COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT, DIV. _____
CIVIL ACTION NO. 16-CI_____

COMMONWEALTH OF KENTUCKY, *ex. rel.* PLAINTIFF
ANDY BESHEAR, ATTORNEY GENERAL

v.

FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a
Fresenius Medical Care North America

FRESENIUS USA, INC.

FRESENIUS USA MANUFACTURING, INC.

FRESENIUS USA MARKETING, INC.

FRESENIUS USA SALES, INC. DEFENDANTS

COMPLAINT

The Plaintiff, the Commonwealth of Kentucky ("the Commonwealth"), by and through its duly elected Attorney General, Andy Beshear, for its Complaint against the Defendants named herein, states a follows:

INTRODUCTION

1. This is a public interest lawsuit brought by the Kentucky Attorney General under Kentucky state constitutional, statutory, regulatory and common law authority on behalf of the Kentucky Medicaid program to recover damages, statutory civil penalties, injunctive relief, and other relief deemed appropriate by the Court from the Defendants as a result of their unlawful, unfair, false, misleading and deceptive practices related to GranuFlo Dry Acid Concentrate ("GranuFlo"), a dialysate product used in the kidney dialysis process.

2. The Defendants are the largest provider of kidney dialysis and renal care products, treatment and services in the country and own and operate at least 50 dialysis clinics in

Kentucky. The Defendants also provide dialysis products to both its own clinics and to non-Fresenius owned dialysis clinics.

3. GranuFlo is a dialysate product used in screening the blood to remove impurities during the dialysis process. GranuFlo is a dry powder designed to be mixed with purified water. Fresenius also manufactures NaturaLyte, a liquid acid concentrate dialysate.

4. On June 27, 2012, the U.S. Food and Drug Administration ("FDA") issued a Class I recall of GranuFlo because the use of GranuFlo can result in high bicarbonate levels which resulted in metabolic alkalosis, a condition that had been linked to a nationwide epidemic of dialysis-related adverse cardiac events including arrhythmia, heart attacks, strokes and death. Class I 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 serious, adverse health consequences or death.

5. Prior to the FDA recall, Fresenius knew that the use of GranuFlo in the dialysis process resulted in dangerously increased bicarbonate levels. In 2010, Fresenius conducted a clinical study which revealed that 941 patients in 667 Fresenius dialysis facilities had cardiopulmonary arrests and that the patients' risk of cardiopulmonary arrest was up to six times higher if they had an elevated pre-dialysis bicarbonate level. On November 4, 2011, Fresenius issued an internal memo ("the Fresenius Secret Memo") disclosing the results of this study. Fresenius shared the Fresenius Secret Memo with its own dialysis clinical staff, but they did not disclose it to their non-Fresenius outside customers.

6. At some point, a copy of the Fresenius Secret Memo was anonymously leaked to the FDA. On March 27, 2012, Fresenius received an inquiry from the FDA in regard to the GranuFlo-related products and alkalosis. After the FDA inquiry, on March 29, 2012, Fresenius

finally released a 2-page, stripped-down, scientifically-vague, memo to its non-Fresenius customers that omitted critical information and references contained in the Fresenius Secret Memo.

7. For numerous years, Fresenius withheld vital critical GranuFlo-related information from its own clinical staff and from the clinical staff of its non-Fresenius customers that could have prevented numerous adverse heart attacks and deaths.

8. The Kentucky Medicaid program has paid millions of dollars for kidney dialysis treatment and services, and for emergency room admissions, inpatient hospitalizations and rehabilitation services for Kentucky Medicaid recipients injured by GranuFlo. This lawsuit seeks to recover damages, statutory civil penalties, injunctive relief, and other relief deemed appropriate by the Court from the Defendant under the Kentucky Consumer Protection Act, the Kentucky Medical Assistance Fraud Statute, the Kentucky Medicaid Fraud Statutes and other applicable Kentucky law as a result of their unlawful, unfair, false, misleading and deceptive practices related to the manufacturing, sale, marketing, compounding and use of GranuFlo.

PARTIES

9. At all times relevant hereto, the Plaintiff, the Commonwealth of Kentucky is and was a sovereign State of the United States having been admitted as a new and entire member of the United States of America on June 1, 1792, 1 Stat. at L. 567 191, 189, chaps. 7, 4. The Commonwealth is a body politic created by the Kentucky Constitution and laws of the Commonwealth of Kentucky and, as such, is not a citizen of any State.

10. Andy Beshear is the duly elected Attorney General of Kentucky, an independent constitutional officer of the Commonwealth and its chief law enforcement officer, with full authority to initiate and prosecute all cases in which the Commonwealth has an interest. The

Attorney General is vested with specific constitutional, statutory and common law authority to commence proceedings to enforce KRS 194A.505, KRS 205.8451 through KRS 205.8483, KRS 367.170 *et seq.*, to initiate actions necessary to guard against unauthorized demands against the Treasury of the Commonwealth pursuant to KRS 15.060, to exercise all common law duties and authority pertaining to the office of the Attorney General under the common law pursuant to KRS 15.020, and pursuant to the Attorney General's *parens patriae* authority, to bring an action on behalf of the Commonwealth, its departments and agencies, and its citizens. The Attorney General has determined that these proceedings are in the public interest.

11. At all times relevant hereto, the Defendant, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America (individually "FMCNA" and collectively "Fresenius" with the other defendants named herein), is and was a corporation organized pursuant to the laws of New York**,** with its headquarters and principal place of business located at 920 Winter Street, Waltham, Massachusetts. FMCNA is not authorized to transact business within the Commonwealth and by reason thereof the Kentucky Secretary of State shall be deemed to be its statutory agent for service of process pursuant to KRS 454.210.

12. At all times relevant hereto, the Defendant, Fresenius USA, Inc. (individually "FUSA" and collectively "Fresenius" with the other Defendants named herein), is and was a corporation organized pursuant to the laws of Massachusetts, with its headquarters and principal place of business located at 920 Winter Street, Waltham, Massachusetts. FUSA is not authorized to transact business within the Commonwealth and by reason thereof the Kentucky Secretary of State shall be deemed to be its statutory agent for service of process pursuant to KRS 454.210. Upon information and belief, FUSA is and was a wholly owned subsidiary of FMCNA.

13. At all times relevant hereto, the Defendant, Fresenius USA Manufacturing, Inc. (individually "Fresenius Manufacturing" and collectively "Fresenius" with the other Defendants named herein) is and was a corporation organized pursuant to the laws of Delaware, with its principal place of business located at 920 Winter Street, Waltham, Massachusetts. Fresenius Manufacturing is not authorized to transact business within the Commonwealth and by reason thereof the Kentucky Secretary of State shall be deemed to be its statutory agent for service of process pursuant to KRS 254.210. Upon information and belief, Fresenius Manufacturing is and was a wholly owned subsidiary of FMCNA.

14. At all times relevant hereto, the Defendant, Fresenius USA Marketing, Inc. (individually "Fresenius Marketing" and collectively "Fresenius" with the other Defendants named herein) is and was a corporation organized pursuant to the laws of Delaware with its headquarters and principal place of business located at 920 Winter Street, Waltham, Massachusetts. Its registered agent for service of process within the Commonwealth is CT Corporation System, 306 W Main St, Suite 512, Frankfort, KY 40601. Upon information and belief, Fresenius Marketing is and was a wholly owned subsidiary of FMCNA.

15. At all times relevant hereto, the Defendant, Fresenius USA Sales, Inc. (individually "Fresenius Sales" and collectively "Fresenius" with the other Defendants named herein) is and was a corporation organized pursuant to the laws of Massachusetts with its principal place of business located 920 Winter Street, Waltham, Massachusetts. Fresenius Manufacturing is not authorized to transact business within the Commonwealth and by reason thereof the Kentucky Secretary of State shall be deemed to be its statutory agent for service of process pursuant to KRS 454.210. Upon information and belief, Fresenius Sales is and was a wholly owned subsidiary of FMCNA.

16. The Defendant, Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America, is a vertically integrated company that, through its wholly owned corporate subsidiaries and associated limited liability companies and clinics, including but limited to FMCNA, FUSA, Fresenius Manufacturing, Fresenius Marketing and Fresenius Sales, is the largest provider of kidney dialysis and renal care products, treatment and services in the country. Fresenius designs, tests, manufactures, labels, advertises, markets, promotes, sells and distributes various dialysis equipment, including dialysis machines and disposables, dialyzers, bloodlines, acid dialysate concentrates and other products used in the dialysis process, including GranuFlo. Fresenius also operates over 2,200 Fresenius dialysis clinics nationwide including at least 50 in Kentucky including those clinics listed on Exhibit A attached hereto. Fresenius also sells dialysis equipment and products, including GranuFlo, to other to non-Fresenius dialysis companies and clinics.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over the Commonwealth's claims pursuant to KRS 15.060, KRS 23A.010, KRS 194A.505(8), KRS 205.8469, and KRS 367.190 as the claims enumerated herein arise exclusively under Kentucky statutory and common law and from the *parens patriae* authority of the Attorney General to act on behalf of the Commonwealth of Kentucky and its citizens. The Commonwealth's claims are in excess of any minimum dollar amount necessary to establish the jurisdiction of the Court.

18. This Court has personal jurisdiction over the Defendants pursuant to KRS 454.210, because the Defendants have regularly transacted and/or solicited business in the Commonwealth and/or derived substantial revenue from goods used or consumed or services rendered in the Commonwealth and/or contracted to supply good or services in the

Commonwealth and/or caused tortious injury by an act or omission in the Commonwealth and/or caused tortious injury in the Commonwealth by an act or omission outside the Commonwealth.

19. The Complaint herein sets forth exclusively state law claims against the Defendants. Nowhere does the Commonwealth plead, expressly or implicitly, any cause of action or request any remedy that arises under or is founded upon federal law. The issues presented in the Complaint herein do not implicate significant or substantial federal issues and do not turn on the necessary interpretation of federal law. The Commonwealth expressly asserts that the only causes of action asserted and the only remedies sought herein, are founded upon the statutory, regulatory, common, and decisional laws of the Commonwealth of Kentucky. The Commonwealth does not assert any cause of action herein on behalf of any individual or class of individuals.

20. The claims asserted herein by the Commonwealth of Kentucky consist of claims on behalf of the Commonwealth of Kentucky and not on behalf of individual claimants or members of a purported class, and are asserted pursuant to state statutes specifically the Kentucky Consumer Protection Act, KRS 367.110, *et seq*., the Kentucky Assistance Program Fraud Statute, KRS 194A.505, the Kentucky Medicaid Fraud Statutes, KRS 205.8451 through KRS 205.8483 and the common, and decisional laws of the Commonwealth of Kentucky. All other potential causes of action involving individual claimants and/or classes are hereby disclaimed and not brought herein.

21. The Complaint herein does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C. § 1332 and does not invoke federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331. The assertion of federal jurisdiction over the claims asserted herein would improperly disturb the Congressionally-approved balance of federal and

state responsibilities. Accordingly, any attempt by the Defendants to remove this case to federal court would be without a reasonable legal basis in fact or law and in violation of Rule 11 of the Kentucky Rules of Civil Procedure.

22. Venue is proper in Franklin County, Kentucky, pursuant to KRS 452.450 and KRS 452.460, Fresenius entered into contracts with the Commonwealth in Franklin County and because injuries to the Commonwealth occurred in Franklin County and pursuant to KRS 367.190(1) because unlawful methods, acts and/or practices of the Fresenius were committed in Franklin County.

THE MEDICAID PROGRAM

23. The Medicaid Program ("Medicaid") was created in 1965 and operates under Title XIX of the Social Security Act. Medicaid is a cooperative venture between the Federal and State governments to assist States in the provision of adequate medical care to its poorest and most vulnerable citizens, including the poor, the disabled, the elderly, the blind, pregnant women, infants and dependent children. Medicaid is the largest program providing medical and health-related services to America's poorest people.

24. Within broad federal statutory and regulatory guidelines a State: (a) establishes its own eligibility standards; (b) determines the type, amount, duration, and scope of services; (c) sets the rate of payment for services; and (d) administers its own program. These statutes and regulations are set forth generally in the Grants to States for Medical Assistance Programs sections of the United States Code (42 U.S.C. § 1396 *et seq*.) and the Code of Federal Regulations (42 C.F.R. §430 *et seq*.). The Medicaid program is administered at the federal level by the United States Department for Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").

25. The Medicaid program is administered at the state level by the Kentucky Department for Medicaid Services ("Kentucky Medicaid"). The Kentucky Department for Medicaid Services is body politic created by the Kentucky Constitution and laws of the Commonwealth of Kentucky and, as such, is not a citizen of any State. The Department for Medicaid Services is an agency of the Executive Branch of Kentucky State Government and is the single state agency charged with the administration of the Kentucky Medicaid program pursuant to Title XIX of the Federal Social Security Act. 42 U.S.C. 1396a(a)(5), 42 C.F.R. § 431.10. 42 C.F.R. § 100, KRS 12.020 (II)(8)(k), KRS 194A.030(2), Chapter 205 of the Kentucky Revised Statutes, Title 907 of the Kentucky Administrative Regulations and other applicable law.

26. Medicaid currently covers over 829,826 men, women and children, or approximately one (1) out of every five (5) Kentuckians.

HEMODIALYSIS

27. The kidneys are a pair of bean-shaped organs located in the back of the abdomen whose primary functions are to regulate the balance of electrolytes in the blood and to filter out the blood removing water-soluble wastes which are then diverted to the bladder as urine.

28. Chronic kidney disease and acute kidney injury can cause the kidneys to lose their ability to filter the blood and remove waste and extra fluid from the body. End stage renal disease ("ESRD") is a complete loss of kidney function. People with ESRD require regular dialysis for survival. More than 650,000 patients per year in the United States and an estimated 2 million patients worldwide are affected by ESRD. ESRD is increasing in the United States by 5% per year.

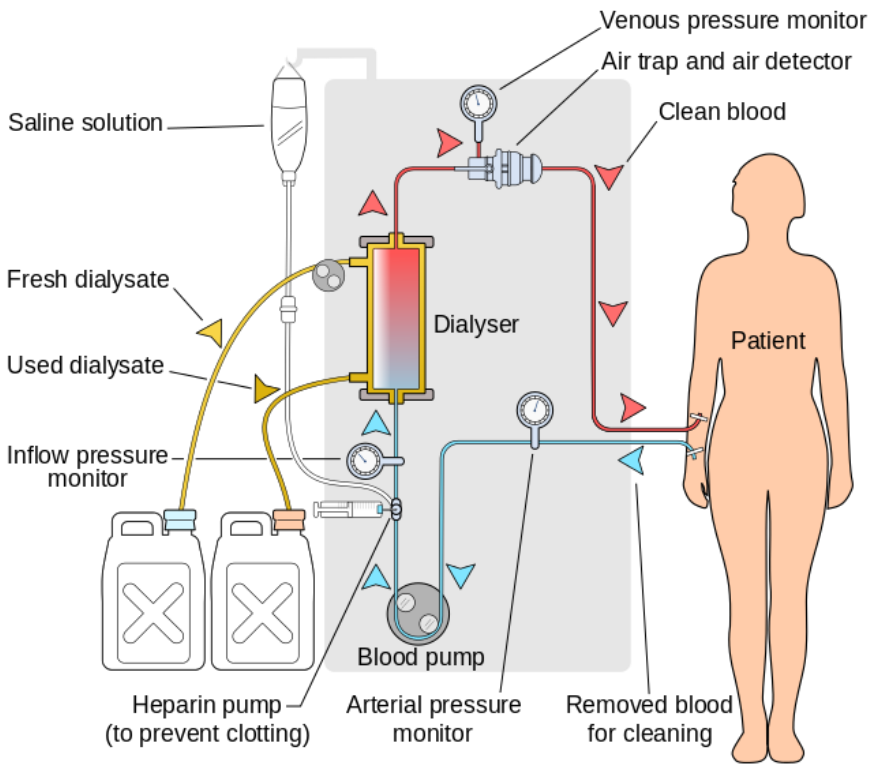
29. Hemodialysis is a process where the blood is slowly pumped from the body through tubing into an external dialysis machine where the waste products are filtered out. Because of the rate of buildup of the waste products in the blood, it may be necessary to perform hemodialysis as many as three times per week for an average of 3-4 hours for each treatment.

30. The dialysis machine contains an artificial kidney dialyzer that has two compartments; a blood compartment and a dialysate compartment. The two compartments are separated by a thin semi-permeable membrane. While the blood is in the blood compartment, portions of the blood pass through the semipermeable membrane into the dialysate compartment. Blood cells, protein and other important things remain in the blood in the blood compartment because they are too big to pass through the membrane. Smaller waste products in the blood, such as urea, creatinine, potassium and extra fluid pass through the membrane and are washed away by the fluid in the dialysate compartment. The dialysate solution containing the toxic substances removed from the blood is discarded. The filtered blood is then pumped back into the body.

31. The dialysate is a solution consisting of water and chemicals (electrolytes) that passes through the artificial kidney dialyzer to remove excess fluids and waste products from the blood. The dialysate is also called the "bath."

32. A dialysate delivery system monitors and controls the temperature, conductivity, flow rate, and pressure of the dialysate solution that circulates through the dialysate compartment of the dialyzer. The dialysate delivery system include dialysate concentrate for hemodialysis, either in liquid form such as NaturaLyte or dry powder form such as GranuFlo.

33. The hemodialysis process is graphically depicted in the following diagram:



34. Most dialyzers use a "three stream method" wherein the dialysate in made by mixing purified water in appropriate proportions with a bicarbonate concentrate base and an acid concentrate. This solution delivers needed minerals to the body and removes waste products that would be otherwise be removed by the kidneys in a healthy person.

35. The bicarbonate base portion of the dialysate solution is an alkali which serves to neutralize or buffer some of the excess blood in the patient's blood, thereby preventing metabolic acidosis, a potentially life threatening condition that occurs when the body produces excessive quantities of acid or when the kidneys are not removing enough acid from the body. To combat this dangerous issue, physicians prescribe a specific amount of bicarbonate, which is based upon each patient's blood serum level, to be delivered during the dialysis process.

36. An acid concentrate, usually acetic acid, citric acid, or sodium diacetate, maintains the proper pH of the dialysate and helps keep the minerals in the solution. When the bicarbonate base and the acid solution are combined to form the dialysate, a chemical reaction

takes place wherein the organic acid consumes an amount of bicarbonate in the final dialysate equivalent to the amount of acid. This loss of bicarbonate is balanced by an equal gain in acetate which the liver rapidly converts to bicarbonate.

37. As a result of the chemical reaction referenced above, dialysis patients receive bicarbonate from two sources; from the bicarbonate concentrate used in the dialysate and, indirectly, from the acid concentrate used in the dialysate, which the liver rapidly converts into bicarbonate. Collectively, 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 abnormal conditions that are potentially life threatening.

STATEMENT OF FACTS

38. GranuFlo is not regulated by the FDA as a "drug." There is no National Drug Code, HCPCS J-Code or other code that has been assigned to GranuFlo. GranuFlo is approved and regulated by the FDA as Class III medical "device."

39. The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act ("the MDA") established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most stringently regulated devices are in Class III.

40. A device is a Class III device if it is one that is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury. 21 C.F.R. § 860.3(c)(3). A life-supporting or life-sustaining device is a device that is essential to, or that yields information

that is essential to, the restoration or continuation of a bodily function important to the continuation of human life. 21 C.F.R. § 860.3(e).

41. Because of the potential unreasonable risk of illness or injury, under Section 515 of the MDA, all manufacturers wishing to market a Class III device must submit Premarket Approval Application ("PMA"), which initiates a stringent pre-market scientific certification process to ensure the safety and effectiveness of Class III device similar to the process employed by the FDA to approve new drugs.

42. However, Section 510(k) of the MDA establishes a streamlined procedure that permits the device manufacturer to make a premarket submission to FDA demonstrating that the device to be marketed is safe and effective because it is substantially equivalent to a previously-approved Class III device already on the market. If the FDA determines that the new device is substantially equivalent to the predicate device, it will issue a letter to the manufacturer assigning it a 510(k) number and authorizing the manufacturer to immediately market the device.

43. On February 14, 2003, using the Section 510(k) process, Fresenius provided the FDA with notice that it intended to market GranuFlo as the substantial equivalent of a Fresenius dialysate predicate device. On May 20, 2003, the FDA cleared GranuFlo for marketing. By utilizing the Section 510(k) process, Fresenius avoided the FDA's rigorous pre-market scientific certification process to ensure the safety and effectiveness of GranuFlo that new device manufacturers ordinarily would have been forced to undergo.

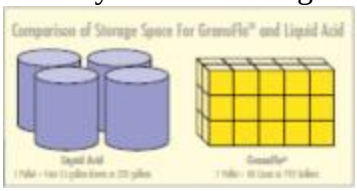
44. After being cleared by the FDA, Fresenius immediately began to aggressively market the new concentrated dialysate under the name GranuFlo, intended to be used in three-stream hemodialysis machines calibrated for acid and bicarbonate concentrates.

45. Fresenius advertising claims for GranuFlo include:

a. 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.

b. 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.

c. The Dry Acid Advantage



d. 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.

e. 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.http://www.fmcna-concentrates.com/acid_acetic_granuflo.html.

46. Many acid concentrates contain acetic acid or citric acid. However in GranuFlo, contains sodium diacetate. Sodium diacetate is composed of equal parts acetic acid and sodium acetate. As with the chemical reaction discussed above, when sodium diacetate combines with bicarbonate to make the dialysate, the acetic acid portion consumes an equal amount of bicarbonate and produces and equal amount of acetate. The sodium acetate portion, however, does not consume bicarbonate. Instead, it enters the bloodstream without reacting, where, because it is also a bicarbonate precursor, it is metabolized by the liver resulting in an unintended increase in the amount of bicarbonate delivered during dialysis.

47. Upon information and belief, as early as 2004, Fresenius was aware that patients with increased pre-dialysis metabolic alkalosis levels were more likely to experience a heart attack or sudden cardiac death if the bicarbonate prescription was not lowered.

48. Due to GranuFlo's combination of both acetic acid and sodium diacetate, GranuFlo can dangerously increase bicarbonate levels beyond the levels prescribed by a patient's physician. Based on the Defendants' knowledge of the chemical structure, and resulting metabolic process in the human body, combined with the knowledge readily available to the Defendants as early as 2004, the Defendants knew or should have known of the increased risk of metabolic alkalosis attributed to the use of GranuFlo. The Defendants also knew at this time that their dialysis machines required special instructions when using GranuFlo to reduce the risk of dangerously high bicarbonate levels associated with the concentrated GranuFlo dialysate.

49. Starting in 2008, the Defendants began advising the employees in their Fresenius clinics to reduce the amount of bicarbonate in dialysis treatment by manipulating the dialysis machine settings. Defendants revised the instruction manual that is used by operators for certain Defendant-manufactured dialysis machines, including the 2008T model. The revisions instructed users, "When entering the Acetate value for GranuFlo concentrate, only half of the listed value on the label should be entered. For example, if the label shows an Acetate value of 8, then only enter 4." (2008T Machine Operator's Manual PIN 490122 Rev E Copyright 2008-2010).

50. Despite this internal knowledge, the Defendants chose not to inform other non-Fresenius clinics, the nephrology/dialysis medical community at large, or end users of GranuFlo of the dangers associated with their product and the discrepancy in dialysis machine settings and data entry.

51. In April 2009, the Defendants employees, including their Chief Medical Officer Dr. Raymond Hakim, M.D., Ph. D., attended a four-day conference in Boston, Massachusetts entitled "ESRD: State of the Art and Charting the Challenges for the Future." The main purpose of the conference was to "address the lack of improvement in dialysis patient survival over the last twenty years." Dr. Hakim served on the Steering Committee for the conference.

52. At the Boston conference attendees were advised that "sudden cardiac death was identified as the #1 cause of death for dialysis patients, accounting for 59% of cardiovascular-related deaths." These deaths were attributed to factors other than atherosclerotic disease. Specifically, the cardio-pulmonary arrest-related deaths were caused by "uremic cardiomyopathy, characterized by left ventricular hypertrophy (L VH), L V dysfunction, and L V dilatation." In less technical terms, the enlarged muscle walls of the left ventricle become fibrotic and fail to conduct electrical impulses correctly. This happens because of repeated and continual fluid overloads in the body - a common occurrence in patients on dialysis because of their reduced urine production.

53. Following the Boston conference, from January 1 to December 31, 2010, Dr. Hakim and other Fresenius employees conducted a case-control study to determine what was killing patients in Fresenius clinics. The study revealed that 941 patients from 667 facilities suffered from cardiopulmonary arrest while in Fresenius' facilities. This figure is over six times higher than that of competing products.

54. On September 15, 2010, the FDA sent a Warning Letter to Fresenius after an investigation revealed that, among other things, Fresenius was inadequately addressing complaints filed by patients using the company's products. The letter addressed five major areas of fault, including "Failure to establish procedures for investigating the cause of nonconformities

stemming from incidents pertaining to NaturaLyte Acid Concentrate" and "Failure to establish and maintain an adequate preventative action to ensure identification of actions needed to corrects and prevent problems." A copy of the FDA's Warning Letter is attached as Exhibit B.

55. On or about November 4, 2011, Dr. Hakim authored the Fresenius Secret Memo referenced above entitled "*RE: Dialysate Bicarbonate, Alkalosis, and Patient Safety*, which summarized the results of the case-control study." The Fresenius Secret Memo concluded, among other things that:

a. "Recent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit,"

b. "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 independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. We further recommend that pre-dialysis serum bicarbonate level of >24 mEq/L should prompt immediate review of dialysate bicarbonate prescription."

c. "Over time, the progressive shift towards higher *pre-dialysis* serum bicarbonate level not only implies that more patients have alkalosis prior to dialysis, but that an even higher percentage of patients have alkalosis post-dialysis."

d. "The current analysis determined that "*borderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater risk of CP arrest and sudden cardiac death in the dialysis facility"* [Emphasis added]."

e. "In light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate level of >24 mEq/L. The bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate - by -8 mEq/L in the case of dialysate prepared from Granuflo (powder) or by -4 mEq/L in the case of dialysate prepared from NaturaLyte (liquid) - since acetate is rapidly converted into bicarbonate by the liver. Please familiarize yourself with the formulation utilized in each of your facilities and consider lower bicarbonate prescriptions (e.g. 31-33 mEq/L so that total buffer is no greater than 39-41

mEq/L when using GranuFlo), and adjust monthly depending on each patient's pre-dialysis bicarbonate level."

f. "A case-control study evaluated risk factors in HD patients who suffered from CP arrest in the facility (N=941 patients from 667 facilities) compared to other HD patients (N=S0,516) within the same facilities between January 1 and December 31 , 2010."

Recommendations:

g. "Pre-dialysis alkalosis and hypokalemia are modifiable risk factors associated with CP arrest. Previous reports have identified hypokalemia as a risk factor for cardiac arrest and sudden cardiac death in the HD facility and this was related to the use of low potassium dialysate (OK, 1 K). Thus, FMCNA policies and practices have required routine review of dialysate potassium orders and have limited use of very low potassium dialysate. However, there has not been enough of a quality focus on alkalosis because the clinical guidelines have primarily emphasized avoidance of metabolic acidosis.5 Over time, there has been a shift towards higher dialysate bicarbonate prescriptions accompanied by increasing serum bicarbonate levels before dialysis and presumably much higher post dialysis. This issue needs to be addressed urgently."

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

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

A copy of the Fresenius Secret Memo is attached hereto as Exhibit C.

56. The Fresenius Secret Memo also reflects that:

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

57. The Fresenius Secret Memo was purposefully released solely to Fresenius' own dialysis clinics, facilities, doctors, and technicians, warning of the significant risk of CPA and sudden cardiac death in patients with elevated bicarbonate levels as a result of using GranuFlo in dialysis treatments. Fresenius did not provide copies of the Fresenius Secret Memo to non-Fresenuis companies and dialysis clinics that used GranuFlo that they purchased from Fresenius, nor did it otherwise warn inform those companies or clinics..

58. On Nov. 16, 2011, twelve days after the Fresenius Secret Memo was released, Fresenius issued a press release indicating that Dr. Hakim was stepping down as Fresenuis' Medical Director as of December 12, 2011, and that he would be replaced Dr. Frank Maddux.

59. Sometime in March, 2012, over four months after the Fresenius Secret Memo was circulated to Fresenius clinics or companies, someone anonymously leaked a copy to the FDA. Upon information and belief, on March 27, 2012, Fresenius received an inquiry from the FDA in regard to the GranuFlo-related products and alkalosis.

60. On March 29, 2012, two days after the FDA inquiry, Fresenius finally released a 2-page, abbreviated, scientifically-vague, memo to its non-Fresenius customers warning doctors of the dangers associated with its products. The abbreviated memo omitted critical information

and references contained in the original Fresenius Secret Memo. The abbreviated memo concluded among other things that "Previous reports have identified an association between elevated pre-dialysis bicarbonate levels and an increased mortality risk. Recent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. A major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration." A copy of the Fresenius abbreviated memo is attached as Exhibit D

61. Also on March 29, 2012, the FDA issued a statement informing the public of the notice in which it stated:

> "The manufacturer is cautioning clinicians to be aware of the concentration of acetate or sodium diacetate (acetic acid plus acetate) contained in Fresenius' Naturalyte Liquid and Granuflo Dry Acid Concentrate. Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest. This product may cause serious adverse health consequences, including death.
>
> FDA has issued a general safety communication related to inappropriate prescription and resultant alkali dosing errors in the dialysate concentrates used in hemodialysis."

A copy of the FDA's statement is attached as Exhibit E.

62. On June 27, 2012, the FDA issued a Class I Recall of GranuFlo and NaturaLyte citing that "Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis." Class I recalls are the most serious recalls of the FDA issues. A copy of the FDS's Class I Recall Notice is attached hereto as Exhibit F.

CAUSES OF ACTION

COUNT I

VIOLATIONS OF THE KENTUCKY CONSUMER PROTECTION ACT

(KRS 367.110 *et seq*.)

63. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of its Complaint herein as if pleaded anew.

64. KRS 367.170 (1) provides: "Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

65. By engaging in the conduct set forth above, the Defendants have willfully engaged in unfair, false, misleading, or deceptive acts or practices in the conduct of trade or commerce within the Commonwealth in violation of KRS 367.170.

66. As a direct result of Defendants' violations of KRS 367.170, the Commonwealth is entitled to the entry of injunctive relief pursuant to KRS 367.190.

67. The Commonwealth is entitled pursuant to KRS 367.200 to restoration of moneys paid out when the Kentucky Medicaid program was required to make payments on behalf of Kentucky Medicaid beneficiaries for dialysis treatment and for medical treatment related to the heart attacks, strokes, deaths and other adverse health consequences, and will be required make payments for ongoing medical care payments on behalf of Kentucky Medicaid recipients in the future

68. For each of Defendants' willful violations of KRS 367.170, the Commonwealth is entitled to recover a civil penalty of not more than two thousand dollars ($2,000) per violation, or a civil penalty of not more than ten thousand dollars ($10,000) per violation where the Defendants' conduct is directed at a person aged sixty (60) or older and the Defendants knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public.

COUNT II

VIOLATIONS OF KENTUCKY ASSISTANCE PROGRAM FRAUD STATUTE
(KRS 194A.505(6))

69. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of the Complaint herein, as if pleaded anew.

70. KRS 194A.505(6) provides: "No person shall, with intent to defraud or deceive, devise a scheme or plan a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations or intentionally engage in conduct that advances the scheme or artifice."

71. The Defendants, by reason of the acts and/or omission set forth herein, with the intent to defraud or deceive, devised a scheme or artifice to obtain benefits from any assistance program by means of false or fraudulent representations it obtain benefits from the Kentucky Medicaid program that they were not entitled to receive, in violation of KRS 194A.505(6).

72. KRS 194A.505(8) provides: "The Attorney General on behalf of the Commonwealth of Kentucky may commence proceedings to enforce this section, and the Attorney General shall in undertaking these proceedings exercise all powers and perform all duties that a prosecuting attorney would otherwise perform or exercise."

73. KRS 194A.990(5) provides: "Any person who violates KRS 194A.505(1) to (6) shall, in addition to any other penalties provided by law, forfeit and pay a civil penalty of payment to the cabinet in the amount of all benefits and payments to which the person was not entitled."

74. KRS 194A.990(6) provides: "Any provider who violates KRS 194A.505(1) to (6) shall, in addition to any other penalties provided by law, including the penalty set forth in subsection (5) of this section, forfeit and pay civil penalties of: (a) Payment to the State

Treasury's general revenue fund in an amount equal to three (3) times the amount of the benefits and payments to which the person was not entitled; and (b) Payment to the State Treasury's general revenue fund of all reasonable expenses that the court determines have been necessarily incurred by the state in the enforcement of this section.

75. By engaging in the conduct set forth above, the Defendants violated of KRS 194A.505(6) and the Kentucky Medicaid program was required to make payments on behalf of Kentucky Medicaid beneficiaries for dialysis treatment and for medical treatment related to the heart attacks, strokes, deaths and other adverse health consequences, and will be required make payments for ongoing medical care payments on behalf of Kentucky Medicaid recipients in the future.

76. By engaging in the conduct set forth above and violations of KRS 194A.505(6), the Commonwealth is entitled to recover damages from the Defendants in an amount to be proved at trial.

77. By engaging in the conduct set forth above and violations of KRS 194A.505(6), the Commonwealth is entitled to recover civil penalties in the amount of all benefits and payments to which the Defendants were not entitled in accordance with the provisions of KRS 194A.990(5).

78. By engaging in the conduct set forth above and violations of KRS 194A.505(6), the Commonwealth is entitled to recover civil penalties in an amount equal to three (3) times the amount of the benefits and payments to which the Defendants were not entitled in accordance with the provisions of KRS 194A.990(6)(a).

79. By engaging in the conduct set forth above and violations of KRS 194A.505(6), the Commonwealth is entitled to recover from the Defendants all reasonable expenses that the

court determines have been necessarily incurred by the Commonwealth state in the prosecution of this action in accordance with the provisions of KRS 194A.990(6).

COUNT III

VIOLATIONS OF KENTUCKY MEDICAID FRAUD STATUTE
(KRS 205.8463 and KRS 446.070)

80. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of its Complaint herein as if pleaded anew.

81. By enrolling in the Medicaid Program, a provider, among other things, agrees to ". . . Comply with all applicable federal laws, state statutes, and state administrative regulations related to the applicant's provider type and provision of services under the Medicaid Program " 907 KAR 1:672 Section 2(6)(k).

82. As noted above, GranuFlo is not a drug. It is regulated by the FDA as a medical "device."

83. A "device" is an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or [is] intended to affect the structure or any function of the body of man or other animals . . ." 21 U.S.C. § 321(h).

84. A "device" is a "piece of equipment or a mechanism designed to serve a special purpose or perform a special function." Merriam-Webster Dictionary.

85. The licensing and operation of ESRD clinics in Kentucky is governed by 902 KAR 20:018. Pursuant to this regulation, "The licensee shall be legally responsible for the operation of the facility and for compliance with federal, state, and local laws and regulations pertaining to the operation of the facility." 902 KAR 20:018 Section 3(1)(a). The regulation

also requires that equipment used in the ESRD facility "shall be maintained free of a condition posing a potential hazard to patients or personnel." 902 KAR 20:018 Section 5(1)(a).

86. The Defendants failed to maintain their dialysis equipment free of conditions posing potential hazards to dialysis patients in violation of 902 KAR 20:018 Section 5(1)(a) when they continued to use GranuFlo even though they knew, or should have known that the use of the device created an increased risk of heart attacks, strokes, deaths and other adverse health consequences.

87. By enrolling in the Medicaid Program, a provider, among other things, agrees to ". . . Not engage in any activity that would constitute an unacceptable practice 907 KAR 1:672 Section 2(6)(i).

88. The term "unacceptable practice" includes conduct by a provider which constitutes "fraud" as defined by KRS 205.8451(2) which reads as follows:

> "Fraud" means an intentional deception or misrepresentation made by a recipient or a provider with the knowledge that the deception could result in some unauthorized benefit to the recipient or provider or to some other person. It includes any act that constitutes fraud under applicable federal or state law."

89. The term "unacceptable practice" also includes conduct by a provider which constitutes "provider abuse, as defined by KRS 205.8451(8) which reads as follows:

> "Provider abuse" means, with reference to a health care provider, practices that are inconsistent with sound fiscal, business, or medical practices, and that result in unnecessary cost to the Medical Assistance Program established pursuant to this chapter, or that result in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes practices that result in unnecessary cost to the Medical Assistance Program."

90. Unacceptable practices can also include "Furnishing medical care, services, or supplies that fail to meet professionally recognized standards, or which are found to be noncompliant with licensure standards promulgated under KRS Chapter 216B and failing to

correct the deficiencies or violation as reported to the department by the Office provider's professional qualifications or licensure; 907 KAR 1:671 Section 40(k) and 907 KAR 1:672 Section 4(11).

91. By engaging in the conduct set forth above, the Defendants committed unacceptable practices in violation of 907 KAR 1:671 Section 40(k) and 907 KAR 1:672 Section 4(11).

92. The Defendants acts and/or omissions as set forth herein failed to meet professionally recognized standards for health care and resulted in unnecessary cost to the Kentucky Medicaid program and are "unacceptable practices" and which conduct constitutes which constitutes "fraud" or "provider abuse", as defined by 907 KAR 1:672 Section 5.

93. KRS 205.8463 (1) provides: "No person shall knowingly or wantonly devise a scheme or plan a scheme or artifice, or enter into an agreement, combination, or conspiracy to obtain or aid another in obtaining payments from any medical assistance program under this chapter by means of any fictitious, false, or fraudulent application, claim, report, or document submitted to the Cabinet for Health and Family Services, or intentionally engage in conduct which advances the scheme or artifice."

94. By engaging in the conduct set forth above, the Defendants, knowingly or wantonly devised a scheme or artifice, or entered into an agreement, combination, or conspiracy to obtain payments from the Kentucky Medicaid program that they were not entitled to in violation of KRS 205.8463 (1).

95. KRS 205.8463(2) provides "No person shall intentionally, knowingly, or wantonly make, present, or cause to be made or presented to an employee or officer of the Cabinet for Health and Family Services any false, fictitious, or fraudulent statement,

representation, or entry in any application, claim, report, or document used in determining rights to any benefit or payment."

96. By engaging in the conduct set forth above and violating KRS 194A.505(6), the Defendants intentionally, knowingly, or wantonly made, presented, or caused to be made or presented to an employee or officer of the Cabinet for Health and Family Services false, fictitious, or fraudulent statements, representations for the illegal purpose of obtaining payments from the Kentucky Medicaid program that they were not entitled to in violation of KRS 205.8463(2).

97. KRS 205.8463(4) provides: "No person shall, in any matter within the jurisdiction of the Cabinet for Health Services under this chapter, knowingly falsify, conceal, or cover-up by any trick, scheme, or device a material fact, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry."

98. By engaging in the conduct set forth above and violating KRS 194A.505(6),the Defendants, in matters within the jurisdiction of the Kentucky Cabinet for Health Services, Department for Medicaid Services, knowingly falsified, concealed, or covered-up by tricks, schemes, or devices material facts and made false, fictitious, or fraudulent statement or representation for the illegal purpose of obtaining payments from the Kentucky Medicaid program that they were not entitled to in violation of KRS 205.8463(4).

99. KRS 446.070 provides that: "A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation."

100. By engaging in the conduct set forth above and violating KRS 205.8463 , the Kentucky Medicaid program was required to make payments on behalf of Kentucky Medicaid beneficiaries for dialysis treatment and for medical treatment related to the heart attacks, strokes, deaths and other adverse health consequences, and will be required make payments for ongoing medical care payments on behalf of Kentucky Medicaid recipients in the future.

101. By engaging in the conduct set forth above and violations of KRS 205.8463, the Commonwealth is entitled to recover damages from the Defendant in an amount to be proved at trial.

COUNT IV

STRICT LIABILITY

102. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of its Complaint herein as if pleaded anew.

103. At all times relevant hereto, the Defendants' GranuFlo was defective and unreasonably dangerous for foreseeable use by Kentucky kidney dialysis patients.

104. The GranuFlo was used in the dialysis treatment of Kentucky Medicaid beneficiaries in the same, or substantially similar condition as it was when it left the Defendants' manufacturing facilities.

105. The Commonwealth did not misuse or materially alter the GranuFlo concentrate that was used in the dialysis treatment of Kentucky Medicaid beneficiaries.

106. The Defendants are strictly liable for the Commonwealth's injuries in the following ways:

a. GranuFlo, as designed, marketed, distributed, packaged, manufactured, sold, supplied and compounded by the Defendants, was defectively designed and placed into the stream of commerce by the Defendants in a defective and unreasonably dangerous condition;

b. The Defendants failed to properly market, design, manufacture, distribute, supply, package and sell GranuFlo;

c. The Defendants failed to warn and place adequate warnings and instructions on GranuFlo;

d. The Defendants failed to adequately test GranuFlo;

e. The Defendants failed to provide timely and adequate warnings and instructions after they knew of the risk of injury or death associated with the use of GranuFlo prior to the injuries suffered by the Commonwealth;

f. The Defendants actively concealed the risk of injury or death associated with the use of GranuFlo from the Commonwealth and the medical community; and,

g. The Defendants failed to market a feasible alternative design for the subject GranuFlo that would have prevented the injuries suffered by the Commonwealth.

107. By engaging in the conduct set forth above, the Kentucky Medicaid program was forced to make payments on behalf of Kentucky Medicaid beneficiaries for dialysis treatment and for medical treatment related to the heart attacks, strokes, deaths and other adverse health consequences, and will be required make payments for ongoing medical care payments on behalf of Kentucky Medicaid recipients in the future.

108. By engaging in the conduct set forth above, the Commonwealth is entitled to recover damages from the Defendants in an amount to be proved at trial.

COUNT V

COMMON LAW FRAUD

109. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of the Complaint herein as if pleaded anew.

110. Fresenius fraudulently, intentionally, willfully or recklessly made material statements and representations to the FDA, the Commonwealth, the medical community and to dialysis patients in regard to the safety and efficacy of GranuFlo for use in hemodialysis.

111. Fresenius' statements and representations were false.

112. Fresenius knew that these statements and representations were false, as its own research and testing demonstrated that GranuFlo was not safe for use in hemodialysis and had been linked to a nationwide epidemic of dialysis-related adverse cardiac events including arrhythmia, heart attacks, strokes and death.

113. Fresenius' false statements and misrepresentations induced the Commonwealth to make payments to Fresenius dialysis clinics for hemodialysis treatment and services provided to Kentucky Medicaid recipients.

114. The Commonwealth relied on Fresenius' false statements and misrepresentations.

115. Fresenius' false statements and misrepresentations caused injuries to the Commonwealth.

116. By engaging in the conduct set above, the Kentucky Medicaid program was required to make payments on behalf of Kentucky Medicaid beneficiaries for dialysis treatment and for medical treatment related to the heart attacks, strokes, deaths and other adverse health consequences, and will be required make payments for ongoing medical care payments on behalf of Kentucky Medicaid recipients in the future.

117. By engaging in the conduct set forth above, the Commonwealth is entitled to recover damages from the Defendants in an amount to be proved at trial.

COUNT VI

BREACH OF CONTRACT

118. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of the Complaint herein as if pleaded anew.

119. The Defendants, through their wholly owned corporate subsidiaries and associated limited liability companies and clinics, including but not limited to the Fresenius clinics listed on Exhibit A, entered into written Provider Agreements with the Commonwealth's Department for Medicaid Services under the terms of which the Defendants had a duty to comply with all state and federal laws and regulations applicable to the provision of medical services and medical goods, including the provisions of KRS 205.8451 to KRS 205.8483 relating to Medicaid Program Fraud and Abuse and the applicable Kentucky Administrative Regulations as specified in Title 907 relating to Provider Agreements.

120. The Defendants breached their contractual obligations to the Commonwealth by violating the provisions of KRS 205.8451 to KRS 205.8483 relating to Medicaid Program Fraud and Abuse, and the applicable Kentucky Administrative Regulations as specified in Title 907 relating to Provider Agreements.

121. By engaging in the conduct set forth above in breach of its contractual obligations, to the Commonwealth is entitled to recover its damages in an amount to be proved at trial pursuant.

COUNT VII

UNJUST ENRICHMENT

122. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of the Complaint herein as if pleaded anew.

123. The Commonwealth is responsible for the payment costs of health care and medical costs for Medicaid recipients pursuant to the State Medicaid Program, as administered by the Kentucky Department for Medicaid Services

124. The Defendants submitted claims to the Kentucky Medicaid program for dialysis treatment and services rendered to Kentucky Medicaid beneficiaries and Kentucky Medicaid reimbursed the Defendants for those claims. .

125. By engaging in the conduct set forth above, the Kentucky Medicaid program has been forced to make additional payments on behalf of Kentucky Medicaid beneficiaries for medical treatment and services related to the heart attacks, strokes, deaths and other adverse health consequences caused by GranuFlo, and will be required make payments for ongoing medical care payments on behalf of Kentucky Medicaid recipients in the future

126. While the Commonwealth and the Kentucky Medicaid program are struggling to pay for the burgeoning health care and medical costs of Medicaid beneficiaries, the Defendants have been unjustly enriched in the form of increased market share and resulting increased profits.

127. In equity and fairness, it is the Defendants and not the taxpayers of the Commonwealth of Kentucky who should bear the costs of the medical expenses occasioned by the Defendants' irresponsible promotion and use of GranuFlo.

128. By engaging in the conduct set forth above in breach of its contractual obligations, to the Commonwealth is entitled to recover its damages in an amount to be proved at trial.

COUNT VIII

PUNITIVE DAMAGES

(KRS 411.186)

129. The Commonwealth repeats, reiterates and incorporates by reference each and every allegation of the Complaint herein as if pleaded anew.

130. By engaging in the conduct set forth above, the Defendants acted toward the Commonwealth with oppression, fraud or malice, gross negligence, and/or reckless disregard for the lives and safety of others to a degree sufficient to warrant the imposition of punitive damages pursuant to KRS 411.186 to deter such further conduct on behalf of the Defendants, or similarly situated parties.

WHEREFORE, the Plaintiff, the Commonwealth of Kentucky, by and through its duly elected Attorney General, Andy Beshear, prays for a judgment:

A. Declaring that Defendants committed willful violations of KRS 367.170;

B. An Order permanently enjoining Defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with defendants, from future false, misleading, deceptive, and/or unfair acts or practices in relation to the promotion and sale of their dialysis products in the Commonwealth of Kentucky pursuant to KRS 367.190;

C. Declaring pursuant to KRS 446.070 that Defendants committed repeated violations of KRS 205.8463;

D. Declaring pursuant to KRS 446.070 that Defendants committed repeated violations of KRS 517.030;

E. Declaring that Defendants have engaged in conduct, acts, or practices which resulted in fraudulent, erroneous, or illegal payments out of the Kentucky State Treasury.

F. Permanently enjoining Defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with defendants, from continuing their unlawful conduct, acts and practices;

G. Awarding treble damages pursuant to KRS 205.8467 and KRS 446.070 on account of the damages caused to it as a result of defendants' unlawful conduct;

H. Awarding civil penalties of $2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);

I. Awarding civil penalties of $10,000 for each violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990 (2), where defendants' where the Defendants' conduct is directed at a person aged sixty (60) or older and the Defendants knew or should have known that the person aged sixty (60) or older is substantially more vulnerable than other members of the public;

J. Awarding punitive damages against Defendants pursuant to KRS 411.184;

K. Awarding the Commonwealth of Kentucky its costs and attorneys' fees;

L. Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law;

M. Awarding any other relief to which the Commonwealth is entitled or the Court deems appropriate and just; and

N. For a trial by jury on all issues so triable.

Respectfully Submitted,

ANDY BESHEAR
Attorney General of Kentucky

By: s/s Mitchel T. Denham
Mitchel T. Denham
Assistant Deputy Attorney General
Mitchel.Denham@ky.gov
OFFICE OF THE ATTORNEY GENERAL
Capitol Building, Suite 118
700 Capitol Avenue
Frankfort, KY 40601-3449
(502) 696-5300
(502) 564-8310 FAX

C. David Johnstone
Assistant Attorney General
David.Johnstone@ky.gov
Wesley W. Duke
Assistant Attorney General

Wesley.Duke@ky.gov
OFFICE OF THE ATTORNEY GENERAL
Medicaid Fraud and Abuse Control Division
1024 Capital Center Drive, Suite 200
Frankfort, Kentucky 40601
(502) 696-5300
(502) 573-8316 FAX

LeeAnne Applegate
Assistant Attorney General
LeeAnne.Applegate@ky.gov
John M. Ghaelian
Assistant Attorney General
John.Ghaelian@ky.gov
OFFICE OF THE ATTORNEY GENERAL
Office of Consumer Protection
1024 Capital Center Drive, Suite 200
Frankfort, Kentucky 40601
(502) 696-5300
(502) 573-573-8317 FAX

Counsel for Plaintiff,
Commonwealth of Kentucky

FRESENIUS KENUCKY CLINICS

1. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC of Grayson and/or Fresenius Kidney Care Grayson, is and was a renal dialysis center with its principal place of business located at 286 State Highway 1947, Grayson, KY 41143.

2. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care Bowling Green Warren County and/or Fresenius Kidney Care Bowling Green Warren County, 262 Natchez Trace Avenue, Bowling Green, KY 42103.

3. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of Central Richmond and/or Fresenius Central Richmond, 1036 Center Dr., Suite C Richmond, KY 40475.

4. The Defendant, Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care of Winchester and/or Fresenius Kidney Care Winchester, 1145 W Lexington Ave., Winchester, KY 40391.

5. Defendant, Bio-Medical Applications of Kentucky, Inc., d/b/s Fresenius Medical of Danville, d/b/a FMS Dialysis Services of Danville and/or Fresenius Kidney Care Danville, Hustonville Road, Suite 1, Danville, KY 40422.

6. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC Dialysis Services of Audubon and/or Fresenius Kidney Care Audubon, 2355 Poplar Level Road, G2-10, Louisville, KY 40217.

7. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care Central Ashland and/or Fresenius Kidney Care Central Ashland, 424 River Hill Dr., Ashland, KY 41101.

8. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care Glasgow and/or Fresenius Kidney Care Glasgow, 205 Professional Park Dr., Glasgow, KY 42141.

9. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC-NA Dialysis Services of Harlan and/or Fresenius Kidney Care Harlan, 136 Village Center Road, Harlan, KY 4083

10. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC-NA of Hazard and/or Fresenius Kidney Care Hazard , 516 Village Lane, Hazard, KY 41701.

11. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care of Jackson and/or Fresenius Kidney Care Jackson, 1550 US Highway 15 South, Suite 30, Jackson, KY 41339

12. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Dialysis Services of Oldham County and/or Fresenius Kidney Care Oldham County, 2100 Button Lane, LaGrange, KY 40031.

EXHIBIT A

13. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of East Louisville and /or Fresenius Kidney Care East Louisville, 6455 Bardstown Road, Louisville, KY 40291.

14. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC Kentuckiana Home Therapies and/or Fresenius Kidney Care Kentuckiana Home Therapies, 6400 Dutchmans Pkwy., Louisville, KY 40205.

15. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care South Louisville and/or Fresenius Kidney Care South Louisville, 1514 Crums Lane, Louisville, KY 40216.

16. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care Madisonville and/or Fresenius Kidney Care Madisonville, 1020 Waterfall Court, Madisonville, KY 42431.

17. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of Morehead and/or Fresenius Kidney Care Morehead, 250 Norman Wells Lane, Morehead, KY 40351.

18. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC of Paintsville and/or Fresenius Kidney Care Paintsville, 620 Jefferson Avenue, Paintsville, KY 41240.

19. Bio-Medical Applications of Kentucky, Inc., d/b/a, BMA of Prestonsburg and/or Fresenius Kidney Care Prestonsburg, 61 Dewey Street, Prestonsburg, KY 41653.

20. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC-NA Lake Cumberland and/or Fresenius Kidney Care Somerset, 119 Tradepark Drive, Somerset, KY 42503.

21. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC-NA of Greenup and/or Fresenius Kidney Care Greenup, 965 Townhill Plaza, Greenup, KY 41144.

22. The Defendant, Bio-Medical Applications of Kentucky, Inc., d/b/a FMC Dialysis Services Mt. Sterling and/or Fresenius Kidney Care Mt. Sterling, 75 Sterling Way, Mount Sterling, KY 40353.

23. Bio-Medical Applications of Kentucky, Inc., d/b/a FMC-Nicholasville and/or Fresenius Kidney Care Nicholasville, 115 Orchard Place Drive, Nicholasville, KY 40356.

24. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Medical Care South Central Louisville and/or Fresenius Kidney Care South Central Louisville, 8319 Preston Hwy., Louisville, KY 40219.

25. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of Ashland and/or Fresenius Kidney Care Ashland, 432 16th Street, Ashland, KY 41101.

26. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of Louisville and/or Fresenius Kidney Care Louisville, 720 E Broadway, Louisville, KY 40202.

EXHIBIT A

27. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of Suburban and/or Fresenius Kidney Care Suburban, 3991 Dutchmans Lane, Suite G-02, Louisville, KY 40207.

28. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of West Louisville and/or Fresenius Kidney Care West Louisville, 2600 West Broadway, Louisville, KY 4021.

29. Bio-Medical Applications of Kentucky, Inc., d/b/a Fresenius Dialysis Services of Louisville Northeast and/or Fresenius Kidney Care Louisville Northeast, at 3701 Chamberlain Lane, Louisville, KY 40241.

30. Bio-Medical Applications of Kentucky, Inc., d/b/a FMS Southwest Louisville and/or Fresenius Kidney Care Rockford Lane, 9616 Dixie Hwy., Louisville, KY 40272

31. Bio-Medical Applications of Kentucky, Inc., d/b/a FMS-NA of Pike County and/or Fresenius Kidney Care Pike County, 146 Adams Lane, Pikeville, KY 41501.

32. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of Shelbyville and/or Fresenius Kidney Care Shelbyville, 150 Stonecrest Road, Shelbyville, KY 40065.

33. Bio-Medical Applications of Kentucky, Inc., d/b/a BMA of Somerset and/or Fresenius Kidney Care Somerset, 119 Tradepark Drive, Somerset, KY 42503. .

34. Fresenius Medical Care Boone County, LLC, d/b/a Fresenius Medical Care Edgewood and/or Fresenius Kidney Care Edgewood, 210 Thomas More Pkwy., Crestview Hills, KY 41017.

35. Fresenius Medical Care Boone County, LLC, d/b/a Fresenius Medical Care Boone County and/or Fresenius Kidney Care Boone County, 7205 Dixie Hwy., Florence, KY 41042.

36. Fresenius Medical Care Hopkinsville, LLC., d/b/a Fresenius Medical Care Hopkinsville, LLC, and/or Fresenius Kidney Care Hopkinsville, 510 Heritage Way, Hopkinsville, KY 42240,

37. Fresenius Medical Care Masonic Home, LLC., d/b/a Fresenius Medical Care - Masonic Home and/or Fresenius Kidney Care Masonic Home, 3501 Moyers Circle, Suite 200, Masonic Home, KY 40041,

38. Fresenius Medical Care NAK Bardstown, LLC., d/b/a Fresenius Medical Care of Bardstown and/or Fresenius Kidney Care Bardstown, 317 Kentucky Home Square, Bardstown, KY 40004.

39. Fresenius Medical Care NAK Bardstown, LLC., d/b/a Fresenius Medical Care of Bardstown and/or Fresenius Kidney Care Bardstown, 317 Kentucky Home Square, Bardstown, KY 40004.

EXHIBIT A

40. Fresenius Medical Care NAK Berea, LLC., d/b/a Fresenius Medical Care NAK Berea and/or Fresenius Kidney Care NAK Berea, with its principal place of business located at 509 Richmond Road, Berea, KY 40403.

41. Fresenius Medical Care NAK Campbellsville, LLC., d/b/a Fresenius Medical Care of Campbellsville and/or Fresenius Kidney Care Campbellsville, 107 Medical Park Drive, Campbellsville, KY 42718.

42. Fresenius Medical Care NAK Elizabethtown, LLC., d/b/a Fresenius Medical Care Hardin County Suite, d/b/a Fresenius Kidney Care od Hardin County, 1324 Woodland Drive, Suite 8, Elizabethtown, KY 42701.

43. Fresenius Medical Care NAK Frankfort, LLC, d/b/a Fresenius Medical Care NAK Frankfort, LLC and/or Fresenius Kidney Care NAK Frankfort, 608 Chamberlin Avenue, Frankfort, KY.

44. Fresenius Medical Care NAK Lebanon, LLC, d/b/a Fresenius Medical Care Lebanon Marion County and/or Fresenius Kidney Care Lebanon Marion County, 703 E Main St., Lebanon, KY.

45. Fresenius Medical Care NAK Shepherdsville, LLC, d/b/a Fresenius Medical Care of Shepherdsville and/or Fresenius Kidney Care Shepherdsville, 421 Adam Shepherd Pkwy, Shepherdsville, KY 40165.

46. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, d/b/a Fresenius Medical NALCO Home Program, 1591 Winchester Road, Lexington, KY 40505.

47. Home Dialysis of Muhlenberg County, Inc., d/b/a Dialysis Specialist of Central City and/or Fresenius Kidney Care DS of Central City, 222 Phillip Stone Way, Central City, KY 42330.

48. Kentucky Renal Care Group, LLC, d/b/a Kentucky Renal Care Group Lexington North and/or Fresenius Kidney Care Lexington North, 1600 Leestown Road, Lexington, KY 40511.

49. Kentucky Renal Care Group, LLC, d/b/a Kentucky Renal Care Group Lexington South and/or Fresenius Kidney Care Lexington East, 1101 Winchester Road, Suite 100, Lexington, KY 40505.

50. NNA of Paducah, LLC, d/b/a FMC Trigg County and/or Fresenius Medical Care-Trigg County and/or Fresenius Kidney Care Trigg County, 2484 Main Street, Cadiz, KY 42211.

EXHIBIT A

51. NNA of Paducah, LLC, d/b/a RCG Kuttawa and/or Fresenius Kidney Care Kuttawa, 95 Lakeshore Drive, Kuttawa, KY 42055.

52. NNA of Paducah, LLC, d/b/a RCG Mayfield, and/or Fresenius Kidney Care Mayfield, 1029 Medical Center Circle, Suite 301, Mayfield, KY 42066.

53. NNA of Paducah, LLC, d/b/a RCG of Murray and/or Fresenius Kidney Care Murray Calloway, 609 S 12th Street, Murray, Kentucky 4207.

54. NNA of Paducah, LLC, d/b/a RCG Paducah and/or Fresenius Kidney Care Paducah, 1532 Lone Oak Road, Paducah, KY 42003.

55. NNA of Paducah, LLC, d/b/a RCG Paducah South and/or Fresenius Kidney Care Paducah South, 1061 Husbands Road, Paducah, KY 42003.

56. NRA-Georgetown, Kentucky, LLC d/b/a Georgetown Dialysis Clinic and/or Rai Care Center and/or Fresenius Medical Care/Georgetown Dialysis, 98 Mary Lynn Dr., Georgetown, KY 40324.

57. NRA-London, Kentucky, LLC, (individually "NRA-London" and collectively "Fresenius" with the other Defendants named d/b/a London Dialysis Clinic and/or Fresenius Medical Care London, 775 North Laurel Road, London, KY 40741.

58. NRA-Princeton, Kentucky, LLC, d/b/a Caldwell County Dialysis Center and/or Rai Care Center Jefferson-Princeton and/or Fresenius Medical Services Princeton, 401 S Jefferson St, Princeton, KY 42445.

59. RCG University Division, Inc., d/b/a Kentucky Renal Care Group Lexington South and/or Fresenius Kidney Care Lexington South, 171 Eagle Creek Drive, Lexington, KY 40511.

EXHIBIT A

Fresenius Medical Care Holdings, Inc. 9/15/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
One Montvale Avenue
Stoneham, Massachusetts
02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER

NWE-21-10W

VIA UPS Next Day Air

September 15, 2010

Mr. Rice Powell
Chief Executive Office
Fresenius Medical Care Holdings, Inc.
920 Winter Street
Waltham, MA 02451-1521

Dear Mr. Powell:

During an inspection of your firm located in Waltham, MA on June 15 through August 6, 2010, investigator(s) from the United States Food and Drug Administration (FDA) determined that your firm manufactures kidney dialysis products, including Optiflux Dialyzers and Liberty Cycler Sets. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h),

EXHIBIT B

these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. We received a response from Mr. Joseph P. Winslow, Vice President of Quality Systems, dated August 27, 2010 concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. We address this response below, in relation to the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain adequate procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a).

Liberty Cassettes:
Your firm failed to follow your health hazard assessment procedure in that you failed to identify any actions to reduce the risk of Liberty Cassettes in commercial distribution. Your firm investigated 118 complaints from January 2001 thru October 2009 of cassette leaks during patient hemodialysis treatments which included 6 MDRs and two confirmed cases of peritonitis. Your firm indentified a root cause, initiated shipping holds on existing inventory and ordered a product rework in November, 2009, but failed to identify an action to address units in commercial distribution.

Your documented health hazard assessment, conducted according to your procedure, determined the "level of concern" (hazard) to be critical (i.e. death or serious injury) and the "likelihood of occurrence" to be remote which produced a risk acceptability result of "undesirable". For this risk acceptability category your procedure requires that risk be reduced to as low as reasonably practical in order to continue operations. Actions were only identified for existing inventory. No actions were identified to reduce the risk of product in the field. During the inspection your firm indicated that a calculated turn over rate of **(b)(4)** weeks for the Liberty cassettes addressed the concern of product in the market, however the Agency disagrees that a turn over rate is an action to reduce known risk to patients.

2. Failure to establish procedures for investigating the cause of the nonconformities, as required by 21 CFR 820.100(a)(2).

Naturalyte Acid Concentrate products:
Fresenius complaint, PIR200701295, received in 2007 reported a patient suffered "symptomatic hypocalcemia with parethesias and tetani" after having used the wrong concentration of Naturalyte Acid Concentrate product which was delivered to their residence. The complaint documented the difficulty discerning between different concentrates of calcium values for this product and using it in error. The complaint also noted that this was the second instance in which the incorrect concentration of a Naturalyte Acid Concentrate product had been delivered to the patient. No investigation into product labeling was initiated.

EXHIBIT B

An investigation into to the root cause of product mix ups by the delivery and end user was not initiated for this PIR200701295. A review of complaints from January 2007 thru July 2010 revealed additional complaints regarding difficulty differentiating product by labeling. The additional complaints included, but are not limited to one stating the user facility had nearly used the wrong product (2010), and one stating the wrong product had been used in the past (2008). We did not observe an actual CAPA for this event.

3. Failure to establish and maintain an adequate corrective and preventive action procedure which ensures identification of actions needed to correct and prevent the recurrence of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(3).

Liberty Cassettes:
Your procedure for determining and identifying appropriate actions for product in commercial distribution is inadequate and lead to the failure to identify actions to address the risk of product in commercial distribution. The Product Assessment Report (PAR) documented that a field action was not required because the likelihood of occurrence was remote and the "severity" was determined to be "minor". Neither the term "severity" or "minor" are defined in either your "Health Hazard Assessment" procedure or your "Determining the Need for Remedial Product Action Level II" procedure used by your Product Assessment Committee to make this decision. Yet the decision against implementing a field action relied on the conclusion of a severity level of minor as documented in section 9.1 of the Product Assessment Report.

4. Failure to establish and maintain procedures for verifying or validating your corrective and preventive actions, to ensure that such action is effective and does not adversely affect the finished device, as required by 21 CFR 820.100(a)(4).

Liberty Cassettes:
Your firm failed to verify that the corrections, implemented to existing inventory to address leaks in the Liberty cassettes, were effective in addressing the nonconformity. After determining no field action was necessary for Liberty cassettes in commercial distribution your firm received 42 additional complaints, which included 2 MDRs with confirmed cases of peritonitis related to identified lots in commercial distribution.

Naturalyte Acid Concentrate products:
Your firm has not verified that labeling revisions to the Naturalyte Acid Concentrate product line have addressed the potential for product mix ups by the end user. No formal CAPA was opened for this issue, however your firm stated during the inspection that the changes were made to some labeling to address mixups such as in PIR200701295.

We have received your response to the FDA 483 dated August 27, 2010 which did contain proposed corrective actions to your CAPA system, and find it to be inadequate. We understand that on August 26, 2010, Fresenius initiated a voluntary recall of the 98 lots of Liberty Cassettes described above. We also acknowledge your plan to perform a thorough review of your CAPA and risk assessment procedures and to perform a retrospective review of all CAPA's.

EXHIBIT B

In response to this Warning Letter, please provide documentation of your revised procedures to demonstrate that they are capable in preventing these significant failures from recurring. These procedures need to clarify how hazard, likelihood, and final risk acceptability will be used in decision making and contain clear definitions for the terms used throughout your organization.

Also, we would like to review documentation of your CAPA review when complete. We are especially interested in your review of all the HHA's that were performed that resulted in a risk acceptability of "undesirable" to assure the actions identified were appropriate for product remaining on the market.

Your response indicated that Fresenius opened a CAPA 2010012 to document the investigation into labeling revisions. In response to this Warning Letter, please provide additional data on how your film is implementing effective labeling changes to prevent further mix-ups.

5. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a).

Naturalyte Acid Concentrate products:
For example, on June 09, 2009, your company received a complaint (PIR 200901506) regarding a possible dialyzer reaction incident that occurred on April 6, 2009 in which a dialysis patient experienced lose of pulse/consciousness and CPR was required. Related complaint, PIR 200901614 was received on June 10, 2010, and referenced a second occurrence of a possible dialyzer reaction on April 20, 2009 in which the patient loss consciousness again, and required CPR a second time. The patient ultimately died on May 08, 2009 due to coronary artery disease, end stage renal failure, and sepsis.

The second complaint was voided, contrary to your own SOP S100006-01, even though two events were clearly reported. The original complaint file was subsequently closed on July 17, 2009 without investigation to determine that the event was not reportable under 21 CFR Part 803. The file did not include any documentation that your devices did not cause the events described in the two separate incidents. We are concerned that you relied on your own internal assessment to make such a decision, without further investigation or contact with the complainant.

Also, your firm received a complaint on June 23, 2008 (PIR 200801118) involving Naturalyte products (08-4017) which indicated that since the labels look the same, "the wrong product actually has been used on one occasion". The complaint did not include any documentation that indicated an attempt was made to follow-up with the complainant to determine whether a patient reaction was involved.

You should take prompt action to correct the violation(s) addressed in this letter. Failure to promptly correct these violation(s) may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be

EXHIBIT B

approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violation(s), or similar violation(s), from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Upon further review of the inspectional findings, we are concerned with your firm's oversight of your contract manufacturers, specifically drug manufacturers. We understand that Fresenius has the responsibility for the final approval and release of finished products for distribution,including Phoslo gelcaps which are contract manufactured for Fresenius by **(b)(4)**. On at least two occasions, we observed the release of these above drug products that did not meet quality specifications.

- In one instance your firm was in receipt of OOS stability results for a lot of Phoslo gelcaps (#1308035) at three separate time points, (12, 15 and 18 months). Your investigation into these non-conforming reports concluded that no action to product in the field was necessary because the risk of hazard was "acceptable" and made a number of conclusions that do not appear to be based on sound scientific data. A thorough review of the contractor's investigation into these stability failures was also lacking.

- We also observed the commercial release of Phoslo gelcaps that were found to contain grease. This decision was made after a previous Fresenius PAR report indicated that the three finished lots were to be used by the contractor for stability purposes and would not be released for commercial distribution. This failure in oversight of your release decisions is very concerning. FDA considers contamination of finished drug products with foreign material (e.g., grease) a significant product quality issue.

We understand that you have initiated a recall of two lots of Phoslo gelcaps (#1308035 and #1308039) that had failing stability results. We also note that you have terminated your business with the contract manufacturer of this product. In your response to this item, please address how your firm plans to prevent these types of failures from recurring with other contract manufacturers.

Please direct your response or any questions you may have to Karen Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180. Her telephone number is (781) 596-7707.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violation(s) at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violation(s) noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violation(s) and to bring your products into compliance.

EXHIBIT B

Sincerely,

/s/

Mufahar S. Shamsi
Acting District Director
New England District

Close Out Letter

- Fresenius Medical Care Renal Therapies Group, LLC - Close Out Letter 11/5/15 (/ICECI/EnforcementActions/WarningLetters/2015/ucm471573.htm)

More in Warning Letters (/ICECI/EnforcementActions/WarningLetters/default.htm)

2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)

2015 (/ICECI/EnforcementActions/WarningLetters/2015/default.htm)

2014 (/ICECI/EnforcementActions/WarningLetters/2014/default.htm)

2013 (/ICECI/EnforcementActions/WarningLetters/2013/default.htm)

2012 (/ICECI/EnforcementActions/WarningLetters/2012/default.htm)

2011 (/ICECI/EnforcementActions/WarningLetters/2011/default.htm)

2010 (/ICECI/EnforcementActions/WarningLetters/2010/default.htm)

2009 (/ICECI/EnforcementActions/WarningLetters/2009/default.htm)

2008 (/ICECI/EnforcementActions/WarningLetters/2008/default.htm)

2007 (/ICECI/EnforcementActions/WarningLetters/2007/default.htm)

2006 (/ICECI/EnforcementActions/WarningLetters/2006/default.htm)

2005 (/ICECI/EnforcementActions/WarningLetters/2005/default.htm)

Tobacco Retailer Warning Letters (/ICECI/EnforcementActions/WarningLetters/Tobacco/default.htm)

EXHIBIT B

Fresenius Medical Care

Internal Memo

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

To: Medical Directors and Attending Physicians

From: FMS Medical Office

Date: November 4, 2011

Re: Dialysate Bicarbonate, Alkalosis and Patient Safety

Conclusion:

Recent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration. As recommended in previous communications, physicians should individualize dialysate bicarbonate and total buffer prescriptions. We further recommend that pre-dialysis serum bicarbonate level of >24 mEq/L should prompt immediate review of dialysate bicarbonate prescription.

Summary of findings:

- In September, 2011 the mean pre-dialysis bicarbonate level for FMCNA was 24.1±3.4 mEq/L, with over 25% of patients at ≥26.0 mEq/L, 15% with ≥28.0 mEq/L and 3% with ≥30.0 mEq/L.

- Over time, the progressive shift towards higher ***pre-dialysis*** serum bicarbonate levels not only implies that more patients have alkalosis prior to dialysis, but that an even higher percentage of patients have alkalosis post-dialysis.

- The current analysis determined that: "*borderline elevated pre-dialysis bicarbonate levels and overt alkalosis are significantly associated with 6 to 8 fold greater risk of CP arrest and sudden cardiac death in the dialysis facility*".

- In light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate level of >24 mEq/L.

- The bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate – *by ~8 mEq/L in the case of dialysate prepared from Granuflo (powder) or by ~4 mEq/L in the case of dialysate*

EXHIBIT C

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

Background:

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

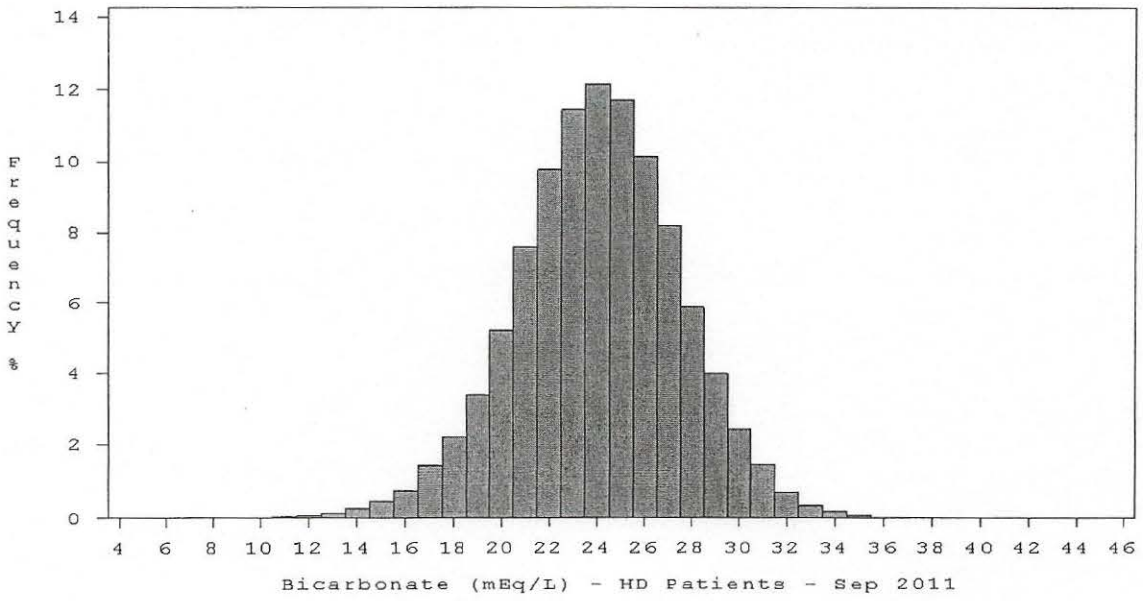


Figure 1. Distribution of pre-dialysis serum bicarbonate for the month of September, 2011.

EXHIBIT C

Fresenius Medical Care

Internal Memo

Date: 11/4/2011

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

FMCNA Analysis:

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

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

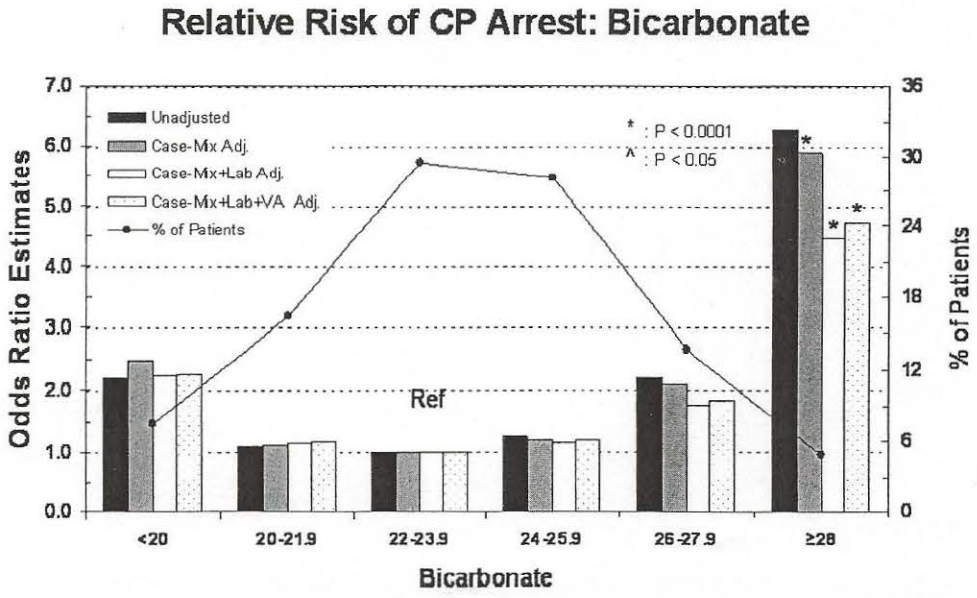


Figure 2. Relative risk associated with pre-dialysis serum bicarbonate categories.

EXHIBIT C

Fresenius Medical Care

Internal Memo

Date: 11/4/2011

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

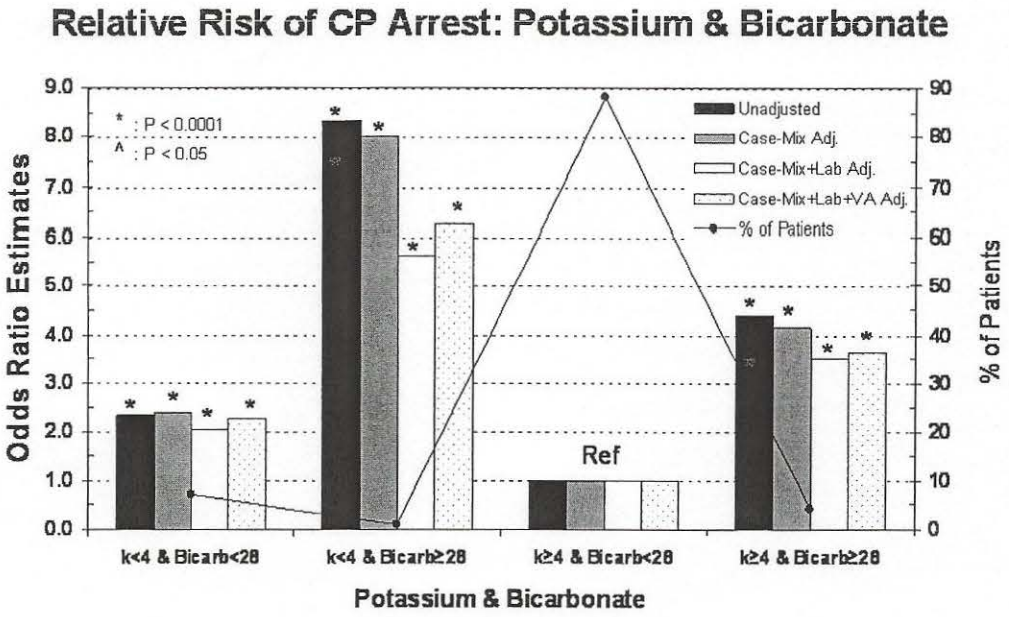


Figure 3. Relative risks associated with 4 combinations of bicarbonate and potassium categories.

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

Recommendations:

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

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

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

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

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

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

EXHIBIT C

Reference List

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

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

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

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

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

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

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

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

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

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

EXHIBIT C

Fresenius Medical Care

*** Important Prescribing Information ***

NaturaLyte Liquid and Granuflo Acid Concentrate

Bicarbonate Alkalosis

DATE: **March 29, 2012**

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

PRODUCT CODES: See Attached

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

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

Previous reports have identified an association between elevated pre-dialysis bicarbonate levels and an increased mortality risk.[1,2,3,4] Recent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. A major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration.

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

EXHIBIT D

Fresenius Medical Care

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

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

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

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

The FDA has been advised of this product notification

Sincerely,

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

Enclosure:
Reply Form

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

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

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

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

EXHIBIT D

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Fresenius Medical Care North America, Naturalyte and Granuflo Acid Concentrate

Recall Class: Class I

Date Recall Initiated: March 29, 2012

Product: Naturalyte and Granuflo Acid Concentrate

Serial numbers for Naturalyte Liquid Acid Concentrate range from:

08-0231-4, 08-1001-0, 08-1201-8, 08-1231-3, 08-1251-1, 08-1301-4, 08-2201-5, 08-2231-2, 08-2251-0, 08-2301-3,08-2351-8, 08-3201-4, 08-3231-1, 08-3251-9, 08-3301-2, 08-4123-1, 08-4223-7, 08-4225-1, 08-4230-2, 08-4231-0, 08-4323-5, 08-4325-1, 13-1251-1, 13-2201-5, 13-2231-2, 13-2251-0, 13-3231-1, 13-3251-9, 13-4123-1, 13-4220-1, 13-4225-1, 13-4325-1

Serial numbers for Naturalyte GranuFlo (powder) Acid Concentrate range from:

OFD1201-3B, OFD1251-3B, OFD2123-3B, OFD2201-38, OFD2220-3B, OFD2223-3B, OFD2225-3B, OFD2231-3 B, OFD2251-3B, OFD2301-3B, OFD2323-3 B, OFD2325-3B, OFD3201-3B, OFD3231-3B, OFD3251-3B, OFD3301-3B

This concentrate was manufactured and distributed from January 2008 through June 2012.

Use: The Naturalyte and Granuflo Dry Acid Concentrate are used in the treatment of acute and chronic renal failure during hemodialysis. The concentrate is formulated to be used with a three-stream hemodialysis machine, which is calibrated for acid and bicarbonate concentrates.

Recalling Firm:

Fresenius Medical Care North America
920 Winter Street
Waltham, MA 02451

Reason for Recall:

The manufacturer is cautioning clinicians to be aware of the concentration of acetate or sodium diacetate (acetic acid plus acetate) contained in Fresenius' Naturalyte Liquid and Granuflo Dry Acid Concentrate. Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may

EXHIBIT E

contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest. This product may cause serious adverse health consequences, including death.

FDA has issued a general safety communication related to inappropriate prescription and resultant alkali dosing errors in the dialysate concentrates used in hemodialysis.

Public Contact:

Consumers may contact the firm at 1-800-662-1237.

FDA District: New England District Office

FDA Comments:

On March 29, 2012, the firm sent an Urgent Product Notification to their clinics and customers. This notification provided clinicians with prescribing information regarding the Naturalyte Liquid and Granuflo Acid Concentrate.

Class I 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 serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)** either online, by regular mail or by FAX.

Additional Links:

- **FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm305477.htm)**
- **Firm Urgent Product Notification (http://www.fmcna.com/fmcna/idcplg?IdcService=GET_FILE&allowInterrupt=1&RevisionSelectionMethod=LatestReleased&Rendition=Primary&dDocName=PDF_300045654)**

EXHIBIT E

Class 1 Device Recall Fresenius GranuFlo (powder) Acid Concentrate

New Search Back to Search Results

Class 1 Device Recall Fresenius GranuFlo (powder) Acid Concentrate

See Related Information[22]

Date Posted	June 25, 2012
Recall Status[1]	Open
Recall Number	Z-1827-2012
Recall Event ID	62108[23]
510(K)Number	K030497[24]
Product Classification	Dialysate concentrate for hemodialysis (liquid or powder)[25] - **Product Code** KPO[26]
Product	Fresenius GranuFlo (powder) Acid Concentrate Product Codes: OFD1201-3B, OFD1251-3B, OFD2123-3B, OFD2201-3B, OFD2220-3B, OFD2223-3B,OFD2225-3B, OFD2231-3B, OFD2251-3B, OFD2301-3B, OFD2323-3B, OFD2325-3B, OFD3201-3B, OFD3231-3B, OFD3251-3B, OFD3301-3B. For the treatment of acute and chronic renal failure during hemodialysis procedure.
Code Information	All lots
Recalling Firm/ Manufacturer	Fresenius Medical Care Holdings, Inc. 920 Winter St Waltham MA 02451-1521
For Additional Information Contact	800-662-1237
Manufacturer Reason for Recall	Risk of Alkalosis with acetate containing dialysis acid concentrates
FDA Determined Cause [2]	Labeling False and Misleading
Action	Fresenius Medical Care sent an "IMPORTANT PRESCRIBING INFORMATION" letter dated March 29, 2012 to all affected customers. The letter identifies the product, problem, and actions to be taken by the customers. A Reply Form was enclosed for customers to complete and return via fax to 781-699-9635. Contact Customer Service at 1-800-323-5188 or Medical Information at 1-855-616-2309 for questions regarding this recall.
Distribution	Nationwide Distribution and the country of Guam.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = KPO and Original Applicant = FRESENIUS MEDICAL CARE[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=62108
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K030497
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KPO
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KPO
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=KPO
28. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=KPO&knumber=&applicant=FRESENIUS%20MEDICAL%20CARE

Page Last Updated: 05/06/2016

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA