IN THE UNITED STATES DISTRICT COURT,
SOUTHERN DISTRICT OF OHIO,
EASTERN DIVISION (COLUMBUS)

DEBORAH SWIGERT AND AARON W. PORTERFIELD, AS ADMINISTRATOR OF THE ESTATE OF CHARLES M. SWIGERT, DECEASED, *Plaintiffs* *vs.* FRESENIUS USA, INC.; FRESENIUS, USA MANUFACTURING, INC.; FRESENIUS MEDICAL CARE HOLDINGS, INC.; FRESENIUS MEDICAL CARE NORTH AMERICA, INC.; FRESENIUS USA MARKETING, INC.; AND FRESENIUS SE & CO., KGAA, *Defendants.*	:	**Case No. _____** **COMPLAINT AND JURY DEMAND**

NOW COMES the Plaintiffs, by and through undersigned counsel, and for their causes of action, hereby bring this Complaint for damages against the Defendants named in the above styled matter and allege the following:

I. INTRODUCTION

A. SUMMARY OF THE ACTION

1. This is a product liability action relating to Defendants' design, manufacture and sale of GranuFlo® and NaturaLyte®, medical products used in the dialysis process.

2. Decedent, Charles Swigert, underwent dialysis at a Fresenius dialysis center where they dispensed Defendants' GranuFlo® or NaturaLyte® product. During the dialysis process, Mr. Swigert suffered cardiac arrest and was taken by ambulance to a local hospital. Despite heroic efforts, Mr. Swigert died

before reaching his 57th birthday, leaving behind his wife, Deborah Swigert, and their two children.

3. His death was an avoidable tragedy, a direct result of Defendants' refusal to conduct a single safety study, Defendants' suppression of clinical data revealing life-threatening risks, and Defendants' flagrant disregard for safety by failing to disclose the risks to health care providers.

4. Despite being aware of research and clinical reports that foretold of these risks and evidenced that Defendants' product formulation was flawed and that their warnings and instructions were inadequate, Defendants disregarded, and even suppressed, the risks to the detriment of thousands of dialysis patients, including the Decedent.

5. Mr. Swigert's widow, Deborah Swigert, individually, along with Aaron W. Porterfield as Administrator of Mr. Swigert's estate, bring these claims for personal injuries, damages, and death caused by Defendants' product, GranuFlo® and/or NaturaLyte®.

B. BACKGROUND CONCERNING DEFENDANTS' PRODUCT

6. Dialysis is required for people who have impaired or non-functioning kidneys. Patients receiving dialysis have a condition called acidosis, which is a buildup of acid in their blood. Dialysis corrects this condition by neutralizing or buffering the excessive acid through use of bicarbonates, an alkaline (a base, the opposite of an acid) used by the kidneys as part of the body's natural process of neutralizing accumulated acids.

7. The dialysis process uses a solution, dialysate, which is a mixture of three

fluids including bicarbonate concentrate and acid concentrate. These levels must be carefully controlled to ensure that the patient's pH level remains stable.

8. Without sufficient scientific testing and while disregarding various safety signals, Defendants formulated a new dialysate product and introduced it to the market in 2003. There are two sources of bicarbonate in the product – bicarbonate from the concentrate, which passes into the blood, and acetate in the acid concentrate. While in the patient's blood, the acetate coverts rapidly into additional bicarbonate.

9. The term "total buffer" encompasses for this "double delivery" of bicarbonate. It accounts for the direct bicarbonate plus the converted bicarbonate from the acetate in the dialysate. Physicians prescribe a patient-specific dialysate bicarbonate level and total buffer level that are controlled and monitored by settings and readings on the dialysis machines.

10. Because of Defendants' product's unique formulation, the effects of the acetate in the acid concentration are different from what medical providers anticipated. As an illustration, Defendants' formulation uses sodium diacetate, which **doubles the amount of acetate in dialysate** compared to pre-existing alternative formulations with acetic acid. This increased the amount of bicarbonate, causing dangerous pH levels in the blood, resulting in a precipitous drop in blood pressure, and ultimately leading to sudden cardiac arrest, as happened to Mr. Swigert.

11. For years before Mr. Swigert's use of Defendants' product, Defendants were

aware that nephrologists, dialysis nurses and technicians, physicians, and patients were not properly educated, trained, or informed about the acetate, acetic acid, and/or citrate levels in their dialysis concentrates and the need to consider the impact of these substances when ordering or administering patients' dialysate prescriptions. These individuals were unaware that the dialysate acid concentrate contained acetic acid, acetate, or citrate and that these substances convert in the body to bicarbonate, thereby contributing to metabolic alkalosis, a significant risk factor associated with cardiac arrest.

12. Moreover, they were unaware that Defendants' product delivers additional acetate that converts to bicarbonate in patients' bodies during dialysis. Additional calculations were therefore necessary to determine the total buffer that accounts for the extra bicarbonate. Further, dialysis machines displayed a bicarbonate value that did not reflect the right total buffer value; it represented only the bicarbonate level in the dialysate **NOT** the 4 mEq/L acetate delivered by the liquid acid solution in NaturaLyte® or the 8 mEq/L delivered by the GranuFlo® acid powder. As a result, default settings on the dialysis machines had to be changed and the product mixture had to be reconfigured in order to accommodate the unusual formula. None of this occurred. Thus, Defendants were aware patients were receiving more bicarbonate than their doctors had prescribed, which proved to be a deadly condition for Mr. Swigert and thousands of others.

13. With full knowledge of these grave safety risks and despite expressly admitting in their own internal discussions over several years the need for

remedial action, Defendants' flagrantly disregarded patient safety by doing almost nothing about these concerns. Defendants should have informed users of these risks, properly trained medical providers and staff, and modified their dialysis products to account for the necessary calculation and prevent user error. Had they, Mr. Swigert would be alive today.

C. JURISDICTION AND VENUE

14. At all times relevant to this action Decedent, Charles Swigert, was a United States citizen and resident of Fayette County, Ohio.

15. Decedent's widow, Plaintiff Deborah Swigert, is a United States citizen and a resident of Fayette County, Ohio.

16. Decedent's estate, administered by Aaron Porterfield, a United States Citizen who opened the estate in Fayette County, Ohio.

17. Defendant, Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America ("FMCNA"), is a corporation organized and existing under the laws of New York with its principal place of business located at 95 Hayden Avenue Lexington, Massachusetts 02420. FMCNA is the country's leading full-service provider of dialysis care. FMCNA, through various affiliates, treats approximately 79,600 patients in its approximately 1080 U.S. dialysis clinics, some of which are located in this district. At all times relevant, FMCNA, regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

18. Defendant, Fresenius Medical Care North America, Inc. ("FMCNA") is a

corporation organized and existing under the laws of the state of Massachusetts with its principal place of business at 920 Winter Street Waltham, Massachusetts 02451. At all relevant times, FMCNA regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

19. Defendant, Fresenius USA, Inc. ("FUSA") is, and at all times herein mentioned was, a corporation organized and existing under the laws of Massachusetts. FUSA is a wholly owned subsidiary of Fresenius Medical Care AG & Co. KGaA. At all times relevant, FUSA regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

20. Defendant, Fresenius USA Manufacturing, Inc. ("Fresenius Manufacturing") is a corporation of the state of Delaware with its principal place of business at 920 Winter Street Waltham, Massachusetts 02451. At all relevant times, Fresenius Manufacturing was in the business of promoting, manufacturing, labeling, and distributing NaturaLyte® Liquid and Granuflo® Acid Concentrates. Defendant does business throughout the United States and at all relevant times hereto, regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

21. Defendant, Fresenius USA Marketing, Inc. ("Fresenius Marketing") is a foreign corporation authorized to transact business in Plaintiffs' state of residence. Fresenius Marketing is a wholly owned subsidiary of Fresenius Medical Care AG & Co. KGaA. At all times relevant hereto, Fresenius Marketing regularly and continuously did business within regularly and continuously did business within this judicial district including, designing, testing, manufacturing, marketing, advertising, promoting, selling, and/or distributing GranuFlo® and/or NaturaLyte®.

22. Upon information and belief, each Defendant is a wholly owned subsidiary of Fresenius Medical Care AG & Co. KGaA.

23. At all relevant times each Defendant acted in all aspects as agent and alter ego of for each corporate entity and as agent and alter ego of Fresenius Medical Care AG & Co. KGaA.

24. This Court has personal jurisdiction over the Defendants. At all times material hereto, the Defendants maintained systematic and continuous contacts in this judicial district, regularly transact business within this judicial district, and regularly avail themselves of the benefits of this judicial district. The Defendants also have employed people and received substantial revenue in this judicial district.

25. Fresenius Medical Care is a publicly traded company with net revenue of $12,795 million dollars in 2011 and $12,053 million dollars in 2010. Fresenius is the world's largest integrated provider of products and services for individuals undergoing dialysis. "Through its network of 3,123 dialysis

clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 256,456 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products."

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

27. Defendants are subject to personal jurisdiction in this Court pursuant to Ohio Revised Code Section 2307.382(A)(1)-(8), Federal Civil Rule 4 and 28 U.S.C. Section 115(b)(2).

28. This matter is properly venued in this Court pursuant to 28 U.S.C. Section 1391(b)-(d), (g) and Southern District of Ohio Local District Court Rule 82.1(b).

II. COMMON FACTUAL ALLEGATIONS APPLICABLE TO EACH CAUSE OF ACTION

A. Decedent Charles Swigert's Use of GranuFlo® and/or NaturaLyte®

29. On November 11, 2010, Decedent's physician prescribed dialysis for Mr. Swigert. He received his dialysis treatment at the Fresenius Medical Care in Washington Court House, Ohio.

30. Mr. Swigert received patient acknowledgment of risks and informed consent forms. Those forms did not disclose any risks related to the allegations made

herein.

31. On that day, the technicians connected Mr. Swigert to the dialysis machine. Defendants' GranuFlo® and/or NaturaLyte® were used in the dialysis treatment.

32. While the dialysis treatment was being performed, Mr. Swigert and his wife met with a social worker, dietician, and physician, who checked Decedent's heart and lungs. A nurse informed Decedent's wife that she would be taking Mr. Swigert off the dialysis machine in 15 minutes.

33. Minutes later, Mr. Swigert suffered a cardiac arrest. An ambulance took Mr. Swigert to Fayette Memorial Hospital in Washington Court House. Despite life saving efforts, Decedent died on or about November 11, 2010.

34. As a direct and proximate result of Defendants' conduct described herein, the product Decedent received caused the injuries and damages alleged herein, including but not limited to his wrongful death.

35. When Decedent received the product, neither its label, packaging, instructions, nor any other product related information, provided adequate instructions and/or warnings regarding its proper and safe the use.

36. Decedent would not have used the product had Defendants properly disclosed the risks of serious injury and/or death associated with and/or caused by it.

37. The persons involved in Decedent's treatment would not have approved, purchased, and/or used the product had Defendants properly disclosed the risks of serious injury and/or death associated with and/or caused by it.

B. Background Facts Regarding GranuFlo® and/or NaturaLyte®.

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

39. FMC has a vertically integrated business. It owns thousands of dialysis clinics and manufactures the machines and nearly all the medical products used in dialysis including dialyzers, blood lines, needles, and dialysis concentrate.

40. The Fresenius products division sells products to its own clinics and to many of its leading competitors, including DaVita, DCI, and Renal Ventures.

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

42. Defendants never communicated this increased buffer level information to treating clinicians, physicians, nurses, or technicians nor that it could lead to significantly increased bicarbonate levels and the associated risks of heart attack, cardio pulmonary arrest, and/or sudden cardiac death.

43. Lacking clinical knowledge, as well as a lack of effective product-related labeling, warning, and instruction from Defendants, caused these individuals to provide hemodialysis treatments in an unsafe and ineffective manner.

44. Before Decedent received Defendants' product, Defendants, through their agents, officers, directors and employees had notice and knowledge of the

increased risk of death and cardiovascular injuries.

45. Regardless, Defendants knowingly and deliberately failed to warn Decedent or healthcare personnel properly of the increased risks.

46. The Defendants intentionally proceeded with the manufacturing, marketing, advertising, sale and distribution of GranuFlo® and NaturaLyte® knowing that patients and consumers would be exposed to serious injury and death.

47. Defendants' executives knew of the risks since the product's introduction.

48. Even after the clinical crisis was irrefutable by no later than 2010, they chose not to properly report this problem. They intentionally withheld the information from non-Fresenius physicians and clinics using the product.

49. Based on information and belief, there was collusion involving individuals in several Fresenius departments and organizations to hide, mislead, and obscure information about the extreme patient safety hazards associated with the use of the product to maintain their market share and minimize legal risks. Hence, the conduct described herein occurred with Defendants' officers', directors', and managing agents' knowledge, authorization, and ratification.

50. Ultimately, when the correlation between the use of GranuFlo® and NaturaLyte® and the increased risk of alkalosis and cardiopulmonary arrest was inescapable, Defendants chose to make this information and urgent medical recommendations solely available to their own physicians and clinics.

51. An internal memo from Fresenius dated November 4, 2011 indicated Defendants long knew of the significant increased risk of cardiac arrest and death during hemodialysis treatments associated their product.

52. The memo recommended action for patients with pre-dialysis bicarbonate levels of >28mEq/L and especially for those who also had pre-dialysis serum potassium levels of <4 mEq/L.

53. It admitted that, "[r]ecent analyses performed using FMCNA hemodialysis (HD) patient safety data confirms that alkalosis is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia" and that the major cause of metabolic alkalosis in dialysis patients [wa]s inappropriately high dialysate total buffer concentrate."

54. It acknowledged that GranuFlo® use was associated with increased serum bicarbonate levels and alkalosis, as well as the increased possibility of cardiopulmonary arrests. It observed that Defendants' patients' serum pre-dialysis bicarbonate levels had gradually increased from 2004 to 2011.

55. It stated in its "summary of findings" that: "The current analysis determined that: *"borderline elevated pre-dialysis bicarbonate levels and over alkalosis are significantly associated with 6 to 8 fold greater increase of cardiopulmonary 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." (emphasis in original). The memo further urges that this dangerous issue "needs to be addressed urgently."

56. Defendants circulated this memo internally only. Thus, for at least 15 months,

they did not share this information with the thousands of non-Fresenius physicians and clinics that were using GranuFlo® and NaturaLyte®.

57. Despite Defendants' knowledge of this serious safety risk, they actively converted more non-Fresenius clinics to the product and continued aggressively marketing the product through various methods including routinely bundling it with other Fresenius products for pricing discounts.

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

59. On March 27, 2012, Fresenius received an inquiry from the FDA specifically about the risks associated with using GranuFlo® and NaturaLyte®.

60. Only then, on or about March 29, did Defendants provide a scientifically ambiguous 2-page memorandum containing far less actionable information to non-Fresenius customers. It did not mention any patient blood levels and failed to discuss the most at-risk population of all, "acute" dialysis patients. It contained only one of the ten references included in the November memo.

61. The tortious actions and misdeeds of the Defendants as alleged herein are ongoing and at all times relevant hereto were ongoing and continuous torts.

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

63. Defendants intentionally ignored and/or withheld information regarding the

increased risks of serious injury and death associated with and/or caused by GranuFlo® and NaturaLyte® at the time Defendants manufactured, marketed, advertised, promoted, sold and distributed the products.

64. Defendants knew that if they disclosed such increased risks, patients and healthcare providers would not purchase GranuFlo® and NaturaLyte®.

65. Defendants' conduct was wanton and willful, and displayed a flagrant disregard for the safety of the public and particularly of Decedent.

III. CAUSES OF ACTION

COUNT I

Inadequate Warnings and Instructions Pursuant to the Ohio Product Liability Act ("OPLA"), Ohio Revised Code §§ 2307.76

66. Plaintiffs incorporate by reference every paragraph of this Complaint as though set forth in full in this cause of action.

67. Defendants at all relevant times designed, developed, formulated, tested, produced, constructed, created, assembled manufactured, packaged, marketed, advertised, distributed, promoted, and sold GranuFlo® and NaturaLyte®, placing the product into the stream of commerce.

68. Defendants knew or in the exercise of reasonable care should have known at the time of marketing and when the product left Defendants' control about the risks of death and serious injury associated with and caused by the product that harmed Decedent, including that bicarbonate induced alkalosis could cause a dialysis patient's blood pressure to plummet leading to cardiac arrest and stroke.

69. Defendants knew or in the exercise of reasonable care should have known at

the time of marketing and when the product left their control that nephrologists, nurses, technicians, physicians, and patients were not properly trained or informed about the acetate, acetic acid, and/or citrate levels in their dialysis concentrates and the need to consider the impact of these substances when ordering or administering patients' dialysate prescriptions.

70. Defendants knew or in the exercise of reasonable care should have known at the time of marketing and when the product left Defendants' control that these individuals were unaware that the dialysate acid concentrate contained acetic acid, acetate, or citrate and that these substances convert in the body to bicarbonate, thereby contributing to metabolic alkalosis, a significant risk factor associated with cardiac arrest.

71. Defendants knew or in the exercise of reasonable care should have known at the time of marketing and when the product left their control that these individuals were unaware of the defective formulation and were insufficiently informed that Defendants' product delivers additional acetate; thus, patients were not receiving the treatment prescribed due to the type of acid in Defendants' concentrates on dialysate buffer.

72. Defendants knew or in the exercise of reasonable care should have known at the time of marketing and when the product left their control that these individuals were unaware that dialysis machines displayed a bicarbonate value that did not reflect the total buffer value; instead, only the bicarbonate level in the dialysate, **NOT** the 4 mEq/L acetate delivered by the liquid acid solution in NaturaLyte® or 8 mEq/L delivered by the GranuFlo® acid powder.

73. Defendants knew or in the exercise of reasonable care should have known at the time of marketing and when the product left their control that changing dialysate concentrations presented increased risks and required additional calculations and changes to the dialysis machines. Changing from NaturaLyte® acid concentrate to GranuFlo®, for example, can change the bicarbonate prescription to alter the total delivered buffer up to 4 mEq/L.

74. Defendants knew or in the exercise of reasonable care should have known at the time of marketing and when the product left their control that additional calculations were necessary, changes to the product mixture were necessary to deliver safe dialysate levels to patients, and changes to calculate the total buffer and to the dialysis machines' default settings were required; however, this never happened as Defendants refused to provide complete information, adequate product formulation, and proper warnings and instructions.

75. Defendants failed to provide the warnings or instructions that a manufacturer exercising reasonable care would have provided concerning the risks described herein in light of the likelihood that the product would cause the harm for which Plaintiffs seek recovery and in light of its likely seriousness.

76. Defendants' internal data; prior product experience; information learned during product development; internal adverse event reports; adverse event reports available through FDA; and the body of research concerning acetates, dialysis, clinical reports, and related to the product and substances at issue, all extending over decades, foretold of the risks.

77. A reasonably prudent company in Defendants' position would have conducted

safety tests to formulate the product properly, identify these risks and proper ways to warn consumers and the medical community and staff, and to instruct them properly to avoid these risks.

78. The risks described herein are those that Defendants should have recognized while exercising the attention, perception, memory, knowledge, and intelligence that a reasonable manufacturer should possess and in light of Defendants' superior attention, perception, memory, knowledge, and intelligence that they possessed given their decades of industry experience, resources, prior experience, access to data, capabilities, and intimate involvement with the product and industry.

79. Defendants failed to provide the warnings, instructions, and training that a manufacturer exercising reasonable care would have provided concerning the risks, in light of the likelihood the product would cause the harm for which Plaintiffs seek recovery and in light of the likely seriousness of that harm.

80. Defendants' product is unreasonably dangerous, even when used in a foreseeable manner as designed and intended by Defendants.

81. Decedent did not have the same knowledge as Defendants and no adequate warning was communicated to Decedent.

82. Defendants had a continuing duty to warn and instruct users of increased health risks associated with their products, but failed to do so by:

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

b. Failing to provide adequate and/or proper instructions regarding the proper use of GranuFlo® and NaturaLyte®;

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

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

e. Failing to inform Decedent that the clinicians, nurses, and/or physicians were not adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective; and

f. Failing to educate and instruct users about the unique characteristics of their product and the proper way to administer it and operate the dialysis machines.

83. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent sustained injuries and damages alleged herein.

84. Defendants fraudulently and in violation of applicable industry standards withheld known to be material information relevant to the harm that the Decedent suffered and misrepresented this information by omitting the risks and proper uses from their marketing, website, patient, and clinical materials, including Defendants' acknowledgment of risks and informed consent forms.

85. Defendants knew and should have known of the risks had they exercised

reasonable care in the design, manufacture, research and development, testing, processing, advertising, marketing, labeling, formulation, packaging, distribution, promotion, and sale of the product, but Defendants failed to act as they should have under the circumstances in the following ways:

a. failing to test GranuFlo® and NaturaLyte® properly and thoroughly before releasing the products on the market;

b. failing to test GranuFlo® and NaturaLyte® properly and thoroughly after releasing the products on the market and learning of safety issues;

c. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of GranuFlo® and NaturaLyte®;

d. failing to analyze and report data resulting from pre- and post-marketing tests of GranuFlo® and NaturaLyte® which indicated risks associated with using the products;

e. failing to conduct adequate post-market monitoring and surveillance of GranuFlo® and NaturaLyte®;

f. failing to conduct adequate analysis of adverse event and clinical reports;

g. designing, manufacturing, marketing, advertising, distributing, formulating, training, and selling GranuFlo® and NaturaLyte® to consumers, including Decedent, without proper and/or adequate instructions to avoid the harm which could foresee ably occur as a result of using the products;

h. failing to use due care in the preparation and development of GranuFlo® and NaturaLyte® to prevent and/or avoid and/or minimize the risk of injury and/or death to individuals when the products were used;

i. failing to use due care in the design of GranuFlo® and NaturaLyte® to prevent and/or avoid and/or minimize the risk of injury and/or death to individuals when the products were used;

j. failing to conduct adequate pre-clinical testing and research to determine the safety of GranuFlo® and NaturaLyte®;

k. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing;

l. failing to use due care in the promotion and education of GranuFlo® and NaturaLyte® to prevent the risk of injuries to individuals when the products were used in dialysis despite recognizing the shortcomings in users' knowledge and practices;

m. failing to educate non-defendant healthcare providers and the public about the safest use of the products;

n. failing to utilize and implement a reasonably safe design in the manufacture of GranuFlo® and NaturaLyte®;

o. failing to manufacture GranuFlo® and NaturaLyte® in a reasonably safe condition;

p. failing to design and modify the dialysis devices to account for the product's unique formulation; and

q. failing, through adequate training, instruction, monitoring, supervision, and hiring principles, to ensure that their clinicians, nurses, contractors, employees, users, and physicians properly knew how to use all hemodialysis products in a safe and effective manner.

86. As a direct and proximate cause of Defendants' inadequate warnings and instructions, Plaintiffs suffered the injuries and damages alleged herein.

COUNT II

Defective Manufacturing Pursuant to OPLA 2307.74

87. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

88. GranuFlo® and NaturaLyte® contained manufacturing defects in that each product caused and/or increased the risk of experiencing an adverse cardiovascular event, including but not limited to death, sudden cardiac death, heart attack, cardiac arrest, and/or congestive heart failure.

89. Defendants' product was defective in manufacture and construction because, when it left Defendants' control, it materially differed and deviated from Defendants' design specifications, formula, and performance standards.

90. Defendants' product also deviated from industry standards.

91. Defendants' specifications, formulas, and performance standards required the product to be safe.

92. As a direct and proximate cause of Defendants' defective manufacture, Plaintiffs suffered the injuries and damages alleged herein.

COUNT III

Defective Design and Formulation Pursuant to OPLA 2307.75

93. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

94. Defendants' product was defective in design and formulation because of its use of sodium diacetate, which doubles the amount of acetate in the dialysate compared to existing alternative formulations using acetic acid. This increased

the bicarbonate, resulting in dangerous pH levels in the blood, leading to a precipitous drop in blood pressure, and causing sudden cardiac arrest.

95. GranuFlo® and NaturaLyte® were expected to reach, and did reach, users and/or consumers, including Decedent, without substantial change in their defective and/or unreasonably dangerous condition.

96. Defendants' product that Decedent received was used in the foreseeable manner Defendants intended, recommended, promoted, and/or marketed.

97. GranuFlo® and/or NaturaLyte® were defective and unreasonably dangerous when each entered the stream of commerce as the foreseeable health risks associated with their design or formulation exceeded the benefits associated with that design or formulation in one or more of the following:

a. Each carried an unreasonable and unnecessary risk of serious injury and death, but were marketed and promoted for use in hemodialysis treatment;

b. Each were insufficiently and/or inadequately tested by the Defendants;

c. Each failed to perform safely and as expected when used in dialysis treatment provided to ordinary consumers, including Decedent;

d. As designed, the risks serious injury and/or death posed by using each product exceeded any benefits they were designed to or might bestow;

e. Each were dangerous to an extent beyond that contemplated by ordinary and foreseeable users, consumers, and patients, including Decedent; and

f. Each was unsafe for normal or reasonably anticipated use.

98. As a direct and proximate cause of the defective and/or unreasonably dangerous condition of Defendants' product, Plaintiffs suffered the injuries

and damages alleged herein.

COUNT IV

Failure to Conform to Representations and Warranties Pursuant to OPLA 2307.77

99. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

100. At all times relevant here, Defendants materially misrepresented and omitted complete and accurate information in their products' labeling, advertising, marketing, sales and marketing persons, seminars, publications, notices, oral promotional efforts, websites, product information, training, and clinical forms, including acknowledgment of risks and informed consent forms.

101. Defendants expressly and/or impliedly represented to Decedent and his medical providers that use of Defendants' product was safe for use, including as instructed, during dialysis treatment.

102. On the day Decedent received dialysis and prior to, Defendants misrepresented that GranuFlo® and NaturaLyte® were as safe, and/or safer than other similar products used in dialysis treatment.

103. In the materials Decedent and his providers received prior to his dialysis use in November 2011, Defendants represented that their warnings, instructions, training, and product information were complete and sufficient.

104. At all times, Defendants represented on their website and other mediums that they would "deliver the highest quality care with respect and compassion."

105. At all times, Defendants represented on their website and via other mediums that they would "treat [Decedent] well—to help [him] feel better.

106. Defendants misrepresented and omitted information regarding the true safety

and/or efficacy and proper uses of GranuFlo® and NaturaLyte®.

107. Defendants knew and intended that GranuFlo® and NaturaLyte® be used in dialysis treatment when the products were placed into the stream of commerce were not of the character, quality, or safety that they represented they were.

108. Defendants withheld and/or concealed and/or downplayed information that the products were associated with an increased risk of serious injury and/or death.

109. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market.

110. GranuFlo® and NaturaLyte® did not conform and/or perform in accordance with the Defendants' representations and warranties as they were not safe, efficacious, adequately tested, of merchantable quality, properly formulated or fit for dialysis use.

111. At all times, Defendants represented on their website and via other mediums that they provided "technologically-advanced care."

112. Defendants presented themselves as experts in the field on their website and in marketing, sales, product, and clinical materials.

113. Defendants' superior knowledge and expertise, their relationship of trust and confidence with doctors and patients, their specific knowledge regarding the risks and dangers of GranuFlo® and NaturaLyte®, and their intentional dissemination of promotional and marketing information about GranuFlo® and NaturaLyte® for the purpose of maximizing their sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material

information about the risks and harms associated with the products.

114. Decedent and his medical providers reasonably relied upon Defendants' expertise, skill, judgment, and knowledge and upon the express and/or implied warranty that their product was safe, efficacious, adequately tested, of merchantable quality, properly formulated, and fit for dialysis use.

115. The healthcare professionals involved in the dialysis treatment Decedent received reasonably relied upon Defendants' expertise, skill, judgment, and knowledge, and upon the express and/or implied warranty, that Defendants' product was safe, efficacious, adequately tested, of merchantable quality, properly formulated, and fit for dialysis use.

116. In deciding to purchase and use Defendants' product, Decedent and healthcare providers relied upon Defendants' representations.

117. As a direct and proximate consequence of Defendants' conduct, Plaintiffs sustained injuries and damages alleged herein.

COUNT V

Common Law Fraud

118. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

119. Defendants represented that their product was safe, effective, of a particular quality, and could be used in the manner described in their product, instructions, marketing, training, and educational materials.

120. Defendants fraudulently represented to Decedent, physicians, and other persons and professionals on whom it was known by Defendants that Decedent would rely that GranuFlo® and NaturaLyte® were safe for use in

dialysis treatment and that the utility of each product outweighed any risk associated with using the products.

121. On the day of and prior to Decedent's use of the product, in written materials provided, statements, and through omissions, Defendants fraudulently misrepresented GranuFlo® and NaturaLyte® in the following particulars:

a. The omission of details about the increased risks of death and serious injury associated with using GranuFlo® and NaturaLyte® including that bicarbonate induced alkalosis could cause a dialysis patient's blood pressure to plummet leading to cardiac arrest;

b. That the product could be used as instructed and educated when in fact the formulation required additional calculations and machine calibrations;

c. That GranuFlo® and NaturaLyte® had not been adequately tested to determine the safety and risks associated with using the products;

d. That Defendants had withheld clinical data and safety information from the medical community and those charged with evaluating and overseeing the product;

e. Defendants misrepresented the safety of GranuFlo® and NaturaLyte® in the products' labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, training, clinical forms, and/or product information;

f. Defendants withheld and/or concealed and/or downplayed the information and/or evidence that the products were associated with an increased risk of serious injury and/or death;

g. Defendants fraudulently concealed information about the safety of GranuFlo® and NaturaLyte® including information that the products were not safer than alternative dialysis products available on the market;

h. Defendants misrepresented information, regarding the true safety and/or efficacy of the GranuFlo® and NaturaLyte®; and

i. Defendants misrepresented to Decedent that the clinicians, nurses, and/or physicians were adequately trained, instructed, credentialed, and prepared for proper use of all GranuFlo® and/or NaturaLyte® hemodialysis products in a manner that was safe and effective.

122. Defendants' fraudulent representations evidence flagrant, willful, and depraved indifference to patient health, safety, and welfare.

123. Defendants had a duty to disclose, but instead concealed facts concerning the proper use, calculation, and formulation of the product as well as its quality and safety, including safety data, adverse events, and clinical reports.

124. The information Defendants misrepresented and withheld was material to Decedent's and his medical providers' decisions to use the product.

125. Defendants were aware of their concealments and knew of the falsity of the representations made, but acted with flagrant disregard and recklessness as to whether the truth or falsity might be inferred.

126. Defendants' purpose was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of GranuFlo® and NaturaLyte® in order to increase sales.

127. As a direct and proximate result of Defendants' fraudulent misrepresentations

and intentional concealment of facts, upon which Decedent reasonably relied, Plaintiffs suffered injuries and damages as alleged herein.

COUNT VI

Supplier Negligence Pursuant to OPLA 2307.78

128. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

129. Defendants were negligent and that negligence was a proximate cause of the harm alleged in this Complaint.

130. Defendants' product did not conform when it left Defendants' control to Defendants' representation.

131. Defendants' representations and the product's failure to conform to them were a proximate cause of the harm alleged herein.

132. As suppliers, Defendants are subject to liability based on Plaintiffs' claims as if they were the manufacturer of the product because the product manufacturer is subject to liability.

133. Defendants were suppliers when they supplied that product and were owned, in whole or in part, by the manufacturer of that product.

134. Alternatively, Defendants own, or when they supplied the product, owned, in whole or in part, the manufacturer of that product.

135. Defendants altered, modified, or failed to maintain the product after it came into their possession and before it left their possession, and the alteration, modification, or failure to maintain it rendered it defective.

136. Defendants marketed it under their own label or trade name.

COUNT VII

Consumer Sales Practices Act

137. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

138. Defendants knowingly violated the Act by engaging in unfair, deceptive, or unconscionable acts, omissions, and practices.

139. Defendants' practices were unfair because they were characterized by injustice, deception, and inequitable business dealings.

140. Defendants' conduct created a belief in consumers' minds, including Decedent and his medical providers', that did not accord with the facts.

141. Defendants' deceptive acts were per se because Defendants represented that the product had approval, performance characteristics, accessories, uses, and benefits that it did not have.

142. Defendants represented that the product was of a particular standard, quality, and prescription, when it was not.

143. Defendants' practices were unconscionable because there were unscrupulous, outrageous, and offensive to the public conscience.

144. Defendants knew at the time Decedent received their product of his inability to receive a substantial benefit from the subject of the consumer transaction.

COUNT VIII

Loss of Consortium (Plaintiff Deborah Swigert)

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

146. Plaintiff was married to Decedent prior to his injury.

147. She was with him after his injury and prior to his death. During that time, she lost the family relationship with her husband.

148. Consequently, she suffered loss of consortium between the time of his injury and his death, and can recover for that loss.

COUNT IX

Wrongful Death and Survival Claim

149. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

150. Aaron W. Porterfield is the duly appointed Administrator of the Estate of Charles Swigert, Deceased, having been so appointed by the Probate Court of Fayette County, Ohio. Ms. Porterfield brings this claim for the exclusive benefit of Decedent's next of kin pursuant to ORA Chapter 2125.

151. As a direct and proximate result of each Defendants' acts described herein, Plaintiff's next of kin have suffered loss of Decedent's support from the reasonably expected earning capacity; services; society; companionship; consortium; care; assistance; attention; protection; advice; guidance; counsel; instruction; training; education; and prospective inheritance.

152. As a further direct and proximate result of each Defendant's conduct, Decedent's next of kin have suffered mental anguish.

153. As a further direct and proximate result of each Defendant's conduct, Decedent's estate has incurred funeral, burial, and estate expenses.

154. Despite reasonable diligence by Plaintiffs, the first Plaintiffs learned of any information that caused Plaintiffs to consider a possible connection between Decedent's death and Defendants' product was September 2012.

155. Plaintiffs were not informed by competent medical authority that Decedent's death was related to the exposure to the product before then.

156. Defendants' misrepresentations and omissions concealed the information required to consider a connection between Decedent's death and their product.

157. Because of Defendants' actions, Decedent and the non-defendant healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Decedent had been exposed to the risks identified in this Complaint, and that those risks were the result of acts, omissions, and misrepresentations of each Defendant.

158. Accordingly, no limitations period accrued until Plaintiffs knew or reasonably should have known of the causal connection between the product and harm.

159. Additionally, the accrual and running of any applicable statute of limitations has been tolled because of Defendants' conduct.

160. Each Defendant's fraudulent concealment and other misconduct described herein estopps each from asserting any limitations defense.

COUNT X

PUNITIVE DAMAGES PURSUANT TO OPLA 2307.80[1]

161. Plaintiffs incorporate every paragraph of this Complaint as if set forth herein.

162. As described in the foregoing, Defendants acted with malice, aggravated, or egregious fraud.

163. Defendants wantonly and recklessly designed, manufactured, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold the product with a flagrant disregard for the safety of persons who might be harmed by GranuFlo® and NaturaLyte®.

[1] Plaintiffs intend only plead the allegations sufficient to justify a punitive damages award in the absence of a separate cause of action for punitive damages.

164. For years, Defendants knew that GranuFlo® and NaturaLyte® had unreasonably dangerous risks and caused serious side effects of which neither Decedent, nor his providers were aware. Defendants knew patients and healthcare providers received incorrect and incomplete information, and required additional information and instruction about the product's nature, character, quality, safety, and proper uses. Defendants knew there were safer methods and products for dialysis treatment. Defendants knew they defectively formulated, manufactured, and labeled their product. Defendants nevertheless advertised, marketed, sold, labeled, distributed, and instructed/trained on the use of it anyway.

165. Defendants' failure to act on the literature, presentations, clinical data, and adverse events, comply with their own and industry's standards, or to perform required safety testing, as well as their egregious misrepresentations, evince a flagrant disregard for safety.

166. Defendants' deliberate choice to warn only some, but not all clinics, when they finally released some safety and product information, and to withhold critical safety information for years, reflected a flagrant disregard for the safety of persons who might be harmed by these products.

167. Decedent's injury resulted from Defendants' misconduct, which manifested a flagrant disregard for users of Defendants' product.

168. As a direct and proximate result of the wanton and reckless actions and inactions of the Defendants manifesting a flagrant disregard of the safety of persons who might be harmed by these products as set forth above, Plaintiffs

sustained injuries and damages as alleged herein.

IV. GLOBAL PRAYER FOR RELIEF APPLICABLE TO ALL CLAIMS

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

a. compensatory damages;

b. past medical expenses

c. funeral, burial, and estate expenses;

d. past and future lost wages and loss of earning capacity;

e. pain and suffering;

f. past and future emotional distress;

g. loss of enjoyment of life;

h. wrongful death;

i. consequential damages;

j. loss of survival;

k. treble damages pursuant to O.R.A. Ch. 1345.09;

l. punitive damages;

m. reasonable attorneys' fees where recoverable;

n. costs;

o. post-judgment and all other interest recoverable; and

p. such other additional relief to which Plaintiffs are entitled in law or equity.

V. JURY DEMAND

Plaintiffs respectfully request a jury trial of all issues presented in this act.

Respectfully filed,

/s/ Penny Unkraut Hendy
Penny Unkraut Hendy, Esq. (0068864)
Schachter, Hendy & Johnson, P.S.C
909 Wright's Summit Parkway, Ste. 210
Ft. Wright, KY 41011
Phone: 859-578-4444
Fax: 859-578-4440
Email: phendy@pschachter.com
PLAINTIFFS' TRIAL ATTORNEY

Robert K. Jenner (pro hac vice motion to be filed)
Brian D. Ketterer (pro hac vice motion to be filed)
Justin A. Browne (pro hac vice motion to be filed)
Janet, Jenner & Suggs, LLC
1777 Reisterstown Road, Suite 165
Baltimore, MD 21208
(410) 653-3200
RJenner@MyAdvocates.com
BKetterer@MyAdvocates.com
JBrowne@MyAdvocates.com
CO-COUNSEL FOR PLAINTIFFS

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Deborah Swigert & Aaron Porterfield, As Adm'r of the Estate of Charles M. Swigert, Deceased

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

(c) Attorney's (Firm Name, Address, and Telephone Number)

Penny U. Hendy, Schachter, Hendy & Johnson, PSC, 909 Wright's Summit Pkwy. #210, Ft. Wright, KY 41011 (859-578-4444)

DEFENDANTS

Fresenius USA, Inc., et al

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

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

Attorneys (If Known)

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

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

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

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

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

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury

PERSONAL INJURY
- ❒ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 444 Welfare
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 440 Other Civil Rights

PRISONER PETITIONS
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition

FORFEITURE/PENALTY
- ❒ 610 Agriculture
- ❒ 620 Other Food & Drug
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 630 Liquor Laws
- ❒ 640 R.R. & Truck
- ❒ 650 Airline Regs.
- ❒ 660 Occupational Safety/Health
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 730 Labor/Mgmt.Reporting & Disclosure Act
- ❒ 740 Railway Labor Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 463 Habeas Corpus - Alien Detainee
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 810 Selective Service
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 875 Customer Challenge 12 USC 3410
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 892 Economic Stabilization Act
- ❒ 893 Environmental Matters
- ❒ 894 Energy Allocation Act
- ❒ 895 Freedom of Information Act
- ❒ 900Appeal of Fee Determination Under Equal Access to Justice
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from another district (specify) ❒ 6 Multidistrict Litigation ❒ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**: 28 USC 1332

Brief description of cause: defective medical product

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☑ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 11/13/2012

SIGNATURE OF ATTORNEY OF RECORD /s/ Penny U. Hendy

FOR OFFICE USE ONLY

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