating physicians and/or healthcare providers and the public, regarding these results and/or risks.

158. Upon information and belief, despite the results of their 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.

159. Upon information and belief, despite the results of their 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.

160. Upon information and belief, despite the results of their 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.

161. Upon information and belief, despite the results of their 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 Plaintiff(s), Plaintiff'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.

162. Upon information and belief, despite the results of their 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.

163. Upon information and belief, despite the results of their 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.

164. On or about November 4, 2011, Fresenius Defendants sent an Internal Memo ("Fresenius' Internal Memo") to Fresenius medical directors and attending physicians regarding the severe health risks associated with their NATURALYTE and/or GRANUFLO.

165. Within Fresenius' Internal Memo, Fresenius 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.

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

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

168. According to Fresenius' Internal Memo, the results of the case-control study identified within Fresenius' Internal Memo revealed that for the patients receiving Defendants' NATURALYTE and/or GRANUFLO, 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.

169. According to Fresenius' Internal Memo, the results of the case-control study 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.

170. According to Fresenius' Internal Memo, Fresenius 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."

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

172. Upon information and belief, Fresenius' Internal Memo was not sent to the medical facilities at which the Plaintiff was administered and/or received NATURALYTE and/or GRANUFLO.

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

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

175. Upon information and belief, these previous internal memos were not sent to the medical facilities at which the Plaintiff was administered and/or received NATURALYTE and/or GRANUFLO.

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

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

178. Upon information and belief, the Medical Staff Newsletter dated January 2010 was not sent to the medical facilities at which the Plaintiff was administered and/or received NATURALYTE and/or GRANUFLO.

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

180. After Fresenius Defendants learned and/or should have learned of the severe health risks associated with their NATURALYTE and/or GRANUFLO, Fresenius Defendants intentionally and affirmatively elected not to report these risks to the FDA as required by law.

181. After Fresenius Defendants learned and/or should have learned of the severe health risks associated with their NATURALYTE and/or GRANUFLO, Fresenius Defendants intentionally and affirmatively elected not to report these risks to the entire medical community, the Plaintiff(s), Plaintiff's treating physicians and healthcare providers and the public at large.

182. Upon information and belief, Fresenius Defendants colluded to hide, conceal and obscure information about the severe health risks associated with their NATURALYTE and/or GRANUFLO so that dialysis patients, such as the Plaintiff, and Plaintiff's treating physicians and/or healthcare facilities would rely on and/or continue to use their NATURALYTE and/or GRANUFLO in dialysis treatments.

183. Upon information and belief, Fresenius Defendants colluded to misrepresent information regarding the safety of their NATURALYTE and/or GRANUFLO so that dialysis patients, such as the Plaintiff, and Plaintiff's treating physicians and/or healthcare facilities would rely on and/or continue to use their NATURALYTE and/or GRANUFLO in dialysis treatments.

184. Upon information and belief, Fresenius Defendants colluded to hide, conceal and obscure information about the severe health risks associated with their NATURALYTE and/or GRANUFLO in order to maintain their market share and to minimize and diffuse the legal risks for Fresenius.

185. Upon information and belief, Fresenius Defendants colluded to misrepresent information regarding the safety of their NATURALYTE and/or GRANUFLO in order to maintain their market share and to minimize and diffuse the legal risks for Fresenius.

186. Upon information and belief, rather than informing the FDA, the medical community, the Plaintiff(s), Plaintiff's treating physicians and healthcare providers and the public at large of the severe health risks associated with their NATURALYTE and/or GRANUFLO, Fresenius Defendants decided to manufacturer, market, promote, distribute and/or sell a new acid concentrate, Citrasate, to replace their NATURALYTE and/or GRANUFLO.

187. Upon information and belief, Fresenius 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 NATURALYTE and/or GRANUFLO and, thus, the Fresenius Defendants could justify a discontinuance of their NATURALYTE and/or GRANUFLO for reasons other than product safety.

188. In reliance upon Defendants' misrepresentations, omissions and/or concealments as set forth herein, the Plaintiff, Plaintiff's treating physicians and/or healthcare facilities used NATURALYTE and/or GRANUFLO.

189. Had the severe health risks associated with Defendants' NATURALYTE and/or GRANUFLO been properly and/or adequately disclosed, the Plaintiff(s), Plaintiff's treating physicians and/or healthcare facilities would not have purchased and/or used NATURALYTE and/or GRANUFLO.

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

191. In or about March 2012, the FDA discovered Defendants' knowledge and unlawful concealment of the severe health risks associated with their NATURALYTE and/or GRANUFLO.

192. In or about March 2012, the FDA discovered that the Fresenius Defendants had violated federal law by failing to report their knowledge of the severe health risks associated with their NATURALYTE and/or GRANUFLO.

193. As a result of the FDA's discovery of Defendants' knowledge and unlawful concealment of the severe health risks associated with their NATURALYTE and/or GRANUFLO, on or about March 27, 2012, Fresenius received an inquiry from the FDA regarding the severe health risks associated with their NATURALYTE and/or GRANUFLO.

194. Following the FDA's inquiry, on or about March 29, 2012, Defendants 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 NATURALYTE and/or GRANUFLO.

195. Upon information and belief, after further investigation conducted by the FDA into the severe health risks associated with their NATURALYTE and/or GRANUFLO, including Defendants' knowledge and unlawful concealment thereof, on July 10, 2012, the FDA issued a Class I recall of Defendants' NATURALYTE and/or GRANUFLO.

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

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

198. Plaintiff(s), Plaintiff'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' NATURALYTE and/or GRANUFLO, until the products were recalled by the FDA on July 12, 2012.

C. Fresenius Defendants

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

200. As vertically integrated companies, Fresenius Defendants offer both dialysis clinics and products used in dialysis care, such as acid concentrates.

201. Fresenius Defendants sell their products, including NATURALYTE and/or GRANUFLO, not only to their own dialysis clinics, but also to their "competitors."

202. Fresenius Defendants are, and at all relevant times were, responsible for ensuring, through adequate warnings, training, instructing and monitoring, that their NATURALYTE and/or GRANUFLO were being properly used and/or administered by treating physicians, technicians and/or healthcare facilities.

203. In 2011, Fresenius 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%).

204. In 2010, Fresenius 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%).

205. Fresenius 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.

206. Despite Fresenius Defendants' representations, upon discovering the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants' intentionally, willfully, recklessly and/or negligently failed to advise and/or warn dialysis patients, including the Plaintiff(s), their customers (i.e. treating physicians, healthcare facilities, distributors), their suppliers, the government, other payors and/or the general public of said serious consequences and risks.

207. Despite Fresenius Defendants' representations, upon discovering the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants permitted their NATURALYTE and/or GRANUFLO 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 NATURALYTE and/or GRANUFLO.

208. Despite Fresenius Defendants' representations, upon discovering the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants' permitted their NATURALYTE and/or GRANUFLO 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 NATURALYTE and/or GRANUFLO.

209. Despite their knowledge of the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO, Defendants engaged in a marketing campaign to promote the purchase and/or sales of their NATURALYTE and/or GRANUFLO.

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

211. 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.

212. Defendants successfully marketed their NATURALYTE and/or GRANUFLO throughout the United States by, among other things, conducting promotional campaigns that misrepresented the risks and benefits associated with their NATURALYTE and/or GRANUFLO in order to induce widespread use and consumption.

213. Defendants' misrepresentations regarding and/or promotions about their NATURALYTE and/or GRANUFLO 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.

214. Upon information and belief, Fresenius Defendants did not disclose the serious health consequences and risks associated with their NATURALYTE and/or GRANUFLO because they knew that physicians and/or healthcare facilities would not purchase their NATURALYTE and/or GRANUFLO, and, as a result, their sales would decline.

215. 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.

216. 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 Plaintiff, thus entitling Plaintiff(s) to punitive damages so as to punish and deter such similar conduct in the future.

D. Injuries and Damages

217. As a result of Defendants' concealment and/or failure to advise and/or warn all doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO experienced higher than normal post-dialysate bicarbonate levels.

218. As a result of Defendants' concealment and/or failure to advise and/or warn all doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO experienced higher than normal pre-dialysate bicarbonate levels.

219. As a result of Defendants' concealment and/or failure to advise and/or warn doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO have suffered and/or are suffering from metabolic alkalosis.

220. As a result of Defendants' concealment and/or failure to advise and/or warn doctors and/or other healthcare providers of the defectiveness and/or serious adverse health risks associated with their NATURALYTE and/or GRANUFLO as set forth herein, dialysis patients, such as the Plaintiff, who received Defendants' NATURALYTE and/or GRANUFLO 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.

221. As a result of the defective nature of NATURALYTE and/or GRANUFLO, which was known and/or should have been known by the Fresenius Defendants at all relevant times, those persons who were administered, prescribed and/or ingested and/or were exposed to NATURALYTE and/or GRANUFLO, including the Plaintiff(s), 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.

COUNT I
FIRST CAUSE OF ACTION
(NEGLIGENCE & NEGLIGENCE *PER SE*)

222. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

223. Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of NATURALYTE and/or GRANUFLO into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

224. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of NATURALYTE and/or GRANUFLO into interstate commerce in that Defendants knew or should have known that using NATURALYTE and/or

GRANUFLO created a high risk of unreasonable, dangerous side effects, including, *inter alia,* death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, stroke coma, and hypotension, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

225. Defendants had a duty to adequately warn, train, instruct and/or monitor treating physicians and/or healthcare facilities to ensure that their NATURALYTE and/or GRANUFLO were being properly used and/or administered by treating physicians, technicians and/or healthcare facilities.

226. Defendants failed to uphold their duty to adequately warn, train, instruct and/or monitor treating physicians and/or healthcare facilities to ensure that their NATURALYTE and/or GRANUFLO were being properly used and/or administered by treating physicians, technicians and/or healthcare facilities, especially in light of their knowledge that using NATURALYTE and/or GRANUFLO created a high risk of unreasonable, dangerous side effects, including, *inter alia,* death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, stroke coma, and hypotension.

227. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Manufacturing, producing, promoting, formulating, creating and/or designing NATURALYTE and/or GRANUFLO without thoroughly testing them;

b. Manufacturing, producing, promoting, formulating, creating and/or designing NATURALYTE and/or GRANUFLO without adequately testing them;

c. Not conducting sufficient testing programs to determine whether or not NATURALYTE and/or GRANUFLO were safe for use, in that Defendants herein knew or should have known that NATURALYTE and/or GRANUFLO were unsafe and unfit for use by reason of the dangers to their users;

d. Selling NATURALYTE and/or GRANUFLO without creating and/or conducting proper and sufficient tests to determine the dangers to their users;

e. Negligently failing to adequately and correctly warn the Plaintiff(s), the public, the medical and healthcare profession, and the FDA of the dangers of NATURALYTE and/or GRANUFLO;

f. Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, NATURALYTE and/or GRANUFLO;

g. Failing to test NATURALYTE and/or GRANUFLO and/or failing to adequately, sufficiently and properly test NATURALYTE and/or GRANUFLO;

h. Negligently advertising and recommending the use of NATURALYTE and/or GRANUFLO without sufficient knowledge as to their dangerous propensities;

i. Negligently representing that NATURALYTE and/or GRANUFLO was safe for use for their intended purposes, when, in fact, they were unsafe;

j. Negligently representing that NATURALYTE and/or GRANUFLO had equivalent safety and efficacy as other acid concentrates used during hemodialysis;

k. Negligently designing NATURALYTE and/or GRANUFLO in a manner which was dangerous to their users;

l. Negligently manufacturing NATURALYTE and/or GRANUFLO in a manner which was dangerous to their users;

m. Negligently producing NATURALYTE and/or GRANUFLO in a manner which was dangerous to their users;

n. Negligently assembling NATURALYTE and/or GRANUFLO in a manner which was dangerous to their users;

o. Negligently communicating the dangers and/or risks of NATURALYTE and/or GRANUFLO to the Plaintiff(s), the medical community, the FDA and the public;

p. Concealing information from the Plaintiff(s), the medical community, the FDA and the public, in knowing that NATURALYTE and/or GRANUFLO were unsafe, dangerous, and/or non-conforming with FDA regulations;

q. Improperly concealing information from and/or misrepresenting information to the Plaintiff(s), healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of NATURALYTE and/or GRANUFLO compared to other acid concentrates used during hemodialysis; and

r. Negligently handling the recall of NATURALYTE and/or GRANUFLO.

228. Defendants violated statutes, ordinances, and rules and/or regulations concerning the manufacturing, marketing and/or testing of their products.

229. Defendants under-reported, underestimated and downplayed the serious dangers of NATURALYTE and/or GRANUFLO.

230. Defendants negligently compared the safety risk and/or dangers of NATURALYTE and/or GRANUFLO with other acid concentrates on the market.

231. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of NATURALYTE and/or GRANUFLO in that they:

a. Failed to use due care in designing and manufacturing NATURALYTE and/or GRANUFLO so as to avoid the aforementioned risks to individuals when NATURALYTE and/or GRANUFLO were used as acid concentrates during hemodialysis;

b. Failed to accompany their products with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of NATURALYTE and/or GRANUFLO;

c. Failed to accompany their products with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of NATURALYTE and/or GRANUFLO;

d. Failed to accompany their products with accurate warnings regarding the risks of all possible adverse side effects concerning NATURALYTE and/or GRANUFLO;

e. Failed to warn Plaintiff(s) of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

f. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of NATURALYTE and/or GRANUFLO;

g. Failed to warn Plaintiff(s), prior to actively encouraging the sale of NATURALYTE and/or GRANUFLO, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects resulting from exposure to NATURALYTE and/or GRANUFLO; and,

h. Were otherwise careless and/or negligent.

232. Despite the fact that Defendants knew or should have known that NATURALYTE and/or GRANUFLO caused unreasonably dangerous side effects, including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke and hypotension, Defendants continued to market, manufacture, distribute and/or sell NATURALYTE and/or GRANUFLO to consumers, including the Plaintiff(s) and/or members of the health care community, including the Plaintiff's healthcare providers.

233. Based on the aforesaid, Defendants had a duty to warn physicians and/or healthcare providers of the dangers of using NATURALYTE and/or GRANUFLO, but failed to do so.

234. Defendants' actions, by violating statutes, ordinances and/or rules and regulations constituted negligence per se.

235. Defendants knew or should have known that consumers, including the Plaintiff(s), would be injured and damaged as a result of Defendants' failure to exercise ordinary care, as set forth above.

236. Defendants' negligence was the proximate cause of the injuries and damages alleged herein.

237. As a result of the Defendants' negligence and/or the foregoing acts and/or omissions alleged above, the Plaintiff(s) suffered injuries and damages alleged herein.

238. 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(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
SECOND CAUSE OF ACTION
(STRICT PRODUCTS LIABILITY)

239. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein. At all times herein mentioned, the Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed NATURALYTE and/or GRANUFLO as hereinabove described that was administered to and/or used by the Plaintiff(s).

240. That NATURALYTE and/or GRANUFLO were expected to and did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the conditions in which they were produced, manufactured, sold, distributed, and marketed by Defendants.

241. At those times, NATURALYTE and/or GRANUFLO were in an unsafe, defective, and inherently dangerous condition, which were dangerous to users, and in particular, the Plaintiff herein.

242. The acid concentrates, NATURALYTE and/or GRANUFLO, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design or formulation in that, when they left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of NATURALYTE and/or GRANUFLO.

243. The acid concentrates, NATURALYTE and/or GRANUFLO, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective in design and/or formulation, in that, when they left the hands of the Defendants' manufacturers and/or suppliers, they were unreasonably dangerous, and they were more dangerous than an ordinary consumer would expect.

244. At all times herein mentioned, NATURALYTE and/or GRANUFLO 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 the Defendants.

245. Defendants knew, or should have known, that at all times herein mentioned their NATURALYTE and/or GRANUFLO were in a defective condition, and were and are inherently dangerous and unsafe.

246. During the dialysis treatment provided to the Plaintiff, NATURALYTE and/or GRANUFLO were being used for the purposes and in a manner normally intended, namely during hemodialysis for the treatment of kidney disease.

247. Defendants, with this knowledge, voluntarily designed their NATURALYTE and/or GRANUFLO in a dangerous condition for administration to and/or use by the public, and in particular the Plaintiff.

248. Defendants had a duty to create products that were not unreasonably dangerous for their normal, intended use.

249. Defendants created products unreasonably dangerous for their normal, intended use.

250. The acid concentrates, NATURALYTE and/or GRANUFLO, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were manufactured defectively in that NATURALYTE and/or GRANUFLO left the hands of Defendants in defective conditions and were unreasonably dangerous to their intended users.

251. The acid concentrates, NATURALYTE and/or GRANUFLO, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants reached their intended users in the same defective and unreasonably dangerous condition in which the Defendants' NATURALYTE and/or GRANUFLO were manufactured.

252. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed defective products which created an unreasonable risk to the health of consumers and to the Plaintiff(s) in particular, and Defendants are therefore strictly liable for the injuries and damages alleged herein.

253. Plaintiff(s) could not, by the exercise of reasonable care, have discovered NATURALYTE's and/or GRANUFLO's defects herein mentioned and perceived their danger.

254. The acid concentrates, NATURALYTE and/or GRANUFLO, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants, were defective due to inadequate warnings or instructions, as Defendants knew or should have known that the products created a risk of serious and dangerous health risks including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke and hypotension, and Defendants failed to adequately warn of said risks.

255. The acid concentrates, NATURALYTE and/or GRANUFLO, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate warnings and/or inadequate testing.

256. The acid concentrates, NATURALYTE and/or GRANUFLO, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants were defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious and dangerous health risks that could occur by virtue of exposure to NATURALYTE and/or GRANUFLO including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke and hypotension, they failed to

provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their products, NATURALYTE and/or GRANUFLO.

257. By reason of the foregoing, the Defendants became strictly liable in tort to the Plaintiff(s) for the manufacturing, marketing, promoting, distribution, and selling of defective products, NATURALYTE and/or GRANUFLO.

258. Defendants' defective design, manufacturing defect, and inadequate warnings of NATURALYTE and/or GRANUFLO were acts that amount to willful, wanton, and/or reckless conduct by Defendants.

259. Defects in Defendants' NATURALYTE and/or GRANUFLO were a substantial factor in causing the injuries and damages alleged herein.

260. 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(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
THIRD CAUSE OF ACTION
(BREACH OF EXPRESS WARRANTY)

261. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

262. Defendants expressly warranted that NATURALYTE and/or GRANUFLO were safe and well accepted by users.

263. The acid concentrates NATURALYTE and/or GRANUFLO do not conform to these express representations because NATURALYTE and/or GRANUFLO are not safe and have numerous serious side effects, many of which were not accurately warned about by Defendants. As a direct and proximate result of the breach of said warranties, Plaintiff(s) suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

264. Plaintiff(s), Plaintiff's healthcare providers and/or healthcare facilities did rely on the express warranties of the Defendants herein.

265. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendants for use of NATURALYTE and/or GRANUFLO as acid concentrates during hemodialysis and in recommending, prescribing, and/or dispensing NATURALYTE and/or GRANUFLO to persons who were undergoing hemodialysis.

266. The Defendants herein breached the aforesaid express warranties, as their products NATURALYTE and/or GRANUFLO were defective and did not contain adequate warnings.

267. Defendants expressly represented to Plaintiff(s), Plaintiff's healthcare providers, and/or the FDA that NATURALYTE and/or GRANUFLO were safe and fit for use for the purposes intended, that they were of merchantable quality, that they did not produce any dangerous side effects in excess of those risks associated with other acid concentrates, that the side effects they did produce were accurately reflected in the warnings and that they were adequately tested and fit for their intended use.

268. Defendants knew or should have known that, in fact, said representations and

warranties were false, misleading and untrue in that NATURALYTE and/or GRANUFLO were not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants.

269. As a result of the foregoing acts and omissions, the Plaintiff(s) suffered the injuries and damages alleged herein.

270. 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(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
FOURTH CAUSE OF ACTION
(BREACH OF IMPLIED WARRANTIES)

271. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

272. At all times herein mentioned, the Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold NATURALYTE and/or GRANUFLO for use as acid concentrates.

273. At the time Defendants marketed, sold, and distributed NATURALYTE and/or GRANUFLO for use by the Plaintiff(s), Defendants knew of the use for which NATURALYTE and/or GRANUFLO were intended and impliedly warranted the product to be of merchantable

quality and safe and fit for such use.

274. Defendants impliedly represented and warranted to the users of NATURALYTE and/or GRANUFLO, including the Plaintiff(s), Plaintiff's physicians and healthcare providers, and/or the FDA that NATURALYTE and/or GRANUFLO were safe and of merchantable quality and fit for the ordinary purpose for which said products were to be used.

275. That said representations and warranties aforementioned were false, misleading, and inaccurate in that NATURALYTE and/or GRANUFLO were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

276. Plaintiff(s), Plaintiff's healthcare providers, healthcare facilities and/or members of the medical community did rely on said implied warranties of merchantability and of fitness for a particular use and purpose.

277. Plaintiff(s), Plaintiff's healthcare providers, healthcare facilities and/or members of the medical community reasonably relied upon the skill and judgment of Defendants as to whether NATURALYTE and/or GRANUFLO were of merchantable quality and/or safe and fit for their intended use.

278. The acid concentrate NATURALYTE and/or GRANUFLO were placed into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and accompanying materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

279. The Defendants herein breached the aforesaid implied warranties, as their products NATURALYTE and/or GRANUFLO were not fit for their intended purposes and uses.

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, Plaintiff(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
FIFTH CAUSE OF ACTION
(FRAUDULENT MISREPRESENTATION)

281. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

282. The Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff(s), Plaintiff's healthcare providers, the FDA, and/or the public in general, that said products, NATURALYTE and/or GRANUFLO, had been tested and were found to be safe and/or effective for use as acid concentrates during hemodialysis.

283. The representations made by Defendants were, in fact, false.

284. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

285. These representations were made by Defendants with the intent of defrauding and deceiving the Plaintiff(s), the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and

healthcare community in particular, to recommend, prescribe, dispense and/or purchase said products, NATURALYTE and/or GRANUFLO, for use as a means of treating kidney disease during hemodialysis, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff(s) herein.

286. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff(s) was administered and/or received NATURALYTE and/or GRANUFLO, the Plaintiff(s), the Plaintiff's treating physicians and/or healthcare providers were unaware of the falsity of said representations and reasonably believed them to be true.

287. In reliance upon said representations, Plaintiff(s), Plaintiff's treating physicians and/or healthcare providers, were induced to and did use NATURALYTE and/or GRANUFLO, thereby causing the Plaintiff(s) to sustain severe and permanent personal injuries, and/or be at an increased risk of sustaining severe and permanent personal injuries.

288. Defendants knew and were aware or should have been aware that NATURALYTE and/or GRANUFLO had not been sufficiently tested, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

289. Defendants knew or should have known that NATURALYTE and/or GRANUFLO had a potential to, could, and would cause severe and grievous injury to the users of said product and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

290. Defendants brought NATURALYTE and/or GRANUFLO to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff(s).

291. 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(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
SIXTH CAUSE OF ACTION
(FRAUDULENT CONCEALMENT)

292. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

293. At all times during the course of dealing between Defendants and Plaintiff(s), Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the safety of NATURALYTE and/or GRANUFLO for their intended use.

294. At all times during the course of dealing between Defendants and Plaintiff(s), Plaintiff's healthcare providers, and/or the FDA, Defendants misrepresented the serious and grave health risks that could occur by virtue of exposure to NATURALYTE and/or GRANUFLO including, but not limited to, death, cardiopulmonary arrest, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke and/or hypotension.

295. Defendants knew or were reckless in not knowing that its representations were false.

296. In representations to Plaintiff(s), and/or Plaintiff's healthcare providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted the following material information:

a. That NATURALYTE and/or GRANUFLO were not as safe as other acid concentrates;

b. That the risks of adverse events with NATURALYTE and/or GRANUFLO were higher than those with other acid concentrates;

c. That the risks of adverse events with NATURALYTE and/or GRANUFLO were not adequately tested and/or known by Defendants;

d. That Defendants were aware of dangers in NATURALYTE and/or GRANUFLO;

e. That the administration of NAUTRALYTE and/or GRANUFLO to dialysis patients resulted in higher than normal post-dialysis bicarbonate levels;

f. That the administration of NATURALYTE and/or GRANUFLO to dialysis patients resulted in higher than normal pre-dialysis bicarbonate levels;

g. That the administration of NATURALYTE and/or GRANUFLO to dialysis patients resulted in an increase in metabolic alkalosis;

h. That physicians and/or healthcare facilities administering GRANUFLO to dialysis patients should monitor more frequently the dialysis patient's post-dialysis bicarbonate levels;

i. That physicians and/or healthcare facilities administering NAUTRALYTE and/or GRANUFLO to dialysis patients should monitor more frequently the dialysis patient's pre-dialysis bicarbonate levels;

j. That the administration of NATURAYLYTE and/or GRANUFLO to dialysis patients resulted in dangerous side effects, including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke and hypotension

k. That NATURALYTE and/or GRANUFLO were defective, and that they caused dangerous side effects, including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, and hypotension, in a much more and significant rate than other acid concentrates;

l. That patients needed to be monitored more regularly than normal while using NATURALYTE and/or GRANUFLO;

m. That NATURALYTE and/or GRANUFLO were manufactured, marketed, produced and distributed negligently;

n. That NATURALYTE and/or GRANUFLO were manufactured, marketed, produced and distributed defectively;

o. That NATURALYTE and/or GRANUFLO were manufactured, marketed, produced and distributed improperly;

p. That NATURALYTE and/or GRANUFLO were designed negligently;

q. That NATURALYTE and/or GRANUFLO were designed defectively; and

r. That NATURALYTE and/or GRANUFLO were designed improperly.

297. Defendants were under a duty to disclose to Plaintiff(s), Plaintiff's treating physicians, hospitals, healthcare providers, and/or the FDA the defective nature of NATURALYTE and/or GRANUFLO, including but not limited to the serious and grave health risks associated with NATURALYTE and/or GRANUFLO including but not limited to death, cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke and hypotension.

298. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used NATURALYTE and/or GRANUFLO, including the Plaintiff(s), in particular.

299. Defendants' concealment and omissions of material facts concerning, *inter alia,* the safety of NATURALYTE and/or GRANUFLO was made purposefully, intentionally, willfully, wantonly, and/or recklessly, to mislead Plaintiff(s), Plaintiff's physicians, hospitals and healthcare providers into reliance and continued use of NATURALYTE and/or GRANUFLO,

and actions thereon, and to cause them to purchase, prescribe, and/or dispense NATURALYTE and/or GRANUFLO and/or otherwise use the products.

300. Defendants knew that Plaintiff(s), Plaintiff's physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding NATURALYTE and/or GRANUFLO, as set forth herein.

301. Plaintiff(s), Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendants.

302. Plaintiff(s), Plaintiff's doctors, healthcare providers, and/or hospitals reasonably relied on Defendants' representations that their NATURALYTE and/or GRANUFLO were safe for their intended use.

303. Had the severe health risks associated with Defendants' NATURALYTE and/or GRANUFLO been properly and/or adequately disclosed, Plaintiff(s), Plaintiff's treating physicians, healthcare providers, and/or healthcare facilities would not have purchased and/or used NATURALYTE and/or GRANUFLO.

304. 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(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
SEVENTH CAUSE OF ACTION
(NEGLIGENT MISREPRESENTATION)

305. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

306. Defendants had a duty to represent to the medical and healthcare community, and to the Plaintiff(s), the FDA and the public in general that said products, NATURALYTE and/or GRANUFLO, had been tested and found to be safe and effective for their intended use.

307. The representations made by Defendants were, in fact, false.

308. Defendants failed to exercise ordinary care in the representation of NATURALYTE and/or GRANUFLO, while involved in their manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendants negligently misrepresented NATURALYTE's and/or GRANUFLO's high risk of unreasonable, dangerous side effects.

309. Defendants breached their duty in representing NATURALYTE's and/or GRANUFLO's serious side effects to the medical and healthcare community, to the Plaintiff(s), the FDA and the public in general.

310. Defendants knew and/or were aware or should have known that NATURALYTE and/or GRANUFLO had been insufficiently tested, and/or had not been tested, that they lacked adequate and/or accurate warnings, and/or that they created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks of severe and grave health consequences, including but not limited to the serious and grave health risks associated with NATURALYTE and/or GRANUFLO including but not limited to death, cardiopulmonary arrest,

electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke and hypotension.

311. 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(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
EIGHTH CAUSE OF ACTION
(FRAUD AND DECEIT)

312. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

313. Defendants conducted research and/or had a duty to conduct research using NATURALYTE and/or GRANUFLO.

314. 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 Plaintiff(s), the Plaintiff's doctors, hospitals, healthcare professionals, and/or the FDA that NATURALYTE and/or GRANUFLO were safe and effective for their intended use as acid concentrates.

315. 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 Plaintiff(s) and Plaintiff's healthcare providers.

316. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, the Plaintiff(s), Plaintiff's respective healthcare providers and/or the FDA.

317. The information distributed to the public, the FDA, and the Plaintiff(s) 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.

318. The information distributed to the public, the FDA, and Plaintiff(s) by Defendants intentionally included representations that Defendants' acid concentrates NATURALYTE and/or GRANUFLO were safe and effective for their intended use as acid concentrates.

319. The information distributed to the public, the FDA, and the Plaintiff(s) by Defendants intentionally included representations that Defendants' acid concentrates NATURALYTE and/or GRANUFLO carried the same risks, hazards, and/or dangers as other acid concentrates on the market.

320. The information distributed to the public, the FDA, and the Plaintiff(s) by Defendants intentionally included representations that Defendants' acid concentrates NATURALYTE and/or GRANUFLO were more effective for the treatment of kidney disease during hemodialysis, thereby encouraging the use of NATURALYTE and/or GRANUFLO in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risk associated with NATURALYTE and/or GRANUFLO.

321. The information distributed to the public, the FDA, and the Plaintiff(s) by Defendants intentionally included false representations that exposure to NATURALYTE and/or GRANUFLO was not injurious to the health and/or safety of its intended users.

322. The information distributed to the public, the FDA, and the Plaintiff(s) by Defendants intentionally included false representations that exposure to NATURALYTE and/or GRANUFLO was as potentially injurious to the health and/or safety of its intended users as other acid concentrates.

323. These representations were all false and misleading.

324. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that NATURALYTE and/or GRANUFLO were not safe as a means of an acid concentrate and/or were not as safe as other means of acid concentrates.

325. Defendants intentionally made material representations to the FDA and the public, including the medical profession, the Plaintiff(s) and/or the Plaintiff's healthcare providers, regarding the safety of NATURALYTE and/or GRANUFLO, specifically but not limited to exposure to NATURALYTE and/or GRANUFLO not having dangerous and serious health and/or safety concerns.

326. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, the Plaintiff(s) and/or the Plaintiff's healthcare providers, regarding the safety of NATURALYTE and/or GRANUFLO, specifically but not limited to NATURALYTE and/or GRANUFLO being as safe a means of acid concentrate as other acid concentrates on the market.

327. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, the Plaintiff(s) and/or the Plaintiff's healthcare providers, to gain the confidence of the public, healthcare professionals, the FDA, and the Plaintiff(s) to falsely ensure the quality and fitness for use of NATURALYTE and/or GRANUFLO and to induce the public, and/or the Plaintiff(s) to purchase, request, dispense, prescribe, recommend, and/or continue to use NATURALYTE and/or GRANUFLO.

328. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and the Plaintiff(s) that NATURALYTE and/or GRANUFLO were fit and safe for use as acid concentrates in hemodialysis.

329. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and the Plaintiff(s) that NATURALYTE and/or GRANUFLO 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.

330. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, the Plaintiff(s) and/or the Plaintiff's healthcare providers that exposure to NATURALYTE and/or GRANUFLO did not present serious health and/or safety risks.

331. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, the Plaintiff(s) and/or the Plaintiff's healthcare providers that exposure to NATURALYTE and/or GRANUFLO did not present health and/or safety risks greater than other acid concentrates on the market.

332. That these representations and others made 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.

333. That these representations and others made by Defendants were made with the intention of deceiving and defrauding the Plaintiff(s) the Plaintiff's healthcare providers and/or the FDA, and were made in order to induce the Plaintiff(s) and/or Plaintiff's respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff(s) and/or Plaintiff's healthcare providers to purchase, use, rely on, request, dispense, recommend, and/or prescribe NATURALYTE and/or GRANUFLO.

334. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of exposure to NATURALYTE and/or GRANUFLO to the public at large, the Plaintiff(s) and/or Plaintiff'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.

335. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of exposure to NATURALYTE and/or GRANUFLO by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of NATURALYTE and/or GRANUFLO.

336. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff(s), Plaintiff's healthcare providers and/or Plaintiff's healthcare professionals into a sense of security so that Plaintiff(s) and/or Plaintiff's healthcare providers would rely on the representations and purchase, use and rely on NATURALYTE and/or

GRANUFLO and/or that their respective healthcare providers would dispense, prescribe, and/or recommend the same.

337. 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 Plaintiff(s), Plaintiff's healthcare providers would rely upon the information being disseminated.

338. Defendants utilized direct to consumer adverting to market, promote, and/or advertise NATURALYTE and/or GRANUFLO.

339. Plaintiff(s), Plaintiff'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 acid concentrates and were thereby induced to purchase, use and rely on Defendants' acid concentrates NATURALYTE and/or GRANUFLO.

340. That at the time the representations were made, the Plaintiff(s) and/or Plaintiff's respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of exposure to NATURALYTE and/or GRANUFLO.

341. That the Plaintiff(s) and/or the Plaintiff'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 Plaintiff(s) and/or the Plaintiff's healthcare providers with reasonable diligence have discovered the true facts.

342. That had the Plaintiff(s) and/or the Plaintiff's healthcare providers known the true facts with respect to the dangerous and serious health and/or safety concerns of NATURALYTE and/or GRANUFLO, Plaintiff(s) the and/or Plaintiff's healthcare providers would not have

purchased, used and/or relied on Defendants' acid concentrates NATURALYTE and/or GRANUFLO.

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

344. 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(s) sustained the injuries and damages alleged herein.

WHEREFORE, Plaintiff(s) 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
NINTH CAUSE OF ACTION
(WANTONNESS)

345. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

346. Defendants wantonly and recklessly designed, manufactured, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold NATURALYTE and/or GRANUFLO in this district and through the United States.

347. 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 NATURALYTE and/or GRANUFLO.

348. Defendants negligently mixed, distributed, promoted, marketed, advertised, and sold NATURALYTE and/or GRANUFLO in this district and throughout the United States.

349. At all times material hereto, Defendants had a duty to exercise reasonable care in the mixing, distribution, promotion, marketing, advertising, and sale of and NATURALYTE and/or GRANUFLO.

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

a. Failing to test and inspect NATURALYTE and/or GRANUFLO in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, delivered, and sold;

b. Failing to utilize and implement a reasonably safe design in the manufacture of NATURALYTE and/or GRANUFLO;

c. Failing to manufacture NATURALYTE and/or GRANUFLO in a reasonably safe condition;

d. Failing to warn Plaintiff(s) of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NATURALYTE and/or GRANUFLO;

e. Failing to label NATURALYTE and/or GRANUFLO reasonably so as to warn Plaintiff(s) of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NATURALYTE and/or GRANUFLO;

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 NATURALYTE and/or GRANUFLO.

351. Defendants knew that NATURALYTE and/or GRANUFLO had unreasonably dangerous risks and caused serious side effects of which Plaintiff(s) would not be aware. Defendants nevertheless advertised, marketed, sold, labeled, distributed, and instructed/trained on the use of NATURALYTE and/or GRANUFLO knowing that there were safer methods and

products for dialysis treatment.

352. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants as set forth above, Plaintiff(s) sustained injuries and damages as alleged herein.

WHEREFORE, Plaintiff(s) 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 X
TENTH CAUSE OF ACTION
(UNJUST ENRICHMENT)

353. Plaintiff(s) repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

354. At all times relevant to this action, Defendants designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold NATURALYTE and/or GRANUFLO.

355. NATURALYTE and/or GRANUFLO were used during dialysis treatment provided to Plaintiff(s).

356. Defendants received payment for the cost of NATURALYTE and/or GRANUFLO purchased and used in the dialysis treatment provided to Plaintiff(s).

357. Plaintiff(s) did not receive the safe and effective product intended.

358. It is inequitable and unjust for Defendants to retain this money because Plaintiff(s) did not receive the product Defendants represented NATURALYTE and/or GRANUFLO to be.

WHEREFORE, Plaintiff(s) 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 XI
ELEVENTH CAUSE OF ACTION
(NEW JERSEY PRODUCTS LIABILITY ACT)

359. Plaintiff(s) incorporates herein each allegation set forth above.

360. The defendants are liable to Plaintiff(s) under the New Jersey Products Liability Act, N.J.S.A. 2A58C-1 et seq.

361. As a direct and proximate result of Defendants' acts or omissions, WILLIAM C. JONES suffered painful injuries, including a heart attack and incurred the numerous expenses and damages alleged herein.

WHEREFORE, Plaintiff(s) 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

362. Plaintiff(s) 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(s) demands judgment against each Defendant, jointly and severally, on each count as follows:

a. Compensatory damages for the described losses with respect to each cause of action in excess of Seventy-five Thousand Dollars ($75,000.00);

b. Past and future medical expenses;

c. Past and future lost wages and loss of earning capacity;

d. Past and future pain and suffering;

e. Past and future emotional distress;

f. Past and future loss of enjoyment of life;

g. Consequential damages;

h. Disgorgement of profits;

i. Restitution;

j. Punitive damages with respect to each cause of action;

k. Reasonable attorneys' fees where recoverable;

l. Costs of this action;

m. Prejudgment and all other interest recoverable; and

n. Such other additional and further relief as Plaintiff(s) 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 Plaintiff(s) and any non-defendant healthcare providers the true and significant risks associated with NATURALYTE and/or GRANUFLO .

364. As a result of Defendants actions, neither the Plaintiff(s) nor the Plaintiff's healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff(s) 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(s) knew or reasonably should have known of some causal connection between the use of

NATURALYTE and/or GRANUFLO 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(S) DEMANDS A TRIAL OF ALL ISSUES BY STRUCK JURY.

RESPECTFULLY SUBMITTED, this the 8th day of February, 2013.

BY: **LOCKS LAW FIRM**

BY: _____

Michael B. Leh
Michael Galpern
Attorneys for Plaintiff
LOCKS LAW FIRM
457 Haddonfield Road, Suite 500
Cherry Hill, NJ 08002
Telephone: (856) 663-8200
Fax: (856) 661-8400
Email: mleh@lockslaw.com
mgalpern@lockslaw.com
and
Kristian Rasmussen (Pro Hac Vice to be filed)
Cory, Watson, Crowder, & DeGaris
2131 Magnolia Avenue, STE 200
Birmingham, AL 35205
Telephone: (205) 328-2200
Fax: (205) 324-7896
E-Mail: krasmussen@cwcd.com