

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO

Civil Action No.:

DONALD THORNTON, individually and as Personal Representative of the  
ESTATE OF JEAN THORNTON, and on behalf of all others similarly situated,

Plaintiff,

v.

DAVITA HEALTHCARE PARTNERS, INC.,

Defendant.

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**CLASS ACTION COMPLAINT AND JURY DEMAND**

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## TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION .....	1
II. STATEMENT OF VENUE AND JURISDICTION .....	5
III. PARTIES .....	5
IV. COMMON FACTS.....	6
A. The Dialysis and Related Lab Services Business .....	6
B. GranuFlo in Dialysis .....	8
1. GranuFlo and Dialysis Complications. ....	8
C. How GranuFlo May Harm Dialysis Patients .....	9
D. Fresenius Promoted Its Product as Safe.....	10
E. DaVita Markets Itself as Superior Care .....	11
F. Fresenius is Aware of the Increased Risk of Cardiac Arrest from GranuFlo .....	15
G. GranuFlo is Recalled.....	18
H. Studies Show 941 Deaths.....	19
I. DaVita Knew or Should Have Known that use of GranuFlo was Contributing to High Dialysate Buffer Concentrations .....	20
V. CLASS ACTION ALLEGATIONS .....	20
VI. CAUSES OF ACTION .....	23
FIRST CAUSE OF ACTION Failure to Warn .....	23
SECOND CAUSE OF ACTION Breach of Implied Warranties.....	25
THIRD CAUSE OF ACTION Breach of Express Warranty.....	26
FOURTH CAUSE OF ACTION Fraudulent Concealment.....	27
FIFTH CAUSE OF ACTION Negligence .....	30
SIXTH CAUSE OF ACTION Strict Products Liability .....	33

SEVENTH CAUSE OF ACTION Wrongful Death.....	35
RELIEF REQUESTED.....	35
DEMAND FOR JURY TRIAL .....	36

Plaintiff, Donald Thornton, by and through the undersigned counsel, brings this Complaint in his capacity as personal representative of the estate of his deceased wife, Jean Thornton. For his Complaint against Defendant, Plaintiff alleges as follows:

## **I. INTRODUCTION**

1. On March 29, 2012, the U.S. Food and Drug Administration (“FDA”) issued a Class 1 recall of GranuFlo and NaturaLyte, dialysis products manufactured by Fresenius Medical Care (“Fresenius”). The use of either product can result in high bicarbonate levels that can cause metabolic alkalosis – a significant risk associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia, which may culminate in cardiopulmonary arrest and death.

2. Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause adverse health consequences – or death.

3. Medical research links GranuFlo and NaturaLyte to high bicarbonate levels that can cause a variety of health problems including:

- Cardiopulmonary arrest
- Heart problems
- Metabolic alkalosis
- Low blood pressure
- Sudden MI or heart attack
- Stroke, and
- Death

4. The GranuFlo and NaturaLyte recall states that Fresenius failed to disclose vital information to the FDA and health-care providers about the possible risk of high bicarbonate levels when administering these products.

5. In response to the high rate of cardiac arrests that occurred in Fresenius Medical Care (“FMC”) clinics in 2010, the company submitted an internal memo to its own dialysis clinics on November 4, 2011.

6. After the FDA received an anonymous copy of the November 4th internal memo, company executives were forced to issue an urgent public product warning and recall to its customers that GranuFlo and NaturaLyte were associated with elevated bicarbonate levels and an increased risk for cardiopulmonary arrest and sudden cardiac death as well as stroke and other serious or even fatal complications.

7. Fresenius conducted a case-control study that evaluated risk factors in hemodialysis patients who suffered from cardiopulmonary arrest in FMC facilities compared to other dialysis patients within the same facilities between January 1 and December 31, 2010. This study identified 941 patients in 667 FMC facilities who had cardiopulmonary (CP) arrests within the facilities. Looking at the data for these 941 patients, the study found that the patients’ risk of cardiopulmonary arrest was up to six times higher if they had an elevated pre-dialysis bicarbonate level.

8. Cardiac death is recognized as the number one cause of death for dialysis patients, accounting for 59% of those deaths. By 2010, the medical community had concluded that these cardiovascular-related deaths were not due primarily to atherosclerotic (plaques and arterial stiffening) disease, but rather uremic cardiomyopathy, characterized by left ventricular hypertrophy (LVH), LV dysfunction, and LV dilatation. This conclusion caused many in the

medical community, including FMC, to research the issue – too late to prevent GranuFlo and NaturaLyte related injuries.

9. GranuFlo formulations are unique in that they use sodium diacetate (note the “di”). What was virtually unnoticed by the prescribing physicians with the introduction of GranuFlo in 2003 is that it doubles the amount of acetate in dialysate compared to formulations made with acetic acid. Instead of adding 4 mEq/L of acetate, it adds 8mEq/L. This means that for dialysates made from GranuFlo, the total buffer level is 8 mEq/L higher than the bicarbonate level delivered from the bicarbonate concentrate.

10. Lacking clinical knowledge, as well as a lack of effective product-related education from the manufacturer or from DaVita, often exacerbates this situation. If a physician orders a bicarbonate level of 37 mEq/L for the patient, the clinic may set the dialysis machine to deliver 37 mEq/L from the bicarbonate concentrate alone. If the clinic is using GranuFlo, the patient may receive a total buffer load of 45 mEq/L instead of the 37 mEq/L of bicarbonate normally prescribed by the physician. Some DaVita clinics may have delivered, or may still be delivering, total buffer levels as high as 48 mEq/L, exposing patients to increased risk.

11. The result is the delivery of higher bicarbonate levels than warranted, which can cause danger to patients.

12. DaVita administered GranuFlo while providing dialysis to patients in its clinics. DaVita knew, or was negligent in not knowing, that its patients’ pre-dialysis serum bicarbonate levels were gradually increasing and that patients were at an increased risk of cardiac arrest as a result. DaVita physicians were not conducting prompt review of dialysate bicarbonate prescription levels in patients with a pre-dialysis Serum bicarbonate level of >24mEq/L.

13. There were several things DaVita could and should have done, but did not do, to protect its patients. First, DaVita should have inspected and reviewed the composition of the concentrate and noticed changes. Second, DaVita should have noticed that there was a significant upswing overall in the bicarbonate blood levels when their patients were returning for their dialysis treatments (which individually might not mean much because diet or dialysis sessions could account for it, but in the aggregate those explanations are unlikely to explain the uptick). Third, they should be getting death and complication reports, so they should have noticed many more problems. Each of these things would have alerted them on the front-end of the problems and avoided many issues with pH imbalances and alkalosis. DaVita failed to do any of the above and thus exposed patients to problems caused by pH imbalance and alkalosis.

14. This case arises out of a death caused by cardiac arrest following use of GranuFlo. On November 3, 2011, Jean Thornton went in for a dialysis treatment at DaVita Harbor View Dialysis Clinic in Racine, Wisconsin. On information and belief, Fresenius' products NaturaLyte and/or GranuFlo were administered to Ms. Thornton as part of that treatment at a DaVita clinic. Approximately three hours after her treatment, after Ms. Thornton had returned to her home, she began to experience severe nausea and chest pains and informed her daughter that her entire body hurt. Ms. Thornton was in obvious pain and distress. After complaining to her daughter that she "did not feel right," Ms. Thornton took a deep breath, started shaking uncontrollably and collapsed into her daughter's arms. Emergency medical services were immediately summoned, but their efforts to revive Ms. Thornton were unsuccessful and she was declared dead that same day. Ms. Thornton ultimately died not from the renal failure that required her to undergo dialysis, but rather from a heart attack, which as is described more fully below, was brought on by Fresenius' defective NaturaLyte and/or GranuFlo products.

15. Ms. Thornton's death, as with the death or injury of thousands of similarly situated dialysis patients treated at DaVita clinics all over the United States, was preventable. These deaths occurred because the medical providers administering Fresenius' defective products were negligent in recognizing that these products caused elevated levels of bicarbonate resulting in an increased risk for cardiopulmonary arrest and sudden cardiac death, as well as stroke and other serious or even fatal complications. DaVita failed to adequately investigate or study the NaturaLyte and/or GranuFlo products prior marketing it for use in dialysis. DaVita knew or should have known of its dangerous propensities long before the Fresenius 2011 internal memorandum or the 2012 FDA recall notice.

## **II. STATEMENT OF VENUE AND JURISDICTION**

16. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. There is complete diversity of citizenship between Plaintiff and Defendant, and the amount in controversy exceeds \$75,000.00.

17. Venue is proper in this jurisdiction under 28 U.S.C. § 1391. Defendant resides and has its principal place of business in Colorado and is subject to personal jurisdiction in this judicial district.

## **III. PARTIES**

18. Decedent, Jean Thornton, at all times relevant to this complaint was a resident of the State of Wisconsin. Plaintiff Donald Thornton is over the age of 18, is a resident of the State of Wisconsin and the husband of the late Jean Thornton and the personal representative of her estate. Plaintiff brings this action to recover damages for personal injuries sustained by decedent, Jean Thornton, after receiving dangerous dialysis treatment by Defendant and for wrongful death, on behalf the Estate of Jean Thornton and the beneficiaries of that Estate.



19. Defendant DaVita Healthcare Partners, Inc. (“DaVita”) is a Delaware corporation with its principal place of business at 2000 16th Street, Denver, Colorado. DaVita’s U.S. dialysis and related lab services business is a leading provider of kidney dialysis services for patients suffering from chronic kidney failure or ESRD. As of December 31, 2012, DaVita provided dialysis and administrative services through a network of 1,954 outpatient dialysis centers in the U.S. throughout 44 states and the District of Columbia, serving a total of approximately 153,000 patients. DaVita also provides acute inpatient dialysis services in approximately 970 hospitals and related laboratory services throughout the U.S.

20. As of December 31, 2012, DaVita operated or provided administrative services to a total of 1,954 U.S. outpatient dialysis centers. A total of 1,929 such centers are consolidated in its financial statements. The locations of the 1,929 U.S. outpatient dialysis centers consolidated in its financial statements at December 31, 2012, were as follows:

<u>State</u>	<u>Centers</u>	<u>State</u>	<u>Centers</u>	<u>State</u>	<u>Centers</u>
California	228	New York	41	Nevada	20
Texas	164	Minnesota	39	Oregon	20
Florida	149	New Jersey	38	Nebraska	15
Georgia	110	Wisconsin	37	Massachusetts	13
Ohio	89	Colorado	35	Mississippi	11
Pennsylvania	84	Kentucky	34	District of Columbia	10
Illinois	74	Arkansas	32	Idaho	9
Michigan	69	Oklahoma	32	Utah	4
North Carolina	65	Louisiana	27	New Mexico	4
Virginia	57	South Carolina	27	West Virginia	4
Tennessee	55	Washington	27	Maine	3
Maryland	54	Arizona	25	South Dakota	3
Indiana	50	Kansas	24	New Hampshire	2
Missouri	50	Connecticut	23	North Dakota	2
Alabama	47	Iowa	22	Rhode Island	1

#### IV. COMMON FACTS

##### A. The Dialysis and Related Lab Services Business

The loss of kidney function is normally irreversible. Kidney failure is typically caused by Type I and Type II diabetes, high blood pressure, polycystic kidney disease, long-term

autoimmune attack on the kidney and prolonged urinary tract obstruction. ESRD is the stage of advanced kidney impairment that requires continued dialysis treatments or a kidney transplant to sustain life. Dialysis is the removal of toxins, fluids and salt from the blood of ESRD patients by artificial means. Patients suffering from ESRD generally require dialysis at least three times a week for the rest of their lives.

21. According to United States Renal Data System, there were approximately 415,000 ESRD dialysis patients in the U.S. in 2010 and the underlying ESRD dialysis patient population has grown at an approximate compound rate of 4.0% from 2000 to 2010, the latest period for which such data is available. The growth rate is attributable to the aging of the population, increased incidence rates for diseases that cause kidney failure such as diabetes and hypertension, lower mortality rates for dialysis patients and growth rates of minority populations with higher than average incidence rates of ESRD.

22. Hemodialysis, the most common form of ESRD treatment, is usually performed at a freestanding outpatient dialysis center, at a hospital-based outpatient center, or at the patient's home. The hemodialysis machine uses an artificial kidney, called a dialyzer, to remove toxins, fluids and salt from the patient's blood. The dialysis process occurs across a semipermeable membrane that divides the dialyzer into two distinct chambers. While blood is circulated through one chamber, a pre-mixed fluid is circulated through the other chamber. The toxins, salt and excess fluids from the blood cross the membrane into the fluid, allowing cleansed blood to return into the patient's body. Each hemodialysis treatment that occurs in the outpatient dialysis centers typically lasts approximately three and one-half hours and is usually performed three times per week.

23. Hospital inpatient hemodialysis services are required for patients with acute kidney failure primarily resulting from trauma, patients in early stages of ESRD, and ESRD patients who require hospitalization for other reasons. Hospital inpatient hemodialysis is generally performed at the patient's bedside or in a dedicated treatment room in the hospital, as needed.

24. Some ESRD patients who are healthier and more independent may perform home-based hemodialysis in their home or residence through the use of a hemodialysis machine designed specifically for home therapy that is portable, smaller and easier to use. Patients receive training, support and monitoring from registered nurses, usually in outpatient dialysis centers, in connection with their dialysis treatment. Home-based hemodialysis is typically performed with greater frequency than dialysis treatments performed in outpatient dialysis centers and on varying schedules.

## **B. GranuFlo in Dialysis**

### **1. GranuFlo and Dialysis Complications.**

25. Sudden cardiac arrest, also known as cardiopulmonary arrest, is the most dangerous complication of dialysis. Unfortunately, the Fresenius dialysis product GranuFlo, a product given to a majority of hemodialysis patients in the United States, makes patients several times more susceptible to cardiac arrest.

26. Dialysates such as GranuFlo are administered to patients to maintain the balance of acid and base in the blood. This is because the kidneys of dialysis patients do not remove enough acid from the blood, which may consequently become too acidic, a serious condition known as acidosis. To prevent acidosis, substances known as "dialysates" are administered during dialysis to neutralize acid in the blood. A dialysate is a solution that includes both a bicarbonate and an acid. A bicarbonate is an alkali, also known as a "base," and serves to

neutralize or “buffer” some of the excess acid in the dialysis patient’s blood. The acid, or acetate, used in dialysates also serves to buffer some of the excess acid in the patient’s blood. This is because the liver quickly converts acetate to bicarbonate.

27. As a result, dialysis patients actually receive bicarbonate from two sources – from the bicarbonate concentrate used in the dialysate and, indirectly, from the acid concentrate used in the dialysate, which is then quickly converted into bicarbonate by the liver. Taken together, the bicarbonate delivered to the patient through the bicarbonate concentrate and the bicarbonate converted by the liver from the acetate are known as the “total buffer.” These elements must be carefully balanced because both low pH levels (“acidosis”) and high pH levels (“alkalosis”) are extremely dangerous – and an excess total buffer can lead to alkalosis.

### **C. How GranuFlo May Harm Dialysis Patients**

28. The acid concentrate traditionally used in dialysis has been a liquid acid. GranuFlo is a newer product composed of a dry acid powder which replaces the traditional liquid concentration. The powder form is more concentrated than the liquid form leading to reduced shipping and storage costs compared to liquid formulations. There is, however, an additional and crucial difference between the traditional acid concentrates and GranuFlo. GranuFlo, unlike liquid acid concentrates, uses sodium diacetate, the powder form of acetic acid.

29. The problem is that sodium diacetate – the material used in Fresenius’ GranuFlo product – produces higher levels of bicarbonate in the body than more traditional dialysates. When an acetate is combined with bicarbonate to make a dialysate, the combination results in no net increase in the amount of bicarbonate. Stated simply, the acetate “consumes” an amount of bicarbonate equal to the amount that is produced by the liver as a result of the introduction of the acetate. However, the introduction of sodium diacetate actually results in a net increase in the amount of bicarbonate being delivered by nearly twice that of any other product.

30. The machines used to control the dialysis process track the levels of bicarbonate being introduced into the patient's body through a "bicarb value" displayed on the machine. This value, however, includes only the bicarbonate introduced via the bicarbonate concentrate – it does not include the bicarbonate being produced by the acetate.

31. The result, as recognized in an internal Fresenius memo, is that the use of GranuFlo in the formulations given to dialysis patients can cause the blood of patients treated with GranuFlo to become not merely neutral but basic, a condition known as alkalosis which has been found to increase the risk of cardiac arrest several fold. The FDA found this danger sufficient to issue a Class 1 FDA recall of GranuFlo, their most serious form of recall.

#### **D. Fresenius Promoted Its Product as Safe**

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

33. Fresenius promoted GranuFlo as the "safest" product:

**GranuFlo**

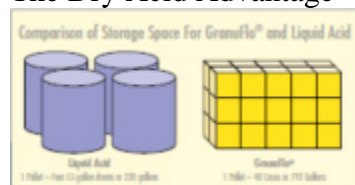
#### **Formulations – Procedure Card – Material Important Prescription Information**

GranuFlo® is the most-widely prescribed dry acid product in the dialysis industry today. Its unique composition of evenly distributed electrolytes is the result of our exacting production technology. With GranuFlo's distinctive proportional component blend in each bag, **you have made the safest choice for onsite concentrate mixing.**

**Safe for your patients and your staff,** our utilization of dry Sodium Diacetate eliminates the need for hazardous liquid glacial Acetic Acid, making GranuFlo **the safest dry** acid product. Other risks of injury to staff can be reduced as well by eliminating the handling of heavy liquid acid drums weighing 570 lbs. A case of

GranuFlo weighs less than 50 lbs, with individual bags weighing approximately 15 lbs each.

#### The Dry Acid Advantage



GranuFlo Dry Acid Dissolution System eliminates 55-gallon drums providing your clinic with valuable storage space (4 times the concentrate with the same amount of space). One pallet consisting of four (4) 55-gallon drums is equivalent to 220 total gallons of liquid acid concentrate. One pallet of GranuFlo dry acid concentrate consisting of 48 cases is equivalent to 792 gallons - a ratio of nearly 4 to 1.

The cost advantage of dry acid, allows us to deliver the most competitive price per gallon over liquid concentrate, while at the same time, **offering superior clinical outcomes**. (Emphasis added.)

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

35. The Fresenius products division “sells” products not only to its own clinics’ division, but also sells them to many of its leading competitors, including DaVita, DCI, Renal Ventures, and many others.

#### E. DaVita Markets Itself as Superior Care

DaVita promotes itself as providing superior care to patients:

Why Choose DaVita?



When it comes to choosing a dialysis provider, you want to know that you will receive superior care to maximize your quality of life.

### **Discover Five Reasons to Choose DaVita**

- **Personalized Care Team**  
(<http://www.davita.com/services/why-choose-davita/personalized-care-team>)
- **Breadth of Care Options**  
(<http://www.davita.com/services/why-choose-davita/breadth-of-care-options>)
- **Clinical Leadership** (<http://www.davita.com/services/why-choose-davita/clinical-leadership>)
- **Accolades and Awards** (<http://www.davita.com/services/why-choose-davita/accolades-and-awards>)
- **Industry-Leading Education**  
(<http://www.davita.com/services/why-choose-davita/industry-leading-education>)

36. DaVita represents that it has a team of specialists dedicated to patients:

#### **Personalized Care Team**



At DaVita®, our approach is to treat you, not just your kidney disease. Our dedicated and highly trained clinical care team works

closely with a broad range of specialists to address your physical, emotional and financial needs:

- **Nephrologists (kidney doctors):** As physicians specializing in kidney care, nephrologists determine the treatment plan for their kidney care patients. DaVita's physician partners work closely with their clinical care team to identify the dialysis treatment option best suited to your unique health and lifestyle needs.
- **Nurses:** Nurses carry out the treatment plans outlined by the nephrologists and are integral members of the clinical care team. Nurses oversee each dialysis treatment from start to finish, checking vitals, reviewing any new lab results and supporting other members of the care team.
- **Dietitians:** Maintaining a kidney-friendly diet is a primary component of any dialysis treatment plan. DaVita's dietitians, who are specially trained in nutrition for people with chronic kidney disease, meet with patients to educate them about which foods to seek and which to avoid based on their unique dietary needs.
- **Social Workers:** DaVita's social workers actively support patients and their families during and after the transition to dialysis, helping manage the emotional, financial, career and lifestyle adjustments involved.
- **Care Technicians:** Dialysis care technicians facilitate the comfort and safety of patients in the dialysis center, monitoring the patients before, during and after treatment.
- **Insurance Specialists:** If you need help navigating your insurance options, DaVita has insurance specialists to help answer your questions.
- **Travel Planners:** DaVita has more than 1,600 dialysis centers nationwide, including ones located in virtually every popular vacation destination. Regardless of where you normally dialyze, let DaVita travel planners make arrangements for your next trip.
- **Facility Administrators:** DaVita's facility administrators manage the patient treatment schedule and all other aspects of dialysis centers' operations.
- **Emergency Services Providers:** When natural disasters or severe weather prevents dialysis centers from delivering care, DaVita's emergency services team responds so patients are accounted for and placed in alternate dialysis centers.
- **Call Center Support Specialists:** At DaVita, answers are just a phone call away — day or night. Support specialists are standing by to help you find the nearest dialysis center to your home or vacation destination, explain your treatment options, guide you through learning about kidney disease and more.



Your specialized clinical and support team works together to deliver personalized care.

**Learn more about DaVita:**

- Why Choose DaVita? (<http://www.davita.com/services/why-choose-davita>)
- **Breadth of Care Options** (<http://www.davita.com/services/why-choose-davita/breadth-of-care-options>)
- **Clinical Leadership** (<http://www.davita.com/services/why-choose-davita/clinical-leadership>)
- **Accolades and Awards** (<http://www.davita.com/services/why-choose-davita/accolades-and-awards>)
- **Industry-Leading Education** (<http://www.davita.com/services/why-choose-davita/industry-leading-education>)

37. DaVita represents itself as having “superior clinical research.”

### CLINICAL LEADERSHIP



Superior care begins with superior clinical leadership. Led by some of the world’s most acclaimed nephrologists, our Office of the Chief Medical Officer drives DaVita’s clinical quality programs at our 1,600-plus dialysis centers around the country. Through continued innovation, DaVita® has produced 10 consecutive years of improvement in the DaVita Quality Index (DQI), a benchmarking tool created by our Physician Council to measure each dialysis center’s outcomes against company-wide performance.

Through this dedication to providing high quality care, DaVita, our physician partners and our clinical care teams have achieved the following results for our patients:

- According to our annual patient satisfaction survey results, 96% of our patients would recommend DaVita for dialysis services
- Our clinical outcomes are the best or among the best in virtually every category, including 10 consecutive years of continued improvement
- In 2009, DaVita had the lowest day-90 catheter rates (the less preferred access method) among large dialysis providers, reducing the risk of hospitalization from infections and blood clots for its patients
- Since 2006, DaVita has exceeded other providers' influenza vaccination rates by as much as 40%, and vaccinations reduce hemodialysis patients' odds of hospitalization by 7%

38. A reasonable consumer would have expected, based on the foregoing, that DaVita was carefully monitoring the safety and efficacy of GranuFlo.

**F. Fresenius is Aware of the Increased Risk of Cardiac Arrest from GranuFlo**

39. Through information and belief, an internal memo from Fresenius dated November 4, 2011, indicated that Fresenius had knowledge that there was a significant increased risk of cardiac arrest and death during hemodialysis treatments associated with their GranuFlo dialysis concentrate product that contains sodium diacetate.

40. Top Fresenius executives knew about the increased risk of cardiac arrest and death during hemodialysis treatments associated with their GranuFlo dialysis concentrate product since its introduction.

41. When Fresenius finally decided to reveal the problem, top Fresenius executives chose not to properly report these complications or GranuFlo specific risks to the FDA or other government agencies.

42. When the clinical problem finally became irrefutably evident to the Fresenius Medical Services division around 2010, top Fresenius executives also decided to withhold these complications or GranuFlo specific risks from non-Fresenius physicians and clinics that were using the GranuFlo product.

43. Fresenius decided to hide, mislead, and obscure information about the extreme patient safety hazard associated with the use of GranuFlo and NaturaLyte products in order to maintain market share as well as to minimize and diffuse the legal risks for Fresenius.

44. Ultimately, after the correlation between GranuFlo use, alkalosis, and cardiopulmonary arrest was made by Fresenius, the company chose to make this information, and associated urgent medical recommendations, solely available to its own physicians and clinics.

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

46. The November internal Fresenius memo went on to state that, “[r]ecent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration. As recommended in previous communications, physicians should individualize dialysate bicarbonate and total buffer prescriptions. We further recommend that pre dialysis serum bicarbonate level of  $>24\text{ mEq/L}$  should prompt immediate review of dialysate bicarbonate prescription.”

47. The internal November memorandum went on to further state in its “summary of findings” that: “The current analysis determined that: *borderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater increase of cardiopulmonary arrest and sudden cardiac death in the dialysis facility.*” (italics in original). “In light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate level of >24 mEq/L.” The memo further urges that this dangerous issue “needs to be addressed urgently.”

48. On March 27, 2012, Fresenius received an inquiry from the FDA specifically about GranuFlo-related products and alkalosis.

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

50. The March 29th memo to non-Fresenius clinics and physicians contained only one of ten medical references that the FMC internal memo did. The March 29th memo also bundled the risks of GranuFlo with another FMC acid concentrate product, NaturaLyte.

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

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

53. Also in the internal November 4, 2011 Fresenius memo, the company noted that its own patients' serum pre-dialysis bicarbonate levels had gradually increased from 2004 to 2011. Despite Fresenius' knowledge of this patient safety risk, more non-Fresenius clinics were actively being converted to the GranuFlo product even after knowledge of the risks that were made clear in the internal November 4, 2011 Fresenius memo.

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

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

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

#### **G. GranuFlo is Recalled**

57. THE NEW YORK TIMES reported on June 14, 2012, that the Food and Drug Administration was investigating whether the nation's largest operator of dialysis centers violated federal regulations by failing to inform customers of a potentially lethal risk connected to one of its products.

58. The article quoted an FDA official:

“Personally, I’m troubled by the fact that Fresenius on its own initiative didn’t notify its entire customer base of this particular concern,” Steven Silverman, director of compliance for the F.D.A.’s medical devices division, said in an interview this week.

Mr. Silverman said the agency could issue a warning letter to Fresenius if it determined the company should have reported the safety concerns. But even if the company had no legal obligation, he said, “Candidly, I just think it’s bad business and not in the interest of public health to sit on information about risks.”

59. The article also quoted:

Dr. Thomas F. Parker III, chief medical officer at Renal Ventures, a dialysis chain that uses Fresenius products, agreed. “If the data was sufficient to warn their doctors, then all users of the product should have been made aware of it.”

60. On March 29, 2012, the U.S. Food and Drug Administration (FDA) issued a Class 1 recall of GranuFlo and NaturaLyte, dialysis products manufactured by Fresenius Medical Care. The use of either product can result in high bicarbonate levels that can cause metabolic alkalosis – a significant risk associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia, and cardiac arrhythmia, which may culminate in cardiopulmonary arrest and death.

61. Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause adverse health consequences – or death.

#### **H. Studies Show 941 Deaths**

62. FMC conducted a case-control study that evaluated risk factors in hemodialysis patients who suffered from cardiopulmonary arrest in FMC facilities compared to other dialysis patients within the same facilities between January 1 and December 31, 2010. This study identified 941 patients in 667 Fresenius facilities who had cardiopulmonary (CP) arrests within the facilities. Looking at the data for these 941 patients, the study found that the patients’ risk of

cardiopulmonary arrest was up to six times higher if they had an elevated pre-dialysis bicarbonate level.

**I. DaVita Knew or Should Have Known that use of GranuFlo was Contributing to High Dialysate Buffer Concentrations**

63. Prior to use of GranuFlo as a key part of dialysis, DaVita should have understood the difference in how GranuFlo was made and what implications that might present to patient health. DaVita should have inspected and reviewed the composition of the concentrate and noticed changes and investigated the potential impact of those changes.

64. DaVita should have tested for and observed that there was a significant upswing overall in the bicarbonate blood levels when their patients were returning for their dialysis treatments and should have been analyzing aggregate data in this regard.

65. DaVita should have been receiving death and complication reports so it should have observed a pattern of increased health problems associated with use of GranuFlo.

66. To this day, DaVita has not alerted patients or doctors that heart attacks and other health issues following dialysis could have been caused by use of GranuFlo.

**V. CLASS ACTION ALLEGATIONS**

67. Plaintiff brings this action for damages on behalf of himself individually and as personal representative of the estate of Jean Thornton, and pursuant to Fed. R. Civ. P. 23(a); 23(b)(2) and 23(c)(4) on behalf of the Class identified below for injunctive relief and for the determination of certain issues of fact and law that apply generally to the Class.

68. The Class is defined as:

All patients treated with GranuFlo or NaturaLyte at a DaVita clinic.

69. Class certification is warranted under Fed. R. Civ. P. 23 because the members of the Class are so numerous and geographically dispersed that joinder is impracticable; there are

questions of law and fact common to the members of the Class; Plaintiff's claims are typical of the claims of the members of the Class that he represents; and Plaintiff will fairly and adequately protect the interests of the Class.

70. Plaintiff has substantially the same interest in this matter as all other members of the Class, and Plaintiff's claims arise out of the same facts and conduct as all other members of the Class. All of the claims of Plaintiff and Class members arise out of Defendant's sale and distribution of a product Defendant knew was dangerously defective and caused significant risk to patients, and from Defendant's failure to disclose this known safety risk and defect.

71. Plaintiff is committed to pursuing this action and has retained counsel experienced in complex products liability and class action litigation. Accordingly, Plaintiff and his counsel will fairly and adequately protect the interests of the members of the Class. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class members he seeks to represent. Plaintiff has no disabling conflicts with the members of the Class and will fairly and adequately represent the interests of the Class members.

72. The elements for class certification under Rule 23 are met with respect to prerequisites for certification under Rule 23(a)(1) through (4). Further, class certification is appropriate under Rule 23(b)(1) through (3) in that prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications and would establish incompatible standards of conduct for Defendant; Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief with respect to the Class as a whole; and questions of law and fact common to Class members predominate over questions affecting only individual members, and a class is superior to other methods for fairly and efficiently adjudicating the controversy.



73. Plaintiff seeks class certification specifically under Rule 23(c)(4) to adjudicate discrete questions of law and fact common to members of the Class. Specifically, Plaintiff seeks a determination of the following common questions of fact and law:

- a. Whether GranuFlo and NaturaLyte is unreasonably dangerous and defective in its design and formulation in that it causes unsafe, rapid increases in bicarbonate levels and dangerously high levels of bicarbonate during dialysis treatment;
- b. Whether GranuFlo and NaturaLyte is defective and unreasonably dangerous in design, formulation and distribution because it lacks adequate and appropriate instructions and warnings;
- c. Whether Fresenius' 2003 510(k) Premarket Notification for GranuFlo and NaturaLyte was accurate when it declared that the product was substantially equivalent to the predicate devices, had the same chemical composition as the predicate devices, and that its safety and effectiveness were supported by performance testing;
- d. When DaVita knew or should have known that GranuFlo and NaturaLyte formulated with sodium diacetate in the concentration utilized from 2003 to date causes rapid increases in bicarbonate levels, elevated bicarbonate levels, and a 6 to 8 fold increased risk of CPA and sudden cardiac death; and
- e. Whether DaVita concealed from clinics, clinicians, and patients that GranuFlo was dangerously defective in that it caused or contributed to dangerously high bicarbonate levels and the potential for CPA, sudden cardiac death, or other life-threatening conditions.

74. Plaintiff also seeks to certify the Class for injunctive relief under Fed. R. Civ. P. 23(b)(2) requiring that DaVita: (1) disclose the identity of DaVita clinics and health care providers which sold or otherwise distributed GranuFlo and NaturaLyte, and (2) notify members of the Class, or permit the putative class representative to notify members of the Class, pursuant

to Fed. R. Civ. P. 23(b)(2), of the information known to DaVita regarding GranuFlo and NaturaLyte.

## **VI. CAUSES OF ACTION**

### **FIRST CAUSE OF ACTION**

#### **Failure to Warn**

75. Plaintiff realleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

76. DaVita used NaturaLyte and/or GranuFlo products in treating Plaintiff and they reached Plaintiff without substantial change in the condition in which they left the possession of the Defendant. The products were used and administered in the manner which had been contemplated.

77. The NaturaLyte and GranuFlo supplied by the Defendant was defective due to inadequate warnings and/or instructions. Defendant knew and/or should have known that NaturaLyte and GranuFlo products had not been adequately tested prior to marketing and that those products created significant risks of serious bodily harm and death to consumers – risks which were reasonably foreseeable at the time of sale and/or could have been discovered by way of reasonable testing prior to marketing the product.

78. Defendant had a duty to, but failed to adequately warn dialysis patients including Plaintiff, and the FDA, of such risks and/or provide adequate instructions that would allow its products to be used without creating an unreasonable risk of harm to the consumer. Had it issued such warnings or instructions, the injuries and resulting death suffered by Plaintiff as well as thousands of similarly situated dialysis patients throughout the United States, could have been reduced or avoided altogether. Had DaVita provided adequate instructions or warnings, dialysis providers could have altered their prescription practices, adjusted their dialysis machines, or

otherwise taken steps to ensure that they were accurately calculating the amount of bicarbonate being introduced into their patients' systems, thus preventing unintentional overdoses of bicarbonate.

79. DaVita knew and/or should have known of the products' increased dangerous propensities as compared to other similar and comparable alternatives. Those increased risks were known or discoverable through reasonable investigation to Defendant at the time of sale, yet DaVita failed to warn regarding these increased risks.

80. DaVita, one of the world's largest users of dialysis concentrate products, is held to the level of knowledge of an expert in the field. DaVita had or should have had specific actual knowledge of the dangerous risks and side effects of NaturaLyte and GranuFlo of which it failed to warn Jean Thornton, and/or protect her by providing adequate warnings or instructions to dialysis providers using its products such as the clinic that administered those products to Ms. Thornton.

81. Plaintiff did not have the same knowledge as Defendant and no adequate warning was communicated to her. The risks posed by these products were not obvious or generally known.

82. DaVita had a continuing duty to warn consumers and the FDA of the risks and dangers associated with these products. It negligently and/or wantonly breached its duty as follows:

a. Failed to include adequate warnings with the hemodialysis products that would alert consumers to the dangerous risks and serious side effects of NaturaLyte and GranuFlo;

b. Failed to include adequate instructions with the hemodialysis products that would allow these products to be used in a manner that would not create unreasonable risks to consumers;

c. Failed to provide adequate warnings and instructions after the Defendant knew or should have known of the significant risks of heart attack, cardiac arrest, sudden cardiac death, and other adverse medical conditions from the use of NaturaLyte and GranuFlo; and

d. Failed to inform Plaintiff that NaturaLyte and GranuFlo had not been adequately and thoroughly tested for safety as a hemodialysis treatment.

83. As a direct and proximate result of Defendant's failure to warn regarding the significant risks associated with its NaturaLyte and GranuFlo products that were sold, supplied, and introduced into the stream of commerce by Defendant or to provide adequate instructions for their use as set forth above, Plaintiff sustained injuries and died.

## **SECOND CAUSE OF ACTION**

### **Breach of Implied Warranties**

84. Plaintiff realleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

85. When Defendant placed NaturaLyte and GranuFlo into the stream of commerce, it knew or should have known that the dialysis concentrates would be used for dialysis treatments just as Plaintiff received. Defendant impliedly warranted to the users of NaturaLyte and GranuFlo, as well as to other similarly situated dialysis patients and dialysis providers – that the products it used were safe and fit for their intended use in dialysis treatment.

86. In fact, NaturaLyte and GranuFlo were not of merchantable quality and were not safe or fit for their intended use. As described above, NaturaLyte and GranuFlo were unreasonably dangerous and unfit for the ordinary purposes for which they were used because

they created elevated levels of bicarbonate leading to significantly increased risks of serious or even fatal complications. Moreover, as described above, Defendant failed to provide adequate instructions or warnings regarding these risks, which constitutes a further breach of its implied warranties.

87. NaturaLyte and GranuFlo breached the warranties because they were unduly dangerous and not fit for their intended purpose as a result of defects in the design of the product and/or due to DaVita's failure to provide adequate instructions or warnings regarding its products.

88. DaVita placed NaturaLyte and GranuFlo products into the stream of commerce in an unsafe, defective and inherently defective condition. Those products were intended to and did reach users including Plaintiff and other similarly situated dialysis patients without a substantial change in the condition in which DaVita sold the products.

89. As a direct and proximate result of the breach of implied warranties by the Defendant, Plaintiff sustained injuries and died.

### **THIRD CAUSE OF ACTION**

#### **Breach of Express Warranty**

90. Plaintiff realleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

91. Defendant expressly warranted that NaturaLyte and GranuFlo were safe and fit for use in dialysis treatment, that they did not produce any dangerous side effects in excess of the risks associated with other acid concentrates used in dialysis treatments, that the products were adequately tested, and that the side effects they did produce were accurately reflected in the warnings accompanying the product.

92. The NaturaLyte and GranuFlo manufactured and provided by Defendant did not conform to these express representations because they were not safe and were unfit for the use for which they were intended. As described more fully above, NaturaLyte and GranuFlo were defective in that their use in the manner and for the purposes intended creates an unreasonable risk of serious or even fatal complications and side effects in dialysis patients. The products therefore are unsafe and unfit for use in dialysis treatment. DaVita did not disclose or warn of these defects, complications or side effects, nor did it disclose that it had failed to adequately test its products prior to marketing them and warranting their fitness for use in dialysis treatments.

93. Plaintiff, as well as other similarly situated dialysis patients, dialysis providers and medical professionals making decisions regarding dialysis patients' treatments, reasonably relied upon the skill, judgment, representations and express warranties of DaVita as described above.

94. DaVita knew or should have known that its warranties were false, misleading and untrue in that NaturaLyte and GranuFlo were not safe or fit for their intended purposes and in fact caused serious and even fatal complications and side effects that were not identified or included in warnings by DaVita.

95. DaVita thus breached the express warranties described above because the products NaturaLyte and GranuFlo were defective and did not contain adequate warnings.

96. As a direct and proximate result of the breach of express warranties by the Defendant, Plaintiff sustained injuries and died.

#### **FOURTH CAUSE OF ACTION**

##### **Fraudulent Concealment**

97. Plaintiff realleges and incorporates herein by reference the foregoing paragraphs of this Complaint as though fully set forth herein.

98. Defendant DaVita intentionally, willfully, wantonly or recklessly deceived Ms. Thornton and others, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, the FDA, and similarly situated dialysis patients and the public in general, by concealing from them the true and material facts concerning NaturaLyte and GranuFlo, which DaVita had a duty to disclose.

99. DaVita knew or should have known as early as 2010 that NaturaLyte and GranuFlo were not safe, fit, and effective for use in dialysis treatment. Furthermore, Defendant was aware that the use of NaturaLyte and GranuFlo was hazardous to health, and that NaturaLyte and GranuFlo have a significant propensity to cause serious injuries to users, including but not limited to cardiac arrest, stroke and other serious and even fatal complications.

100. DaVita was under an obligation to disclose the true facts regarding NaturaLyte and GranuFlo, including the increased risk of alkalosis and resulting increased risks serious and fatal complications and side effects because the disclosure of those facts was necessary to keep its prior statements – including statements that its products were the “safest choice” and offered “superior clinical outcomes” as well as express warranties regarding the safety and efficacy of its products – from being misleading. Moreover, the non-disclosed facts regarding the safety and fitness of NaturaLyte and GranuFlo for use in dialysis is basic to and goes to the very essence of the transaction.

101. DaVita knew, but intentionally, willfully, wantonly or recklessly concealed and suppressed the true facts concerning NaturaLyte and GranuFlo with the intent to defraud Ms. Thornton and other similarly situated dialysis patients, her prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general.

102. Specifically, DaVita fraudulently concealed or intentionally, willfully, wantonly or recklessly omitted the following facts:

- a. That NaturaLyte and GranuFlo were not as safe as other acid concentrates;
- b. That the risks of serious adverse side effects and complications associated with the use of NaturaLyte and/or GranuFlo were higher than those associated with the use of other acid concentrates in dialysis;
- c. That neither Fresenius or DaVita had not adequately tested risks of adverse side effects and complications associated with the use of NaturaLyte and/or GranuFlo prior to marketing the products for use in dialysis;
- d. That the use of NaturaLyte and/or GranuFlo in connection with dialysis treatments resulted in elevated bicarbonate levels;
- e. That the use of NaturaLyte and/or GranuFlo in connection with dialysis treatments resulted in increased instances of alkalosis, a condition it knew could result in dangerous side effects and complications, including but not limited to cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke, hypotension and even death;
- f. That NaturaLyte and/or GranuFlo were defective in that they caused dangerous side effects, including but not limited to cardiopulmonary arrest, electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke, hypotension and even death at a much higher rate than other acid concentrates used in dialysis;
- g. That the administration of NaturaLyte and/or GranuFlo to dialysis patients resulted in dangerous side effects, including but not limited to cardiopulmonary arrest,



electrolyte imbalances, hypokalemia, hypoxemia, hypercapnia, cardiac arrhythmias, coma, stroke, hypotension and even death;

h. That physicians, dialysis providers, and or health care facilities administering NaturaLyte and/or GranuFlo should monitor patients' bicarbonate levels more frequently than is common with other acid concentrates used in dialysis;

i. That there existed procedures, adjustments and calculations that could render the use of NaturaLyte and/or GranuFlo for dialysis more safe and/or that could reduce or eliminate the increased risk of alkalosis and associated serious or even fatal side effects and complications;

j. That NaturaLyte and/or GranuFlo were designed, manufactured, marketed, produced and distributed negligently.

103. The foregoing facts were material, and indeed were central to the purpose of the underlying transaction – which was to receive effective and safe dialysis treatment. Ms. Thornton would not have used NaturaLyte and GranuFlo if she had known the true facts concerning the dangers of NaturaLyte and GranuFlo.

104. As a result of the foregoing fraudulent and deceitful conduct by Defendant as set forth above, Plaintiff sustained injuries and died and Plaintiff suffered the injuries and damages as alleged herein.

## **FIFTH CAUSE OF ACTION**

### **Negligence**

105. Plaintiff realleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

106. DaVita had a duty to exercise reasonable care in researching, supplying, selling and/or distributing of NaturaLyte and/or GranuFlo and introducing such products into the stream

of commerce. This duty included the duty to ensure that the products would not cause users to suffer unreasonable, dangerous side effects.

107. DaVita failed to exercise ordinary care in carrying out these duties and therefore breached them. DaVita knew or should have known that NaturaLyte and/or GranuFlo, when used in for their ordinary purpose and in the intended manner, caused elevated levels of bicarbonate in dialysis patients and created an unreasonable risk of dangerous and even lethal side effects including cardiac arrest, stroke, and other grave and serious conditions. DaVita further knew or should have known that it had failed to adequately review, test and study the NaturaLyte and/or GranuFlo products to adequately ascertain their safety and efficacy prior to introducing them into the stream of commerce.

108. DaVita had a duty to adequately warn, train, instruct and/or monitor treating physicians and dialysis treatment facilities to ensure that the NaturaLyte and/or GranuFlo products were being properly used and/or administered.

109. Defendant failed to meet those duties and did not provide adequate warnings, training, instruction or monitoring to physicians and facilities administering the NaturaLyte and/or GranuFlo products.

110. DaVita's negligence, including the wrongful acts and omissions of its agents, servants and/or employees, includes:

a. Selling NaturaLyte and/or GranuFlo without adequately or thoroughly testing them to determine whether and under what conditions they were safe for use despite knowing the significant dangers the products could pose to dialysis patients;

b. Failing to provide adequate instructions regarding safety precautions and procedures to be observed in the administration and use of NaturaLyte and/or GranuFlo;

- c. Failing to adequately and accurately warn of the risks and dangers of NaturaLyte and/or GranuFlo;
- d. Advertising and recommending the use of NaturaLyte and/or GranuFlo without sufficient knowledge as to their dangerous propensities;
- e. Representing that NaturaLyte and/or GranuFlo were safe for use in dialysis treatment as intended, when in fact they were not safe;
- f. Negligently representing that NaturaLyte and/or GranuFlo were as or more safe and effective as other acid concentrates used in dialysis;
- g. Negligently designing, manufacturing, producing, or assembling NaturaLyte and/or GranuFlo in a manner that was dangerous to their users;
- h. Negligently communicating the dangers and risks associated with the use of NaturaLyte and/or GranuFlo to Plaintiff, to the medical community, and to the general public, including other similarly situated dialysis patients.
- i. Concealing, misrepresenting or failing to reveal information to Plaintiff, to the medical community, to the FDA and to the general public including other similarly situated dialysis patients suggesting that NaturaLyte and/or GranuFlo were unsafe, dangerous and/or did not conform to FDA regulations;
- j. Concealing, misrepresenting or failing to reveal information to Plaintiff, to the medical community, to the FDA and to the general public including other similarly situated dialysis patients suggesting that NaturaLyte and/or GranuFlo presented more severe risks and dangers than other acid concentrates used in dialysis; and
- k. Under-reporting, underestimating and downplaying the serious and even lethal risks and dangers associated with the use of NaturaLyte and/or GranuFlo in dialysis.

111. Despite the fact that DaVita knew or should have known that NaturaLyte and/or GranuFlo caused unreasonably dangerous side effects, including but not limited to cardiac arrest, stroke and even death among other serious conditions, Defendant continued to distribute NaturaLyte and/or GranuFlo to consumers, including Plaintiff.

112. Defendant's actions, by violating statutes, ordinances and/or other rules and regulations, constituted negligence *per se*.

113. Defendant's negligence was the proximate cause of the injuries and damages alleged herein.

## **SIXTH CAUSE OF ACTION**

### **Strict Products Liability**

114. Plaintiff realleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

115. At all times herein mentioned, DaVita researched, advertised, promoted, marketed, sold, and/or distributed NaturaLyte and/or GranuFlo as described above, which was administered to and/or used by Plaintiff.

116. DaVita expected NaturaLyte and/or GranuFlo to and those products did reach the usual consumers, handlers, and persons coming into contact with said products without substantial change in the conditions in which they were sold, distributed, and marketed by DaVita.

117. At all times relevant to this action, NaturaLyte and/or GranuFlo were in an unsafe, defective, and inherently dangerous condition, which were dangerous to users, and in particular, Plaintiff. Plaintiff could not, by the exercise of reasonable care, have discovered the defects described above or perceived their danger. DaVita, on the other hand, knew or could

have discovered through reasonable investigation that such products were defective and unsafe, particularly when used in the form and manner prescribed by Defendant.

118. The acid concentrates, NaturaLyte and/or GranuFlo, promoted, sold and distributed by DaVita were defective in design or formulation in that, when they left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of NaturaLyte and/or GranuFlo, were unreasonably dangerous, and were more dangerous than an ordinary consumer would expect.

119. During the dialysis treatment provided to Plaintiff, which ultimately led to her experiencing cardiac arrest and to her death, the NaturaLyte and/or GranuFlo products were being used for the purposes and in the manner normally intended.

120. Defendant had a duty to create products that were not unreasonably dangerous for their normal, intended use. Instead, Defendant did create products, specifically NaturaLyte and/or GranuFlo, which were unreasonably dangerous when put to their normal intended uses.

121. The acid concentrates, NaturaLyte and/or GranuFlo, researched, tested, promoted, marketed, sold and distributed by Defendant were manufactured defectively in that NaturaLyte and/or GranuFlo left the hands of Defendant in defective conditions and were unreasonably dangerous to their intended users. They reached their intended users in the same defective and unreasonably dangerous conditions.

122. Defendant researched, tested, promoted, sold and distributed defective products which created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendant is therefore strictly liable for the injuries and damages alleged herein.

## **SEVENTH CAUSE OF ACTION**

### **Wrongful Death**

123. Plaintiff realleges and incorporates herein by reference each of the foregoing paragraphs of this Complaint as though fully set forth herein.

124. As a direct and proximate result of Defendant's negligence and otherwise culpable acts described herein, the Decedent, Jean Thornton, received NaturaLyte and/or GranuFlo which caused her to sustain injuries that caused her to experience conscious suffering and caused her death.

125. Jean Thornton's injuries and death as alleged more fully herein directly resulted from Defendant's negligent and otherwise culpable acts, omissions, and/or misrepresentations.

### **RELIEF REQUESTED**

WHEREFORE, Plaintiff prays for judgment against Defendant as appropriate to each cause of action alleged as follows:

- A. Determining that this action is a proper class action and certifying Plaintiff as Class representative under Rule 23 of the Federal Rules of Civil Procedure;
- B. Past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
- C. Past and future economic and special damages according to proof at the time of trial;
- D. Loss of earnings and impaired earning capacity according to proof at the time of trial;
- E. Medical expenses, past and future, according to proof at the time of trial;
- F. For past and future mental and emotional distress, according to proof;
- G. Punitive or exemplary damages according to proof at the time of trial;

- H. Restitution and other equitable relief;
- I. Injunctive relief;
- J. Attorney's fees;
- K. For costs of suit incurred herein;
- L. For pre-judgment interest as provided by law; and
- M. For such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff, through undersigned counsel, hereby demands a jury trial on all counts in this Complaint.

DATED: March 6, 2013

By: /s/ Leif Garrison

Leif Garrison

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

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UNITED STATES DISTRICT COURT

for the  
District of Colorado

DONALD THORNTON, individually and as Personal )  
Representative of the ESTATE OF JEAN )  
THORNTON, and on behalf of all others similarly )  
situated, )

Plaintiff, )

v. )

DAVITA HEALTHCARE PARTNERS, INC., )

Defendant. )

Civil Action No.

**SUMMONS IN A CIVIL ACTION**

To: DaVita Healthcare Partners, Inc.  
2000 16th Street  
Denver, Colorado 80202

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:

Leif Garrison  
HAGENS BERMAN SOBOL SHAPIRO LLP  
2301 East Pikes Peak Avenue  
Colorado Springs, CO 80909-6082

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*

Civil Action No. \_\_\_\_\_

**PROOF OF SERVICE***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))*

This summons for *(name of individual and title, if any)* \_\_\_\_\_  
 was received by me on *(date)* \_\_\_\_\_.

☐ I personally served the summons on the individual at *(place)* \_\_\_\_\_  
 \_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* \_\_\_\_\_  
 \_\_\_\_\_, a person of suitable age and discretion who resides there,  
 on *(date)* \_\_\_\_\_, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* \_\_\_\_\_, who is  
 designated by law to accept service of process on behalf of *(name of organization)* \_\_\_\_\_  
 \_\_\_\_\_ on *(date)* \_\_\_\_\_; or

☐ I returned the summons unexecuted because \_\_\_\_\_; or

☐ Other *(specify)*: \_\_\_\_\_.

My fees are \$ \_\_\_\_\_ for travel and \$ \_\_\_\_\_ for services, for a total of \$ \_\_\_\_\_.

I declare under penalty of perjury that this information is true.

Date: \_\_\_\_\_

\_\_\_\_\_  
*Server's signature*

\_\_\_\_\_  
*Printed name and title*

\_\_\_\_\_  
*Server's address*

Additional information regarding attempted service, etc: