

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:15-cv-02686-RBJ

SHERRI SALDANA individually and as Personal Representative of the ESTATE  
OF GARY GENE SALDANA,

Plaintiff,

v.

DAVITA HEALTHCARE PARTNERS, INC.,

Defendant.

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**FIRST AMENDED COMPLAINT AND JURY DEMAND<sup>1</sup>**

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<sup>1</sup> This Complaint is amended pursuant to agreement by the Parties. *See*, 6/24/16 Stipulation and Order, Dkt. No. 211, also attached hereto as Exhibit “A.”

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Plaintiff, Sherri Saldana brings this complaint on behalf of herself and the estate of his deceased husband, Gary Gene Saldana. For her Complaint against Defendant DaVita Healthcare Partners, Inc. (“DaVita”), Plaintiff alleges as follows:

## **I. INTRODUCTION**

1. DaVita is one of the largest operators of dialysis centers in the United States, with a network of over 2,000 outpatient dialysis centers in the U.S. throughout 44 states and the District of Columbia, serving a total of approximately 175,000 patients. For each dialysis center, DaVita engages a nephrologist or nephrology group as a “medical director.” DaVita pays these medical directors exorbitant sums of money ostensibly for services performed as required by the FDA, but really in return for the referral of their patients to DaVita clinics to provide dialysis services to the patients.

2. At each clinic, DaVita provides management and operations services, supplies the equipment for dialysis services, and supplies the products and drugs, including acid concentrates, which are used in the dialysis process and sold to patients. This case involves acid concentrates sold under the brand name GranuFlo.

3. During the dialysis process, the patient’s blood is circulated through the dialysis machine and waste products in the blood, which can no longer be removed by the patient’s failed kidneys, diffuse across the dialysis membrane into the dialysate solution. Critical electrolytes, including potassium, sodium, calcium and bicarbonate also diffuse across the membrane in order to restore proper levels. Critical to this case is bicarbonate. Bicarbonate maintains proper blood PH levels by neutralizing acid that accumulates in dialysis patients without proper functioning kidneys. A patient’s nephrologist is responsible for prescribing levels of bicarbonate (and other electrolytes) to be administered to the patient. Significantly, a nephrologist does not prescribe a

type or brand of dialysate. Rather, it is the responsibility of DaVita to choose the dialysate and safely administer the electrolyte levels prescribed by the treating nephrologist.

4. Since at least 2004, DaVita knew that certain dialysates, specifically GranuFlo dialysis solution manufactured by Fresenius, contained the chemical acetate (in the form of sodium diacetate), which when metabolized by patients causes (and was intended to cause) a rapid spike in bicarbonate levels. Both the rapidity of the spike and the increase in bicarbonate may in turn lead to serious complications including cardiopulmonary arrest, myocardial infarctions (colloquially, a heart attack) and ischemic stroke. Treating physicians do not prescribe acetate levels in a dialysate; rather, the amount of acetate administered is determined by DaVita.

5. Since at least 2004, DaVita knew that the acetate contained in GranuFlo would predictably raise the bicarbonate levels in its patient's blood. DaVita also knew that the amount of acetate in GranuFlo was far in excess of the minimal amount necessary to keep calcium from precipitating from the dialysate. Despite this, DaVita told its medical staff that the switch to GranuFlo "would not change your bicarb prescription."

6. In November 2011, DaVita was provided with Fresenius's own internal study demonstrating that the use of GranuFlo resulted in a 6-8 fold increase in cardiac arrests during the dialysis process. Despite receiving this memorandum the same day it was issued by Fresenius, DaVita took no actions to address the serious risks of GranuFlo administration and failed to provide the memorandum to the FDA in violation of its reporting obligations. Nor did DaVita provide the memorandum to any of its clinic medical directors for months, despite the medical directors ostensibly being responsible for selecting acid concentrates for their clinics.

7. Specifically, DaVita took no actions to cease using GranuFlo or to ensure that physician's bicarbonate prescriptions were uniformly adjusted to take into account the extra acetate delivered to patients. Nor did DaVita undertake any additional monitoring of patient bicarbonate levels. Instead it continued monitoring pre-dialysis bicarbonate levels only once a month. It instituted no post-dialysis bicarbonate testing even though post-dialysis bicarbonate testing is far more likely to detect GranuFlo induced alkalosis

8. Shockingly, as recently as April 2015, DaVita publicly and falsely claimed that it had not received the November 2011 memorandum at the time it was issued.

9. In March 2012, a copy of the November 2011 memorandum was leaked to the U.S. Food and Drug Administration ("FDA"), which immediately instituted a Class 1 recall of GranuFlo dialysis products manufactured by Fresenius Medical Care ("Fresenius"). 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. The FDA found that the use of GranuFlo 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. The FDA required Fresenius to immediately update its label to warn users of the extra acetate.

10. Yet again, DaVita did nothing to address the severe risks of GranuFlo induced metabolic alkalosis in its vulnerable patient populations except state that doctors should account for the additional acetate in GranuFlo. This response was obviously inadequate for numerous reasons. To begin with, DaVita does not include the type of dialysate in a patient's medical records and therefore a prescribing nephrologist may not know if GranuFlo is used. In any case,

DaVita did not provide attending physicians with sufficient information about the amount of acetate to expect post-dialysis or rate at which ESRD patients metabolize acetate. Thus, prescribing physicians had no way of determining how much additional bicarbonate would be contributed post-dialysis by the acetate in GranuFlo.

11. As a result of DaVita's negligence, thousands of its patients have likely suffered and continue to suffer GranuFlo induced alkalosis. For a percentage of these, the consequences have been more severe. Their alkalosis has triggered serious medical complications of cardiopulmonary arrest, myocardial infarction or ischemic stroke, which in some instances killed them. Decedent was one of those unlucky patients. Decedent died as a result of DaVita's continued administration of GranuFlo, its failure to inform clinic staff, clinic medical directors or treating nephrologists of its risks and its failure to take any other steps to mitigate the exposure to excess acetate.

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

12. 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.

13. 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**

14. Plaintiff, Sherri Saldana, wife and anticipated personal representative of the estate of Gary Gene Saldana, is over the age of 18 and is a resident of the state of Arizona. Decedent, Gary Gene Saldana, at all relevant times was a resident of the state of California.

15. 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. DaVita provides dialysis and administrative services through a network of over 2,000 outpatient dialysis centers throughout the United States, serving a total of approximately 175,000 patients.

#### **IV. FACTS**

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

16. The loss of kidney function is normally irreversible. Kidney failure is typically caused by Type I or 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 absent a kidney transplant.

17. 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.

18. 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.

## **B. The Dialysate**

19. Dialysates 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. In part to prevent acidosis, a dialysate is used during dialysis to neutralize or "buffer" the acid in the blood. Dialysate is a solution that includes both bicarbonate and an acid concentrate. Bicarbonate is an alkali, also known as a "base," and serves to buffer some of the excess acid in the dialysis patient's blood. In addition, dialysate contains other electrolytes vital for patient's health and well-being, including potassium, sodium and calcium.

20. Dialysates must also contain a small amount of an acid—less than 2.5 mEQ/L. This acid, typically citrate or acetate, is necessary to keep calcium in the dialysate from precipitating out of solution (which would be lethal to the patient). The citrate or acetate, however, does not cause acidosis because it is quickly converted by the liver into bicarbonate. For all practical purposes, acetate converts to bicarbonate at a 1:1 ratio. That is, 1 mEQ/L of serum acetate generates 1 mEQ/L of serum bicarbonate. Consequently, acetate results in

additional bicarbonate buffer being delivered to the patient beyond the amount delivered directly by the bicarbonate in the dialysate.

21. In short, dialysis patients actually receive bicarbonate from two sources, directly from the bicarbonate concentrate used in the dialysate and, indirectly, from the acid concentrate used in the dialysate which is 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 is 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.

22. 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, which shows “post-reaction” or actual amount of bicarbonate delivered to the patients from the bicarbonate concentrate. This value, however, does not include the bicarbonate being produced by the acetate.

23. The rate at which bicarbonate diffuses from the dialysate across the dialysate membrane is determined by the difference between the amount of bicarbonate in the dialysate and the amount in the patient’s blood. This difference is known as the “concentration gradient.” The steeper the concentration gradient is the faster bicarbonate diffuses into the patient’s blood. Thus, if two patients are dialyzed with a 35 mEQ/L bicarbonate bath and the first patient has blood bicarbonate levels of 20 mEQ/L while the second has blood bicarbonate levels of 30 mEQ/L, then the first patient has a steeper bicarbonate concentration gradient. This principal holds true not only for bicarbonate but for any substance in the dialysate, including acetate: the steeper the concentration gradient, the faster the substance will diffuse into the patient’s blood.

**C. GranuFlo**

24. The acid concentrate traditionally used in dialysis has been a liquid acid. GranuFlo is a newer product composed of a dry acid powder. The powder form, which is mixed with purified water at the dialysis clinic before use with patients, weighs less than liquid acid 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 contains far more acetate than is necessary. Specifically, GranuFlo delivers 8 mEQ/L of acetate to the patient in the form of sodium diacetate. As DaVita well knew, the express intention of this formulation was to deliver more bicarbonate faster to the patient.

25. DaVita also knew or should have known that basic principles of diffusion meant that the high amount of acetate in GranuFlo would cause a large amount of bicarbonate to be in the patient's blood *after* the dialysis process. Specifically, normal blood acetate levels are extremely low—less than .025 mEQ/L. The amount of acetate in the dialysate (8 mEQ/L) was therefore approximately 320x the amount normally in a patient's blood. Given this extremely steep concentration gradient, acetate predictably diffuses rapidly into the patient's blood. As dialysis progresses, the patient's acetate levels will therefore approach or even equal 8 mEQ/L and when disconnected from the dialysis machine the patient will still have up to 8 mEQ/L in his bloodstream. Possessing such a large amount of acetate in the blood post-dialysis is inherently dangerous because the liver will metabolize it in an unpredictable fashion when the patient is outside of DaVita's care and far away from the clinic's lifesaving equipment and trained medical staff.

26. DaVita also knew or should have known that the large amount of excess acetate in GranuFlo could cause a patient's bicarbonate levels to potentially exceed the level prescribed by his or her nephrologist. The reason for this is simple. In a dialysis patient with healthy liver

function, the liver rapidly breaks down acetate within minutes. As acetate is broken down by the liver, it increases the concentration gradient resulting in even more acetate diffusing into the patient's blood. Once a patient's bicarbonate levels exceed the bicarbonate level in the dialysate, bicarbonate will begin to diffuse *out* of the patient's blood into the dialysate. However, initially this process will be very slow because the bicarbonate concentration gradient initially would not be steep. For example, if the dialysis prescription is 35 mEQ/L and the patient achieves a serum level of 36 mEQ/L that is a difference of only 1 mEQ/L, representing an extremely flat concentration gradient. In contrast, the acetate concentration gradient remains steeper in patients with healthy liver function because, unlike bicarbonate, the acetate is continuously being broken down by the liver. The net result is that in a patient with healthy liver function bicarbonate levels during the dialysis process or soon thereafter could actually exceed the levels prescribed by the treating nephrologist by a significant margin.

27. The above phenomenon has been observed in clinical practice but was hitherto unexplained.

28. For a small percentage of patients who suffer from severe *acidosis*, the administration of GranuFlo conceivably might have been beneficial if accompanied by proper pre- and post-dialysis bicarbonate monitoring and full disclosure of risks and benefits for treating physicians. Even for those patients, however, oral bicarbonate pills are likely a much safer alternative. The reason is that even in patients with dangerously low bicarbonate levels the speed at which GranuFlo changes their bicarbonate level is dangerous. In other words, GranuFlo is dangerous both because of the amount of bicarbonate delivered and the rapidity of the delivery.

29. For the vast majority of patients, however, GranuFlo provided no benefits over traditional dialysates and exposed them to the risk of severe metabolic alkalosis caused by high bicarbonate levels.

30. Nevertheless, because GranuFlo was a powered dialysate, its use saved DaVita millions in shipping costs. DaVita therefore decided to launch an extensive program to convert all clinics to GranuFlo where it was economically feasible to do so taking into account the space requirements of the mixer. DaVita also agreed that all new clinics would use GranuFlo.

31. At new and converted clinics, patients were given GranuFlo without regard to whether they were exhibiting symptoms of metabolic acidosis.

**D. DaVita Knew and Concealed the Harmful Effects of GranuFlo**

32. DaVita decided to convert clinics wholesale to GranuFlo even though as early as 2003 Fresenius showed data to DaVita demonstrating that the use of GranuFlo on an entire patient population can cause the blood of patients treated with GranuFlo to become dangerously alkalotic. Severe metabolic alkalosis can result in serious injury including cardiopulmonary arrest, myocardial infarction and stroke.

33. Despite this knowledge, DaVita did not inform its patients of the risks of GranuFlo.

34. By November 2011 at the latest, DaVita possessed epidemiological data demonstrating that the risk of sudden cardiac death during dialysis was 6-8 times higher when GranuFlo was used. DaVita knew this because it obtained a November 4, 2011 memorandum from Fresenius containing a study of Fresenius patients which identified the above risk.

35. The November 4, 2011 memo presented findings based on Fresenius' 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 patient's risk of cardiopulmonary arrest was six to eight times higher if they had an elevated pre-dialysis bicarbonate level.

36. The November 4, 2011 Fresenius memo 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  $<4\text{ mEq/L}$ .

37. The 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.”

38. It 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.”

39. In the memo, GranuFlo use was associated with increased serum bicarbonate levels and alkalosis, as well as the increased possibility of cardiopulmonary arrests.

40. Also in the memo, the company noted that its own patients’ serum pre-dialysis bicarbonate levels had gradually increased from 2004 to 2011. Despite DaVita’s knowledge of this increase due to GranuFlo, DaVita continued converting clinics to the GranuFlo product as part of its “Dry-Acid Initiative.”

41. During this same period of time, DaVita’s use of GranuFlo to its patients increased steadily, as did the predialysis serum bicarbonate levels of its patients. As a result of DaVita’s gathering of statistics regarding patient outcomes both for its internal analysis of the performance of its dialysis clinics and as a result of governmental regulations and reporting requirements, DaVita had access to a steadily increasing pool of data which showed, both a gradual increase in the serum pre-dialysis bicarbonate levels like that found by Fresenius, as well as an increased incidence of adverse events including cardiopulmonary arrest and sudden cardiac death associated with those increased levels.

42. Despite having this data, DaVita never conducted a retrospective study when it introduced GranuFlo even though its own expert in other litigation concerning GranuFlo testified that such a study should have been conducted following GranuFlo’s introduction.

43. In addition, 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.

#### **E. DaVita Does Nothing to Mitigate the Risks of GranuFlo**

44. DaVita received a copy of the November 4, 2011 memorandum on the day it was released to Fresenius clinics. While DaVita’s Office of Chief Medical Officer debated how to

respond to the memo, it took no steps to cease using GranuFlo in its patient population or in any subset of its patient population.

45. Nor did DaVita take any other steps to mitigate the known dangers of GranuFlo in response to November 4, 2011 memorandum.

46. DaVita could have, but did not, adequately educate nephrologists with privileges at its facilities of the amount of acetate in GranuFlo and its potential effects. Had DaVita done so, bicarbonate levels could have been adjusted or more carefully monitored in susceptible patients.

47. DaVita could have, but did not, adequately educate its medical staff about the acetate in GranuFlo and its potential effects. Had DaVita done so, bicarbonate levels could have been adjusted or more carefully monitored in susceptible patients.

48. DaVita could have, but did not, instruct its staff to account for the excess acetate when setting the machine bicarbonate setting. This action would have reduced the total bicarbonate buffer thereby reducing the chances of metabolic alkalosis. Because of DaVita's failure to do so, when physicians prescribed, for example, bicarbonate levels of 37 mEq/L, the DaVita clinic staff generally set the dialysis machine to deliver 37 mEq/L bicarbonate concentrate. If the clinic is using GranuFlo, the hypothetical patient would receive a total buffer load of 45 mEq/L. Some DaVita clinics have delivered, and may still be delivering, total buffer levels as high as 48 mEq/L, exposing patients to increased risk. No doctor would ever intentionally prescribe bicarbonate in excess of 40 mEq/L, and dialysis machines are made with an upper limit for bicarbonate of 40 mEq/L, preventing accidental or intentional treatment of a patient with more than 40 mEq/L of bicarbonate.



49. DaVita could have, but did not, require more frequent pre-dialysis bicarbonate testing. Instead, it tested only monthly. Had DaVita required more frequent pre-dialysis testing staff could have immediately switched patients with high pre-dialysis bicarbonate to a dialysate with less acetate.

50. DaVita could have, but did not, require post-dialysis bicarbonate testing for patients switched to GranuFlo. Post-dialysis bicarbonate testing for GranuFlo patients is critical because pre-dialysis bicarbonate testing does not reveal peak bicarbonate serum levels. The risk of an adverse event correlates to the magnitude of the peak bicarbonate levels. Had DaVita required such testing, staff could have used a different dialysate on patients with dangerously high post-dialysis bicarbonate.

**F. GranuFlo is Recalled**

51. THE NEW YORK TIMES reported on June 14, 2012, that the Food and Drug Administration was investigating whether Fresenius violated federal regulations by failing to inform customers of a potentially lethal risk connected to one of its products.

52. 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.”

53. 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.”

54. On March 29, 2012, the FDA issued a Class 1 recall of GranuFlo on the ground that its use 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.

55. 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.

56. DaVita had the same report and access to similar information as Fresenius and did not take adequate steps to inform its clinics of the issue.

57. After the recall, DaVita’s reaction was to do nothing other to state that doctors should adjust the bicarbonate prescription levels and that attending physicians were responsible for accounting for the “total buffer.” Even after hearing from physicians that this approach was unworkable, DaVita continued to tell doctors it was their responsibility. Among other reasons, this approach was clearly unworkable because DaVita did not provide attending physicians with sufficient information about the amount of serum acetate to expect post-dialysis or rate at which ESRD patients metabolize acetate. Thus, prescribing physicians had no way of determining how much additional bicarbonate would be contributed post-dialysis by the acetate in GranuFlo.

58. 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.

**G. DaVita Markets Itself as Providing Superior Care**

59. DaVita ubiquitously promotes itself as providing superior care to patients. For example:

Why Choose DaVita?

[image omitted]

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>)

60. DaVita represents that it has a team of specialists dedicated to patients. For example:

Personalized Care Team

[image omitted]

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>)

61. DaVita represents itself as having “superior clinical research.” For example:

### CLINICAL LEADERSHIP

[image omitted]

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%

62. A reasonable consumer would have expected, based on the foregoing and similar ubiquitous statements of DaVita's superiority, that DaVita was carefully monitoring the safety and efficacy of GranuFlo.

#### **H. The Injuries and Death of Gary Gene Saldana**

63. Gary Gene Saldana began receiving dialysis in approximately December 2005 due to renal failure.

64. On August 14, 2010, Mr. Saldana presented to his routine dialysis treatment at DaVita Almond Wood Dialysis in Madera, California. Pretreatment assessment noted Mr. Saldana to have diminished breath sounds. On this day, he was scheduled for 240 minutes of treatment with a GranuFlo dialysate bath of Potassium 2, Calcium 2.5, Bicarbonate 37 and 8 meq/l of acetate. Treatment was initiated at 12:57.

65. At 13:32, Mr. Saldana became unresponsive. O<sub>2</sub> was increased to 3 L/minute. Six minutes later, Mr. Saldana responded to his wife's voice. 250 ml of nasal saline was give, a cold compress was applied and O<sub>2</sub> was increased to 5 L/minute.

66. By 13:44, Mr. Saldana was only responding to painful stimulus and 911 was called. Mr. Saldana was admitted to the hospital with a diagnosis of altered mental status. He was discharged on August 31, 2010 with a diagnosis of hypotension, cellulitis of arm, hypercapnic respiratory failure, bacterial suppurative tenosynovitis of flexor tendon of hand or wrist, deconditioning and positive MRSA culture.

67. Mr. Saldana's last basic metabolic labs prior to this injury were taken August 3, 2010 and read: Potassium 3.7 mMol/L and Bicarbonate 26 mMol/L.

68. On October 2, 2010, Mr. Saldana again presented to his routine dialysis treatment at DaVita Almond Wood Dialysis.

69. On this date, he was scheduled for 300 minutes of treatment with a GranuFlo dialysate bath of Potassium 2, Calcium 2.5, Bicarbonate 37 and 8 meq/l of acetate.

70. Treatment was initiated at 09:57 and concluded 312 minutes later at 15:09. His pre-treatment assessment indicated that he had no complaints. However, his post-treatment assessment notes that his respirations were diminished at the bases and his heart rate was tachycardia. At 12:32, he was noted to have a low blood pressure and was given 100ml of saline.

71. He was discharged home and was last seen alive at 2100 that same night.

72. At around 1:30 A.M. on October 3, 2010, Mr. Saldana was found without a pulse and not breathing by family. An ambulance arrived at the scene and pronounced him dead at the age of 60, with the cause of death being arteriosclerotic cardiovascular disease per the death certificate.

73. On information and belief, DaVita supplied and sold GranuFlo to Mr. Saldana and those products were administered to Mr. Saldana as part of both of those treatments.

74. Like many, if not most ESRD patients, Mr. Saldana had underlying medical conditions that made him particularly vulnerable to the adverse effects of Granuflo.

75. Mr. Saldana ultimately died not from the end stage renal failure that required him to undergo dialysis, or any of his other comorbidities, but rather from the effects of the defective GranuFlo products sold to him by DaVita and administered to him in a DaVita clinic, as described more fully herein.

## V. STATUTE OF LIMITATION TOLLING ALLEGATIONS

### A. Fraudulent Concealment

76. As described further below, DaVita intentionally, willfully, fraudulently, and knowingly concealed the dangerous propensities of the products it used in administering dialysis treatment to its patients, such that Plaintiff could not have known or discovered the cause of Decedent's death and her injuries.

77. Most obviously, DaVita intentionally does not include the type of dialysate used in patient's medical records. Thus, a nephrologist looking at a DaVita patient's medical records would not be able to determine whether GranuFlo had been used.

78. In addition, and without limitation, DaVita willfully failed to inform patients or their physicians (i) of the November 2011 Fresenius memorandum and the risks of metabolic alkalosis and death described therein<sup>2</sup>; (ii) that clinic medical staff would not adjust the dialysis machine bicarbonate setting to take into account the additional acetate; (iii) that acetate in GranuFlo could cause a patient's blood bicarbonate level to exceed the prescription; (iv) that significant amounts of acetate would remain in the patient's bloodstream post-dialysis, potentially even exceeding 8mEQ/L; (v) that it conducted no safety studies of GranuFlo prior to introducing it into the market; (vi) that it conducted no retrospective study once GranuFlo were introduced at its clinics, and (vii) that it did not know the effect of the additional acetate in GranuFlo on post-dialysis bicarbonate levels because it failed to conduct such tests.

79. Had patients or their physicians known these facts, it would have been readily apparent that the extra acetate provided by GranuFlo rendered it dangerous and unsafe for use without, at minimum, (i) training medical staff to account for the additional acetate, (ii)

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<sup>2</sup> As discussed, *supra* ¶ 8, as recently as April 2015 DaVita falsely claimed that it had not received the November 2011 memorandum.



identifying patients at risk for metabolic alkalosis and (ii) conducting post-dialysis bicarbonate testing.

80. Neither Plaintiff nor Decedent learned of the dangers and risks associated with the GranuFlo DaVita used at the clinic where Decedent received his dialysis treatment until September 3, 2012, when Ms. Saldana saw a commercial warning of the dangers and risks associated with GranuFlo and she called counsel to inquire about her potential rights as her husband's representative. Before then, Plaintiff and Decedent did not know and could not have known that the injuries were caused by DaVita's negligence and concealment as described herein. Plaintiff was surprised to learn that there was a problem with the products used in the dialysis process, because Plaintiff believed them to be safe and effective. Neither Plaintiff nor Decedent could have discovered the underlying facts and causes of the injuries because DaVita willfully and intentionally withheld and concealed that information from the public, physicians, and its customers.

**B. *American Pipe Tolling***

81. On March 6, 2013, a putative class action was filed in this District against DaVita alleging that DaVita negligently provided its patients with GranuFlo dialysates manufactured by Fresenius. The action was captioned *Thorton v. Davita Healthcare Partners*, No. 13-cv-00573-RBJ-KMT.

82. The *Thorton* complaint alleged that the use of GranuFlo can result in dangerously high bicarbonate levels that cause metabolic alkalosis—a significant risk associated with low blood pressure, hypokalemia, hypoxemia, and cardiac arrhythmias.

83. Plaintiff Donald Thorton brought suit on behalf of his deceased wife Jean Thorton whose death he alleged resulted from GranuFlo exposure.

84. In addition, Plaintiff Thorton brought suit on behalf of a putative class defined as: “All patients treated with GranuFlo or NaturaLyte at a Davita clinic.” Although the complaint anticipated that damages for class members with wrongful death or bodily injury claims would be determined on an individualized basis, it sought certification under Rule 23(c) of liability questions, including general causation.

85. The *Thorton* complaint was consolidated with several other pending cases and a master consolidated complaint was filed on May 28, 2013.

86. First and second amended master consolidated complaints were filed on July 8, 2013 and July 29, 2013 respectively.

87. Plaintiff here fell within the class definition of the original and each amended *Thorton* complaint.

88. On June 18, 2015, this Court declined to certify a liability questions under Rule 23(c).

89. As a result, the running of the statute of limitations on Plaintiffs’ claims was tolled from March 6, 2013 to June 18, 2015.

#### **VI. COMPLIANCE WITH CAL. CIV. PROC. CODE § 364**

90. Pursuant to Cal. Civ. Proc. Code § 364, Plaintiff has given DaVita at least 90 days prior notice of her intention to commence this action.

91. Pursuant to Cal. Civ. Proc. Code §§ 1012, 1013, and 1013a, Plaintiff served the notice by mail on August 24, 2015.

92. Plaintiff added ten additional days to the 90-day notice period as required by Cal. Civ. Proc. Code § 1013 for service by mail.

## **VII. CAUSES OF ACTION**

### **FIRST CAUSE OF ACTION Fraudulent Concealment**

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

94. DaVita intentionally, willfully, wantonly or recklessly deceived Plaintiff, Decedent, and Decedent's prescribing physicians and healthcare providers by concealing from them the true and material facts concerning GranuFlo, which DaVita had a duty to disclose.

95. DaVita knew that GranuFlo could become unsafe, unfit, and ineffective for use in dialysis treatment. Furthermore, DaVita knew that the improper use of GranuFlo was hazardous to health, and that GranuFlo had a significant propensity to cause serious injuries to users.

96. DaVita was under an obligation to disclose the true facts regarding GranuFlo and its administration of GranuFlo, including the increased risk of alkalosis and resulting increased risks of serious and fatal complications and adverse 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 GranuFlo as administered by DaVita is basic to and goes to the very essence of the transaction.

97. DaVita knew, but intentionally, willfully, wantonly, or recklessly concealed and suppressed the true facts concerning GranuFlo with the intent to defraud Plaintiff, Decedent's prescribing physician and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general.

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

- a. That GranuFlo was not as safe as other acid concentrates, such as Citrasate;
- b. That the risks of serious adverse side effects and complications associated with the use of GranuFlo were higher than those associated with the use of other acid concentrates in dialysis and that DaVita had specifically been informed of this fact by the manufacturer Fresenius;
- c. That DaVita had not adequately tested, through a retrospective study, risks of adverse side effects and complications associated with the use of GranuFlo;
- d. That the use of GranuFlo in connection with dialysis treatments resulted in elevated bicarbonate levels;
- e. That the use of 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 physicians, dialysis providers, and/or health care facilities administering GranuFlo should monitor patients' bicarbonate levels more frequently than is common with other acid concentrates used in dialysis;

- g. That physicians, dialysis providers, and/or health care facilities administering GranuFlo should conduct post-dialysis bicarbonate testing when GranuFlo is used; and
- h. That there existed procedures, adjustments and calculations that could render the use of 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.

99. 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. The Decedent would not have chosen to use GranuFlo if adequately informed of the true facts concerning the dangers of GranuFlo.

100. As a result of the foregoing fraudulent and deceitful conduct by DaVita as set forth above, Plaintiff sustained the injuries described herein.

**SECOND CAUSE OF ACTION**  
**Negligence**

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

102. DaVita had a duty to exercise reasonable care in providing dialysis services.

103. DaVita had a duty to exercise reasonable care in using or providing, GranuFlo to its patients and clinics, including a duty to train its employees in how to properly use GranuFlo. This duty included the duty to ensure (i) that the products would not cause its patients to suffer unreasonable, dangerous side effects that could be avoided by proper administration, (ii) that providing dialysis to patients would be done in accordance with the prescription written by treating doctors, and (iii) that the dialysis services were provisioned appropriately.

104. DaVita had a duty to exercise reasonable care in providing sufficient information to treating nephrologists so that they would be aware of, at minimum, (i) the use of GranuFlo; (ii) its dangers; (iii) the amount of acetate in GranuFlo; (iv) the rate at which ESRD patients' metabolize acetate into bicarbonate and (v) the amount of acetate anticipated to remain in a patient's blood post-dialysis.

105. DaVita failed to exercise reasonable care in carrying out these duties and therefore breached them.

106. DaVita knew or should have known that GranuFlo caused elevated levels of bicarbonate and that these elevated bicarbonate levels in turn caused adverse effects in dialysis patients and created an unreasonable risk of dangerous and even lethal side effects. DaVita further knew or should have known that it had failed to adequately review, test, and study GranuFlo through a retrospective study to adequately ascertain its safety and efficacy. DaVita knew that its technicians and nurses were inadequately trained in the appropriate use of GranuFlo and executing the prescription written by the patient's treating physician, resulting in the improper provision of dialysis and use of GranuFlo.

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

108. DaVita failed to meet those duties and did not provide adequate warnings, training, instruction, or monitoring to physicians and facilities administering the GranuFlo products.

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

- a. Using GranuFlo without adequately or thoroughly testing to determine whether and under what conditions it was safe for use despite knowing the significant dangers it could pose to dialysis patients;
- b. Failing to provide adequate instructions and training regarding safety precautions and procedures to be observed in the administration and use of GranuFlo;
- c. Failing to adequately and accurately warn DaVita patients and physicians with privileges at DaVita clinics of the risks and dangers of GranuFlo;
- d. Constructively representing that GranuFlo was safe for use in dialysis treatment as intended, when in fact it was not safe;
- e. Failing to communicate the dangers and risks associated with the use of GranuFlo to Decedent and Plaintiff;
- f. Concealing, misrepresenting, or failing to reveal information to Plaintiff and Decedent suggesting that GranuFlo was unsafe, dangerous, and/or did not conform to FDA regulations, or even when GranuFlo would be used;
- g. Concealing, misrepresenting, or failing to reveal information to Decedent and Plaintiff, suggesting that GranuFlo presented more severe risks and dangers than other acid concentrates used in dialysis;
- h. Inadequately training technicians and other staff members in the use of dialysis machines with respect to the use of GranuFlo;
- i. Providing GranuFlo not in accordance with the prescription of the treating physicians;

- j. Introducing new products without adequate testing, evaluation and risk assessment;
- k. Failing to conduct pre-dialysis bicarbonate testing frequently enough to detect GranuFlo induced metabolic alkalosis;
- l. Failing to conduct post-dialysis bicarbonate testing to detect GranuFlo induced metabolic alkalosis;
- m. Using GranuFlo in place of safer alternative acid concentrates; and
- n. Failing to communicate to Decedent's nephrologist complete information regarding the dangers of GranuFlo.

110. Despite the fact that DaVita knew or should have known that GranuFlo caused unreasonably dangerous side effects, including, but not limited to, cardiac arrest, stroke and even death among other serious conditions, DaVita continued to use GranuFlo.

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

112. DaVita's negligence was the proximate cause of the injuries and damages alleged herein.

### **THIRD CAUSE OF ACTION Medical Malpractice**

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

114. DaVita had a duty to use such skill, prudence, and diligence as other professionals providing dialysis services commonly possess and exercise.

115. DaVita's conduct, as more fully described herein, breached its duty.



116. Among other things, the DaVita had a duty to (i) not introduce new products without adequate testing and knowledge of their effects; (ii) communicate clearly to patients and their physicians the risks of GranuFlo; (iii) use safe dialysates; (iv) monitor their patient population to detect untoward effects of new products; (v) conduct post-dialysis bicarbonate testing given the known dangers of GranuFlo; (vi) institute proper training, policies and procedures to ensure that the additional bicarbonate delivered by GranuFlo is taken into account by prescribing nephrologists and DaVita clinic staff operating the dialysis machine; and (vii) conduct retrospective studies when new products are introduced to detect any increased mortality risks.

117. DaVita's breach of its duty was the proximate cause of Decedent's suffering and death and Plaintiff's injuries.

118. Plaintiff suffered actual loss and damage resulting from DaVita's negligence and otherwise culpable acts described herein.

**FOURTH CAUSE OF ACTION**  
**Wrongful Death**

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

120. As a direct and proximate result of DaVita's negligence and otherwise culpable acts described herein, Decedent received GranuFlo which caused injuries that resulted in conscious suffering and death.

121. DaVita's negligence, breach of the applicable standard of care, and otherwise culpable acts were the proximate cause of the injuries and damages alleged herein.

**FIFTH CAUSE OF ACTION**  
**Loss of Consortium**

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

123. At the time of the injury, Plaintiff and Decedent had a lawful and valid marriage.

124. The Decedent, Plaintiff's spouse, suffered tortious injuries.

125. Plaintiff suffered a loss of consortium with Decedent such that Plaintiff was deprived of the comfort, society, aid, services, consortium, and support of Plaintiff's spouse and has otherwise suffered economic and other loss, the extent of which will be more fully adduced at the trial of this matter.

126. Plaintiff's loss was proximately caused by the DaVita's actions.

**SIXTH CAUSE OF ACTION**  
**Violation of the California Consumer Legal Remedies Act,**  
**Cal. Civ. Code § 1750, et seq.**

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

128. DaVita is a "person" as defined by Cal. Civ. Code § 1761(c).

129. Decedent was a "consumer" as defined by Cal. Civ. Code § 1761(d) who sought DaVita's dialysis services.

130. DaVita engaged in unfair or deceptive trade practices in violation of Cal. Civ. Code § 1750, *et. seq.*, by intentionally, willfully, wantonly or recklessly deceiving Plaintiff, Decedent, and Decedent's prescribing physicians by concealing from them the true and material facts concerning GranuFlo and its use of those products in administering dialysis treatments, which DaVita had a duty to disclose, and by making the statements alleged *supra* in paragraphs

59-62, and other similar statements made to its customers, that DaVita knew to be false or recklessly disregarded the falseness of the statements.

131. DaVita knew that GranuFlo was not safe, fit, and effective for use in dialysis treatment. Furthermore, DaVita was aware that the use of GranuFlo was hazardous to health, and that GranuFlo has a significant propensity to cause serious and potentially fatal injuries to users.

132. DaVita was under an obligation to disclose the true facts regarding GranuFlo, including the increased risk of alkalosis and resulting increased risks of 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 dialysis services – from being misleading. Moreover, the non-disclosed facts regarding the safety and fitness of GranuFlo for use in dialysis is basic to and goes to the very essence of the transaction.

133. DaVita knew, but intentionally, willfully, wantonly or recklessly concealed and suppressed the true facts concerning its dialysis services and its use of GranuFlo with the intent to mislead Plaintiff, Decedent, Decedent’s prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general with statements it knew to be false.

134. Specifically, DaVita fraudulently misrepresented, or concealed or intentionally, willfully, wantonly, or recklessly omitted the following facts to induce Decedent to select DaVita for dialysis treatments:

- a. That GranuFlo was not as safe as other acid concentrates;

- b. That the risks of serious adverse side effects and complications associated with the use of GranuFlo were higher than those associated with the use of other acid concentrates in dialysis;
- c. That DaVita had not adequately tested, , through a retrospective study, risks of adverse side effects and complications associated with the use of GranuFlo;
- d. That the use of GranuFlo in connection with dialysis treatments resulted in elevated bicarbonate levels;
- e. That the use of 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.
- g. That the administration of 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 GranuFlo should monitor patient's 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 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; and

j.

135. Plaintiff suffered actual injuries resulting from DaVita's concealment of the true dangerous nature of the products it administered to Decedent. Decedent would not have permitted the use of GranuFlo if adequately informed of the true facts concerning the dangers of GranuFlo.

136. As a result of the foregoing conduct in violation of the California Consumer Legal Remedies Act by DaVita as set forth above, Plaintiff sustained the injuries described herein

137. Plaintiff has complied with the notice requirement set forth in Cal. Civ. Code § 1782.

**SEVENTH CAUSE OF ACTION**  
**Battery**

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

139. DaVita intentionally provided excess acetate through the administration of GranuFlo to Decedent through dialysis resulting in harmful or offensive contact.

140. DaVita obtained consent to perform the dialysis procedure in accordance with the treating physician's prescription. Decedent's treating physician did not prescribe the administration of 8 mQ/L of acetate, which represents an amount far in excess of the minimal level to keep calcium from precipitating from the dialysate.

141. DaVita did not provide the dialysis services in accordance with the physician's prescription or the patient's consent resulting in unauthorized physical contact—specifically the introduction of excess acetate into Decedent's bloodstream. .

142. As a result of unauthorized physical contact, Decedent was harmed.

143. Decedent was not capable of giving consent to the use of GranuFlo with 8 mEQ/L acetate as she was not informed of the risks associated with exposure to that amount of acetate, or even that those products would be used.

### **RELIEF REQUESTED**

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

- A. 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;
- B. Past and future economic and special damages according to proof at the time of trial;
- C. Loss of earnings and impaired earning capacity according to proof at the time of trial;
- D. Medical expenses, past and future, according to proof at the time of trial;
- E. For past and future mental and emotional distress, according to proof;
- F. Punitive or exemplary damages according to proof at the time of trial;
- G. Restitution and other equitable relief;
- H. Injunctive relief;
- I. Attorney's fees;
- J. For costs of suit incurred herein;
- K. For pre-judgment interest as provided by law; and

L. For such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

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

DATED: December 27, 2016

By: /s/ Robert B. Carey

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 27th day of December, 2016, a true and correct copy of the foregoing was filed with the U.S. District Court ECF/PACER system, which will send an electronic copy via email to the following:

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