IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF GEORGIA

WADDELL BISHOP, individually, as next of kin of and as Administrator of the estate of FRANCES CAROL BISHOP, deceased,	)	
Plaintiff,	)	
vs.	)	**CASE NO.:** CV612-86
FRESENIUS USA, INC., FRESENIUS USA MANUFACTURING, INC., FRESENIUS MEDICAL CARE HOLDINGS, INC., FRESENIUS MEDICAL CARE NORTH AMERICA, INC., and FRESENIUS USA MARKETING, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiff, by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants named in the above styled matter, and allege the following:

INTRODUCTION

1. This is an action for damages relating to the Defendants' design, manufacture, sale, testing, marketing, advertising, promotion, and/or distribution of GranuFlo® and NaturaLyte®.

2. Plaintiff brings these claims, individually, for personal injuries and death caused by GranuFlo® and/or NaturaLyte®.

3. The use of GranuFlo® and/or NaturaLyte® is associated with, and causes, an increased risk of death and serious cardiovascular injuries: cardiovascular death, sudden cardiac death, cardiopulmonary arrest, heart attack, congestive heart failure and other catastrophic

cardiovascular injuries.

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

5. At all times relevant to this action, Defendants intentionally, recklessly, and/or negligently advertised, promoted, marketed, sold, and/or distributed GranuFlo® and NaturaLyte® as a safe and effective when, in fact, Defendants had reason to know, and/or did know, that GranuFlo® and NaturaLyte® were not safe and was associated with an increased risk of death and serious injuries.

6. Defendants are and, at all times material hereto were, strictly liable for injuries caused by GranuFlo® and NaturaLyte® because each product is unreasonably dangerous in that neither was accompanied by adequate instructions regarding the safe use of the products, proper monitoring of patients using the products, or adequate warnings about the increased health risks associated with using the products nor dangers.

PARTIES, VENUE & JURISDICTION

7. At all times relevant to this action Decedent, FRANCES CAROL BISHOP, was an adult resident citizen of Emanuel County, GA.

8. At all times relevant to this action, Plaintiff, WADDELL BISHOP, was an adult resident citizen of Emanuel County, GA.

9. Plaintiff, WADDELL BISHOP, is surviving the child and next-of-kin to the Decedent.

10. Defendant, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America ("FMCNA") is a corporation organized and existing under the laws of New York with its principal place of business in Lexington, Massachusetts. FMCNA is the country's leading full-service provider of dialysis care. FMCNA, through various affiliates, treats

approximately 79,600 patients in its approximately 1080 U.S. dialysis clinics, some of which are located in this district. At all times relevant hereto, the Defendant, FMCNA, regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

11. Defendant, Fresenius Medical Care North America, Inc. ("FMCNA") is a corporation organized and existing under the laws of the state of Massachusetts with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, FMCNA regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

12. Defendant, Fresenius USA, Inc. ("FUSA") is, and at all times herein mentioned was, a corporation organized and existing under the laws of Massachusetts. FUSA is a wholly owned subsidiary of Fresenius Medical Care AG & Co. KGaA. At all times relevant hereto, the Defendant, FUSA, regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

13. Defendant, Fresenius USA Manufacturing, Inc. ("Fresenius Manufacturing") is a corporation of the state of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, Fresenius Manufacturing was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

14. Defendant, Fresenius USA Marketing, Inc. ("Fresenius Marketing") is a foreign corporation authorized to transact business in Plaintiff's State of residence. Fresenius Marketing is a wholly-owned subsidiary of Fresenius Medical Care AG & Co. KGaA. At all times relevant hereto, Fresenius Marketing regularly and continuously did business within regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

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

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

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

18. At all relevant times, the Defendants were engaged in the business of designing, testing, manufacturing, marketing, promoting, selling, labeling, packaging, and distributing , promoting, and selling GranuFlo® and NaturaLyte® in this district and throughout the United States.

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

20. Fresenius Medical Care is a publicly traded company with net revenue of $12,795 million dollars in 2011 and $12,053 million dollars in 2010. Fresenius is the world's largest integrated provider of products and services for individuals undergoing dialysis. "Through its network of 3,123 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 256,456 patients around the globe.

Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products."[1]

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

22. At all relevant times, the Defendants, intentionally, recklessly and/or negligently advertised, promoted, marketed, sold and distributed GranuFlo® and NaturaLyte® 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 caused serious medical problems, and in certain patients, catastrophic, life threatening, injuries.

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

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

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

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

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

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

29. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C.A.

[1] http://www.fmc-ag.com/59.htm

§ 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000, and because there is complete diversity of citizenship between Plaintiff and Defendant.

30. Venue is proper in this federal judicial district.

COMMON FACTUAL ALLEGATIONS APPLICABLE TO EACH CAUSE OF ACTION

31. This action arises from the injuries and damages caused by the use of NaturaLyte® and/or Granuflo® ("NaturaLyte" and "GranuFlo") in the dialysis treatment provided to Decedent.

A. Use of GranuFlo® and/or NaturaLyte®

32. GranuFlo® and/or NaturaLyte® were used in the dialysis treatment provided to Decedent.

33. On or about September, 2010 Decedent received dialysis treatment that included the use of GranuFlo® and/or NaturaLyte®.

34. After using GranuFlo® and/or NaturaLyte®, Decedent suffered an adverse cardiovascular event and died on or about September 16, 2010.

35. GranuFlo® and/or NaturaLyte® were lawfully obtained and used as indicated in the dialysis treatment provided to Decedent.

36. The GranuFlo® and/or NaturaLyte® were used in a proper and reasonably foreseeable manner.

37. The GranuFlo® and/or NaturaLyte® used during the dialysis treatment material to the claims made herein was in a condition that was the same or substantially similar to the same condition in which the product was manufactured, distributed and sold.

38. The Decedent was not aware and through diligent effort was not able to discover the risk of serious injury and/or death associated with and/or caused by using GranuFlo® and/or NaturaLyte®.

39. The healthcare providers involved in the dialysis treatment provided to the

Decedent were not aware and through diligent efforts were not able to discover the risk of serious injury and/or death associated with and/or caused by GranuFlo® and/or NaturaLyte®.

40. Decedent would not have purchased and used GranuFlo® and/or NaturaLyte® had Defendants properly disclosed the risks of serious injury and/or death associated with and/or caused by the drug.

41. The healthcare providers involved in the dialysis treatment provided to the Decedent would not have approved, purchased and/or used GranuFlo® and/or NaturaLyte® had Defendants properly disclosed the risks of serious injury and/or death associated with and/or caused by the drug.

42. When GranuFlo® and/or NaturaLyte® were used in dialysis treatment provided to the Decedent , neither the product label, packaging, instructions, nor the packages containing the product, provided adequate instructions and/or warnings regarding the use of GranuFlo® and/or NaturaLyte®.

43. When GranuFlo® and/or NaturaLyte® were used in the dialysis treatment provided to the Plaintiff/Defendant, neither the product label, packaging, instructions, nor the packages containing the product, provided adequate instructions and/or warnings regarding monitoring patients using GranuFlo® and/or NaturaLyte®.

When GranuFlo® and/or NaturaLyte® were used in the dialysis treatment provided to the Decedent, neither the product label, packaging, instructions, nor the packages containing the product, provided adequate instructions and/or warnings regarding the increased risk of death and/or serious injury associated with using GranuFlo® and/or NaturaLyte®.

44. At all times that GranuFlo® and/or NaturaLyte® were used in the dialysis treatment provided to the Decedent, Defendants had a duty to adequately instruct, train, and inform the healthcare professionals involved in providing the dialysis treatment.

45. Fresenius is responsible for ensuring (through adequate training, instruction, monitoring, and hiring principles) that its clinicians, nurses, contractors, employees, and physicians know how to properly use all hemodialysis products in a manner that is safe and effective for the recipients.

46. Lacking clinical knowledge, as well as a lack of effective product-related labeling, warning, and instruction from Fresenius, resulted in treating clinicians, physicians, and/or nurses providing hemodialysis treatments to Decedent in a manner that was neither safe nor effective.

B. Injuries and Damages

47. As a direct and proximate result Defendants' negligence and otherwise culpable acts described herein, GranuFlo® and/or NaturaLyte® were used in the dialysis treatment provided to Decedent which caused the injuries and damages alleged herein, including but not limited to the wrongful death of the Decedent.

48. Decedent's death directly resulted from using GranuFlo® and/or NaturaLyte®.

49. The injuries and damages alleged herein directly resulted from Defendants' negligent and otherwise culpable acts, omissions, and/or misrepresentations.

50. Plaintiff's injuries and damages directly resulted from using GranuFlo® and/or NaturaLyte®.

51. Defendant knew, should have known, or could have learned through reasonable diligence that GranuFlo® and/or NaturaLyte® caused and/or was associated with an increased risk of death and serious injuries.

52. As a direct and proximate result of Defendants' negligence and otherwise culpable acts, omissions, and/or misrepresentations, Plaintiff suffered injuries and damages including severe and permanent bodily injury, pain and suffering, disability, mental anguish and loss of capacity for the enjoyment of life, the expense of medical and nursing care; loss of wages, the loss of ability to earn money in the future and death.

53. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Plaintiff sustained injuries, damages and death including incurring the costs for necessary healthcare, treatment and medical services, loss of wages; mental anguish; diminished capacity for the enjoyment of life and diminished quality of life, aggravation of preexisting

conditions and activation of latent conditions; and ultimately death.

54. Plaintiff's injuries and damages include the costs of physician care, monitoring, treatment, medications, and supplies.

55. Plaintiff and decedent have experienced extensive pain and suffering and severe emotional distress.

56. Upon information and belief, Defendants' conduct was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers, including the Decedent, thereby entitling Plaintiff to punitive and exemplary damages so as to punish and deter similar conduct in the future.

57. Decedent relied upon the statement, misrepresentations, and actions of Defendants in so far as that the hemodialysis products he was being provided were safe and effective for use in the dialysis treatment provided to the Decedent.

C. Background Facts Regarding GranuFlo® and/or NaturaLyte®.

58. Fresenius Medical Care Holdings, Inc. is the largest division of Fresenius Medical Care AG, headquartered in Germany, and is the largest dialysis services and products company in both the U.S. and the world.

59. FMC is vertically integrated in its business environment in that FMC both owns thousands of dialysis clinics and it also manufactures the dialysis machines and nearly all the medical products used in dialysis care including dialyzers, blood lines, needles, dialysis concentrate, etc.

60. The Fresenius products division "sells" products not only to its own clinics' division, but also too many of its leading competitors, including DaVita, DCI, Renal Ventures, and many others.

61. An internal memo from Fresenius dated November 4, 2011 indicated that Fresenius had knowledge that there was a significant increased risk of cardiac arrest and death during hemodialysis treatments associated with GranuFlo® and NaturaLyte®.

62. Top Fresenius executives knew about the risk of this potential problem since the

product's introduction.

63. When a clinical crisis finally became irrefutably evident to the Fresenius Medical Services division around 2010, top Fresenius executives chose not to properly report this problem to the FDA, other government agencies, or the public at large.

64. When the clinical crisis finally became irrefutably evident to the Fresenius Medical Services division around 2010, top Fresenius executives also decided to withhold this information from non-Fresenius physicians and clinics that were using GranuFlo® and NaturaLyte®.

65. Through information and belief, there was collusion involving individuals in several Fresenius departments and organizations to hide, mislead, and obscure information about the extreme patient safety hazard associated with the use of GranuFlo® and NaturaLyte® products in order to maintain their market share as well as to minimize and diffuse the legal risks for Fresenius.

66. Ultimately, when the correlation between the use of GranuFlo® and NaturaLyte® and the increased risk of alkalosis, and cardiopulmonary arrest was made by Fresenius, the company chose to make this information, and associated urgent medical recommendations, solely available to its own physicians and clinics.

67. Through information and belief, the internal Fresenius memo which was circulated on November 4, 2011 specifically recommended action for patients with pre-dialysis bicarbonate levels of >28mEq/L and especially for those who also had pre-dialysis serum potassium levels of <4 mEq/L. This 6-page internal FMC memo shows that for at least 15 months, Fresenius did not share this information with the thousands of non-Fresenius physicians and clinics that were using GranuFlo® and NaturaLyte®.

68. The November internal Fresenius memo went on to state that, "[r]ecent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total

buffer concentration. As recommended in previous communications, physicians should individualized dialysate bicarbonate and total buffer prescriptions. We further recommend that pre-dialysis serum bicarbonate level of >24 mEq/L should prompt immediate review of dialysate bicarbonate prescription."

69. The internal November memorandum went on to further state in its "summary of findings" that: "The current analysis determined that: "*borderline elevated pre-dialysis bicarbonate levels and over alkalosis are significantly associated with 6 to 8 fold greater increase of cardiopulmonary arrest and sudden cardiac death in the dialysis facility.*" " (italic in original)..."In 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 level of >24 mEq/L." The memo further urges that this dangerous issue "needs to be addressed urgently."

70. On March 27, 2012, Fresenius received an inquiry from the FDA specifically about the risks associated with using GranuFlo® and NaturaLyte®.

71. Only after the FDA inquiry did Fresenius provide a scientifically-ambiguous, 2-page memorandum, with far less actionable information, to its non-Fresenius customers. This correspondence did not mention any patient blood levels and failed to discuss in any manner the most at-risk population of all, "acute" dialysis patients.

72. The March 29th memo to non-Fresenius clinics and physicians contained only one of ten medical references that the FMC internal memo did.

73. Through information and belief, the Granuflo product line saw steadily increased its market share since its introduction in 2003 and as of 2012 was used by the majority of nearly 400,000 hemodialysis patients in the U.S.

74. In the internal November 4, 2011 Fresenius memo, Granuflo use was associated with increased serum bicarbonate levels and alkalosis, as well as the increased possibility of cardiopulmonary arrests.

75. Also in the internal November 4, 2011 Fresenius memo, the company noted that its own patients' serum pre-dialysis bicarbonate levels had gradually increased from 2004 to

2011. Despite Fresenius' knowledge of this patient safety risk, more non-Fresenius clinics were actively being converted to the Granuflo product even after knowledge of the risks that were made clear in the internal November 4, 2011 Fresenius memo.

76. Despite these patient safety issues and possible Federal Trade Commission and FDA violations and penalties, Fresenius product sales divisions continued to aggressively market the product and routinely bundled Granuflo with other Fresenius products for pricing discounts.

77. Granuflo formulations are unique in the dialysis treatment world in that they use sodium diacetate. Through this formulation, Granuflo doubles the amount of acetate in dialysate compared to formulations made with acetic acid. Instead of adding 4 mEq/L of acetate, it adds 8mEq/L. This means that for dialysates made from Granuflo, the total buffer level is 8 mEq/L higher than the bicarbonate level delivered from the bicarbonate concentrate.

78. This increased buffer level with Granuflo products was never communicated by Fresenius to treating clinicians, physicians, or nurses and could lead to significantly increased bicarbonate levels and the associated risks of heart attack, cardio pulmonary arrest, and/or sudden cardiac death.

79. Lacking clinical knowledge, as well as a lack of effective product-related labeling, warning, and instruction from Fresenius, resulted in treating clinicians, physicians, and/or nurses providing hemodialysis treatments to patients in a manner that was neither safe nor effective.

80. Before GranuFlo® and/or NaturaLyte® were used during the dialysis treatment provided to the Decedent dialysis, the Defendants, through its agents, officers, directors and employees had notice and knowledge of the increased risk of death and cardiovascular injuries associated with using GranuFlo® and NaturaLyte®.

81. Despite such knowledge, the Defendants, knowingly and deliberately failed to properly warn Decedent, patients, consumers and the public of the increased risk of serious injury and/or death associated with using GranuFlo® and NaturaLyte®.

82. The Defendants intentionally proceeded with the manufacturing, marketing, advertising, sale and distribution of GranuFlo® and NaturaLyte® knowing that patients and

consumers would be exposed to serious injury and death.

83. The tortuous actions and misdeeds of the Defendants as alleged herein are ongoing and at all times relevant hereto were ongoing and continuous and constituted ongoing and continuous torts.

84. The Defendant sold GranuFlo® and NaturaLyte® by misleading users about the product and by failing to adequately warn the users of the potential serious dangers, which it knew or should have known, might result from using the products in dialysis.

85. The Defendants widely and successfully marketed GranuFlo® and NaturaLyte® throughout the United States by, among other things, conducting promotional campaigns that misrepresented the safety and efficacy of the respective products, in order to induce widespread use and consumption.

86. The Defendant made misrepresentations by means including but not limited to: media advertisements and statements contained in sales literature.

87. The Defendants intentionally ignored and/or withheld information regarding the increased risks of serious injury and death associated with and/or caused by GranuFlo® and NaturaLyte® at the time Defendants manufactured, marketed, advertised, promoted, sold and distributed the products.

88. Defendants knew that if such increased risks of serious injury and/or death were disclosed, consumers and non-defendant healthcare providers would not purchase GranuFlo® and NaturaLyte®.

89. At all times relevant herein, Defendant engaged in a marketing campaign with the intent that consumers and non-defendant healthcare providers would request and purchase GranuFlo® and NaturaLyte®.

90. Defendant widely and successfully marketed GranuFlo® and NaturaLyte® throughout the United States by, among other things, conducting promotional campaigns that misrepresented the risks and benefits associated with using GranuFlo® and NaturaLyte® in order to induce widespread use and consumption.

91. Defendant made misrepresentations by means of media advertisements and

statements contained in sales literature provided to the non-defendant healthcare providers and other professionals working in the dialysis field.

92. As a result of the manufacturing and marketing of the Defendants' product GranuFlo® and NaturaLyte® Defendant has reaped huge profits while concealing from the public the knowledge of the potential hazards associated with the products.

93. The Defendant should have taken appropriate measures to ensure that GranuFlo® and NaturaLyte® would not be placed into the stream of commerce and/or should have provided full and proper warnings accurately and fully reflecting the risks associated with using the products.

94. Prior to the manufacturing, sale and distribution of GranuFlo® and NaturaLyte® , Defendant, through its officers, directors and managing agents, had notice and knowledge from several sources, that GranuFlo® and NaturaLyte® presented substantial and unreasonable risks of harm to the consumer. As such, dialysis patients were unreasonably subjected to risk of injury or death from the consumption of Defendants' product, GranuFlo® and NaturaLyte®.

95. Prior to the use of GranuFlo® and NaturaLyte® as alleged herein, the Defendant, through its officers, directors and managing agents, had notice and knowledge from several sources, that GranuFlo® and NaturaLyte® presented substantial and unreasonable risks of harm. As such, dialysis patients were unreasonably subjected to risk of injury or death from the consumption of Defendants' product, GranuFlo® and NaturaLyte®.

96. Defendant, through its officers, directors and managing agents for the purpose of increasing sales and enhancing its profits, knowingly and deliberately failed to remedy the known defects of GranuFlo® and NaturaLyte®.

97. Defendant and its officers, agents and managers intentionally proceeded with the manufacturing, marketing, advertising, promotion, distribution and sale of GranuFlo® and NaturaLyte®, knowing that persons would be exposed to serious injury and death, in order to advance its own pecuniary interests.

98. Defendants' conduct was wanton and willful, and displayed a conscious disregard for the safety of the public and particularly of Decedent.

99. Defendant promoted the sale of GranuFlo® and NaturaLyte® by misleading healthcare professionals and professionals working in the dialysis field about the risks associated with using the products and by failing to warn and/or adequately warn the patients and healthcare professionals of increased risk of serious injury and/or death associated with and/or caused by GranuFlo® and NaturaLyte®.

100. Defendant negligently and/or intentionally failed to provide adequate instructions regarding the safe and proper use of GranuFlo® and NaturaLyte®.

101. Defendant negligently and/or intentionally failed to provide adequate instructions regarding the safe and proper monitoring of patients during dialysis when GranuFlo® and NaturaLyte® were used during dialysis.

102. Defendant negligently and/or intentionally failed to monitor, analyze and/or report the data generated by the testing it conducted and adverse event reports identifying GranuFlo® and NaturaLyte®.

103. In promoting GranuFlo® and NaturaLyte® to the medical community, the FDA, and the general public, Defendant negligently and/or intentionally minimized the risks of serious injury and/or death associated with and/or caused by GranuFlo® and NaturaLyte®.

104. Defendant instead engaged in a pattern of reckless behavior and manipulation in a successful effort to enhance profits at the expense of the public health.

105. Defendant acted with conscious and wanton disregard of the health and safety of consumers and dialysis patients including Decedent.

106. The above-described wrongful conduct was done with knowledge, authorization, and ratification of officers, directors, and managing agents of Defendants.

107. Plaintiff requests an award of additional damages for the sake of example and for the purpose of punishing such entities for its conduct, in an amount sufficiently large to be an example to others and to deter Defendant and others from engaging in similar conduct in the future.

108. The Defendants' actions and/or lack thereof demonstrate gross negligence, if not reckless disregard for human life or, worse, intentional misconduct.

109. As a result, consumers, like Decedent, paid the price.

110. At all times material hereto, the Defendants permitted its products to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate warnings of the serious injuries and death associated with and/or caused by using GranuFlo® and NaturaLyte®.

111. At all times material hereto, the Defendants permitted its products 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 GranuFlo® and NaturaLyte®.

112. The Defendants failed to warn and/or adequately warn the Decedent, other dialysis patients, healthcare professionals and other professionals working in the dialysis field of the increased risk of death and serious injuries, which it knew or should have known, resulted from the use of GranuFlo® and NaturaLyte®.

113. The Defendants failed to properly warn physicians through the package insert for GranuFlo® and NaturaLyte®, regarding the catastrophic, potentially fatal, risks.

114. The Defendants' failure to include warnings regarding the risks of serious injury and death was done with full knowledge of such risks.

115. Prior to the injuries and damages caused by GranuFlo® and NaturaLyte® as alleged herein, the Defendants were aware of published medical literature which demonstrated an association and/or causal relationship between GranuFlo® and NaturaLyte® and such serious injuries and death.

COUNT I
STRICT LIABILITY

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

116. At all times relevant and material to this action, the Defendants designed, tested,

manufactured, packaged, marketed, advertised, distributed, promoted, and sold GranuFlo® and NaturaLyte®, placing the products into the stream of commerce.

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

118. GranuFlo® and NaturaLyte® were expected to reach, and did reach, users and/or consumers, including Decedent, without substantial change in the defective and/or unreasonably dangerous condition.

119. GranuFlo® and/or NaturaLyte® were used during the dialysis treatment provided to Decedent in the foreseeable manner normally intended, recommended, promoted, and/or marketed by Defendants.

120. GranuFlo® and/or NaturaLyte® were defective and unreasonably dangerous when each product entered the stream of commerce in one or more of the following particulars:

a. GranuFlo® and NaturaLyte® contained manufacturing defects in that the each product caused and/or increased the risk of experiencing an adverse cardiovascular event, including but not limited to death, sudden cardiac death, heart attack, cardiac arrest, and/or congestive heart failure.
b. GranuFlo® and NaturaLyte® were not safe because the health risks associated with each product outweighed the benefits.
c. GranuFlo® and NaturaLyte® were marketed and promoted for use in hemodialysis treatment, when they carried an unreasonable and unnecessary risk of serious injury and death.
d. GranuFlo® and NaturaLyte® were insufficiently and/or inadequately tested by the Defendants.
e. GranuFlo® and NaturaLyte® were not safe due, in part, to inadequate and/or defective instructions provided by the Defendant.
f. GranuFlo® and NaturaLyte® were not safe due, in part, to inadequate and/or defective warnings provided by the Defendant.
g. GranuFlo® and NaturaLyte® were marketed and promoted for use as safe treatment in hemodialysis treatment, when they were not.
h. GranuFlo® and NaturaLyte® were unreasonably dangerous in that, as designed, each product failed to perform safely when used in dialysis treatment provided to ordinary consumers, including Decedent.
i. GranuFlo® and NaturaLyte® were unreasonably dangerous in that, as designed, the risks serious injury and/or death, posed by using the

products exceeded any benefits the products were designed to or might in fact bestow.

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

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

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

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

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

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

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

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

121. GranuFlo® and NaturaLyte® as manufactured and supplied by the Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injuries from use, Defendants failed to provide adequate warnings to the medical community and the consumers, to whom it was directly marketing and advertising; and, further, it continued to affirmatively promote GranuFlo® and NaturaLyte® as safe and effective.

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

123. Despite the fact that Defendants knew or should have known of the defective nature of GranuFlo® and NaturaLyte®, Defendants continued to design, manufacture, market,

and sell GranuFlo® and NaturaLyte® so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by GranuFlo® and NaturaLyte®.

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

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

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

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

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

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

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

131. The injuries and damages alleged herein were caused by the Defendants.

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

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

COUNT II
NEGLIGENCE

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

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

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

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

a. failing to test GranuFlo® and NaturaLyte® properly and thoroughly before releasing the products on the market;
b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of GranuFlo® and NaturaLyte®;
c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of GranuFlo® and NaturaLyte® which indicated risks associated with using the products;
d. failing to conduct adequate post-market monitoring and surveillance of GranuFlo® and NaturaLyte®;
e. failing to conduct adequate analysis adverse event reports;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

w. Failing to utilize and implement a reasonably safe design in the manufacture of GranuFlo® and NaturaLyte® ;
x. Failing to manufacture GranuFlo® and NaturaLyte® in a reasonably safe condition;
y. Failing to warn Plaintiff of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of GranuFlo® and NaturaLyte® ;
z. Failing to label GranuFlo® and NaturaLyte® to adequately warn Decedent of the increased risk of death and/or injury associated with the products including the increased risk of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions;
aa. Failing (through adequate training, instruction, monitoring, and hiring principles) to ensure that its clinicians, nurses, contractors, employees, and physicians knew how to properly use all hemodialysis products in a manner that was safe and effective for the recipients;
bb. being otherwise reckless, careless and/or negligent.

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

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

139. Defendants knew or should have known that GranuFlo® and NaturaLyte® had unreasonably dangerous risks and caused serious side effects of which the non-defendant healthcare providers involved in the dialysis treatment provided to Decedent would not be aware. Defendants nevertheless advertised, marketed, sold and distributed GranuFlo® and NaturaLyte®.

140. Defendants are guilty of negligence *per se* in that the Defendants s violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*, and the Sherman Food, Drug and Cosmetic Law, as well as other applicable laws, statutes, and regulations.

141. The Defendants' acts and omissions constitute an adulteration and/or misbranding as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331. This is negligence *per se*.

142. Despite the fact that Defendant knew or should have known that GranuFlo® and NaturaLyte® increased the risk of serious injury and/or death, Defendant continued to

manufacture, market, advertise, promote, sale and distribute GranuFlo® and NaturaLyte® to consumers, including Decedent.

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

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

COUNT III
FAILURE TO WARN

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

143. GranuFlo® and NaturaLyte® are unreasonably dangerous, even when used in a foreseeable manner as designed and intended by the Defendants.

144. Defendants failed to warn and/or adequately warn Decedent, consumers, dialysis patients, physicians, and healthcare professionals of the increased health risks associated with using GranuFlo® and NaturaLyte®.

145. Decedent did not have the same knowledge as Defendants and no adequate warning was communicated to Decedent.

146. Defendants had a continuing duty to warn consumers and healthcare professionals of increased health risks associated with its products, and negligently and/or wantonly breached its duty as follows:

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;
b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;
c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;

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

e. Failed to inform Decedent that the clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

147. Defendants breached their duty to warn consumers, including Decedent, of the risks associated with GranuFlo® and NaturaLyte®.

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

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

COUNT IV
BREACH OF WARRANY OF MERCHANTABILITY

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

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

151. Defendants knew and intended that GranuFlo® and NaturaLyte® be used in dialysis treatment as the product(s) were used during the dialysis treatment provided to Decedent.

152. Defendants expressly and/or impliedly warranted to Decedent that use of GranuFlo® and NaturaLyte® was a safe for use during dialysis treatment.

153. Decedent reasonably relied upon the expertise, skill, judgment and knowledge of the Defendants and upon the express and/or implied warranty that GranuFlo® and NaturaLyte® were safe, of merchantable quality, and fit for use during dialysis treatment.

154. The healthcare professionals involved in the dialysis treatment provided to Decedent reasonably relied upon the expertise, skill, judgment and knowledge of the Defendants

and upon the express and/or implied warranty that GranuFlo® and NaturaLyte® were safe, of merchantable quality, and fit for use during dialysis treatment.

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

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

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

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

COUNT V
BREACH OF EXPRESS WARRANTY

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

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

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

160. Defendants breached the express warranties as follows:

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

c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;
d. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment
e. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market; and
f. Defendants misrepresented information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®.

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

162. At all relevant times, including during the period that Decedent received dialysis treatment, GranuFlo® and NaturaLyte® did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

163. At all relevant times, including during the period that Decedent received dialysis treatment, GranuFlo® and NaturaLyte® did not perform in accordance with the Defendants' representations.

164. In deciding to purchase and use GranuFlo® and NaturaLyte® Decedent, other consumers, and the medical community relied upon Defendants' express warranties.

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

WHEREFORE, Plaintiff demands judgment against Defendant 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
BREACH OF IMPLIED WARRANTY

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

167. At all relevant and material times, Defendants manufactured, distributed,

advertised, promoted, and sold GranuFlo® and NaturaLyte®.

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

169. Defendants knew and intended that GranuFlo® and NaturaLyte® be used in dialysis treatment as the product(s) were used during the dialysis treatment provided to Decedent.

170. Defendants expressly and/or impliedly warranted to Decedent that use of GranuFlo® and NaturaLyte® was a safe for use during dialysis treatment.

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

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

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

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

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

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

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

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

179. Defendants impliedly represented to Decedent, consumers and the medical

community that GranuFlo® and NaturaLyte® were:

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

180. Defendants breached the implied warranties as follows:

a. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;
b. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.
c. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;
d. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment
e. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market; and
f. Defendants misrepresented information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®.

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

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

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

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

185. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts

described herein, Decedent sustained injuries, damages and death alleged.

WHEREFORE, Plaintiff demands judgment against Defendant 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
FRAUDULENT MISREPRESENTATION

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

187. At all relevant and material times, Defendants expressly and/or impliedly warranted GranuFlo® and NaturaLyte® products were safe, of merchantable quality and fit for use in dialysis treatment.

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

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

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

191. The false representations of Defendants were fraudulently made, in that the

subject products in fact caused injury, were unsafe, and the benefits of the products were far outweighed by the risk associated with use thereof.

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

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

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

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

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;
b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;
c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;
d. Failed to inform Decedent that GranuFlo® and NaturaLyte® had not been adequately tested to determine the safety and risks associated with using the products.
e. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;
f. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.
g. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;
h. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment
i. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market; and

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

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

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

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

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

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

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

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

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

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

204. Defendant omitted, suppressed and/or concealed material facts concerning the

dangers and risk of injuries associated with the use of GranuFlo® and NaturaLyte® including the increased risk of serious injury and/or death.

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

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

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

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

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

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

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

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

213. As a direct and proximate result of Defendants' fraudulent misrepresentations and

intentional concealment of facts, upon which Decedent reasonably relied, Decedent suffered injuries and damages as alleged herein.

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

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

COUNT VIII
FRAUDULENT CONCEALMENT

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

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

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;
b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;
c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;
d. Failed to inform Decedent that GranuFlo® and NaturaLyte® had not been adequately tested to determine the safety and risks associated with using the products.
e. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;
f. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.
g. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;
h. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment

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

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

k. Defendants concealed from Decedent that the clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

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

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

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

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

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

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

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

COUNT IX
RECKLESS AND/OR NEGLIGENT MISREPRESENTATION & CONCEALMENT

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

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

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

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

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

228. Defendants recklessly and/or negligently failed to disclose to Decedent, and others, important safety and efficacy information, thereby suppressing material facts about GranuFlo® and NaturaLyte®, while having a duty to disclose such information, which duty arose from their actions of making, marketing, promoting, distributing and selling pharmaceutical products to Decedent and others.

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

230. The false representations of the Defendants were recklessly and/or negligently

made in that GranuFlo® and NaturaLyte® in fact caused injury, were unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

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

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

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

a. Failed to include warnings and/or adequate warnings of the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte®;
b. Failed to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;
c. Failed to provide adequate and/or proper instructions regarding monitoring dialysis patients before, during and after dialysis when GranuFlo® and NaturaLyte® were used;
d. Failed to inform Decedent that GranuFlo® and NaturaLyte® had not been adequately tested to determine the safety and risks associated with using the products.
e. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;
f. Defendants misrepresented the risks associated with using GranuFlo® and NaturaLyte®.
g. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;
h. Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment
i. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market; and
j. Defendants misrepresented information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®.
k. Defendants misrepresented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that GranuFlo® and NaturaLyte® were safe and fraudulently

withheld and concealed information about the substantial risks of serious injury and/or death associated with using GranuFlo® and NaturaLyte®;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COUNT X
GROSS NEGLIGENCE

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

245. Defendants had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of GranuFlo® and NaturaLyte®, including a duty to ensure that Defendants' product, GranuFlo® and NaturaLyte®, did not expose dialysis patients to an unreasonable and/or dangerous increased risk of death and/or serious injury.

246. Defendants failed to exercise reasonable care in the warning about, design,

testing, manufacture, marketing, labeling, sale, and/or distribution of GranuFlo® and NaturaLyte®.

247. Defendant knew or should have known that GranuFlo® and NaturaLyte® caused and/or was associated with an increased risk death and/or serious injuries.

248. Defendants were grossly negligent in warning about the, design, testing, manufacture, marketing, labeling, sale, and/or distribution of GranuFlo® and NaturaLyte®.

249. The Defendants gross negligence includes:

a. failing to provide adequate warnings with GranuFlo® and NaturaLyte® regarding the increased risk associated with using the products;
b. failing to exercise due care in designing, developing, and manufacturing GranuFlo® and NaturaLyte®;
c. failing to exercise due care in marketing, advertising, and promotion of GranuFlo® and NaturaLyte®;
d. failing to ensure that the clinicians, nurses, and/or physicians were adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

250. Defendants continued to manufacture, market, advertise, promote, sale and distribute the products despite the fact that the Defendants knew, should have known and/or recklessly disregarded the risks of death and serious injury associated with GranuFlo® and NaturaLyte®.

251. Defendants knew and/or consciously or recklessly disregarded the fact that consumers such as Decedent would suffer injury as a result of Defendants' failure to exercise reasonable care as described above.

252. Despite the risks associated with using the products, the Defendants continued to manufacture, market, advertise, promote, sale and distribute the products so as to maximize sales and profits at the expense of the health and safety of the public, including Decedent, in conscious and/or reckless disregard of the foreseeable harm the health, safety and welfare of consumers, including Decedent.

253. As a direct and proximate consequence of Defendants' negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts

described herein, Decedent sustained injuries and damages as alleged herein.

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

COUNT XI
WANTONNESS

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

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

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

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

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

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

a. Failing to test and inspect GranuFlo® and NaturaLyte® in a reasonable manner in order to ascertain whether or not 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 GranuFlo® and NaturaLyte® ;
c. failing to manufacture GranuFlo® and NaturaLyte® in a reasonably safe condition;
d. failing to warn Plaintiff of the danger of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of GranuFlo® and NaturaLyte® ;

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

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

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

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

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

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

COUNT XII
UNJUST ENRICHMENT

262. Plaintiff incorporates by reference each and every paragraph of this complaint as though set forth in full in this cause of action and further alleges: At all times relevant to this action, Defendants designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold GranuFlo® and NaturaLyte® .

263. GranuFlo® and/or NaturaLyte® was used during dialysis treatment provided to Decedent.

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

265. Decedent did not receive the safe and effective product intended.

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

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

COUNT XIII
WRONGFUL DEATH

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

268. Plaintiff adopts and incorporates by reference all the allegations above.

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

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

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

GLOBAL PRAYER FOR RELIEF

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

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

a. compensatory damages for the described losses with respect to each cause of action;

b. past medical expenses and burial expenses;

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

d. pain and suffering;

e. past and future emotional distress;

f. loss of enjoyment of life;

g. wrongful death;

h. consequential damages;

i. disgorgement of profits;

j. restitution;

k. punitive damages with respect to each cause of action;

l. reasonable attorneys' fees where recoverable;

m. costs of this action;

n. prejudgment and all other interest recoverable; and

o. such other additional and further relief as Plaintiff may be entitled to in law or in equity.

TOLLING OF THE LIMITATIONS PERIOD

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

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

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

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

276. 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.

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

PLAINTIFF DEMANDS A TRIAL OF ALL ISSUES BY STRUCK JURY.

Date: September 14, 2012.

/s/ James E. Carter
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JS 44 (Rev. 12/07)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

WADDELL BISHOP, etc.

DEFENDANTS

FRESENIUS USA, INC., et al.

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

County of Residence of First Listed Defendant Middlesex County, MA
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)

James Carter, Esq., HURT, STOLZ & CROMWELL, LLC
345 West Hancock Avenue, Athens, Georgia 30601

Attorneys (If Known) CV612-86

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

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

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

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

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence

Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 463 Habeas Corpus - Alien Detainee
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes

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

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

VI. CAUSE OF ACTION

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

Brief description of cause: Person Injury Product Liability

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $**

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

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 09/14/2012

SIGNATURE OF ATTORNEY OF RECORD /s/ James E. Carter

FOR OFFICE USE ONLY

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