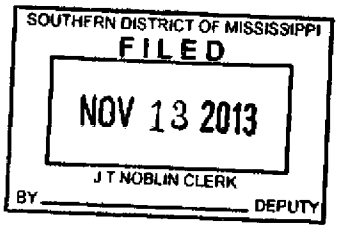
IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI SOUTHERN DIVISION



EDWARD J. LASTORKA, INDIVIDUALLY AND ON BEHALF OF THE WRONGFUL DEATH BENEFICIARIES OF JACKIE LAFAYE LASTORKA, DECEASED

PLAINTIFF

v.

CIVIL ACTION NO. 1:13cv427 HSO-RHW

FRESENIUS MEDICAL CARE HOLDINGS, INC.; FRESENIUS MEDICAL CARE NORTH AMERICA, INC.; FRESENIUS USA, INC.; FRESENIUS USA MANUFACTURING, INC.; FRESENIUS USA MARKETING, INC.; FRESENIUS USA SALES, INC. AND JOHN DOE DEFENDANTS 1-5

DEFENDANTS

COMPLAINT

COMES NOW the Plaintiff, Edward J. Lastorka, Individually and on behalf of the Wrongful Death Beneficiaries of Jackie LaFaye Lastorka, Deceased, by and through the undersigned counsel of record, and would state unto this Honorable Court as cause of action against Defendants, Fresenius Medical Care Holdings, Inc., Fresenius Medical Care North America, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., Fresenius USA Marketing, Inc., Fresenius USA Sales, Inc. ("Fresenius" or "Defendants"), and John Doe Defendants 1-5, the following matters, to-wit:

INTRODUCTION

1. This is a wrongful death case arising from the injuries and death of Jackie LaFaye Lastorka (hereinafter "Decedent"), as a result of dialysis treatments and products manufactured, sold and administered by the Fresenius Defendants. This case also arises from the Defendants' misrepresentations and concealment, wherein the Defendants concealed essential information regarding Fresenius dialysis products marketed under the names GranuFlo® and NaturaLyte®. This action is brought by Edward J. Lastorka, the widower of the Decedent, on behalf of all wrongful death beneficiaries.

2. Decedent, Jackie LaFaye Lastorka, a retired long-time licensed practical nurse, and resident of Harrison County, Mississippi, was a dialysis patient receiving dialysis treatments at the Fresenius Clinic in D'Iberville, Mississippi. In or around late 2010, Decedent suffered a fatal cardiac event while at the Fresenius Clinic in D'Iberville, Mississippi. On December 6, 2010, Decedent suffered a fatal cardiac event during dialysis treatment and died as a result of the conduct of the Defendants as described herein.

3. Fresenius, a German company, is the largest operator of dialysis treatment clinics in Mississippi and the United States. Fresenius maintains forty-nine (49) dialysis clinics in the State of Mississippi alone. Fresenius is also a large distributor of dialysis treatment products, including dialysis equipment and dialysates such as GranuFlo® and NaturaLyte®, which Fresenius employs in its own clinics and sells to non-Fresenius clinics, hospitals and dialysis providers throughout Mississippi and the nation. Dialysates are chemical agents used in screening the blood to remove impurities during the dialysis process. Dialysates contain a bicarbonate employed to offset pH imbalance resulting from the failure of kidneys to purify the blood. Thus,

dialysis patients typically have a high acid content in their blood, and the bicarbonate is used to bring the blood back into a normal balance or pH range.

4. GranuFlo® and NaturaLyte® have been implicated in a national epidemic of deaths of dialysis patients. Fresenius knew or should have known that administration of GranuFlo® and NaturaLyte® resulted in dangerously increased bicarbonate levels during dialysis treatment. Fresenius misrepresented and concealed said dangers, failing to provide proper protocols for clinicians to protect patients and, as a result, patients suffered cardiac arrest, strokes, death and other medical consequences. Even though Fresenius knew or should have known of said dangers, Fresenius failed, for numerous years, to adequately instruct medical providers and clinicians about the extreme dangers posed by the increased bicarbonate levels related to the use of GranuFlo® and NaturaLyte®. In June of 2012, the Food and Drug Administration ("FDA") announced a Class I Recall of these dialysis products. The Recall required Defendants to clarify instructions on their packaging. Defective design, inadequate warnings, and inadequate instructions led to serious patient complications, including sudden cardiac arrest, other cardiovascular injuries, stroke and/or death.

5. Even though Defendants knew or should have known of the danger caused by their products, including bicarbonate overdose, clinicians were unaware that the high levels of bicarbonate resulting from the products heightened the risk of cardiac injury by approximately six-hundred to eight-hundred percent. Furthermore, prior to the Class I Recall of these products, medical providers were never given a proper warning to protect patients treated with said products. Thus, thousands of patients receiving dialysis treatment were unknowingly and repeatedly exposed to bicarbonate overdoses with tragic results.

6. When Defendants finally began disclosing some of the dangers identified with their products, they willfully withheld that information from their "outside" customers. On November 4, 2011, Fresenius issued an internal memo disclosing the results of a study completed in 2010. Fresenius shared the internal memo with their own dialysis clinical staff only, but they refused to disclose their findings to the thousands of other clinics using the products. A copy of the November 4, 2011 memo, attached as "Exhibit A," was subsequently leaked to the FDA by an anonymous source. Fresenius was contacted by the FDA on March 27, 2012. Two days later, on March 29, 2012, before responding to the FDA, Fresenius released a shorter, stripped-down, scientifically-vague, 2-page memo to non-Fresenius clinics. That memo is attached hereto as "Exhibit B." Thus, Fresenius withheld critical information from its customers that could have prevented numerous heart attacks and deaths.

7. This is a wrongful death action filed pursuant to Section 11-7-13 of the Mississippi Code, for all wrongful death beneficiaries. Causes of action are herein asserted against the Defendants for the wrongdoing alleged herein, and damages are sought for the heirs-at-law and wrongful death beneficiaries of Decedent.

PARTIES

8. Edward J. Lastorka is an adult resident citizen of Harrison County, Mississippi. He is the widower of the Decedent, Jackie LaFaye Lastorka. Mr. Lastorka is a retired Master Sergeant of the United States Air Force. Jackie LaFaye Lastorka died on December 6, 2010, of cardiac arrest resulting from the Defendants' products, protocols and misrepresentations, as specified herein. At the time of her death, Mrs. Lastorka was an adult resident citizen of Harrison County, Mississippi. Mr. and Mrs. Lastorka have three (3) children: Patricia Lastorka, Christi Jo Cardwell, and Jack Edward Lastorka. Mr. Lastorka and said three (3) children constitute the

heirs-at-law and wrongful death beneficiaries of Jackie LaFaye Lastorka.

9. Defendant, Fresenius Medical Care Holdings, Inc., doing business as Fresenius Medical Care North America ("FMCNA") is a corporation organized and existing under the laws of New York with its principal place of business located at 95 Hayden Avenue, Lexington, Massachusetts 02420. FMCNA is one of the largest providers of "walk-in" dialysis care in the United States. At all times relevant, FMCNA, regularly and continuously did business within and/or derived substantial revenue from business conducted within this judicial district.

10. Defendant, Fresenius Medical Care North America, Inc. ("FMCNA") is a corporation organized and existing under the laws of Massachusetts with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times, FMCNA regularly and continuously did business within and/or derived substantial revenue from business conducted within this judicial district.

11. 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 Holdings, Inc. FUSA maintains a principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all times relevant, FUSA regularly and continuously did business within and/or derived substantial revenue from business conducted within this judicial district.

12. Defendant, Fresenius USA Manufacturing, Inc. ("Fresenius Manufacturing") is a corporation organized and existing under the laws of Delaware with its principal place of business at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times, 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. Fresenius Manufacturing is registered to do business within the State of Mississippi and may be served with process through service upon its registered agent, CT Corporation System, 645 Lakeland East Drive, Suite 101, Flowood, Mississippi 39232.

13. Defendant, Fresenius USA Marketing, Inc. ("Fresenius Marketing") is a corporation organized and existing under the laws of Delaware with its principal place of business at 920 Winter Street Waltham, Massachusetts 02451. Fresenius Marketing regularly and continuously did business within this judicial district. Fresenius Marketing is registered to do business within the State of Mississippi and may be served with process through service upon its registered agent, CT Corporation System, 645 Lakeland East Drive, Suite 101, Flowood, Mississippi 39232.

14. Defendant, Fresenius USA Sales, Inc. ("Fresenius Sales"), is a corporation organized and existing under the laws of Delaware with its principal place of business located at 920 Winter Street, Waltham, Massachusetts 02451. At all relevant times herein, this Defendant was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and GranuFlo® Dry Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and sold NaturaLyte® Liquid and GranuFlo® Dry Acid Concentrates in the State of Mississippi.

15. John Doe Defendants 1 through 5 are individuals, corporate entities, holding companies, officers, directors, and/or others whose names and identities are unknown at this time, but will be disclosed by discovery in this action. Defendants John Does 1 through 5 conspired with and/or aided and abetted the Defendants, and participated in the planning,

implementation and execution of, and/or knew or should have known of the course of wrongful conduct and breaches of duties alleged herein.

JURISDICTION & VENUE

16. Jurisdiction is proper in this Court pursuant to 28 U.S.C. § 1332, as complete diversity exists among the parties and the amount in controversy exceeds Seventy Five Thousand Dollars ($75,000), exclusive of interests and costs.

17. Venue is proper in this Court pursuant to 28 U.S.C. §1391. The Defendants are corporations subject to personal jurisdiction, doing business within this district and/or a substantial part of the events or omissions that give rise to the claims occurred in this district.

FACTS

I. DECEDENT'S DEATH WAS CAUSED BY THE WRONGFUL CONDUCT OF FRESENIUS

18. At the time of her death in 2010, Decedent was a dialysis patient. Decedent was treated on a regular basis at the Fresenius-owned dialysis clinic in D'Iberville, Mississippi, attending dialysis treatments on Mondays, Wednesdays and Fridays.

19. Decedent sustained a fatal cardiac event in connection with her dialysis treatment. On December 6, 2010, Decedent sustained a fatal heart and died. She was sixty-seven (67) years old when she died of cardiac arrest. She suffered a fatal heart attack during dialysis treatment.

20. Neither Decedent, nor the Plaintiff in this action, knew, or reasonably could have known, that Decedent's injuries and death were caused by or related to the negligence and acts of the Defendants until the Defendants' conduct and actions became public by way of a recall by the FDA of Defendant's products, effective in 2012. Decedent's injuries and death were the direct and proximate result of the negligence and wrongful conduct of the Defendants as described herein.

II. THE FRESENIUS PRODUCTS & CONDUCT RESULT IN INJURIES AND DEATH

21. Through its "walk-in" clinics, Fresenius treats roughly one-third of U.S. dialysis patients. Fresenius maintains forty-nine (49) clinics in the State of Mississippi, its presence in Mississippi being one of the largest per capita of any state. As described above, Fresenius also has a vertically integrated business as it owns thousands of dialysis clinics, and it manufactures and distributes equipment and numerous products used in dialysis treatment, including its dialysates. Fresenius is also a major distributor and seller of dialysis treatment products - including dialysis equipment as well as chemical agents including NaturaLyte® and GranuFlo® - and said products are sold to non-Fresenius dialysis centers and hospitals.

22. Dialysis is required for patients suffering from impaired kidney function. Healthy kidneys typically excrete acid, as acid is a natural byproduct of metabolism in the body. Patients with impaired kidney function are unable to excrete acid. As a result these patients are at risk of developing a condition called acidosis, which is a buildup of excess acid in the blood. Dialysis, also known as hemodialysis, screens the blood for impurities and neutralizes excessive acid in restoring a proper pH to the patient's blood.

23. Bicarbonate is an alkaline, i.e., a base, the opposite of an acid. Bicarbonate is used in dialysis as it acts as a buffer and neutralizes the high acid content of dialysis patients' blood. The bicarbonate acts as a pH buffer and neutralizes patients' acidosis.

24. Dialysis patients' bicarbonate levels must be carefully monitored and controlled to ensure a stable pH level. When pH levels rise too high, the blood has too much alkaline leading to a condition known as "alkalosis." When pH levels are too low, that is too acidic, high acid levels lead to "acidosis." Both "alkalosis" or "acidosis" are dangerous, even life-threatening,

conditions. Alkalosis, for example, is a significant independent and additive risk factor associated with cardiopulmonary arrest and stroke.

25. Part of the protocol employed in dialysis is to establish the desired level of bicarbonate load so that the patient receives a safe "dosage" of bicarbonate. Defendants in this action failed to accomplish this critical component of dialysis treatment as they used products and methods which consistently resulted in bicarbonate overdoses resulting in tragic consequences to dialysis patients including the Decedent.

26. One goal of dialysis treatment is to accomplish a proper pH balance of bicarbonate delivery through use of a solution called dialysate. Dialysate is a mixture of three components including water, bicarbonate concentrate and acid concentrate. The liver quickly converts acetate to bicarbonate. During dialysis involving use of dialysate that contains acetate; therefore, patients receive bicarbonate from two sources - the bicarbonate concentrate and the acid concentrate. This combination of acetate converted to bicarbonate when coupled with the bicarbonate already in the mixture is quantified and the total bicarbonate level delivered to the patient is known as the "total buffer." Excessive total buffer causes a bicarbonate overdose and the condition known as alkalosis. Alkalosis causes extreme low blood pressure, which in turn results in atrial fibrillation causing cardiac arrest, stroke, other cardiac injuries and death.

27. Dialysis providers are acutely aware of the above matters. Thus, dialysis providers attempt to carefully control the total buffer delivered to their patients. However, when using the dialysates NaturaLyte® and GranuFlo®, Defendants failed to properly quantify the total buffer delivered to their patients including Decedent. Defendants failures resulted in bicarbonate overdoses, resulting in alkalosis, and ultimately in Decedent's injuries and death.

III. DEFENDANTS CONCEALED THE DANGERS & FAILED TO PROVIDE SAFE PROTOCOLS TO PROTECT DIALYSIS PATIENTS

28. As set out above, Defendants' products significantly increased patients' total buffer and thus bicarbonate levels. Despite the risks of causing alkalosis and therefore sudden cardiac arrest, stroke, other cardiac events and death, and without conducting proper testing and research studies, Defendants aggressively promoted their products in Mississippi and across the country.

29. Defendants misled consumers of their products, especially when used with their equipment under the protocols adopted by Fresenius. Defendants consistently failed to disclose the high bicarbonate levels their products produced. Such misrepresentations were either grossly negligent or willfully made. Without the benefit of the critical information described herein, including proper product labeling, warning and instruction, dialysis treatments were rendered in an unsafe and dangerous manner. Defendants could and should have prevented the dangers to their patients, and to other consumers of their products, but they knowingly and/or willingly failed to do so.

30. Long before the series of overdoses eventually culminating in Decedent's death, the Defendants knew, or should have known, the following:

(a) that patients using their product were developing post-dialysis alkalosis;

(b) that alkalosis is a significant independent and additive risk factor associated with cardiopulmonary arrest, and leads to other metabolic imbalances that contribute to cardiac arrest;

(c) that the major cause of alkalosis in dialysis patients was inappropriately high levels of bicarbonate, which caused clinicians to fail to recognize the total buffer or dosage of bicarbonate delivered to patients; and

(d) that physicians and clinicians needed warnings and adequate instructions to properly treat patients and prescribe the products, and staff needed adequate instructions regarding proper machine settings and proper review and monitoring of patients.

31. A 2004 study published in the American Journal of Kidney Diseases titled, "Association of Predialysis Serum Bicarbonate Levels with Risk of Mortality and Hospitalization in the Dialysis Outcomes and practice Patterns Study" further informed Defendants of the well-known risk of elevated bicarbonate levels. The article describes the well-known correlation between elevated bicarbonate levels and metabolic alkalosis and the injuries caused thereby.

32. In a patent application filed by Defendants on or about May 17, 2006, Defendants noted the "contribution of bicarbonate [in dialysis treatment] resulting from metabolism of acetate contained in an acid dialysate constituent." The patent application included a diagram of machine settings for GranuFlo® which reflected the extra contribution of bicarbonate derived from acetate to the overall buffer. Thus, Defendants recognized that its dialysate product required special instructions to clinicians in order to reduce the risk of dangerously high bicarbonate levels and alkalosis in patients.

33. Between 2003 and 2012, Defendants were repeatedly advised of the confusion existing among clinicians with respect to the total bicarbonate buffer delivered by its products, NaturaLyte® and GranuFlo®. In particular:

(a) Defendants knew, or should have known, that nephrologists, dialysis nurses and technicians, clinicians, physicians, and patients were not properly educated, trained, or informed about the acetate levels in their dialysis concentrates and that their products significantly increased the total buffer;

(b) Defendants knew, or should have known, that dialysis machines displayed a bicarbonate value that did not reflect an accurate total buffer value and therefore additional calculations and steps were necessary to achieve the proper level of bicarbonate;

(c) Defendants knew, or should have known, that because of their misleading product information and inadequate warnings and instructions, patients were receiving too much bicarbonate, which could cause alkalosis;

(d) Defendants knew, or should have known, that bicarbonate-induced alkalosis could cause a dialysis patient's blood pressure to plummet, which, independently or compounded with other metabolic disturbances, can lead to cardiac arrest and stroke; and

(e) Defendants knew, or should have known, that the major cause of alkalosis in dialysis patients was the aforementioned inappropriately high dialysate total buffer concentration.

34. Thus, Defendants knew, or should have known, they had to warn about the risks and instruct users to account for them when ordering and administering patients' dialysis, and to take additional steps to assure patients received the proper treatments rather than dangerous doses of bicarbonate. Defendants' willful misconduct prevented all this from happening. However, Defendants willfully shirked their duties to Decedent, to their other patients, and to their customers as they permitted their unsafe products and reckless practices to continue unabated.

35. By at least January 2011, Defendants possessed data from their own clinics demonstrating that 941 patients from only 667 clinics within the Fresenius network had suffered cardiopulmonary arrests during dialysis treatments. These cardiac arrests were occurring at an

alarming rate, at least six-hundred to eight-hundred percent greater than cardiac arrests experienced in clinics which were not employing Defendants' defective products. Defendants knew that the high bicarbonate levels caused by their defective products were causing these cardiac events.

36. Even after January 2011, when the clinical crisis was irrefutable, Defendants continued providing misleading information about the recommended protocols, products and equipment. Based on information and belief, there was collusion involving individuals in several Fresenius departments and organizations to hide, mislead, and obscure information and data from patients and consumers about the serious patient safety hazards associated with the use of the Defendants' products and equipment to maintain market share and minimize legal risks. Hence, the Defendants' conduct and wrongdoing described herein was within the knowledge of its officers, directors and managing agents.

37. As noted above, even when the causal relationship between the use of Defendants' products and the increased risk of alkalosis and cardiopulmonary arrest was inescapable, Defendants only provided this information and urgent medical recommendations to their own physicians and clinics.[1] Fresenius's customers who used the same equipment and products in the manner recommended by Fresenius were left in the dark and continued to employ the dangerous protocol which Fresenius had abandoned.

[1] Some of the critical information contained in Internal Memo, attached hereto as "Exhibit A," includes the following: The memo admitted "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" and that the major cause of metabolic alkalosis in dialysis patients "[wa]s inappropriately high dialysate total buffer concentrate." It admitted that Defendants' product was associated with increased serum bicarbonate levels and alkalosis, as well as the increased possibility of cardiopulmonary arrests. It "strongly recommended" certain instructions "[i]n light of these troubling findings." It directed that this dangerous issue "needs to be addressed urgently."

IV. THE FDA RECALL

38. The FDA regulates dialysate products as medical devices. Without sufficient testing and while disregarding various safety signals, the Defendants introduced a new product to the market as a Class II medical device by gaining clearance from FDA through its 510 (k) process. A 510(k) pre-market notification is an application submission to FDA to obtain clearance to market a medical device. Within the application process the applicant must demonstrate that its device is at least as safe and effective, that is, substantially equivalent, to an existing device which has already been FDA approved for marketing. Defendants submitted their 510(k) pre-market notification to FDA (K030497) in early 2003 to introduce NaturaLyte®/GranuFlo® Dry Acid Concentrate. The FDA granted approval for the use of these devices on May 20, 2003.

39. On or about June 27, 2012, the FDA issued a Class I Recall of NaturaLyte® and GranuFlo® Dry Acid Concentrate. As part of the Recall, the FDA issued a public notice cautioning clinicians to be aware of the concentration of acetate in Defendants' products, which might cause serious injury, including death. The FDA warned that "[i]nappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest." Finally, the FDA noted that "[t]his product may cause serious adverse health consequences, including death." While the FDA did not require the product to be pulled from the shelves, Fresenius was directed to include the highest level of warning, known as a black box warning.

40. Only as a result of the FDA investigation and recall, Defendants finally began "enhancing" the labeling of their dialysate product and hemodialysis machine operator's manuals.

Defendants' prior notices regarding product safety fell well short of the required warnings, practices and instructions necessary to address the grave risks their products presented. The FDA warnings gave Plaintiff and Decedent's family their first knowledge of the causal relationship between the Decedent's treatment and her death. Because Defendants wantonly provided inadequate warnings, training and instruction regarding these risks, the amount of bicarbonate that patients actually received was dangerously, or even lethally, high. Indeed, such bicarbonate overdose resulted in the Decedent's death.

41. As a direct and proximate result of the Defendants' conduct as described herein, Decedent received injuries ultimately causing her death.

CAUSES OF ACTION

COUNT I:

NEGLIGENCE

42. The Plaintiff incorporates, adopts by reference, and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

43. At all relevant times, Defendants knew or reasonably should have known that their product was unreasonably dangerous and defective when used as designed and directed. A reasonably careful search and review of the scientific literature and other information, and proper research and testing, indicated:

(a) that health care professionals were unaware that Defendants' product contained acetic acid, acetate, or citrate that converts to bicarbonate;

(b) that as a result, the potential existed for Defendants' product to contribute to metabolic alkalosis;

(c) that metabolic alkalosis was associated with a higher risk of cardiac injury and death in hemodialysis patients; and

(d) that health care professionals needed adequate warnings and instructions to consider the impact of Defendants' acid concentrate on the dialysate buffer and adjust prescription practices, dialysis machine settings, and related dialysis treatment practices.

44. Defendants had a duty to exercise reasonable care, and to comply with the then existing standard of care, in the design, testing, research, development, packaging, distribution, promotion, marketing, advertising, instruction, and sale of their product. Specifically:

(a) Defendants had a continuing duty to ensure that the product they provided was safe and used correctly through proper design, testing, research, adequate instruction, post-market surveillance, and appropriate modifications;

(b) Defendants had a duty to anticipate the environment in which the product would be used ad to design against the reasonably foreseeable risks attending the product's use in that setting, including misuse or alteration;

(c) Defendants had a continuing duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of their product;

(d) Defendants had a duty to provide adequate warnings and instructions, which means they had to be comprehensible to the average user, calculated to convey the material risks to the mind of a reasonably prudent person, and of an intensity commensurate with the danger involved;

(e) Defendants had a continuing duty to assure the product they provided was properly labeled and true to the representations Defendants made about it;

(f) Defendants had a continuing duty to make sure their product had complete and accurate information and instructions concerning its proper use;

(g) Defendants had a continuing duty to assure those writing and carrying out patients' prescriptions fully understood the nature, characteristics, and proper use of Defendants' product to allow them to communicate and effectuate the patients' medical needs safely, the proper dialysis machine settings, and safe treatment;

(h) Defendants had a continuing duty to assure dialysis clinical staff were properly informed of and trained on proper use of Defendants' product and that they complied with said training;

(i) Defendants had a continuing duty to properly program, calibrate and/or design dialysis machines and equipment;

(j) Defendants had a continuing duty to adequately test every patient before and after each dialysis treatment;

(k) Defendants had a continuing duty to modify their products, and their packaging, instructions, promotional and advertising efforts to eliminate confusion and user error, assure compliance, and prevent harm; and

(l) Defendants had a continuing obligation to disseminate appropriate content and employ appropriate methods to convey accurate and complete product information.

45. In violation of the existing standards and duties of care, Defendants, individually and collectively, deviated from reasonable and safe practices in the following ways, by:

(a) designing a defective product in formulation and warnings/instructions;

(b) failing to conduct pre and post market safety tests and studies;

(c) failing to collect, analyze, and report available data regarding dialysis patients' use of Defendants' product;

(d) failing to conduct adequate post-market monitoring and surveillance;

(e) failing to include adequate warnings about and/or instructions concerning the increased risks of death and serious injury;

(f) failing to provide adequate warnings and/or proper instructions regarding proper uses of the product;

(g) failing to provide adequate warnings and/or proper instructions regarding monitoring dialysis patients before, during, and after dialysis;

(h) failing to inform users that Defendants had not adequately tested or researched the product to determine its safety and risks;

(i) failing to inform users that the clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared for proper use of the product in a safe and effective manner;

(j) failing to educate and instruct users about the unique characteristics of their product and the proper way to administer it and operate the dialysis machines because of it;

(k) failing to properly instruct staff regarding machine calibration; product preparation (e.g., specific gravity test); bicarbonate preparation; formula selection (e.g., machine entry); base sodium and bicarbonate (e.g., machine entry); and dialysate verification;

(l) failing to properly select, train, instruct, supervise, and monitor product users and their employees, agents, servants, officers, directors, and clinical staff;

(m) failing to implement and execute corrective and preventive actions to eliminate injuries resulting from errors within clinics caused by the dozens of possible dialysate formulas Defendants provided, which may lead to administration and human errors by nursing staff;

(n) failing to adequately test every patient before and after each dialysis treatment;

(o) making material misrepresentations about the product's safety, nature, characteristics, and proper use; and

(p) continuing to promote and market the product despite the foregoing failures. **58.** The injuries and damages alleged herein were the reasonably foreseeable result of Defendants' conduct.

46. Had Defendants undertaken the tests, studies, and steps described herein, the injuries and damages complained of herein would not have occurred.

47. Defendants held themselves out as experts and specialists and therefore possessed a higher degree of skill and learning. Defendants had a special relationship with the medical providers and clinics involved such that they had a duty to control their behavior. Defendants had a special relationship with Decedent giving rise to the same duty.

48. Defendants are bound for the care of their agents, servants, employees, officers, and directors and for the neglect and fraud of the same. Defendants are liable for the conduct of their agents, servants, employees, officers, and directors committed in the course of their activities on behalf of and in furtherance of the company. Defendants are liable for their agents, employees, officers, and directors conduct attempting to advance Defendants' business. Defendants are also liable for the conduct and/or negligence of their doctors, if any. These persons acted within the scope of those efforts and their employment, as applicable. They were not exercising any

independent business, but rather subject to Defendants' immediate direction and control. Defendants retained the right to direct or control the time and manner of executing the work, and interfered and assumed control with it. Defendants expressly and impliedly authorized and ratified the conduct of their agents, servants, employees, officers, and directors. Defendants received significant benefits as a direct result of their agents', employees', servants', officers', and directors' conduct.

49. Defendants' conduct showed willful, malice, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences. Defendants' wrongdoing constitutes gross negligence, and said gross negligence proximately caused the damages and death of Decedent and her wrongful death beneficiaries.

50. As a direct and proximate result of Defendants' conduct and omissions described herein, Decedent's life was dramatically shortened, depriving her of enjoyment, and robbing her family of her affection and service. Decedent suffered pre-death physical and mental pain and suffering after Defendants' product caused her injuries and before she died. Funeral, medical, and other necessary expenses were incurred as a result of Defendant's misconduct.

COUNT II:

NEGLIGENT MISREPRESENTATION

51. The Plaintiff incorporates, adopts by reference, and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

52. Defendants had a duty to exercise reasonable care to those to whom they provided product information and to all those relying on the information provided. Defendants were aware of the uses to which the information was being put, including foreseeable persons such as Decedent and her medical providers and the clinic staff.

53. In violation of the existing standards and duties of care, Defendants, individually and collectively, in the course of their business and for pecuniary gain, negligently misrepresented, failed to disclose, and concealed material facts concerning the nature, character, quality, safety, and proper use of their product. Defendants knew, or reasonably should have known, that those express and implied representations were false under the circumstances.

54. In violation of the existing standards and duties of care, Defendants, individually and collectively, materially misrepresented and omitted complete and accurate information in their product's labeling, advertising, marketing, sales and marketing persons, seminars, presentations, publications, notices, oral promotional efforts, websites, product information, training, and clinical forms, including acknowledgment of risks and informed consent forms. Defendants concealed information that the product was associated with an increased risk of serious injury and/or death. Defendants concealed that the product was not as safe as alternatives. Defendants failed to exercise reasonable care of competence in obtaining or communicating truthful and accurate information. Defendants failed to exercise reasonable care in obtaining or furnishing information for others' guidance. Defendants failed to discover the falsity of the representations they made. Defendants acted, and failed to act, with the intent to defraud, deceive, and mislead. At no time relevant here, did Defendants correct the misinformation provided.

55. The Decedent reasonably relied upon Defendants' expertise, skill, judgment, and knowledge and upon their express and/or implied warranties that their product was safe, efficacious, adequately tested, administered by properly instructed persons, of merchantable quality, properly formulated, and fit for dialysis use. Decedent justifiably relied upon the misrepresentations and omission described here, and reasonably believed them to be true. In

justifiable reliance upon these misrepresentations, Decedent was induced to use Defendants' product.

56. Had Defendants not made express and implied false statements, or revealed all material information about the product, Decedent would not have used the product and her medical providers would not have administered it.

57. Defendants' conduct showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences. Defendant's conduct was malicious, willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a wanton disregard of the rights of others.

58. Defendants' conduct directly and proximately caused the injuries and damages sustained by the Decedent and Plaintiff, as described herein.

COUNT III:

PRODUCT LIABILITY

59. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

60. The Plaintiff hereby asserts a design defect claim pursuant to the Mississippi Product Liability Statute, MISS. CODE. ANN. § 11-1-63, and other applicable Mississippi law.

61. At all times relevant to the Complaint, the Fresenius Defendants were in the business of designing, manufacturing, marketing, testing and distributing dialysis products. The product at issue was defective and unreasonably dangerous at the time it left the hands of the Defendants. Defendants placed their product into the stream of commerce in a defective and

unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

62. Defendants designed their product differently from preexisting products resulting in an unreasonably dangerous and defective product. According to Defendants, "bicarbonatebased dialysis products deliver additional buffering capacity through mixing and metabolism of acetate, acetic acid or citric acid when mixed for dialysate;" however, only Defendants' product delivered excessive acetate and significantly and unprecedentedly increased the total buffer. The liver quickly converts acetate to bicarbonate in the liver. This can contribute to metabolic alkalosis, which can cause dialysis patients' blood pressure to plummet leading to cardiac arrest and stroke. The cause of bicarbonate-induced alkalosis in dialysis patients was Defendants' inappropriately high dialysate total buffer concentration.

63. Defendants' product was unreasonably and dangerously defective beyond the extent contemplated by ordinary users with ordinary knowledge regarding these products. Decedent and her health care providers were unaware of the danger as Defendants provided ineffective and inadequate warnings and instructions, at best, and deliberately misled them.

64. Defendants' product was defective due to inadequate post-marketing warnings and instructions, and/or inadequate testing and studies, and/or inadequate reporting regarding the results. Defendants' product was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risks, they failed to provide adequate information to the medical community and patients, but continued to promote the product as safe and effective.

65. Defendants' product was defective in light of the dangers posed by its design and the likelihood of those avoidable dangers. Defendants' product was defective because the

inherent risk of harm in Defendants' product design outweighed the utility or benefits of the existing product design. Defendants' product was defective because reasonably cost-effective and feasible state-of-the-art alternatives existed at the time that would not have undermined the product's usefulness.

66. Defendants were aware of effective substitutes for the product, including their own alternative concentrates and dialysis machine enhancements. The gravity and likelihood of the dangers posed by the product's design outweighed the feasibility, cost, and adverse consequences to the product's function of a safer alternative design that Defendants reasonably should have adopted.

67. There was a safer alternative design that would have prevented or significantly reduced the risk of injury. It was reasonable as well as economically and technologically feasible at the time the product left Defendants' control by the application of existing or reasonably achievable scientific knowledge.

68. Defendants failed to comply with industry standards, including federal or state safety standards and regulations, and industry-wide customs, practices, and design standards. Defendants' noncompliance with such standards demonstrates the product design selected was unreasonable considering the feasible choices of which Defendants knew and should have known. Despite any instances of compliance with such standards, Defendants' product still contained a design defect.

69. The defective and unreasonably dangerous conditions discussed herein existed when the product left Defendants' control. They existed when Defendants sold the product. They existed when Decedent received it.

70. Defendants' conduct showed willful, malice, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences.

71. As a direct and proximately result of the design defect and the Defendants' conduct alleged herein, Decedent sustained cardiac arrest and death, and the Plaintiff suffered damages for which a cause of action is hereby stated.

COUNT IV:

FAILURE TO WARN

72. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

73. The Plaintiff hereby asserts a failure to warn/instruct claim pursuant to the Mississippi Product Liability Statute, MISS. CODE. ANN. § 11-1-63, and other applicable Mississippi law.

74. Defendants' product was defective due to inadequate post-marketing warnings and instructions, and/or inadequate testing and studies, and/or inadequate reporting regarding the results. Defendants' product was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of injury from their product, they failed to provide adequate warnings to the medical community and patients, and continued to promote the product as safe and effective. The dangers at issue were of the kind that required warnings and instructions. Said product was defective because it failed to contain adequate warnings or instructions.

75. In part, Defendants failed to provide adequate warnings regarding the existence of additional acetate in their product that the body could convert to bicarbonate, which could cause metabolic alkalosis, a condition associated with a higher risk of cardiac injury and death.

Defendants failed to provide adequate instructions for health care providers to be aware of these risks, alter prescription practices, adjust the dialysis machines, and take other steps before, during, and after the dialysis treatment process to avoid these dangers. Any information Defendants provided about these risks was inadequate in content, presentation, and delivery. They were ineffective for those who would be foreseeably affected by the product. Defendants' product was capable of being made safe for its intended and ordinary use.

76. Decedent and her providers were unaware of the dangers and proper instructions. Neither Decedent, nor her providers understood and appreciated the risks associated with the product or its proper usage. The dangers described herein were not known, obvious, or apparent. They did not result from any unforeseeable and unanticipated use. Defendants' conduct and internal memoranda support these allegations.

77. Defendants' conduct showed willful, malice, wantonness, oppression, or that entire want of care that raises the presumption of conscious indifference to consequences.

78. As a direct and proximately result of the failure to warn and the Defendants' conduct alleged herein, Decedent sustained cardiac arrest and death, and the Plaintiff suffered damages for which a cause of action is hereby stated.

COUNT V:

BREACH OF EXPRESS WARRANTY

79. The Plaintiff incorporates, adopts by reference and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

80. The Defendants represented and warranted to the Decedent, the medical profession and the general public that GranuFlo® and NaturaLyte® were safe for use in dialysis treatment in accordance with the Defendants' protocols. As noted herein, the Fresenius Defendants went to

great lengths, including nationwide marketing and concealment, to warrant the safety of its product. Said affirmation of fact or promise, as well as the description of the goods, became a part of the bargain, creating an express warranty pursuant to Mississippi law.

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

82. 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.

83. 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.

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

85. As a direct and proximate consequence, the Decedent sustained cardiac arrest and died. Plaintiff hereby asserts a claim for breach of express warranty pursuant to the Mississippi Product Liability Act, MISS. CODE. ANN. § 11-1-63, and other applicable Mississippi law.

COUNT VI:

BREACHES OF IMPLIED WARRANTIES OF MERCHANTABILITY & FITNESS FOR PARTICULAR PURPOSE

86. The Plaintiff incorporates, adopts by reference, and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

87. By designing, marketing, and selling the product at issue, the Fresenius Defendants, merchants for goods relating to dialysis, impliedly warranted to the Decedent that said product

was merchantable and fit for ordinary use. The Fresenius Defendants also warranted that said goods were fit for the particular purpose of dialysis treatment of the Decedent.

88. Defendants' product was not fit for the ordinary purpose for which such goods were used. It was unmerchantable when used as directed and defective in design, and the Defendants' failure to provide adequate warnings and instructions resulted in said product being unreasonably dangerous. Defendants' product was dangerous to an extent beyond the expectations of ordinary consumers with common knowledge of the product's characteristics, including Decedent and her medical providers.

89. Defendants breached their implied warranties because the product was not safe, adequately packaged and labeled, did not conform to representations Defendants made, and was not properly usable in its current form according to the labeling and instructions provided. The Defendants' breaches of implied warranties, pursuant to Mississippi law, proximately resulted in the damages sustained by the Decedent and Plaintiff.

COUNT VII:

FRAUDULENT MISREPRESENTATION

90. The Plaintiff incorporates, adopts by reference, and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

91. Defendants committed actual and constructive fraud. Defendants committed constructive fraud by acting contrary to legal or equitable duties, trust, or confidence upon which Decedent relied, and by failing to act, though they should have. Defendants' conduct constitutes constructive fraud because Defendants breached legal and equitable duties and violated their fiduciary relationships. Defendants committed actual fraud by misrepresenting material facts, on which Decedent and her health care providers acted.

92. Defendants made misrepresentations by means including, but not limited to, advertisements, website statements, written and oral information provided to patients and medical providers, marketing materials, clinical forms, and statements contained in product literature and trainings.

93. Defendants intentionally and knowingly provided false product information. By providing the product and in the materials Decedent's providers received prior to her dialysis use in 2010, Defendants represented that their warnings, instructions, training, and product information were complete and accurate. Defendants represented that the product could be used as instructed when in fact the formulation required additional calculations and machine calibrations. Defendants misrepresented the proper use, character, and formulation of their product as well as its quality and safety. Defendants represented that their product had the same total buffer and effect as alternative available products. Defendants identified the bicarbonate level in their concentrates as lower than it in fact was. As an illustration, Defendants' 125 Liter Mix (33 Gal.) 45X GranuFlo® dry acid concentrate listed 48.3 Kg as the quantity. The 36.83X formulation only showed 34.5 Kg. The actual amounts are higher due to the acetate. On the day Decedent received dialysis and before then, Defendants similarly misrepresented the true nature, character, safety, and proper uses of their product.

94. Defendants marketed the product by claiming and representing GranuFlo® was "[s]afe for ... patients and staff' and that using dry sodium diacetate made "GranuFlo the safest dry acid product."

95. Accurate facts were reasonably available to Defendants, even in the absence of knowledge of the falsity.

96. Defendants' corporate and product marketing efforts misrepresented the true nature of the company and its product. Defendants' slogan, "patient centered care" misrepresented safety and diligence in the product's design and delivery. Defendants represented on their website and other mediums that they would "deliver the highest quality care with respect and compassion." Defendants represented on their website and via other mediums that they would "treat [Decedent] well-to help [her] feel better." Defendants represented on their website and via other mediums that they provided "technologically-advanced care." Even today, Defendants' website and product information continues to represent that GranuFlo® is safe for patients and staff and offers "superior clinical outcomes," despite the known risks and inadequate warnings and instructions.

97. The product Decedent received was not safe, efficacious, adequately tested, of merchantable quality, properly formulated, of the nature and character described, or fit for dialysis use, as Defendants knew. Defendants were aware of the falsity of the representations they made, but acted with flagrant disregard and recklessness as to whether the truth or falsity might be inferred.

98. The information Defendants misrepresented was material to Decedent's and her medical providers' decisions in using the product. Defendants intentionally made these material misrepresentations knowing they were false, deceptive, and misleading and they made them intending to defraud, deceive, and mislead. Defendants presented themselves as experts in the field on their website and in marketing, sales, product, and clinical materials. Decedent and her medical providers justifiably relied upon them and reasonably believed them to be true. In justifiable reliance upon them, they were induced to prescribe and use Defendants' product. Had

Defendants not made these express and implied false statements about the product, Decedent would not have used the product and her medical providers would not have administered it.

99. Defendants' fraudulent representations evidence flagrant, willful, and depraved indifference to patient health, safety, and welfare. Defendants' conduct showed willful misconduct, malice, fraud, wantonness, oppression, and that entire want of care that raises the presumption of conscious indifference to consequences.

100. As a direct and proximate result of Defendants' fraudulent misrepresentations and intentional concealment of facts, upon which Decedent reasonably relied, Plaintiff and Decedent suffered injuries and damages as described with particularity herein.

COUNT VIII:

FRAUDULENT CONCEALMENT

101. The Plaintiff incorporates, adopts by reference, and realleges each and every allegation of this Complaint the same as though specifically set out herein again.

102. The Fresenius Defendants fraudulently concealed essential, life-and-death information with respect to GranuFlo® and NaturaLyte® by:

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

(b) failing to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;

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

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

(e) failing to inform Decedent and others of the dangers associated with GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and/or regulatory submissions;

(f) failing to inform Decedent of the risks associated with using GranuFlo® and NaturaLyte®;

(g) withholding and/or concealing and/or downplaying the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;

(h) concealing through affirmative misrepresentations that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment;

(i) concealing information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market;

j) concealing from Decedent information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®; and

(k) concealing 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.

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

104. 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.

105. Defendants made the concealment of information and the misrepresentations about the products with the intent that doctors and patients, including Decedent, rely upon them.

106. Decedent and many others, including other patients and non-defendant healthcare providers involved in providing dialysis treatments, detrimentally relied upon the misrepresentations and material omissions 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.

107. Defendants fraudulently concealed their conduct as described herein. Defendants fraudulently concealed their knowledge of the dangers associated with the devices; their knowledge that the warnings associated with the devices were insufficient; their knowledge that cardiac arrests were occurring within their patient population at an alarming rate; their knowledge that the devices in question were associated with the extremely elevated numbers of cardiac events; and their knowledge that dangerously high bicarbonate levels were being delivered to patients throughout their clinic system on a consistent basis. Defendants made conscious and deliberate efforts to fraudulently conceal all facts and matters which if made known would have alerted the Plaintiff and/or Decedent to the causes of action presented in the

Complaint. That because Defendants were successful in their efforts to fraudulently conceal these and other material matters, the Plaintiff first learned of an actionable claim against Defendants with the public notice and recall issued by the FDA effective June 27, 2012, initially alerting the general public to the claims presented herein. Pursuant to MISS. CODE ANN. § 15-1-67 and other applicable law, any and all causes of action alleged herein are deemed to have first accrued only after the FDA public notice and recall effective June 27, 2012.

108. Had Defendants not fraudulently concealed such information, GranuFlo® and/or NaturaLyte® would not have been used during the dialysis treatment provided to Decedent. As a direct and proximate consequence of Defendants' concealment and wrongful conduct described herein, Decedent sustained cardiac arrest and death.

COMPENSATORY DAMAGES

109. As a direct and proximate result of the conduct and breaches of the Defendants, as aforesaid, the Decedent suffered serious and permanent injuries and damages, for which compensation is required. Specifically, the Defendants' products caused Decedent to sustain cardiac arrest and death. The Plaintiff is seeking monetary damages from the Defendants to compensate the Plaintiff for the following elements of damage:

(a) Wrongful death;

(b) Medical expense;

(c) Conscious pain and suffering;

(d) Mental anguish;

(e) Emotional distress;

(f) Loss of enjoyment of life

(g) Loss of wage earning capacity; and

(h) All other elements of damage pursuant to Mississippi law.

110. At the time of her death, the Decedent was sixty-seven (67) years of age. The average remaining life expectancy of a sixty-seven (67) year old Caucasian-American U.S. female, according to the Statistical Abstract of the United States, Vital Statistics of the United States, U.S. National Center for Health Statistics is in excess of 16.4 years. The said Decedent and her husband and children were looking forward, prior to her tragic and untimely death, to many more productive years of companionship and future support.

111. As a result of the aforementioned acts and/or omissions, the Defendants are liable for all elements of damages arising from the Decedent's wrongful death, including:

(a) Damages for the loss of love, companionship, society, advice and care of Decedent, which the wrongful death beneficiaries have suffered and will suffer in the future because of the untimely, wrongful death of the Decedent;

(b) Damages for the value of the life of Decedent, which was wrongfully taken by the wrongful conduct of the Defendants;

(c) Damages for the loss of support and maintenance;

(d) Damages for the physical pain and suffering suffered by Decedent;

(e) Damages for mental anguish and horror suffered by Decedent prior to death;

(f) Damages for the funeral expenses and other estate expenses resulting from the death of Decedent; and

(g) Damages for all other losses, both economic and intrinsic, tangible and intangible, arising from the death of Decedent, all of which were proximately caused by the acts and/or omissions of the Defendants.

112. The Plaintiff reserves the right to prove the amount of damages at trial. The amount of compensatory damages will be in an amount to be determined by the jury.

PUNITIVE DAMAGES

113. As set forth herein above, Defendants' conduct exhibited gross negligence and a willful, wanton and reckless disregard for the safety of the Decedent and others, as well as fraud and deceit, constituting an independent tort. The Defendants engaged in misrepresentation and concealment of the dangers from the Decedent, as well as other patients, doctors and the public. As a result of said conducted alleged herein, Defendants are liable for punitive damages and attorneys' fees, all litigation expenses and associated costs of litigation, pre-judgment interest and other damages pursuant to the Mississippi Punitive Damages Statute, MISS. CODE ANN. § 11-1-65.

114. In addition to compensatory damages, the Plaintiff seeks punitive damages against the Defendants based on willful, malicious, intentional and gross negligence by said Defendants. The conduct justifying an award of punitive damages includes, but is not limited to, the Defendants' willful, malicious, intentional and gross negligence, the fraudulent and/or negligent acts of misrepresentation and/or concealment, as well as other conduct described herein. The amount of punitive damages to be awarded is an amount to be determined by the jury.

115. Plaintiff prays that punitive or exemplary damages be assessed against the Defendants in an amount sufficient to punish the Defendants for their wrongful conduct and to deter like conduct in the future, and to serve as an example and a warning to others, so as to deter others from engaging in a similar course of conduct and to encourage other companies to have due and proper regard for the rights and lives of dialysis patients, and to protect the general public from future wrongdoing. Plaintiff prays that punitive damages be awarded in the

appropriate amount to accomplish these purposes, taking into consideration the appropriate factors as set forth by Section 11-1-65 of the Mississippi Code Annotated and/or other law, including the degree of reprehensibility of the Defendants' conduct, harm likely to result from the Defendants' conduct, the duration of that conduct, the Defendants' awareness of the wrongfulness of such actions, and the Defendants' financial condition.

WHEREFORE, PREMISES CONSIDERED, the Plaintiff, Edward J. Lastorka, Individually and on behalf of the Wrongful Death Beneficiaries of Jackie LaFaye Lastorka, Deceased, sues and demands judgment from the Defendants, Fresenius Medical Care Holdings, Inc., Fresenius Medical Care North America, Inc., Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., Fresenius USA Marketing, Inc., Fresenius USA Sales, Inc., and John Doe Defendants 1-5, and respectfully requests an order from this Court awarding damages and compensation for the following:

1. An award of actual, consequential and incidental damages in such amounts as are sufficient to compensate in full the Plaintiff for the losses and damages actually incurred as a result of the Defendants' wrongdoing;
2. An award of punitive damages in an amount adequate to punish the Defendants and serve as an example to deter similar conduct in the future;
3. An award of the Plaintiff's costs and expenses incurred in connection with this action, including attorneys' fees, expert witness fees and all other costs herein;
4. An award of pre-judgment and post-judgment interest as the Court deems appropriate; and
5. Granting such other and further relief as the Court deems just and proper, including restitution, imposition of a constructive trust and/or such extraordinary

equitable or injunctive relief as permitted by law, equity or statutory provisions as the Court deems proper to prevent unjust enrichment of the Defendants and to provide the Plaintiff with an effective remedy for the damages caused and injuries suffered as a result of the Defendants' wrongdoing as aforesaid.

Respectfully submitted, this the 11th day of November, 2013.

EDWARD J. LASTORKA, INDIVIDUALLY AND ON BEHALF OF THE WRONGFUL DEATH BENEFICIARIES OF JACKIE LAFAYE LASTORKA, DECEASED

BY: _____

David N. Harris, Jr., (MSB #100790)
W. Corban Gunn, (MSB #101752)

CLYDE H. GUNN, III (MSB #5074)
CHRISTOPHER C. VAN CLEAVE (MSB #10796)
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ATTORNEYS FOR THE PLAINTIFF

Fresenius Medical Care

Internal Memo

Fresenius Medical Care
North America
Corporate Headquarters
Reservoir Woods
920 Winter St.
Waltham, MA 02451-1457

To: Medical Directors and Attending Physicians

From: FMS Medical Office

Date: November 4, 2011

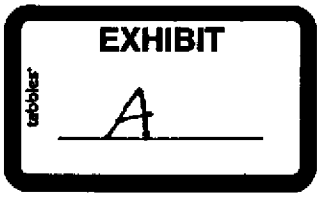
Re: Dialysate Bicarbonate, Alkalosis and Patient Safety

Conclusion:

Recent 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 individualize 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.

Summary of findings:

- In September, 2011 the mean pre-dialysis bicarbonate level for FMCNA was 24.1±3.4 mEq/L, with over 25% of patients at ≥26.0 mEq/L, 15% with ≥28.0 mEq/L and 3% with ≥30.0 mEq/L.
- Over time, the progressive shift towards higher ***pre-dialysis*** serum bicarbonate levels not only implies that more patients have alkalosis prior to dialysis, but that an even higher percentage of patients have alkalosis post-dialysis.
- The current analysis determined that: "*borderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater risk of CP arrest and sudden cardiac death in the dialysis facility*".
- 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 bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate – *by ~8 mEq/L in the case of dialysate prepared from Granuflo (powder) or by ~4 mEq/L in the case of dialysate*



Fresenius Medical Care

Internal Memo

Date: 11/4/2011

prepared from NaturaLyte (liquid) – since acetate is rapidly converted into bicarbonate by the liver. Please familiarize yourself with the formulation utilized in each of your facilities and consider lower bicarbonate prescriptions (e.g. 31-33 mEq/L so that total buffer is no greater than 39-41 mEq/L when using Granuflo), and adjust monthly depending on each patient's pre-dialysis bicarbonate level.

Background:

Uremia leads to accumulation of protein breakdown products contributing to chronic metabolic acidosis.[1] Acidemia contributes to muscle breakdown, protein degradation, decreased synthesis of albumin and vitamin D, and increased resistance to PTH and insulin.[2;3] The HD procedure allows for a transfer of buffers from the dialysate to counteract acidosis and to safely bring acid-base status back into homeostasis.[4] The KDOQI guidelines focused on correction of acidosis,[5] so it was not surprising that pre-dialysis bicarbonate levels have increased over time, from 22.9±3.1 mEq/L in the 2004 FMCNA prevalent HD patient study, to 24.1±3.5 mEq/L for September, 2011 (median 24.0 mEq/L), with 25% of patients at ≥26.0 mEq/L, 15% with ≥28.0 mEq/L and ~3% with ≥30.0 mEq/L – shown in Figure 1, below.

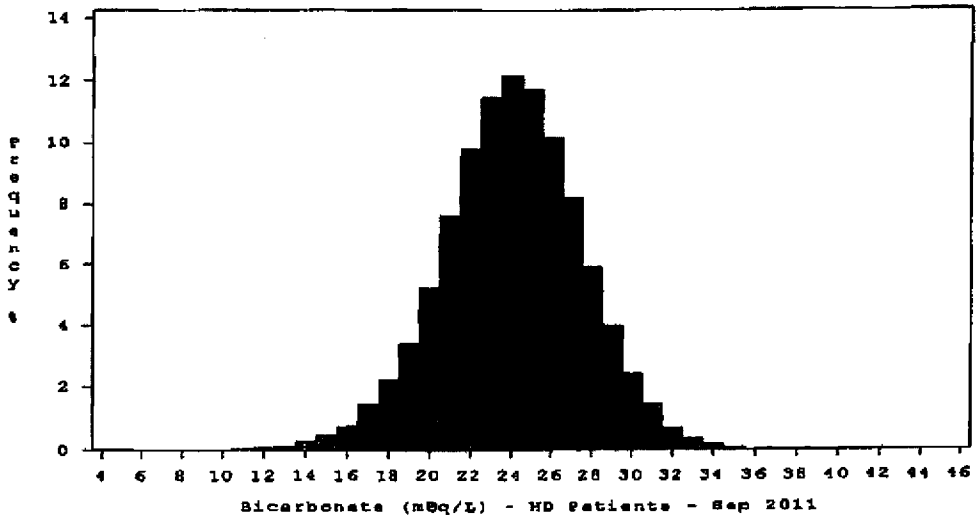


Figure 1. Distribution of pre-dialysis serum bicarbonate for the month of September, 2011.

Fresenius Medical Care

Internal Memo

Date: 11/4/2011

In a recent study from DOPPS, increased death risk was associated not only with acidosis (pre-dialysis bicarbonate <19 mEq/L), but also with high pre-dialysis bicarbonate (>27 mEq/L).[6] There was also increased hospitalization risk observed at pre-dialysis bicarbonate <20 mEq/L and >24 mEq/L. The authors recommended that the lowest risk was likely around pre-dialysis bicarbonate of 20-22 mEq/L.[6] We reviewed mortality data from 2008 (published electronically in the 2009 Medical Director Report) and confirmed similar associations to that observed by DOPPS. (The Spectra lab reference range of 22-29 mEq/L represents a very liberal target for the general population, not for ESRD patients. We are in the process of having Spectra report specific targets for ESRD.)

FMCNA Analysis:

A case-control study evaluated risk factors in HD patients who suffered from CP arrest in the facility (N=941 patients from 667 facilities) compared to other HD patients (N=80,516) within the same facilities between January 1 and December 31, 2010.

Logistic regression models indicated an unadjusted odds ratio (OR) for CP arrest of 6.3 and a case-mix (age, gender, race, and diabetes status) + lab (albumin, hemoglobin, phosphorus, calcium and WBC count) + vascular access adjusted OR for CP arrest of 4.7 (both p<0.0001) with pre-dialysis bicarbonate levels of ≥28 mEq/L, and a trend towards a doubling of risk both at low (<20 mEq/L) and slightly elevated (26-28 mEq/L) levels, shown in Figure 2, below.

Relative Risk of CP Arrest: Bicarbonate

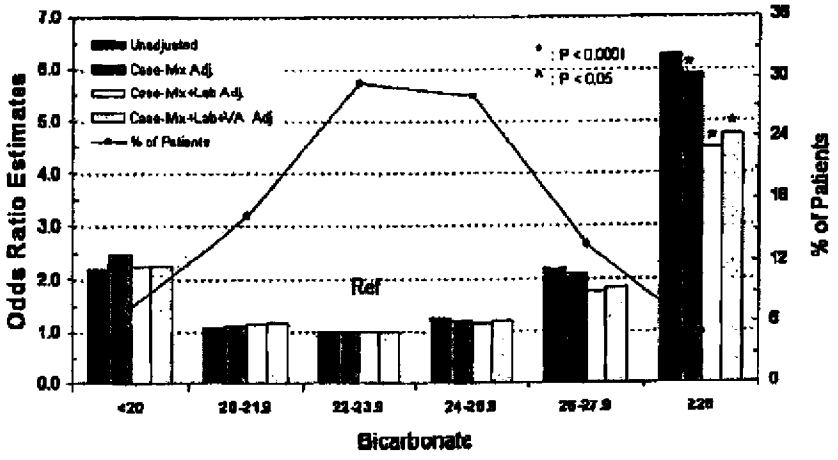


Figure 2. Relative risk associated with pre-dialysis serum bicarbonate categories.

Fresenius Medical Care

Internal Memo

Date: 11/4/2011

The relative risks for CP arrest in HD patients associated with pre-dialysis potassium <4 mEq/L was OR=3.3 (unadjusted) and OR=2.8 (adjusted for case-mix + lab + vascular access), both p<0.0001. Since rapid increases in serum bicarbonate concentration has been associated with a faster decline in serum potassium during dialysis,[7] we hypothesized that the risk would be greatest in the HD patient having a combination of pre-dialysis serum potassium <4 mEq/L and bicarbonate ≥28 mEq/L.

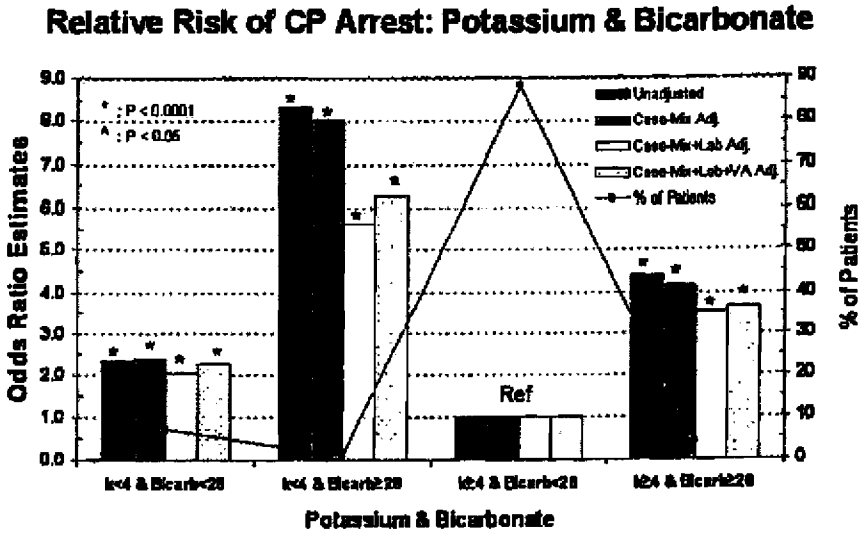


Figure 3. Relative risks associated with 4 combinations of bicarbonate and potassium categories.

Indeed, unadjusted OR=8.3 and case-mix + lab + vascular access adjusted OR=6.3, for CP arrest related to the combination (both p<0.0001). Nevertheless, it is important to recall that serum bicarbonate ≥28 mEq/L remained a significant predictor even with potassium ≥4 mEq/L, with unadjusted OR=4.4 and case-mix + lab + vascular access adjusted OR = 3.6 (both p<0.0001). These results are shown in Figure 3, above.

Recommendations:

Pre-dialysis alkalosis and hypokalemia are modifiable risk factors associated with CP arrest. Previous reports have identified hypokalemia as a risk factor for cardiac arrest and sudden cardiac death in the HD facility and this was related to the use of low potassium dialysate (0K, 1K).[8;9] Thus, FMCNA policies and practices have required routine review of dialysate

Fresenius Medical Care

Internal Memo

Date: 11/4/2011

potassium orders and have limited use of very low potassium dialysate. However, there has not been enough of a quality focus on alkalosis because the clinical guidelines have primarily emphasized avoidance of metabolic acidosis.[5] Over time, there has been a shift towards higher dialysate bicarbonate prescriptions accompanied by increasing serum bicarbonate levels before dialysis and presumably much higher post dialysis. This issue needs to be addressed urgently.

High pre-dialysis serum bicarbonate level was independent of and may potentiate the death risk associated with low pre-dialysis serum potassium. It is an actionable risk factor, by individualization of dialysate bicarbonate prescriptions to keep patients' pre-dialysis serum bicarbonate within a narrower range and to avoid alkalosis. We strongly recommend that physicians individualize dialysate prescriptions, review them monthly, with consideration of patient's pre-dialysis bicarbonate and dialysate total buffer, with immediate attention to decreasing prescribed dialysate bicarbonate in patients with pre-dialysis bicarbonate level of >24 mEq/L.

Many facilities have converted to the Fresenius powdered "Granuflo" formulation that has total buffer equal to "prescribed bicarbonate plus 8" – due to 4 mEq/L of sodium acetate in addition to the 4 mEq/L of acetic acid (acetate). There are instances whereby the physicians' bicarbonate prescriptions were kept the same when shifting to power concentrate (Granuflo) (failing to account for the additional 8 mEq/L of sodium acetate), thus exposing patients to a higher total buffer load than intended. While >60% of current dialysate prescriptions are for 37 mEq/L of bicarbonate, it may be prudent to initially target a prescription of 31-33 mEq/L of dialysate bicarbonate (with total buffer greater by up to ~8 mEq/L from acetate) and adjust according to patients' monthly bicarbonate level. Please recall also that an additional source of bicarbonate may be the phosphate binders that are prescribed to patients.

Previously, several memos were sent to you from the Medical Office to explain the difference in total buffer between NaturaLyte (liquid) and Granuflo (powder) dialysate formulations. The information was accompanied by a recommendation to address pre-dialysis alkalosis found in an increasing proportion of your patients, by decreasing the prescribed dialysate bicarbonate as needed. These previous memos, as well as a related article in the Medical Staff Newsletter,[10] are accessible via Doctors Corner and also upon request. In addition, two presentations containing relevant information were recently presented at the Medical Directors' Symposium, one by Brooks Rogers and the other by Dr. Jeff Sands and both are also available for download in Doctors Corner

If you have questions or recommendations regarding the topic of this memorandum, please contact any member of the Medical Office.

Fresenius Medical Care

Internal Memo

Date: 11/4/2011

Reference List

(1) Mitch WE, Jurkovitz C, England BK. Mechanisms that cause protein and amino acid catabolism in uremia. *Am J Kidney Dis* 1993;21:91-95.

(2) Bailey JL, Mitch WE. Metabolic acidosis as a uremic toxin. *Semin Nephrol* 1996;16:160-166.

(3) Movilli E, Zani R, Carli O et al. Direct effect of the correction of acidosis on plasma parathyroid hormone concentrations, calcium and phosphate in hemodialysis patients: a prospective study. *Nephron* 2001;87:257-262.

(4) Williams AJ, Dittmer ID, McArley A, Clarke J. High bicarbonate dialysate in haemodialysis patients: effects on acidosis and nutritional status. *Nephrol Dial Transplant* 1997;12:2633-2637.

(5) National Kidney Foundation. Clinical practice guidelines for nutrition in chronic renal failure. K/DOQI, National Kidney Foundation. *Am J Kidney Dis* 2000;35:S1-140.

(6) Bommer J, Locatelli F, Satayathum S et al. Association of predialysis serum bicarbonate levels with risk of mortality and hospitalization in the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis* 2004;44:661-671.

(7) Heguilen RM, Sciurano C, Bellusci AD et al. The faster potassium-lowering effect of high dialysate bicarbonate concentrations in chronic haemodialysis patients. *Nephrol Dial Transplant* 2005;20:591-597.

(8) Karnik JA, Young BS, Lew NL et al. Cardiac arrest and sudden death in dialysis units. *Kidney Int* 2001;60:350-357.

(9) Bleyer AJ, Hartman J, Brannon PC, Reeves-Daniel A, Satko SG, Russell G. Characteristics of sudden death in hemodialysis patients. *Kidney Int* 2006;69:2268-2273.

(10) Fresenius Medical Care. Serum Bicarbonate levels. *Medical Staff Newsletter*. January, 2010.

Fresenius Medical Care

*** Important Prescribing Information ***

NaturaLyte Liquid and Granuflo Acid Concentrate

Bicarbonate Alkalosis

DATE: **March 29, 2012**

SUBJECT: **Risk of Alkalosis with acetate containing dialysis acid concentrates**

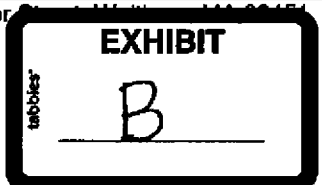
PRODUCT CODES: See Attached

Dear Unit Medical Director/Administrator/Director of Nursing/Home Therapies Manager/Customer,

Fresenius Medical Care North America (FMCNA) is issuing an urgent product notification involving the NaturaLyte Liquid and Granuflo powder product lines (Product Codes: See attached list). Both products contain acetate (NaturaLyte Liquid 4.0 mEq/L; Granuflo 8.0 mEq/L of acetate in the final dialysate); which in addition to bicarbonate, combine to yield the total prescribed buffer. Total buffer should be considered in addition to bicarbonate as part of writing the dialysis prescription.

Previous reports have identified an association between elevated pre-dialysis bicarbonate levels and an increased mortality risk.[1,2,3,4] Recent 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. A major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration.

NaturaLyte Liquid contributes 4.0 mEq/L of acetate and Granuflo contributes 8.0 mEq/L of acetate to the final dialysate; which in addition to bicarbonate, combine to the total buffer that the patient receives from the dialysate. Acetate is also contained in the dialysis acid concentrates produced by other manufacturers. Since acetate is rapidly converted into bicarbonate by the liver, the bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate by ~8 mEq/L with dialysate prepared from Granuflo (powder) or by ~4 mEq/L with dialysate prepared from NaturaLyte (liquid).



Fresenius Medical Care

Fresenius recommends that clinicians exercise their best clinical judgment regarding the bicarbonate and total buffer base prescription for each patient. This includes individualizing dialysate prescriptions and reviewing them monthly with consideration of patient's pre-dialysis bicarbonate and dialysate total buffer.

Please complete and return the enclosed Reply Form, indicating receipt and understanding of this communication. If you have any additional questions, please contact Customer Service at 1-800-323-5188 or Medical Information at 1-855-616-2309.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting by:

- Linking to the MedWatch website at www.fda.gov/medwatch
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178, or by
- Mailing to: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

The FDA has been advised of this product notification

Sincerely,

Jose Diaz-Buxo, MD, FACP
Senior Vice President
Chief Medical and Regulatory Affairs Officer
Fresenius Medical Care North America
Renal Therapies Group

Enclosure:
Reply Form

[1] Gennari FJ. Very low and high predialysis serum bicarbonate levels are risk factors for mortality: what are the Appropriate Interventions? Semin Dial. May-Jun;23(3):253-257 2010

[2] Wu DY, Shinaberger CS, Regidor DL, McAllister CJ, Kopple JD, Kalantar-Zadeh K: Association between serum bicarbonate and death in hemodialysis patients: is it better to be acidotic or alkalotic? Clin J Am Soc Nephrol 1:70–78, 2006

[3] Bommer J, Locatelli F, Satayathum S, Keen ML, Goodkin DA, Saito A, Akiba T, Port FK, Young EW: Association of predialysis serum bicarbonate levels with risk of mortality and hospitalization in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Am J Kidney Dis 44:661–671 2004

[4] Lowrie EG, Lew NL: Death risk in hemodialysis patients: the predictive value of commonly measured variables and an evaluation of death rate differences between facilities. Am J Kidney Dis 15:458–482, 1990

Fresenius Medical Care

PRODUCT CODES

Product Name	Product Code
Manufacturer: Fresenius Medical Care North America	
NaturaLyte	08-0231-4
NaturaLyte	08-1001-0
NaturaLyte	08-1201-8
NaturaLyte	08-1231-3
NaturaLyte	08-1251-1
NaturaLyte	08-1301-4
NaturaLyte	08-2201-5
NaturaLyte	08-2231-2
NaturaLyte	08-2251-0
NaturaLyte	08-2301-3
NaturaLyte	08-2351-8
NaturaLyte	08-3201-4
NaturaLyte	08-3231-1
NaturaLyte	08-3251-9
NaturaLyte	08-3301-2
NaturaLyte	08-4123-1
NaturaLyte	08-4223-7
NaturaLyte	08-4225-1
NaturaLyte	08-4230-2
NaturaLyte	08-4231-0
NaturaLyte	08-4323-5
NaturaLyte	08-4325-1
GranuFlo	0FD1201-3B
GranuFlo	0FD1251-3B
GranuFlo	0FD2123-3B
GranuFlo	0FD2201-3B
GranuFlo	0FD2220-3B
GranuFlo	0FD2223-3B
GranuFlo	0FD2225-3B
GranuFlo	0FD2231-3B
GranuFlo	0FD2251-3B
GranuFlo	0FD2301-3B
GranuFlo	0FD2323-3B
GranuFlo	0FD2325-3B
GranuFlo	0FD3201-3B
GranuFlo	0FD3231-3B
GranuFlo	0FD3251-3B
GranuFlo	0FD3301-3B
Naturalyte	13-1251-1
Naturalyte	13-2201-5
Naturalyte	13-2231-2
Naturalyte	13-2251-0
Naturalyte	13-3231-1

Fresenius Medical Care

Product Name	Product Code
Naturalyte	13-3251-9
Naturalyte	13-4123-1
Naturalyte	13-4220-1
Naturalyte	13-4225-1
Naturalyte	13-4325-1

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.)

1:13cv427 HSO-RHW

I. (a) PLAINTIFFS
EDWARD J. LASTORKA, INDIVIDUALLY AND ON BEHALF OF THE WRONGFUL DEATH BENEFICIARIES OF JACKIE LAFAYE LASTORKA, DECEASED

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

(c) Attorney's (Firm Name, Address, and Telephone Number)
W. CORBAN GUNN, ESQUIRE, CORBAN, GUNN & VAN CLEAVE
P.O. BOX 1916, BILOXI, MISSISIPPI 39533-1916
(228) 432-7826

DEFENDANTS
SEE ATTACHMENT

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

Attorneys (If Known)

SOUTHERN DISTRICT OF MISSISSIPPI
FILED
NOV 13 2013
J T NOBLIN CLERK
BY: _____ DEPUTY

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**):
Title 28 U.S.C. § 1332 and Title 28 U.S.C. §1391
Brief description of cause:

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 11-11-13

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT $400.00 APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

14043005139

ATTACHMENT TO CIVIL COVER SHEET

DEFENDANTS:

FRESENIUS MEDICAL CARE HOLDINGS, INC. D/B/A FRESENIUS MEDICAL CARE NORTH AMERICA;

FRESENIUS MEDICAL CARE NORTH AMERICA, INC.;

FRESENIUS USA, INC;

FRESENIUS USA MANUFACTURING, INC.;

FRESENIUS USA MARKETING, INC.; and

FRESENIUS USA SALES, INC.