IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

EMMA HERNANDEZ, INDIVIDUALLY, AND AS PERSONAL REPRESENTATIVE OF THE BENEFICIARIES AND ESTATE OF SANTOS PENA HERNANDEZ,	)	**CASE NO. _____**
Plaintiff,	)	
v.	)	**COMPLAINT AND JURY DEMAND**
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.; AND FRESENIUS USA MARKETING, INC.; AND FRESENIUS USA SALES, INC.,	)	
Defendants.	)	

NOW COMES the Plaintiff, Emma Hernandez, individually, as Personal Representative of the Estate of Decedent Santos Pena Hernandez, and on behalf of her children and any potential beneficiaries, for her benefit and the benefit of all, by and through undersigned counsel, and for her causes of action files this Complaint for damages against the above-named Defendants alleging the following:

INTRODUCTION

1. This is a product liability case arising out of Defendants' development and sale of GranuFlo® and NaturaLyte®, products used in dialysis treatment.

2. Decedent, Santos Hernandez, was 68 years old when he received dialysis treatment at the Kidney Disease Associates Dialysis Center, 1607 W. Loop 289 Lubbock, Texas

79416, on January 15, 2011. Based upon information and belief, Decedent received Defendants' defective product. He returned home around 10:30 A.M. feeling very weak and could hardly walk. The next day he was very weak. His wife, Plaintiff Emma Hernandez, found him with his head on the table. He was bloated and told her he did not feel well. He woke up the following day, January 17, 2011, at 2:30 A.M. to get dressed. Sitting in his wheelchair, he told his wife he had a headache and then clutched his heart. He began spitting white salvia. Plaintiff frantically called 911. She experienced bystander anxiety resulting from this experience. By the time EMS arrived, he was dead. He was taken to Methodist Hospital at 3615 19th Street in Lubbock, Texas and pronounced dead due to cardiac arrest on January 17, 2011. His wife, Emma Hernandez, and their six children, Dorothy Hernandez Becker; Moses H. Hernandez; Alex Hernandez; George H. Hernandez; Samuel Santos H. Hernandez; and Peter Afonso H. Hernandez, survive him. Defendants are responsible for the suffering Decedent consciously endured before dying.

3. Mr. Hernandez's injury and death, like those striking thousands of similarly situated victims across the country, were avoidable tragedies. GranuFlo® and NaturaLyte® have been implicated in a national epidemic of deaths of dialysis patients. In June of 2012, the FDA announced a Class I recall of these dialysis products. The recall required Defendants to clarify instructions on their packaging because improper use resulting from unclear instructions. Defective design, inadequate warnings, and inadequate instructions led to serious patient complications, including sudden cardiac arrest, as happened to Decedent on January 17, 2011.

4. Even though Defendants knew of the risks for several years, medical providers were unaware that the high levels of bicarbonate in Defendants' products heighten the risk of cardiac injury by six times. As a result, thousands of patients receiving dialysis treatment were unknowingly overdosed. Even when Defendants finally began disclosing some of this

information, they refused to protect patients. For example, they issued an internal memo in 2011 disclosing the results of a study completed in 2010 based on data Defendants had available for many years. They shared it with their own dialysis clinical staff only, however, not the thousands of others unknowingly using the unreasonably dangerous product. This preventable loss of life resulted directly from Defendants' refusal to conduct proper safety studies; defective product design; suppression of information revealing life-threatening risks; wanton failure to provide adequate instructions; and willful misrepresentations concerning the nature and safety of their product. The conduct and product defects complained of herein were substantial factors in bringing about the alleged injuries, reasonably foreseeable consequence of Defendants' conduct and product defects.

PARTIES

5. At all times relevant to this action Decedent, Santos Hernandez, was a resident of Lubbock, Texas.

6. Plaintiff, Emma Hernandez, is a resident of Lubbock, Lubbock County, Texas. She brings this suit as Decedent's spouse. The Lubbock County probate court appointed her Personal Representative of his estate today, January 14, 2013. She will open an ancillary estate in Suffolk, Massachusetts Probate and Family Court this week. Decedent is also survived by his six adult children, who seek recovery for their mental anguish and loss of parental consortium:

a. Dorothy Hernandez Becker, 6762 N 89th Avenue, Glendale, AZ 85305.

b. Moses H. Hernandez, 4706 45th Street, Lubbock, TX 79414.

c. Alex Hernandez, Neal Unit 861998, 9055 Spur 591, Amarillo, TX 79107.

d. George H. Hernandez, 6630 Sabine Pass, San Antonio, TX 78242.

e. Samuel Santos H. Hernandez, 1802 Oak Mountain Street, San Antonio,

TX 78232.

f. Peter Afonoso H. Hernandez, 4928 48th Street, Lubbock, TX 79414.

7. 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 located at 95 Hayden Avenue Lexington, Massachusetts 02420. 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, 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®.

8. Defendant, Fresenius Medical Care North America, Inc. ("FMCNA") is a corporation organized and existing under the laws of the Commonwealth 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 this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

9. 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. At all times relevant, 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®.

10. 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, 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®.

11. Defendant, Fresenius USA Marketing, Inc. (“Fresenius Marketing”) is a foreign corporation authorized to transact business in Plaintiffs’ state of residence. 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®.

12. Defendant, Fresenius USA Sales, Inc. (collectively "Fresenius" or “Defendants” as with all others noted herein), 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 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 this Commonwealth.

JURISDICTION AND VENUE

13. This Court has personal jurisdiction over the Defendants because Defendants

maintained systematic and continuous contacts in this judicial district, regularly transacted business within this judicial district, and regularly availed themselves of the benefits of this judicial district; for example, by employing people and receiving revenue here. Moreover, Defendants incorporated here and have maintained their principal places of business here. Defendants have also caused tortious injury by acts and omissions here, and caused tortious injury in this commonwealth by acts and omissions outside this Commonwealth while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this Commonwealth.

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

15. This Court is the proper venue pursuant to 28 U.S.C. § 1391(b)-(d).

16. Defendants are further subject to this Court's jurisdiction pursuant to Massachusetts's Long Arm Statute, Mass. Gen Laws. ch. 223A, § 3, Rule 4 of the Federal Rules of Civil Produce, and 28 U.S.C. § 101.

FACTUAL ALLEGATIONS

A. Defendants' Product When Used in Dialysis Treatment Causes Acute Cardiac Arrest.

17. Acid is a byproduct of metabolism in the body. The kidneys normally excrete this acid. Patients whose kidneys do not function properly, however, are unable to do this. As a result, they are at risk of developing a condition called acidosis, a buildup of excess acid in the blood. Physicians prescribe dialysis to correct this by neutralizing or buffering the excessive acid through use of bicarbonates.

18. A bicarbonate is an alkaline, *i.e.*, a base, the opposite of an acid. Bicarbonate

levels used in dialysis are slightly higher than normal blood levels to encourage diffusion into the blood. The bicarbonate acts as a pH buffer and neutralizes patients' acidosis.

19. The bicarbonate levels within patients receiving dialysis must be controlled carefully to ensure their pH level remains stable. If it raises too high, patients develop "alkalosis," too low, "acidosis," both of which are very dangerous. Alkalosis, for example, is a significant independent and additive risk factor associated with cardiopulmonary arrest. In part, settings and readings on the dialysis machines control and monitor these levels during dialysis treatment.

20. Proper dialysis treatment accomplishes the proper balance of bicarbonate delivery through use of a solution called dialysate. Dialysate is a mixture of three components, including bicarbonate concentrate and acid concentrate. All bicarbonate-based dialysis products deliver additional buffering capacity through mixing and metabolism of acetate, acetic acid, or citric acid when mixed for dialysate. Acetate, however, is unique.

21. 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 the converted bicarbonate from the acetate, and the bicarbonate from the bicarbonate concentrate, results in what is called "total buffer." Excessive total buffer can cause alkalosis.

22. Dialysis machines display a "bicarb value." That value, however, is **not the total buffer**; it only indicates the bicarbonate concentrate. Thus, **the bicarbonate from the acetate is not included in the machine displays**. Additional calculations are necessary to determine the total buffer and account for the actual full amount of bicarbonate that a patient receives from a specific dialysate.

23. The FDA regulates dialysate products as medical devices. Without sufficient testing and while disregarding various safety signals, 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) premarket notification is an application submission to FDA to obtain clearance to market a medical device. Within it, a company must demonstrate that its device is at least as safe and effective, that is, substantially equivalent, to a pre-existing legally marketed device. Defendants submitted their 510(k) premarket notification to FDA (K030497) in early 2003 to introduce NaturaLyte®/GranuFlo® Dry Acid Concentrate. FDA cleared it on May 20, 2003. Defendants' product contains acetate, sodium diacetate specifically.

24. A different reaction occurs when the acid used to form dialysate is sodium diacetate. Sodium diacetate is composed of equal parts of acetic acid and sodium acetate. When it combines with bicarbonate to make dialysate, the acetic acid consumes an equal amount of bicarbonate and produces an equal amount of acetate, a bicarbonate precursor, so that the amount of bicarbonate remains the same. Sodium acetate, however, does not consume an equal amount of bicarbonate and instead enters the bloodstream and reaches the liver, which metabolizes it thereby increasing the amount of bicarbonate delivered during dialysis above the prescribed amount. When one accounts for the additional bicarbonate from this acetate after the body converts it, Defendants' formulation dangerously increases the total buffer ultimately delivered by the dialysate nearly twice as much as any other marketed product.

B. **Decedent's Use of Defendants' Product Caused His Death.**

25. Decedent, Santos Hernandez, received dialysis treatment at the Kidney Disease Associates Dialysis Center, 1607 W. Loop 289 Lubbock, TX 79416 on January 15, 2011. Decedent received Defendants' defective product, and shortly thereafter suffered acute cardiac

arrest and died on January 17, 2011.

C. **Defendants Engaged in Grossly Negligent, and Willful, Reckless, and Wanton Misconduct for a Decade before Decedent's Death.**

26. Fresenius Medical Care Holdings, Inc. is the largest dialysis services and products company in the U.S. and globally. It has a vertically integrated business that owns thousands of dialysis clinics, and manufactures the machines and nearly all the products used in dialysis treatment such as dialyzers, bloodlines, needles, and dialysis concentrate. The Fresenius products division sells products to its own clinics, and to many leading competitor clinics. One such product is Defendants' NaturaLyte® and GranuFlo® acid concentrate.

27. As explained above, Defendants' product significantly increased patients' total buffer and thus bicarbonate levels. Despite the risks of causing alkalosis and therefore sudden cardiac arrest, and without conducting proper testing and research studies, Defendants aggressively promoted their product across the country.

28. For nearly a decade while doing so, Defendants actively misled everyone about the product's safety and characteristics. Defendants willfully misrepresented the high bicarbonate levels their product produced and the increased buffer levels associated with its use in the information they provided to physicians, nurses, dialysis clinic staff, and patients. Lacking this critical information and effective product labeling, warning, and instruction, caused these individuals to provide and receive dialysis treatments in an unsafe and ineffective manner. Defendants could have prevented this had they addressed the risks of which they were aware.

29. Long before Decedent received Defendants' product, Defendants received, but disregarded, safety signals from various sources forewarning of the risks at issue in this case. Literature dating back to at least the 1990s, for example, revealed the risks of elevated

bicarbonate levels and increased mortality risk, including, but not limited to, the following:

a. Lowie 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);

b. Williams AJ, Dittmer ID, McArley A, Clarke K., High Bicarbonate Dialysis in Haemodialysis Patients: Effects on Acidosis and Nutritional Status, *Nephrol Dial Transplant*, 12:2633-37 (1997);

c. Grassmann A, Uhlenbusch-Korwer I, Bonnie-Schorn E, Vienken J, Composition and Management of Hemodialysis Fluids. *Good Dialysis Practice*, Vol. 2 at 60-99 (Pabst 2000);

d. Karnik JA, Young BS, Lew NL, et al., Cardiac Arrest and Sudden Death in Dialysis Units, *Kidney Int.*, 60:350-57 (2001);

e. 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, *Am. J. Kidney Dis.*, 22:661-71 (2004);

f. 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);

g. Bleyer AJ, Hartman J, Brannon PC, Reeves-Daniel A, Satko SG, Russell G., Characteristics of Sudden Death in Hemodialysis Patients, *Kidney Int*, 69:2268-73 (2006);

h. Gennari FJ. Very Low and High Predialysis Serum Bicarbonate Levels are Risk Factors for Morality: What are the Appropriate Interventions? *Semin Dial*. May-Jun; 23(3): 253-257 (2010).

30. By at least 2001, Defendants recognized there was confusion and protocol issues regarding bicarbonate delivery during dialysis treatment and the labeling on bicarbonate and acid concentrate products. Defendants knew this meant physicians did not have adequate information to inform their medical decision making to assure patients received intended treatments.

31. Defendants further realized that users of dialysis machines, nurses, technicians, and other staff, were trained and informed inadequately regarding the product and dialysis machine configurations. They were aware of the inadequate understanding of the interrelationship between bicarbonate concentrations and dangerous practices associated with **s**etting machine levels and features. They knew staff members were also ill informed about the additional calculations they had to perform, and about who was responsible for making these calculations.

32. By at least 2003, Defendants knew, or should have known:

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 dialysate total buffer concentration; and

d. that physicians needed warnings and adequate instructions to properly treat patients and prescribe the product, and staff needed adequate instructions

regarding proper machine settings and proper review and monitoring of patients.

33. 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 their product's dangers. It observed that patients with increased pre-dialysis metabolic alkalosis levels were more likely to experience a heart attack or sudden cardiac death absent lowering the bicarbonate prescription.

34. In a patent application assigned to Defendants filed May 17, 2006, Defendants described an invention that admitted the "contribution of bicarbonate resulting from metabolism of acetate contained in an acid dialysate constituent." It included a diagram of machine settings for GranuFlo® use that clearly showed the extra contribution of bicarbonate to the overall buffer. Defendants therefore knew by this time that its product required special instructions to reduce the risk of dangerously high bicarbonate levels.

35. Between 2003 and 2012, Defendants repeatedly learned of persistent confusion about the bicarbonate settings on dialysis machines and physicians' prescriptions for bicarbonate. In particular:

a. Defendants knew that nephrologists, dialysis nurses and technicians, physicians, and patients were not properly educated, trained, or informed about the acetate levels in their dialysis concentrates and that their product significantly increased the total buffer;

b. Defendants knew 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 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 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 that the major cause of alkalosis in dialysis patients was the aforementioned inappropriately high dialysate total buffer concentration.

36. Thus, Defendants knew 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.

37. By at least January 2010, nearly a year before Decedent's use of Defendant's product, Defendants had analyzed data and found that 941 patients from 667 facilities had cardiopulmonary arrests, six times as many as that of competing products. Defendants knew that the high bicarbonate levels related to their product was an independent risk factor contributing to these deaths. Because this data was available to Defendants years earlier, they should have known this long before then.

38. Even after January 2010, when the clinical crisis was irrefutable, they continued providing misleading product information. Based on 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 hazards associated with the use of the product to maintain market share and minimize legal risks. Hence, the conduct described herein

occurred with Defendants' officers', directors', and managing agents' knowledge, authorization, and ratification.

39. On September 15, 2011, FDA issued Fresenius a warning letter concerning its inadequate complaint handling and citing its failure to establish and maintain an adequate corrective and preventative program.

40. When Defendants could no longer contain the smoldering conflagration, they prepared presentations to educate some of their internal staff; however, Defendants provided no warning or instruction to competitor dialysis clinics that used Defendants' product and dialysis machines. **Even when the causal relationship between the use of Defendants' product and conduct and the increased risk of alkalosis and cardiopulmonary arrest was inescapable, Defendants provided this information and urgent medical recommendations to their own physicians and clinics only, concealing it from their external customers.**

41. Defendants circulated an 11-page *internal* memorandum disclosing some of the risks on November 4, 2011. It admitted that "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."

42. Despite the life-threatening risks, Defendants wantonly withheld this information for at least 15 months from the thousands of non-Fresenius physicians and clinics that were using

their product and exposing thousands of people to known risks. As Dr. Thomas F. Parker, III, Chief Medical Officer at Renal Ventures complained, "**[i]f the data was sufficient to warn their doctors, then all users of the product should have been made aware of it.**" Furthermore, because the data was available long before then, Defendants should have disclosed it years earlier, yet they failed to do so.

43. Instead, in deliberate disregard of the risks, Defendants aggressively continued to convert more non-Fresenius clinics to the product and market the product through various methods including routinely bundling it with other Fresenius products for pricing discounts.[1] While Defendants willfully exposed patients to a product known to cause serious injury and death, its market share increased. As of 2012, the majority of nearly 400,000 hemodialysis patients in the U.S. were using it. It is the most-widely prescribed dry acid product in the dialysis industry.

44. But on March 27, 2012, Fresenius received an inquiry from the FDA about the risks associated with the product because someone leaked the November 2011 internal memo. Only then, did Defendants provide *limited* information regarding the "[r]isk of Alkalosis with acetate containing dialysis acid Concentrates" to some customers. A "urgent product notification" explained that Defendants' "products contain acetate (NaturaLyte® Liquid 4.0 mEq/L; GranuFlo® powder 8.0 mEq/L of acetate in the final dialysate); which in addition to bicarbonate, combine to yield the total prescribed buffer." It instructed that, "[t]otal buffer should be considered in addition to bicarbonate as part of writing the dialysis prescription."

45. Defendants' warning about the "urgent" need to monitor bicarbonate levels and

[1] As but one example, Defendants promoted "the cost advantage of dry acid." This afforded them the chance to deliver competitive price per gallon savings compared to liquid concentrate, but this financial gain came at the cost of proper development, instruction, and other investments in safety.

adjust prescriptions to avoid the risk of cardiac arrest and death came years after they knew of the risks. Moreover, this scientifically ambiguous 2-page memorandum contained far less actionable information for non-Fresenius customers as compared to the November 2011 internal memo.

46. FDA then issued a statement informing the public of the safety notice. Within it, FDA informed health care providers that Defendants were cautioning clinicians to be aware of the concentration of acetate in Defendants' product, which might cause serious injury, including death.

47. On May 25, 2012, FDA issued a safety communication concerning dialysate concentrates and alkali dosing errors. FDA recognized, as Defendants had known for many years, that health care professionals were unaware that dialysate acid concentrate contained acetate that could convert to bicarbonate, potentially contributing to metabolic alkalosis. After FDA acquired only *some* of the information Defendants had for *many years*, FDA provided some of the recommendations Defendants should have made years earlier, but did not. As FDA unequivocally stated in a June 2012 notice of the product's recall, Defendants had failed to disclose vital information about the possible risks.

48. Not until years after they knew of the risks did Defendants finally begin "enhancing" the labeling of their dialysate product and hemodialysis machine operator's manuals. Defendants nonetheless continued to mislead users by distorting the scope of the problem and their role in it. Defendants downplayed the risks, withheld information, and tried to deflect blame toward the prescribers and staff Defendants had willfully misled and failed to instruct for years, rather than acknowledge the defect in the product's labeling, instruction, and design.

49. Defendants' feeble efforts fell well short of the required warnings and instructions necessary to address the grave safety risks their product presented. Because Defendants wantonly provided inadequate training and instruction regarding these risks, the amount of bicarbonate that patients actually received was dangerously high, and in many cases lethal. Without proper instruction, physicians believed their patients would receive a specific amount of bicarbonate, but instead received significantly more. Similarly, because Defendants' product presented an unprecedented disparity between bicarbonate and total buffer levels, the dialysis center staff thought the machines were delivering a certain amount of bicarbonate to patients, but in fact delivered far more.

50. All this was preventable years earlier. As Defendants admitted in a June 2011 PowerPoint, there was a "simple approach" to this complex issue that could have prevented Decedent's and others' deaths. Industry standards, reasonable care, and the slightest respect for patient safety, demanded Defendants disclose accurate information concerning the nature of their product and its risks, properly instruct medical providers and staff, and modify their product.

51. As a direct and proximate result of their refusal to do so, thousands of patients received greater amounts of bicarbonate than was intended and than was safe, for nearly a decade. This bicarbonate overdosing caused dangerously high pH levels in their blood (*i.e.*, alkalosis), which resulted in a precipitous drop in blood pressure, and ultimately led to sudden cardiac arrest, as happened to Plaintiff's late husband, Santos Hernandez. Had Defendants followed the "simple approach," Mr. Hernandez and thousands of other innocent patients would be alive today.

PLAINTIFF'S CLAIMS ARE WITHIN THE LIMITATIONS PERIOD

52. Decedent died on January 17, 2011. Therefore, Plaintiff's claims come within the

statute of limitations period.

53. Moreover, Defendants' misconduct warrants tolling of the limitations period. Fraud prevented and delayed Plaintiff from filing this action; therefore, the period of limitation shall run only from the time of the Plaintiff learned of the fraud. Plaintiff only this fall even heard of a possible connection between Decedent's injuries and his dialysis treatment. Plaintiff could not have known of this fraud by the exercise of ordinary care because of Defendants' concealment.

CAUSES OF ACTION

COUNT I

NEGLIGENCE

54. Plaintiff incorporates every paragraph of this Complaint as if set forth herein.

55. 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.

56. 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 modify their products, and their packaging, instructions, promotional and advertising efforts to eliminate confusion and user error, assure compliance, and prevent harm; and

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

57. 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. making material misrepresentations about the product's safety, nature, characteristics, and proper use; and

o. 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.

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

60. 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.

61. Defendants committed unexcused violations of various statutory duties. Plaintiffs are members of the class of persons the statutory standard was designed to protect and the injuries alleged are of the type the statutes were designed to prevent. Defendants' violation of statutes, ordinances, and regulations constitute negligence per se, or, at a minimum, evidence of their negligence.

62. Defendants are bound for the care of their agents, servants, employees, officers, and directors and for the neglect and fraud of the same.

63. 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. 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.

64. Defendants expressly and impliedly authorized and ratified the conduct of their agents, servants, employees, officers, and directors.

65. Defendants received significant benefits as a direct result of their agents', employees', servants', officers', and directors' conduct.

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

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

COUNT II

NEGLIGENT MISREPRESENTATION

68. Plaintiff incorporates every paragraph of this Complaint as if set forth herein.

69. 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 his medical providers and the clinic staff.

70. 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.

71. 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.

72. Decedent and his medical providers 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 and his medical providers justifiably relied upon the misrepresentations and omission described here, and reasonably believed them to be true. In justifiable reliance upon these misrepresentations, they were induced to prescribe and use Defendants' product.

73. 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 his

medical providers would not have administered it.

74. 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.

75. Defendants' conduct directly and proximately cause the injuries and damages as described with particularity herein.

COUNT III

FRAUD

76. Plaintiff incorporates every paragraph of this Complaint as if set forth herein.

77. 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 his health care providers acted.

78. 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.

79. Defendants intentionally and knowingly provided false product information. By providing the product and in the materials Decedent's providers received prior to his dialysis use

in December 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.

80. 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."

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

82. 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 [him] 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.

83. 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.

84. The information Defendants misrepresented was material to Decedent's and his 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 his 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 his medical providers would not have administered it.

85. 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.

86. 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 IV

STRICT LIABILITY IN TORT

87. Plaintiff incorporates every paragraph of this Complaint as if set forth herein.

88. Defendants were engaged in the business of designing, manufacturing, and selling the product at issue. Defendants placed it 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.

89. Defendants designed their product differently from preexisting products resulting in an unreasonably dangerous and defective product. According to Defendants, "bicarbonate-based 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.

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

91. 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.

92. 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. 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.

93. 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.

94. 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.

95. 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.

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

97. The product defects alleged herein were a substantial contributing cause of the injuries Decedent and damages Plaintiff suffered.

98. As a direct and proximate result of Defendants' conduct and omissions described herein, the product Decedent received caused the injuries and damages described with particularity, above.

COUNT V

STRICT PRODUCT LIABILITY: FAILURE TO WARN

99. Plaintiff incorporates every paragraph of this Complaint as if set forth herein.

100. 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. Even if the product was not defectively designed, it failed to contain adequate warnings or instructions. The dangers at issue were of the kind that required warnings and instructions.

101. 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.

102. Decedent and his providers were unaware of the dangers and proper instructions. Neither Decedent, nor his 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.

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

104. The conduct and product defects alleged above were a substantial contributing cause of the injuries Decedent and damages Plaintiff suffered. As a direct and proximate result of Defendants' conduct and omissions described herein, the product Decedent received caused the injuries and damages described with particularity herein.

COUNT VI

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR PARTICULAR USE

105. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein.

106. Defendants are merchants with respect to goods of the kind Decedent received.

Defendants impliedly warranted that their product was merchantable. Defendants impliedly warranted that their product was fit for the particular purpose of being used safely in dialysis treatment. Decedent and his health care providers relied on Defendants' skill and judgment when deciding to use Defendants' product.

107. Defendants' product was not fit for the ordinary purpose for which such goods were used. It was defective in design and its failure to provide adequate warnings and instructions, and 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 his medical providers.

108. 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.

COUNT VII

DECEPTIVE TRADE AND BUSINESS PRACTICES ACT VIOLATIONS[2]

109. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein.

110. Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

111. Defendants' violation of implied and express warranties, including the warranty of merchantability, constitutes a violation of the Act. Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

112. As described herein, Defendants represented that their product had characteristics,

[2] Plaintiff has provided written notice under M.G.L. c. 93A, however 30 days has not yet passed, therefore Plaintiff will amend to add a specific reference to a violation of M.G.L. c. 93A once the required timeframe has passed.

uses, and benefits that it did not have.

113. As described herein, Defendants represented that their product was of a particular standard, quality, and grade that they either knew or should have known was not of the standard, quality, or grade described.

114. Defendants failed to provide accurate disclosures of all material information before Decedent and his providers transacted to use Defendants' product.

115. Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of the Act.

116. Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

117. Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

118. Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Publishing instructions and product material containing inaccurate and incomplete factual information;

b. Providing safety information internally only, withholding it from non-Fresenius clinics, and instead providing misleading and incomplete safety information concerning the product;

c. Misrepresenting the nature, quality, and characteristics about the product; and

d. After finally providing information about the product's risks and the

nature of its effect on bicarbonate levels, the information provided was conveyed in a misleading manner by not providing all available information and misleading the scope and nature of the problems.

119. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally they were unethical and unscrupulous, and caused substantial injury to consumers. Defendants' engaged in an unconscionable actions and course of action.

120. Defendants willfully engaged in the conduct described herein, which they knew were deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

121. Defendants are liable to Plaintiff for all statutory, direct and consequential damages, and fees and costs, resulting from this breach, including multiple damages.

COUNT VIII

WRONGFUL DEATH

122. Plaintiff incorporates every paragraph of this Complaint as if set forth herein.

123. Plaintiff, individually and for the benefit of all wrongful death beneficiaries, sues pursuant to the Wrongful Death Act and seeks full value of Decedent Santos Hernandez's life.

124. The conduct described herein was caused by Defendants' and their agents' and servants' wrongful acts, neglect, carelessness, unskillfulness, and default.

125. As a direct and proximate result of Defendants' conduct and omissions described herein, the product Decedent received caused the injuries and damages as described with particularity herein.

126. Plaintiff seeks damages for the fair monetary value of the Decedent, including but

not limited to compensation for the loss of the reasonably expected net income, consortium, services, protection, care, assistance, society, companionship, comfort, guidance, counsel, and advice of the Decedent. Plaintiff seeks recovery for the reasonable funeral and burial expenses of the Decedent.

127. Defendants' willful, wanton, and reckless acts and omission and gross negligence caused Decedent's death and warrant exemplary damages.

COUNT IX

SURVIVAL ACT

128. Plaintiff incorporates every paragraph of this Complaint as if set forth herein.

129. Plaintiff sues individually and in favor of the legal representatives, beneficiaries, and estate of Decedent pursuant to the Survival Act and seeks all damages provided by that statute and available under each cause of action resulting from the injuries sustained by Decedent and that his spouse and children suffered.

130. Because Decedent was aware and conscious after the injurious use of Defendants' product, Plaintiff seeks damages for pain and suffering, consciousness of impending death, and medical and funeral expenses.

131. As a direct and proximate result of Defendants' conduct and omissions described herein, the product Decedent received caused the injuries and damages alleged herein.

GLOBAL PRAYER FOR RELIEF

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

a. mental anguish;

b. all economic losses, including but not limited to reasonable funeral and

burial expenses of the Decedent;

c. the full value of Decedent's life including, without limitation, compensation for conscious pain and suffering, emotional distress, the loss of the reasonably expected net income, services, protection, care, assistance, society, companionship, comfort, guidance, consortium, counsel and advice of the decedent and the monetary value of the benefit that the Plaintiff reasonably expected to receive from the decedent had he lived;

d. costs, attorney's fees, and multiple damages;

e. punitive damages;

f. pre and post-judgment interest and all other interest recoverable; and

g. such other additional relief to which Plaintiff is entitled in law or equity.

JURY DEMAND

Plaintiff respectfully requests a jury trial of all issues presented in this act.

Date: January 14, 2013

Respectfully submitted,

PLAINTIFF Emma Hernandez,

By Her Counsel,

/s/ Kimberly Dougherty
Kimberly Dougherty BBO# 658014
Janet, Jenner & Suggs, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265
Fax: (410) 653-6903
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Robert K. Jenner, *Esq.* (pro hac vice motion to be filed)
Brian D. Ketterer, *Esq.* (pro hac vice motion to be filed)
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Counsel for Plaintiffs

✎JS 44 (Rev. 11/04)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Emma Hernandez, Individually, and as Personal Representative of the Benificiaries & Estate of Santos Pena Hernandez

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

(c) Attorney's (Firm Name, Address, and Telephone Number)
Kimberly Dougherty, Janet, Jenner & Suggs, LLC, 75 Arlington Street, Suite 500, Boston, MA 02116; T: (617)933-1265; E: kdougherty@myadvocates.com

DEFENDANTS

Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America, et al.

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

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

Attorneys (If Known)

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

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

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

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

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

CONTRACT
- ❒ 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

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.A. §1332

Brief description of cause:
defective medical product

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ over $75,000

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Joseph L. Tauro DOCKET NUMBER 12-cv-12296; 12-cv-12295; 12-cv-12306; 1:13-cv-10066

DATE 1/14/2013

SIGNATURE OF ATTORNEY OF RECORD /s/ Kimberly A. Dougherty

FOR OFFICE USE ONLY

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

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. **Title of case (name of first party on each side only)** EMMA HERNANDEZ, INDIVIDUALLY, AND AS PERSONAL REPRESENTATIVE OF THE BENEFICIARIES AND ESTATE OF SANTOS PENA HERNANDEZ

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

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

☐ **II.** **110, 130, 140, 160, 190, 196, 230, 240, 290,320,362, 370, 371, 380, 430, 440, 442, 443, 445, 446, 448, 710, 720, 740, 790, 820*, 840*, 850, 870, 871.**

☑ **III.** **120, 150, 151, 152, 153, 195, 210, 220, 245, 310, 315, 330, 340, 345, 350, 355, 360, 365, 367, 368, 375, 385, 400, 422, 423, 450, 460, 462, 463, 465, 480, 490, 510, 530, 540, 550, 555, 625, 690, 751, 791, 861-865, 890, 896, 899, 950.**

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

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

Johnson v. Fresenius Medical Care North America, Inc. et al (CASE NO 12-cv-12295)

4. **Has a prior action between the same parties and based on the same claim ever been filed in this court?**

YES ☐ **NO** ☑

5. **Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)**

YES ☐ **NO** ☑

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES ☐ **NO** ☐

6. **Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?**

YES ☐ **NO** ☑

7. **Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).**

YES ☐ **NO** ☑

A. **If yes, in which division do all of the non-governmental parties reside?**

Eastern Division ☐ **Central Division** ☐ **Western Division** ☐

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

Eastern Division ☑ **Central Division** ☐ **Western Division** ☐

8. **If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)**

YES ☐ **NO** ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Kimberly A. Dougherty

ADDRESS Janet, Jenner & Suggs, LLC - 75 Arlington St., Suite 500, Boston, MA 02116

TELEPHONE NO. (617) 933-1265

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

Emma Hernandez, Individually, and as PR of the Benificiaries & Estate of Santos Pena Hernandez

Plaintiff

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* FRESENIUS MEDICAL CARE HOLDINGS, INC.
C/O C T CORPORATION SYSTEM
155 FEDERAL STREET, STE 700
BOSTON, MA 02110

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly A. Dougherty, Esquire
JANET, JENNER & SUGGS, LLC
75 Arlington Street, Suite 500
Boston, MA 02116

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

Emma Hernandez, Individually, and as PR of the Benificiaries & Estate of Santos Pena Hernandez

Plaintiff

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* FRESENIUS MEDICAL CARE NORTH AMERICA, INC.
920 WINTER STREET
WALTHAM, MA 02451-1521

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly A. Dougherty, Esquire
JANET, JENNER & SUGGS, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

Emma Hernandez, Individually, and as PR of the Benificiaries & Estate of Santos Pena Hernandez

Plaintiff

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* FRESENIUS USA MANUFACTURING, INC
Registered Agent
C/O C T CORPORATION SYSTEM
155 FEDERAL STREET, STE 700
BOSTON, MA 02110

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly A. Dougherty, Esquire
JANET, JENNER & SUGGS, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

Emma Hernandez, Individually, and as PR of the Benificiaries & Estate of Santos Pena Hernandez

Plaintiff

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* FRESENIUS USA MARKETING, INC.
Registered Agent
C/O C T CORPORATION SYSTEM
155 FEDERAL STREET, STE 700
BOSTON, MA 02110

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly A. Dougherty, Esquire
JANET, JENNER & SUGGS, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

Emma Hernandez, Individually, and as PR of the Benificiaries & Estate of Santos Pena Hernandez

Plaintiff

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* FRESENIUS USA SALES, INC
Registered Agent
C/O: DOUGLAS G. KOTT
920 WINTER STREET
WALTHAM, MA 02451-1521

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly A. Dougherty, Esquire
JANET, JENNER & SUGGS, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

Emma Hernandez, Individually, and as PR of the Benificiaries & Estate of Santos Pena Hernandez

Plaintiff

v.

Fresenius Medical Care Holdings, Inc., et al.

Defendant

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* FRESENIUS USA, INC.
c/o DOUGLAS G. KOTT
920 WINTER ST
WALTHAM, MA 02451

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kimberly A. Dougherty, Esquire
JANET, JENNER & SUGGS, LLC
75 Arlington Street, Suite 500
Boston, MA 02116
Telephone: (617) 933-1265; Fax: (410) 653-6903

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk