ROBINS KAPLAN LLP
Rayna E. Kessler, Esq.
PA ID No. 309607
399 Park Avenue, Suite 3600
New York, New York 10022-4690
Telephone: (212) 980-7431
Facsimile: (212) 980-7499
Email: RKessler@RobinsKaplan.com

Kate Jaycox, Esq. *(Pro hac Vice Motion to be Filed)*
Matthew Leighton, Esq. *(Pro hac Vice Motion to be Filed)*
2800 LaSalle Plaza
800 LaSalle Avenue
Minneapolis, MN 55402-2015
Telephone: 612-349-8500
Facsimile: 612-339-4181
Email: KJaycox@RobinsKaplan.com
MLeighton@RobinsKaplan.com

Attorneys for Plaintiffs Barbara and Thomas Kessler

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BARBARA KESSLER and **THOMAS KESSLER,** *Plaintiffs,* v. **LUITPOLD PHARMACEUTICALS, INC., AMERICAN REGENT, INC., DAIICHI SANKYO, INC., DAIICHI SANKYO US HOLDINGS, INC., VIFOR PHARMA LTD., VIFOR PHARMA PARTICIPATIONS LTD, VIFOR (INTERNATIONAL) AG, and RELYPSA INC.,** *Defendants.*	EASTERN DISTRICT OF PENNSYLVANIA PHILADELPHIA DIVISION CIVIL ACTION NO. 2:21-cv-00746 Civil Action *Filed Electronically* **COMPLAINT** **AND JURY DEMAND**

Plaintiffs Barbara and Thomas Kessler, by and through their undersigned counsel, bring this civil action against the above-named Defendants for personal injuries and damages and allege as follows:

PARTIES

1. Plaintiffs Barbara Kessler and her spouse Thomas Kessler reside in Austin, Texas. Plaintiff Barbara Kessler suffered serious physical injuries and economic damages due to her use of the injectable iron product, Injectafer (ferric carboxymaltose).

The American Regent Defendants

2. Defendant Luitpold Pharmaceuticals, Inc. ("Luitpold") was a New York corporation. At all relevant times, Luitpold maintained its principal offices in Norristown, Pennsylvania and Shirley, New York. Luitpold was registered to do business throughout Pennsylvania, including within the county of Philadelphia. Luitpold was the parent to its subsidiary, American Regent, Inc.

3. At all relevant times, and within Pennsylvania, Luitpold engaged in the business of researching, developing, designing, testing, licensing, manufacturing, distributing, supplying, selling, labeling, promoting, marketing, and/or introducing into commerce the Injectafer product. Luitpold was the Sponsor of the New Drug Application ("NDA") submitted to the FDA on Injectafer in 2013.

4. Defendant American Regent, Inc. ("American Regent") is a New York corporation. At all relevant times, American Regent had a principal place of business at in Shirley, New York, sharing an office with Luitpold. Upon information and belief, American Regent also operates out of its Norristown, Pennsylvania office and is registered to do business in Pennsylvania. American Regent was a subsidiary of Luitpold until approximately December 31, 2008.

5. Upon information and belief, on or about December 31, 2008, Luitpold merged American Regent into itself, and the surviving entity—Luitpold—was renamed American Regent.[1] The new entity of American Regent is a wholly-owned subsidiary of Daiichi Sankyo, Inc.

6. At all relevant times, and within Pennsylvania, American Regent has engaged in the business of researching, developing, designing, testing, licensing, manufacturing, distributing, supplying, selling, labeling, promoting, marketing, and/or introducing into commerce the Injectafer product.

7. Luitpold was the primary holder of a license to manufacture and market Injectafer from Vifor (International) Inc. until the merger. American Regent is the manufacturer currently listed on the Injectafer label, still under license from Vifor (International) Inc.

8. Upon information and belief, both American Regent and Luitpold were and are part of the Daiichi Sankyo Group.

The Daiichi Sankyo Defendants

9. Defendant Daiichi Sankyo, Inc. ("DSI") is a Delaware corporation with its principal place of business in Basking Ridge, New Jersey. DSI is the United States subsidiary of Daiichi Sankyo Co., Ltd. ("DSC"), located in Tokyo, Japan, and is a member of the Daiichi Sankyo Group. DSI is wholly owned by Defendant Daiichi Sankyo U.S. Holdings, Inc.

10. Defendant Daiichi Sankyo U.S. Holdings, Inc. ("DS Holdings") is a Delaware corporation with its principal place of business in Basking Ridge, New Jersey. DS Holdings wholly owns DSI. Upon information and belief, DS Holdings is also a subsidiary of DSC and is a member of the Daiichi Sankyo Group.

[1] Since the merger between Luitpold and American Regent resulted in an entity called American Regent, any allegation throughout the Complaint specific to Luitpold also applies to its successor, American Regent.

11. Upon information and belief, DSI is or was also known as Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma, Inc., Daiichi Sankyo Group, and Daiichi Pharma Holdings, Inc. Upon information and belief, DSI operates as the U.S. headquarters of DSC.

12. At all relevant times, DSI is and was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, and selling the Injectafer product. Starting in or around January 2017, DSI assumed the role of promoting and marketing Injectafer in the United States.

13. Upon information and belief, at all relevant times, DSI exercised control over the DSI subsidiaries, Luitpold and American Regent, with control over all relevant decisions, policies, and conduct regarding the research, development, design, licensing, manufacture, distribution, marketing, promotion, and selling of Injectafer.

14. Upon information and belief, DS Holdings is and was at all times engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, and selling the Injectafer product.

15. Upon information and belief, DS Holdings exercised ultimate control, and was responsible for the actions and omissions of its wholly owned subsidiary, DSI.

16. Upon information and belief, there existed at all relevant times a unity of interest in ownership between DS Holdings and DSI such that independence from, or separation between, these two Defendants does not and has never existed. Each of them is an alter ego of the other.

17. Because of the unity of operations and ownership, DSI and DS Holdings are hereinafter referred to as the "Daiichi Sankyo Defendants."

The Vifor Defendants

18. Defendant Vifor Pharma Ltd. ("Vifor Pharma") is a for-profit corporation headquartered, organized, and existing under the laws of Switzerland, with an office location at Rechenstrasse 37 CH-9014 St. Gallen.

19. Defendant Vifor Pharma Participations Ltd. ("Vifor Participations") is a for-profit corporation headquartered, organized, and existing under the laws of Switzerland, with an office location at Rechenstrasse 37 CH-9014 St. Gallen. Vifor Participations is a wholly owned subsidiary of Vifor Pharma.

20. Defendant Vifor (International) AG a/k/a Vifor (International) Inc. ("Vifor International") is a for-profit corporation headquartered in Switzerland with an office location at Rechenstrasse 37 CH-9014 St. Gallen. Vifor International is a wholly owned subsidiary of Vifor Participations, Ltd.

21. Defendant Relypsa Inc. ("Relypsa") is Delaware corporation with its principal office in Redwood City, California. Relypsa Inc. is a wholly owned subsidiary of Vifor Pharma, and a United States Corporate Affiliate of Vifor International.

22. Because of the unity of operations and ownership, Vifor Pharma, Vifor Participations, Vifor International, and Relypsa are hereinafter referred to as the "Vifor Defendants" or "Vifor."

23. The Vifor Defendants are in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and/or introducing into commerce ferric carboxymaltose, or its European brand bioequivalent, Ferinject.

24. Upon information and belief, the Vifor Defendants for responsible for the original design and development of the bioequivalent ferric carboxymaltose product, branded as Ferinject

in Europe.

25. Upon information and belief, the Vifor Defendants, by and through Vifor International, licensed ferric carboxymaltose to Luitpold, permitting Luitpold to design, manufacture, market, supply, promote, label, distribute, and sell ferric carboxymaltose in the United States, branded as Injectafer. Vifor International was the international "partner" of Luitpold in the sale of Injectafer. The licensing agreement between Vifor International and Luitpold awards Vifor International a "share of partner sales" in regards to Injectafer sales in the United States.

26. Pursuant to this licensing deal and other agreements, the Vifor Defendants assumed a role in the conducting and management of the clinical trials, marketing, promotion, marketing sales organization, and pharmacovigilance for Injectafer.

27. Upon information and belief, the Vifor Defendants provide support to American Regent and DSI, on the design, manufacture, distribution, marketing, promotions, pharmacovigilance, and/or sale of Injectafer.

28. Pursuant to 21 C.F.R. § 207 (2019), foreign manufacturers of a pharmaceutical drug that is imposed or offered into the United States must have a Registered Agent. Vifor's Registered Agent in the United States is American Regent.

29. Since initially introducing ferric carboxymaltose into the world market, Vifor Pharma, and its subsidiaries, have been in the business of collecting, supervising, analyzing, and reporting adverse events, peer-reviewed literature, clinical and nonclinical studies, and other epidemiology on ferric carboxymaltose.

30. Each of the above Defendants played a role in the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer. Plaintiffs' injuries were

caused by the conduct of one or various combinations of Defendants, and through no fault of Plaintiffs.

JURISDICTION AND VENUE

31. This action is properly before this Court pursuant to 28 U.S.C. § 1332(a) because complete diversity of citizenship exists between Plaintiffs and Defendants, the amount in controversy exceeds $75,000, exclusive of interest and costs. Defendants have engaged in continuous and systematic business activities in the Commonwealth of Pennsylvania.

32. This Court has personal jurisdiction over Defendants pursuant to § 42 Pa. C.S. 5301 *et seq.,* because, at all relevant times, Defendants have carried on continuous and systematic business activities within the Commonwealth of Pennsylvania.

33. This Court has general personal jurisdiction over the Luitpold, American Regent, and DSI Defendants because each is registered to do business in Pennsylvania and therefore has consented to general personal jurisdiction in Pennsylvania, 42 Pa. C.S. § 5301 and 42 Pa. C.S. § 5322. DS Holdings, as the parent and alter ago to DSI, thus has inextricable ties to Pennsylvania.

34. This Court has general personal jurisdiction over Vifor, which does business in Pennsylvania. Vifor, engaged in a licensing deal for its ferric carboxymaltose product that would see the continuous and systemic sale of Injectafer in Pennsylvania. Vifor manages the sale of Injectafer in the United States, including in the Commonwealth of Pennsylvania, and provide support to American Regent and DSI on the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer. Vifor's Registered Agent is American Regent. Vifor thus has inextricable ties to Pennsylvania.

35. This court has general personal jurisdiction over Luitpold and American Regent because they operate an office and principal place of business at 800 Adams Street, Norristown,

Pennsylvania 19403, which is located in the Eastern District of Pennsylvania.

36. This Court has personal jurisdiction over each of the Defendants pursuant to 42 Pa. C.S. 5322.

37. This Court has specific personal jurisdiction over the Defendants due to the Injectafer-specific business activities that give rise to this claim, including but not limited to the development, testing, pharmacovigilance, safety monitoring, promotion, and sale of Injectafer that take place in parts of the Commonwealth of Pennsylvania which are located in the Eastern District of Pennsylvania.

38. Upon information and belief, Luitpold headquartered its Clinical Division at its office in Norristown, Pennsylvania. Norristown was also home to Luitpold's Clinical Research and Development Department, to the extent that group existed separately from the Clinical Division. Upon information and belief, following the merger, American Regent is now the sole operating corporate entity at the Norristown, Pennsylvania location.

39. Upon information and belief, Luitpold's senior clinical and scientific staff conducted their Injectafer-specific responsibilities out of the Norristown, PA office, including the Senior Clinical Manager responsible for Injectafer.

40. Luitpold's Regulatory Affairs Department also operated out of the Norristown, Pennsylvania office. Specifically, Marsha E. Simon, Director of Regulatory Affairs, was employed in the Norristown office and used the Norristown address when making regulatory submissions on behalf of Luitpold and Injectafer to the Food and Drug Administration ("FDA").

41. Luitpold's Norristown, Pennsylvania office served as either the monitoring site, organizational headquarters, or specific location for pivotal Injectafer clinical studies run by Defendants, including but not limited to "Intravenous Ferric Carboxymaltose (FCM) Versus IV

Iron Sucrose or IV Iron Dextran in Treating Iron Deficiency Anemia in Women;" "Trial to Evaluate the Utility of Serum Hepcidin Levels to Predict Response to Oral or IV Iron and to Compare Safety, Effect on Quality of Life, and Resource Utilization of Injectafer vs Intravenous Standard of Care for the Treatment of Iron Deficiency Anemia (IDA) in an Infusion Center Setting;" A Study to Characterize the Pharmacokinetics and Pharmacodynamics Profile of Intravenous Ferric Carboxymaltose in Pediatric Subjects 1-17 Years Old with Iron Deficiency Anemia (IDA);" and, "IRON Clad: Can Iron Lessen Anemia Due to cancer and chemotherapy: A multicenter, randomized, double-blinded, controlled study to investigate the efficacy and safety of Injectafer."

42. Upon information and belief, the Norristown office is also the location from which Luitpold conducted its pharmacovigilance and safety reporting for Injectafer. Many of the Injectafer pharmacovigilance and safety positions were employed at the Norristown, Pennsylvania office, including Luitpold's Senior Medical Director, Clinical Quality Assurance, Senior Clinical Project Manager, and Clinical Research Associate.

43. Consequently, Luitpold's pharmacovigilance, medical affairs, clinical design, and regulatory functions related to Injectafer were all conducted in the Norristown, Pennsylvania location – either in whole or in substantial part.

44. Pursuant to the licensing and safety agreements between Vifor International and Luitpold, the Vifor entities directly participated in the registration and clinical trials, marketing, promotions and sales, adverse events arising from clinical trials, and pharmacovigilance obligations for Injectafer, which – either in whole or in substantial part – were conducted or managed in Luitpold's Norristown, Pennsylvania office.

45. In addition, the Vifor entities, by and through Relypsa and other Vifor entities, and

in conjunction with American Regent, are engaged in the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer, which – either in whole or in substantial part – were conducted or managed in Luitpold's Norristown, Pennsylvania office.

46. All other Defendants, as either subsidiary, parent, or licensing partner to Luitpold and American Regent, similarly engaged in the aforementioned development, testing, pharmacovigilance, and safety reporting functions for Injectafer in Pennsylvania. Injectafer was also specifically promoted, marketed, and sold throughout Pennsylvania.

47. Defendants regularly conduct substantial business within the Eastern District of Pennsylvania.

48. Injectafer is marketed, promoted, distributed, and sold to hospitals, medical facilities, infusion centers, home health care agencies, and consumers in the Philadelphia region within the Eastern District of Pennsylvania.

49. Venue is proper pursuant to 28 U.S.C. § 1391(b) in the Eastern District of Pennsylvania because Defendants American Regent and Luitpold operate an office out of Norristown, Pennsylvania.

50. Venue is proper in the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1391(b)(2) because substantial, specific conduct by Luitpold, American Regent, and the Vifor entities that gave rise to this claim originated and occurred in Defendants' Philadelphia region office.

FACTUAL BACKGROUND

Iron Deficiency and Injectafer Overview

51. Injectafer (compound: ferric carboxymaltose) is an iron replacement injection medication manufactured by Defendants indicated "for the treatment of iron deficiency anemia

(IDA) in adult patients who have intolerance to oral iron or have had unsatisfactory response to oral iron, or in adult patients with non-dialysis dependent chronic kidney disease."

52. Iron is an essential mineral which the body uses to produce hemoglobin, a protein within red blood cells that transports oxygen throughout the body to tissues. Most of the body's iron is in hemoglobin; the remainder is stored in the liver, spleen, bone marrow or is located in myoglobin in muscles. Iron helps produce myoglobin, another protein that provides oxygen and is found mainly in muscles. Among other jobs, iron plays an essential role in cellular functioning, immune function, neurological development, and synthesis of some hormones.[2]

53. People in the United States generally obtain adequate iron intake from food, but iron deficiency can be caused by a lack of iron in one's diet, blood loss, an inability to absorb iron, or pregnancy. Certain populations are more at risk of having low iron levels, including women, infants and children, vegetarians, and those with conditions causing blood loss.[3]

54. Iron deficiency anemia ("IDA") occurs with insufficient levels of iron in an individual's body. While mild or moderate IDA may not cause symptoms, more severe IDA may result in pale skin, fatigue, shortness of breath, chest pain, and headache, among other symptoms.[4]

55. IDA rates vary by gender and race. IDA occurs 2% of men, 9 to 12% of non-Hispanic white women, and nearly 20% of black and Mexican-American women.[5] Approximately ten million people in the United States are iron deficient, and five million people have IDA.[6]

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[2] *See* National Institute of Health, Iron Fact Sheet for Professionals, https://ods.od.nih.gov/factsheets/Iron-HealthProfessional/

[3] *See* National Heart, Lung, and Blood Institute, Iron-Deficiency Anemia, available at https://www.nhlbi.nih.gov/health-topics/iron-deficiency-anemia

[4] *See* https://www.hematology.org/education/patients/anemia/iron-deficiency

[5] *See* Killp, S. et al, Iron Deficiency Anemia, Am Fam Physician. 2007 Marc 1: 75(5):671-678), available at https://www.aafp.org/afp/2007/0301/p671.html

[6] Miller, J. Iron Deficiency Anemia: A Common and Curable Disease, Cold Spring Harb Perspect Med. 2013 Jul; 3 (7), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3685880/

56. For years, IDA was treated primarily with oral iron supplements. Early forms of intravenous iron caused severe complications, and doctors recommended these only in extreme conditions. Starting in about the 1990s, the pharmaceutical industry began introducing intravenous iron supplements, for those unwilling or unable to take oral iron supplements.

57. Defendants Luitpold and American Regent brought Injectafer to the United States market in 2013, at the direction and under the control of their parent, the Daiichi Sankyo Defendants.

58. Prior to 2013, the compound ferric carboxymaltose ("FCM") was available on the European and other markets under the brand name of Ferinject. Ferinject was designed, manufactured, promoted, and sold by Vifor. Defendant Vifor licensed and continues to license FCM to all other Defendants who in turn have designed, manufactured, and sold the product in the United States. Vifor provides support to American Regent and DSI on the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer in the United States.

59. Injectafer is intended for rapid and high-dose iron replenishment Injectafer and is to be administered intravenously in two doses separated by at least 7 days. For those weighing over 100 pounds, each dose should be for 750 mg, for a total cumulative dose of 1500 mg of iron per course of Injectafer.

60. Injectafer is one of several products available for intravenous iron, but the only product available in the United States formulated with the unique FCM compound.

61. Unlike the other intravenous iron products available, FCM causes a condition called "Severe Hypophosphatemia" ("Severe HPP") and potentially "persistent hypophosphatemia" ("Persistent HPP").

62. Hypophosphatemia ("HPP") is an electrolyte disturbance in which there is an abnormally low level of phosphate in the body. HPP is rare in the United States and is almost never results from low dietary intakes. Instead – apart from being caused by FCM – HPP is most often caused by medical conditions, such as diabetic ketoacidosis, kidney tubule defects, hyperparathyroidism, rare genetic phosphate regulation disorders, and severe malnutrition causing refeeding syndrome.[7]

63. Phosphorous, or serum or plasma phosphate, is an essential mineral in the body and vital to several of the body's physiological processes. Most phosphorus is stored in the bones, with the rest stored in tissues throughout the body.[8] Phosphorus is a component of bones, teeth, DNA, and RNA. Phosphorous helps with bone growth, energy storage, and nerve and muscle production. Phosphate has a "widespread role in nearly every molecular, cellular function," so abnormal phosphate levels can have high impact on an individual.[9]

64. There are several levels of hypophosphatemia, including mild, moderate, and severe. Agreed upon serum phosphate measurements for each level vary, but typically the measurements break down as: 2.5 – 4.5 mg/dl serum phosphate (normal range); 2.0 – 2.5 mg/dl serum phosphate (mild hypophosphatemia); 1.0 – 2.0 mg/dl serum phosphate (moderate hypophosphatemia); and less than 1.0mg/dl serum phosphate (severe hypophosphatemia). Severe HPP has also been identified in literature as levels less than 1.5 mg/dl or 1.3 mg/dl.

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[7] *See* U.S. Department of Health & Human Services, National Institutes of Health, Phosphorus: Fact Sheet for Health Professionals, available at https://ods.od.nih.gov/factsheets/Phosphorus-HealthProfessional/

[8] *See* U.S. Department of Health & Human Services, National Institutes of Health, Phosphorus: Fact Sheet for Health Professionals, available at https://ods.od.nih.gov/factsheets/Phosphorus-HealthProfessional/

[9] *See* Sharma, S. et al., Hypophosphatemia. StatPearls, updated June 4, 2020, available at https://www.ncbi.nlm.nih.gov/books/NBK493172/

65. Additionally, "persistent hypophosphatemia" is a condition in which an individual can suffer from HPP or Severe HPP for a sustained period.

66. There are clinically significant differences between mild HPP (2.0 –2.5 mg/dl) and Severe HPP (less than 1.5, 1.3, or 1.0 mg/dl). While mild HPP can occur without symptomatology or injury, Severe HPP is a dangerous condition that can cause muscle weakening, severe fatigue, severe nausea, bone and joint pain, and can lead to serious medical complications including osteomalacia, arrhythmias, cardiac arrest, respiratory failure, and/or rhabdomyolysis.

67. The dangers of Severe HPP are not just brought on by the extremely low levels of one's serum phosphate, but also the duration (or prolonged period) of the Severe HPP.

Laws and Regulations Governing the Approval of Labeling Prescription Drugs

68. After a new drug or compound has undergone preclinical development on a drug (e.g., animal studies) and the new drug's sponsor is ready to proceed with human clinical trials with a goal of eventually marketing the drug, the Federal Food, Drug and Cosmetic Act ("FDCA" or the "Act") requires sponsors to file an investigational new drug (IND) application. 21 C.F.R. 312.20 *et seq.*

69. When a new drug sponsor has completed some human trials and wants to request marketing authorization, the manufacturer must file a New Drug Application ("NDA") in order to obtain approval from the FDA before selling the drug in interstate commerce. 21 U.S.C. § 355.

70. Data collected during the IND phase of development becomes part of the NDA, with the NDA being more comprehensive than the IND.

71. The NDA must include, among other things, all data regarding the safety and effectiveness of the drug, information on any patents that purportedly apply to the drug or a method of using the drug and the labeling proposed to be used for the drug. 21 U.S.C. § 355(b).

72. To fulfill their essential responsibilities, NDA holders/drug sponsors must accurately report clinical trial information and must closely evaluate the post-market clinical experience of their drugs, timely providing updated safety and efficacy information to the healthcare community and to consumers.

73. As part of their responsibility to monitor post-market clinical experiences with the drug and provide updated safety and efficacy information to the healthcare community and to consumers, each approved NDA applicant, "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b).

74. An "adverse drug experience" is any adverse event associated with a drug's use, whether or not it is considered drug related. 21 C.F.R. § 314.80(a).

75. A "serious adverse drug experience" is one that results in death or is life-threatening, or results in inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. 21 C.F.R. § 314.80(a).

76. An "unexpected adverse drug experience" is not that is not listed in the drug's current labeling., including those that may be related to an event listed in the drug's labeling but differ because of greater severity or specificity: "'Unexpected'. . . refers to an adverse drug experience that has not been previously observed (i.e., included in the labeling) rather than from the perspective of such experience not being anticipated from the pharmacological properties of the pharmaceutical product." 21 C.F.R. § 314.80(a).

77. Any report of a "serious and unexpected" drug experience, whether foreign or domestic, must be reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. § 314.80(c)(1)(i-ii). Most other adverse event reports must be submitted quarterly for three years after the application is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a "history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated)." 21 C.F.R. § 314.80(c)(2)(ii).

78. After FDA approval, manufacturers may only promote drugs in a manner consistent with the contents of the drug's FDA-approved label. 21 C.F.R. § 202.1.

79. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to prescription drugs rests with the NDA holders and their assigns or agents - and not the FDA. NDA holders have superior, and in many cases exclusive, access to the relevant safety and efficacy information, including clinical trial information and post-market complaints and data

80. Although the FDA eventually approves the label submitted to the FDA by the manufacturer, it is the duty of the drug manufacturer to warn of dangerous adverse reactions that may be associated with its drug and to ensure the label is up to date and/or accurate. 21 CFR § 201, *et. seq*.

81. Under the FDCA, a drug's label must contain specific "highlight" prescribing information regarding indicated usage, dosage form, route of administration, and approval information. 21 C.F.R. § 201.57. In order to inform prescribing physicians of the potential risks of a drug, and therefore to protect patients, the highlights portion of a label must also include multiple sections that the United States Supreme Court has described as ranked to reflect their relative

"severity of risk." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1673 (2019). This ensures that important safety information is overt.

82. The most severe risks—those that could lead to death or serious injury—are to be contained in a "Boxed Warning." 21 C.F.R. § 201.57(c)(1).

83. The next risk level is contained in the "Contraindications" section of the label, reserved for circumstances in which a drug should not be used due to the potential risks outweighing any therapeutic benefit. 21 C.F.R. § 201.57(9).

84. The third level of severity is contained in the "Warnings and Precautions" section of the label. 21 C.F.R. § 201.57(a)(9). This section "must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy) and steps that should be taken if they occur (e.g., dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed as provided under paragraph (c)(7) of this section." 21 C.F.R. § 201.57(c)(6)(i).

85. The Warnings and Precautions "section must contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (e.g., precautions not required under any other specific section or subsection)." 21 C.F.R. § 201.57(c)(6)(ii).

86. The Warnings and Precautions section of the label "must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If

appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during and after therapy." *Id*. § 201.57(c)(6)(iii). According to an FDA Guidance for Industry on the Warnings and Precautions section of the labeling, "[i]nformation about the frequency of testing and expected ranges of normal and abnormal values should also be provided if available."[10]

87. Risks with the lowest level of severity are included in the "Adverse Reactions" section of the label. 21 C.F.R. § 201.57(a)(11). Adverse reactions are "the most frequently occurring adverse reactions" that have not been included in other sections of the label. 21 C.F.R. § 201.57(a)(11)(i).

88. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading, omits material facts regarding possible consequences from use, or does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a) and (b); 352 (f). A drug's labeling satisfies federal requirements if it gives medical practitioners sufficient information—including indications for use and "any relevant hazards, contraindications, side effects, and precautions"—to allow those professionals "to use the drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.100(c)(1).

89. Federal law requires labeling to be updated as information accumulates: "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been

[10] Guidance Document: Warnings and, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products– Content and Format, October 2011, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf.

definitely established." 21 C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is "some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).

90. Under what is known as the "Changes Being Effected" (CBE) regulation, a manufacturer with an approved NDA can, among other things, add to or strengthen a contraindication, warning, precaution, or adverse reaction in its label without prior FDA approval by simply sending the FDA a "supplemental submission" to reflect "newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii). Thus, for instance, if a drug sponsor were to determine that a warning were insufficient based on a new analysis of previously existing data, it could submit a CBE and change its labeling.

Injectafer's FDA Approval

91. Luitpold initially submitted a New Drug Application ("NDA") for Injectafer in 2006. The original proposed dose regimen was 1000 mg in a single dose injection, with a maximum total dose of 2500 mg.

92. This NDA received a non-approval letter due to clinical safety issues, with the FDA finding that the supplied clinical data showed an unacceptable risk for death, serious adverse reactions, and clinically important hypophosphatemia.

93. Luitpold submitted a Complete Response in 2007, but the FDA issued a Not Approvable action in 2008, stating that additional safety data should be obtained and assessed. The FDA also recommended Luitpold consider an alternative dosage regimen to deliver a lower amount of iron.

94. Luitpold submitted another NDA for Injectafer in 2011, but this was not approved due to Chemistry, Manufactuyiouring and Controls deficiency. This NDA was resubmitted in

January 2013 and approved, with a maximum dose of 750 mg per single dose, with maximum total dose of 1500 mg.

Defendants Knew that Injectafer Caused Severe and Persistent Hypophosphatemia

95. Defendants have known or had reason to know, well before marketing Injectafer in the United States, that ferric carboxymaltose – and by extension, Injectafer – causes Severe HPP.

96. Defendants have known or had reason to know, well before marketing Injectafer in the United States, that hypophosphatemia varies in severity and that moderate to severe HPP can result in serious and prolonged injury.

97. Defendants have known or had reason to know, well before marketing Injectafer in the United States, that ferric carboxymaltose increases the levels of the hormone fibroblast growth factor 23 ("FGF23"), which is in turn associated with a decrease in blood phosphorus and hypophosphatemia, at a rate far greater than any other iron drug.[11]

98. During FCM's presence on the European and United States markets, dozens of case reports and other medical literature linked Severe HPP to FCM and revealed the dangers of Severe HPP. These reports put Defendants on notice of the clinically significant adverse reactions caused by Injectafer that were serious and potentially life threatening. These include, but are not limited to, the below studies of which Defendants were on notice:

a. By 2014, at least four case reports had been published involving seven patients who developed severe HPP following FCM use, leading one set of researchers writing a case report of the "potentially life-threatening side effect" to do a retrospective review of patients at their hospital in Belgium.

[11] *See e.g.,* Wolf, M et al., Effects of Iron Deficiency Anemia and its Treatment on Fibroblast Growth Factor 23 and Phosphate Homeostasis in Women, J Bone Miner Res. 2013 Aug; 28 (8): 1793-803.

They found three more cases of Severe HPP following FCM treatment and ultimately concluded, "long-term monitoring of phosphate level is mandatory during FCM treatment and physicians must be aware of this potential side effect."[12]

b. A retrospective review published in 2016 compared patients given ferric carboxymaltose (Injectafer) to those given isomaltoside 1000 (Monofer) found: "[t]he single most important risk factor for the development of hypophosphatemia appears to be the choice of intravenous iron preparations, where [ferric carboxymaltose] was associated with a 20-fold higher risk than [iron isomaltoside] and all 18 cases of severe and life-threatening hypophosphatemia developed after administration of [ferric carboxymaltose]."[13]

c. A retrospective analysis published in 2017 compared patients given ferric carboxymaltose with those given isomaltoside 1000 (Monofer), finding a "significantly higher risk" of HPP among those give FCM. Up to 50% of those given FCM suffered from HPP versus less than 10% of those given isomaltoside 1000; severe HPP only occurred in those given FCM and not

[12] See Vandemergal X and Vandergheynst F. Potentially Life-Threatening Phosphate Diabetes Induced by Ferric Carboxymaltose Injection: A Case Report and Review of the Literature, Case Rpts in Endocrinology, Vol 2014, Article ID 843689, 2014 (describing other case reports, reporting on one case, and conducting retrospective review of patients).

[13] Schaefer et al., Choice of High-Dose Intravenous Iron Preparation Determines Hypophosphatemia Risk, PLoS ONE 11(12): e0167146 (2016), *accessible at* https://doi.org/10.1371/journal.pone.0167146.

in those given isomaltoside 1000.[14]

d. Yet another study had the goal of assessing "the prevalence, duration, and potential consequences of hypophosphatemia after iron injection." Of the group of 78 patients treated with ferric carboxymaltose, 51% developed HPP, including 13% developing severe HPP. Of those 78 patients, "the initial mean phosphate level was 1.08 mmol/L and it decreased to 0.82 mmol/L following the iron administration. "Hypophosphatemia severity correlated with the dose of [ferric carboxymaltose]." In conclusion, "[h]ypophosphatemia is frequent after parenteral [ferric carboxymaltose] injection and may have clinical consequences";[15]

e. A 2018 comparison between Injectafer and ferumoxytol (Feraheme) found that 50.8% of Injectafer users versus only .9% of Feraheme users had severe hypophosphatemia (measured in this study as levels under 2.0 mg/dl); 10% of Injectafer users versus 0% of Feraheme users had extreme hypophosphatemia (measured in this study as levels below 1.3 mg/dl); and, 29.1% of Injectafer users versus 0% of Feraheme users continued to have persistence of severe hypophosphatemia at the end of the five-week study period.[16]

f. A comparison between ferric carboxymaltose (Injectafer) and iron

[14] Bager et al., Drug-specific hypophosphatemia and hypersensitivity reactions following different intravenous iron infusions, 83(5) British J. Clinical Pharm. 1118-1125 (2017), *accessible at* https://doi.org/10.1111/bcp.13189.
[15] Hardy et al., Intravenous Iron Administration and Hypophosphatemia in Clinical Practice, Int'l J. Rheumatology (2015), *accessible at* https://doi.org/10.1155/2015/468675.
[16] Wolf et al., Randomized trials of intravenous iron-induced hypophosphatemia, 23(3) JCI Insight 3 (2018), *accessible at* https://doi.org/10.1172/jci.insight.124486.

isomaltoside (Monofer) published in the Journal of the American Medical Association (JAMA) in February 2020 found that in one trial (Trial A), the incidence of hypophosphatemia with Monofer was only 7.9% compared with 75% in Injectafer patients; in the other trial (Trial B), the incidence of hypophosphatemia with Monofer was only 8.1% compared with 73.7% in Injectafer patients; severe hypophosphatemia was not observed in Monofer patients but occurred in 11.3% of Injectafer patients; and, "even a single course of Injectafer may adversely affect a person's skeleton which may help explain why repeated dosing of ferric carboxymaltose has been associated with osteomalacia and bone fractures."[17]

g. A systematic literature review published in April 2020 found that the highest rates of hypophosphatemia were consistently seen in patients treated with FCM as compared to the other intravenous iron products marketed in the United States, across all types of studies. The authors recommended consistent pre- and post-monitoring of serum phosphate levels in all patients taking intravenous iron.[18]

99. In addition, Luitpold had knowledge of the link between Injectafer and Severe HPP from its own clinical studies, knowledge that it never appropriately shared with the medical community or public and knowledge that never led it to do appropriate testing on FCM and Severe

[17] Wolf et al., Effects of Iron Isomaltoside vs. Ferric Carboxymaltose on Hypophosphatemia in Iron-Deficiency Anemia, 5 J. American Med. 432 (2020), *accessible at* https://doi.org/10.1001/jama.2019.22450.

[18] Glaspy, J. et al., Hypophosphatemia Associated with Intravenous Iron Therapies for Iron Deficiency Anemia: A Systematic Literature Review, Ther Clin Risk Manag., 2020 Apr 8; 16:245-259.

or Persistent HPP.

100. An original New Drug Application ("NDA") submitted by Luitpold to the Food and Drug Administration (FDA) in July 2006 received a non-approval letter in response due to clinical safety concerns. An additional NDA application for Injectafer submitted in September 2007 again received a non-approval letter due to clinical safety concerns. Among the safety concerns that halted approval was "clinically important hypophosphatemia." "Clinically important hypophosphatemia" never made its way onto the Injectafer labeling, even after being identified as a cause of earlier application denial.

101. Despite FDA's concern that Injectafer caused "clinically important hypophosphatemia" and the multiple reports, adverse event reports, and published studies linking Injectafer to Severe HPP, Luitpold nevertheless did not adequately investigate the extent to which Injectafer causes symptomatic, severe, and persistent or chronic hypophosphatemia – nor did they adequately warn of the risk - and brought Injectafer to the United States market in 2013.

Injectafer's Labeling History

102. Injectafer's label currently, and at all relevant times since its introduction into the United States market, omits any reference to Severe HPP or "clinically important hypophosphatemia" and generally omits reference to the type of serious complications that can result from Severe or Persistent HPP. The labeling does not attempt to inform the user and medical community of the clinical differences between the varying levels of hypophosphatemia.

Injectafer's July 2013 Label

103. Injectafer's label at launch in the United States in July 2013 downplayed the risk, severity, and prevalence of hypophosphatemia.

104. There was no mention of phosphate, phosphorous, or hypophosphatemia in the

"Warnings and Precautions" section.

105. While "hypophosphatemia" is mentioned as an adverse reaction, it is downplayed: a table of adverse reactions in clinical trials lists "blood phosphorus decrease" as occurring is 2.1% of patients, and a notation that "***transient*** decreases in laboratory blood phosphorus levels (>2 mg/dl) have been observed."

106. Under the "Post-Marketing Experience" section of the label, one case of "hypophosphatemic osteomalacia" is mentioned as an aberrant experience of one patient who took Injectafer every two weeks for sixteen weeks. This case is also mentioned under the drug's "Overdosage" section, though no maximum total dosage is on the label, which says "Injectafer treatment may be repeated if iron deficiency anemia reoccurs."

107. The 2013 Patient Information guide describes the side effects of Injectafer as "infrequent, usually mild and generally do not cause patients to stop treatment. The most common side effects are . . . **asymptomatic** reductions in blood phosphorus…"

108. Hypophosphatemia or "blood phosphorous decrease" are not equivalent to Severe HPP or Persistent HPP, and "transient" or "asymptomatic reductions in blood phosphorus" does not identify the likelihood or the risks of Severe HPP or Persistent HPP, including dangerous, prolonged, and potentially permanent injuries.

Injectafer's January 2018 Label

109. A January 2018 label revision edited the Patient Information guide. It removed the description of side effects as infrequent and mild, and it edited the side effects description of "asymptomatic reductions in blood phosphorous" to "low levels of phosphorous in your blood." It did not include any additional warning about Severe or Persistent HPP in any of the risk sections and did not edit adverse reaction or post-marketing section of the labels related to phosphorus or

hypophosphatemic osteomalacia.

Injectafer's October 2018 Label

110. Injectafer's label was revised again in 2018, but no new information about Injectafer's link to hypophosphatemia or low phosphate levels was included.

Injectafer's February 2020 Label

111. The most recent revision to the Injectafer label elevated hypophosphatemia to a higher risk category on the label, but it is still downplayed and incomplete. It does not mention either Severe HPP, Persistent HPP, or the severe complications that can result. It suggests only certain patients are at risk for HPP and that only patients undergoing multiple courses of treatment need to be monitored.

112. Under the "Warnings and Precautions" highlights, the label warns of "symptomatic hypophosphatemia" and that physicians should "[m]onitor serum phosphate levels **in patients at risk for low serum phosphate who require a repeat course of treatment**" (emphasis added). The Warnings and Precautions section added a subsection on "Symptomatic hypophosphatemia," which states that cases of symptomatic HPP requiring clinical intervention have been reported in patients at risk of low phosphate. It states that "[t]hese cases have occurred mostly after repeated exposure to Injectafer. . . ." It lists "possible risk factors" for HPP as those with "a history of gastrointestinal disorders associated with malabsorption of fat-soluble vitamins or phosphate, concurrent or prior use of medications that affect proximal renal tubular function, hyperparathyroidism, vitamin D deficiency and malnutrition." This section also notes that HPP resolved within three months in most cases.

113. A new section under dosage and administration was added (section 2.3 - Repeat Treatment Monitoring Safety Assessment) which also added the instruction to "monitor phosphate

levels **in patients at risk for low serum phosphate who require a repeat course of treatment**" (emphasis added).

114. The Post-marketing Experience section was edited to a bulleted list of reported post-marketing spontaneous reports, divided by System Organ Class ("SOC").[19] Hypophosphatemia was added. The previous description of osteomalacia was edited to read "hypophosphatemia osteomalacia (rarely reported event)" without further details.

115. Even the February 2020 label, which remains in use today, does not reflect Defendants' knowledge of Injectafer's propensity to cause Severe HPP or Persistent HPP, conditions that clinically differ in severity from milder forms of HPP, and generally minimizes the risk of HPP to only certain patients who require repeat courses of treatment.

116. Injectafer's current label does not attempt to advise that lower doses of the drug may result in less serious side effects or give any other indication for ways to reduce the very high risk of hypophosphatemia.

117. Despite recommendations in the medical literature, the current Injectafer label still does not recommend phosphate monitoring for *any* patient who takes a dose of Injectafer. As currently written, the label merely advises doctors to monitor phosphate levels if a patient is both at risk for low serum phosphate levels and requires a repeat course of treatment.

118. Though Injectafer's current label lists conditions that increase the risk for hypophosphatemia, the current Injectafer labeling does not provide any contraindication for use in those who are at risk or already have low phosphate.

119. Failure to warn of Severe HPP, along with the injuries it can cause – e.g.,

[19] System Organ Class ("SOC") is the top-level (i.e., broadest) descriptor of adverse events. There are 27 SOCs in MedDRA, a validated international medical terminology used by regulatory authorities and industry. See www.meddra.org.

osteomalacia, rhabdomyolysis, cardiac arrest, cardiac arrhythmia, respiratory failure – given Defendants' knowledge of their occurrence and their seriousness and/or frequency, violates state and federal law.

120. In addition, the Injectafer label also omits reference to FCM's known effect on the FGF23 hormone, which is in turn associated with a decrease in blood phosphorous.

121. With their knowledge dating back to prior to Injectafer's United States launch, Defendants have a duty to explain how to investigate, monitor, and mitigate sharp drops in an Injectafer user's phosphorus levels, but have failed to do so.

122. Defendants' failure meant that the medical community never learned of Injectafer's known risks of Severe HPP, the injuries that can result from Severe HPP, and Injectafer's known propensity to increase FGF23, which in turn can cause both acute and potentially prolonged Severe HPP.

123. Prescribing physicians, healthcare providers, and patients, including Plaintiff Barbara Kessler and her healthcare providers, neither knew, nor had reason to know at the time of their prescribing and use of Injectafer, of the existence of the risks of Severe HPP and Persistent HPP, nor of the injuries that can result from Severe HPP. Ordinary consumers would not have recognized the potential risks or side effects, which Defendants concealed during their promotion of Injectafer.

124. At all times herein mentioned, due to Defendants' failures, Injectafer was prescribed and used as intended by Defendants and in a manner foreseeable to Defendants. Defendants knew or should have known that patients, such as Plaintiff Kessler, would foreseeably suffer injury because of this use.

Injectafer's Design, Testing, and Marketing

125. Before Injectafer entered the United States market, Defendants knew or should

have known that higher doses of Injectafer, in addition to long-term use of Injectafer, could cause more adverse events.

126. Intended for rapid and high-dose iron replenishment, in the United States, Injectafer is to be administered intravenously in two doses separated by at least 7 days. For those weighing over 100 pounds, each dose should be for 750 mg, for a total cumulative dose of 1500 mg of iron per course of Injectafer.

127. Defendants failed to design Injectafer in such a way that mitigated risk of adverse events. For example, Injectafer could have been designed to have a lower single and maximum dose, in order to lessen the risk of adverse events, particularly the risk of Severe HPP and its resulting injuries.

128. Defendants failed to adequately test Injectafer's effect on phosphate levels before Injectafer was marketed in the United States. For example, in the two pivotal clinical studies upon which Injectafer was approved in 2013, upon information and belief, Defendants did not instruct the clinical investigators on clinical symptoms of HPP and left it to each clinical investigator's discretion about whether to report HPP as an "adverse event."

129. Defendants could have adequately tested Injectafer's effect on phosphate after Injectafer was approved for the United States market, but did not. For example, to date, upon information and belief, Defendants have conducted no studies that have been made public on whether Injectafer can cause Persistent or Chronic HPP; no studies on whether long-term use of Injectafer increases the risk of Severe, Symptomatic, Persistent or Chronic HPP; and no studies with long-term follow up on the longer-term effects of Injectafer-caused HPP and related symptoms.

130. Defendants also have a duty not to manufacture, market, and sell a product that is

unreasonably dangerous so that its potential harm outweighs its potential benefits. Defendants have breached their duty to ensure safe, well-tested, well-monitored, and properly labeled products enter into the pharmaceutical market.

131. Upon information and belief, despite the available literature, adverse event reports, clinical studies, and other information that Injectafer could cause Severe HPP, Defendants implemented a sales and marketing strategy that focused on handling objections about Injectafer causing hypophosphatemia by stressing that this hypophosphatemia was asymptomatic and transient. Defendants promoted that claim to treating physicians, including Plaintiff Barbara Kessler's prescribing physicians.

Plaintiff's Use of Injectafer

132. Plaintiffs Barbara and Thomas Kessler are residents of Austin, Texas.

133. Plaintiff Barbara Kessler suffers from iron deficiency anemia. In February 2016, she was prescribed Injectafer for treatment of her low iron.

134. Prior to that, Plaintiff Barbara Kessler received other types of iron infusions, but Dr. Rutherford recommended she switch because Injectafer was safe and delivered a higher dose more quickly, without any additional side effects.

135. Plaintiff Barbara Kessler received Injectafer infusions thirty-five separate times, about every two to six weeks, beginning February 18, 2016 at University of Texas Southwestern Medical Center, prescribed by Dr. Cynthia Rutherford.

136. Dr. Rutherford recommended Plaintiff switch to Injectafer from the Fereheme. After moving, Plaintiff Barbara Kessler continued her Injectafer regimen and was prescribed Injectafer by Dr. Mathew Meeneghan at Texas Oncology. Her last Injectafer infusion occurred in March 8, 2019.

137. After Plaintiff received Injectafer, she suffered symptoms indicative of chronic, severe, and/or symptomatic hypophosphatemia, including bone pain, severe fatigue and weakness, and shortness of breath.

138. After suffering severe symptoms for around three years, Plaintiff Barbara Kessler read an article about Injectafer which led her to ask her doctors about a potential connection between her symptoms and Injectafer in March 2019.

139. Plaintiff Barbara Kessler emailed her original prescribing physician, Dr. Rutherford, who said that 2% of patients get low phosphorus levels, but upon information and belief, Dr. Rutherford did not know that Injectafer could cause Severe or Persistent HPP.

140. Upon information and belief, Dr. Meeneghan was unaware of a connection between Severe and Persistent HPP and Injectafer. He agreed to further investigate it and agreed to check Plaintiff's phosphate levels, which confirmed Severe HPP on March 18, 2019 with 1.4 mg/dL serum phosphate level.

141. Plaintiff's prescribing physicians were both targeted by the sales and marketing team for Injectafer, and their usage of Injectafer was tracked and analyzed. Upon information and belief, they were "detailed" in person or by phone by sales representatives or a sales telemarketing campaign about Injectafer.

142. As a result of her use of Injectafer, Plaintiff has suffered and will likely suffer in the future, severe and permanent injuries and damages.

143. Any applicable statute of limitations have been tolled by the knowing and active concealment and omission or denial of material facts known by the Defendants when they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of omission and concealment have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's

claims, without any fault or lack of diligence on Plaintiff's part, in order to delay Plaintiff's filing of her causes of action. Defendants' fraudulent concealment did result in such delay.

144. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with her medical providers, the nature of her injuries and damages and their relationship to Injectafer was not discovered, and through reasonable case and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

145. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of Injectafer, as well as information related to Injectafer's known ability to cause Plaintiff's injury.

146. Plaintiffs seek the application of the law of the forum state, Pennsylvania, which is also home to Defendants Luitpold and American Regent. However, should this Court determine in a choice of law analysis that another state's law should apply to this matter; Plaintiffs reserve the right to recover pursuant to Texas common and statutory law.

CLAIMS FOR RELIEF

COUNT I—NEGLIGENT FAILURE TO TEST

147. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

148. At all times relevant, the American Regent Defendants, the Daiichi Sankyo Defendants, and Defendant Vifor International were in the business of designing, developing, testing, manufacturing, labeling, marketing, advertising, promoting, monitoring, selling and/or

distributing Injectafer, including the product administered to Plaintiff.

149. Each of the Defendants played a role in the design and testing of Injectafer, either by virtue of the Defendant's control of clinical trials or other studies involving Injectafer or ownership of another entity which controlled those trials or studies; control of the Injectafer product and labeling or ownership of the entity which controlled the product and labeling; or involvement in contractual agreements that required participation and engagement in the design and testing of the Injectafer product.

150. Defendants had a duty to exercise reasonable and ordinary care in the designing, developing, testing, manufacturing, labeling, marketing, advertising, promoting, monitoring, selling and/or distributing of Injectafer so as to avoid exposing others to foreseeable and unreasonable risks of harm.

151. Defendants breached their duty of care to the Plaintiffs and Plaintiff Barbara Kessler's physicians, in the testing, monitoring, and pharmacovigilance of Injectafer.

152. Defendants knew or reasonably should have known that Injectafer was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

153. At the time of the development and design of Injectafer, Defendants knew or should have known that ferric carboxymaltose ("FCM"), the active ingredient in Injectafer, was designed in such a manner that it caused Severe Hypophosphatemia and additional injuries that are known to stem from that diagnosis. Defendants knew or should have known of the problems and defects with FCM due to information and scientific evidence that existed from FCM's time in the European and world markets, known there as Ferinject (the bioequivilant to Injectafer), prior to its approval in the United States.

154. At the time of the development and design of Injectafer, Defendants knew or should

have known that Injectafer caused a sharp increase in the hormone FGF23, which in turn is associated with a decrease in blood phosphorous and a host of other sequelae not evident in other iron injection formulations. Defendants knew or should have known of the problems and defects with FCM and FGF23 due to information and scientific evidence that existed from FCM's time on the European and world markets as Ferinject.

155. At the time of the development and design of Injectafer, Defendants knew or should have known from the available literature, adverse event reports, clinical studies, and case studies that using Injectafer for its intended use to treat IDA or for other indicated or unindicated conditions promoted by Defendants created a significant risk of a patient suffering severe injuries, including but not limited to Severe Hypophosphatemia and the injuries that result from Severe, Chronic or Persistant Hypophosphatemia.

156. Defendants knew or reasonably should have known that the consumers of Injectafer would not realize the danger associated with administration of the drug for its intended use and/or in a reasonably foreseeable manner.

157. Defendants had a duty to perform adequate testing on Injectafer to ensure the product that entered the United States marketplace did not cause Severe HPP at the recommended levels of dosing.

158. Defendants had a duty to perform testing on Injectafer that investigated and demonstrated, if applicable, the extent of blood phosphorus decrease that could result from ingestion of Injectafer.

159. Defendants had a duty to place a product in the United States market that was adequately tested to avoid the potential decrease in blood phosphorous to the life-threatening levels experienced by Plaintiff Barbara Kessler.

160. Defendants breached their duty to exercise reasonable and prudent care in the testing, monitoring, and pharmacovigilance of Injectafer in the following ways:

161. Failing to perform reasonable and adequate pre-and post-market testing of the product—including, but not limited to clinical trials, preclinical trials, surveys, and prospective studies—to investigate Injectafer's (ferric carboxymaltose) propensity to cause Severe or Persistent Hypophosphatemia;

162. Failing to train clinical trial investigators in Defendants' pivotal Injectafer studies about the clinical symptoms of Severe or Persistent Hypophosphatemia;

163. Failing to train clinical trial investigators on when hypophosphatemia should be reported as an adverse event in at least he pivotal clinical trials;

164. Failing to fully follow and report on patients who developed HPP in at least the pivotal clinical trials in order to determine when/if the HPP resolved;

165. Failing to adequately monitor the adverse events related to Injectafer (ferric carboxymaltose) known to Defendants from published case reports, studies, and reports submitted to Defendants and FDA;

166. Failing to establish and maintain an adequate post-marketing surveillance program for Injectafer (ferric carboxymaltose) given Defendants' knowledge of link between product and Severe Hypophosphatemia from experiences with ferric carboxymaltose in non-United States markets.

167. Failing to investigate in clinical trials and other testing for Injectafer the extent of the decrease in blood phosphorous that can result from ingestion of Injectafer;

168. Failing to investigate in clinical trials or other testing the effects of repeated courses or long-term use of Injectafer on phosphate levels;

169. Failing to investigate in clinical trials and other testing for Injectafer the consequence of severe decreases in blood phosphorous and the conditions that can result from Severe or Persistent Hypophosphatemia;

170. Failing to investigate in clinical trials and other testing for Injectafer how to offset or mitigate the sharp increase in the FGF23 hormone that ferric carboxymaltose was known to trigger.

171. Defendants could have adequately tested Injectafer's effect on phosphate levels before Injectafer was marketed in the United States, but did not. For example, upon information and belief, in the pivotal clinical studies upon which Injectafer was approved in 2013, Defendants did not instruct the clinical investigators on clinical symptoms of HPP and left it to each clinical investigator's discretion about whether to report HPP as an "adverse event."

172. Defendants could have adequately tested Injectafer's effect on phosphate after Injectafer was approved for the United States market, but did not. For example, to date, upon information and belief, Defendants have conducted no studies that have been made public on whether Injectafer can cause Persistent or Chronic HPP; no studies on whether long-term use of Injectafer increases the risk of Severe, Symptomatic, Persistent or Chronic HPP; and no studies with long-term follow up on the longer-term effects of Injectafer-caused HPP and related symptoms.

173. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions, given the extensive knowledge of ferric carboxymaltose's link to Severe Hypophosphatemia at the time of development.

174. As a direct and proximate result of Defendants' negligent testing, monitoring, and

pharmacovigilance of Injectafer, Defendants introduced a product into the United States marketplace that is known to cause Severe Hypophosphatemia at the recommended dosing.

175. As a direct and proximate result of Defendants' negligent testing, monitoring, and pharmacovigilance of Injectafer, Plaintiff Barbara Kessler has suffered, and will continue to suffer injury, emotional distress, impairment, loss of enjoyment of life, harm and economic damages.

176. The aforementioned negligence and wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

COUNT II—NEGLIGENT DESIGN DEFECT

177. Plaintiff Barbara Kessler incorporates the factual allegations set forth above as if fully set forth herein and further alleges as follows:

178. Defendants are liable to Plaintiffs for the injuries and damages sustained by Plaintiff Barbara Kessler due to their negligent design and/or formulation of Injectafer.

179. At all relevant times to this lawsuit, Defendants owed a duty to consumers including

Plaintiff and her health care providers, to assess, manage, and communicate the risks, dangers, and adverse effects of Injectafer. Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying, and manufacturing Injectafer.

180. Defendants negligently and carelessly breached these duties to Plaintiff by, among other acts and omissions, negligently and carelessly:

a. Failing to use ordinary care in designing, testing, and manufacturing Injectafer;

b. Failing to design Injectafer as to properly minimize the effects on the hormone FGF23 which was known when increased to decrease serum phosphorous;

c. Failing to counteract in the design the known effects of ferric carboxymaltose that result in an increase in FGF23 and decrease of serum phosphorus;

d. Failing to counteract in the design the known effects of ferric carboxymaltose that result in the condition of rental phosphate wasting;

e. Designing a product with excessive amounts of iron where the benefits of additional iron were greatly outweighed by the risks of excessive iron injected into the body; and

f. Designing a product without taking into consideration the proper dosage, dosage frequency, the break in time between dose administrations, the maximum dosage, or the duration of dose administration to lessen the safety risks.

181. The Injectafer manufactured, distributed, sold and/or supplied by Defendants was

defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, the foreseeable risks exceeded the benefits associated with the design or formulation.

182. The Injectafer manufactured, distributed, sold and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers and/or distributors, it was unreasonably dangerous, it was unreasonably dangerous and more dangerous than an ordinary consumer would expect and more dangerous than other iron injection drugs.

183. The Injectafer manufactured, distributed, sold and/or supplied by Defendants was defective in design or formulation in that there were alternative feasible designs for the product, such as developing a different dosing regimen with less iron amounts injected into the body at once.

184. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Injectafer when the product at all times relevant, Defendants brought the product to market and continued to market the drug when there were safer alternatives available. For example, in order to lessen or mitigate the effects of FMC on FGF23 and phosphate levels and to make the drug safer, Injectafer could have been designed more safely if it:

a. Had been designed to be given in a lower dose than 750 mg;

b. Had been designed to be given in a lower dose than 1500 mg per course (i.e., two doses of 750 mg);

c. Had been designed to be given longer than 7 days between each dose for one course;

d. Had been designed to be given in more than two doses per course, at lower

dosage levels each;

e. Had been designed to have longer time periods between each course of drug;

f. Had been designed with a phosphate additive;

g. Had been designed to be taken along with phosphate supplements.

185. At the time Injectafer left control of the Defendants, the above safer alternative designs were reasonable, economically and technologically feasible, and would have prevented or significantly reduced the risk of harm of Severe or Permanent HPP, including to Plaintiff Barbara Kessler.

186. Other competitor products are also examples safer alternatives to Injectafer because they do not cause the type of Severe or Persistent HPP that Injectafer causes.

187. The aforementioned negligence and wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff .

188. As a direct and proximate result of the Defendants' negligent and reckless design of Injectafer, Plaintiff Barbara Kessler suffered injuries, harm, and economic damages.

COUNT III—NEGLIGENT MISREPRESENTATION

189. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further alleges as follows:

190. At all relevant times, Defendants, specifically American Regent, Luitpold, and the Daiichi Sankyo Defendants, negligently provided Plaintiff Barbara Kessler, her healthcare providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning Injectafer, including, but not limited to, misrepresentations regarding the safety and known risks of Injectafer.

191. The information distributed by the Defendants to the public, the medical community, Plaintiff, and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of Injectafer.

192. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff Barbara Kessler and Plaintiff's health care providers to falsely assure them of the quality of Injectafer and induce the public and medical community, including Plaintiff and her healthcare providers, to request, recommend, purchase, prescribe, and use Injectafer.

193. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, her healthcare providers, and the public, the known risks of Injectafer including its propensity to cause Severe Hypophosphatemia and related injuries.

194. Defendants made and continue to make misrepresentations regarding Injectafer

being adequately tested and safety designed.

195. Defendants made and continue to make omissions regarding their failure to test Injectafer for Persistent and Severe HPP.

196. Defendants made and continue to make misrepresentations and omissions regarding Injectafer's dosing regimen, that the benefits of a higher-dose and few doses outweigh any potential risks.

197. Defendants made and continue to make misrepresentations regarding that only 2% of those in their pivotal clinical trials suffered adverse reactions from low phosphate.

198. Defendants made and continue to make misrepresentations that Injectafer has no more serious side effects than does its competitor products.

199. Defendants also made and continue to make misrepresentations and omissions in the Injectafer labeling, including but not limited to:

a. Decreases in serum phosphorous are simply "transient";

b. Decreases in serum phosphorous are "asymptomatic";

c. Misrepresenting the total number of incidences of low blood phosphorous findings in the multiple clinical studies completed by Defendants;

d. Misrepresenting the severity of hypophosphatemia associated with Injectafer by only referencing in passing an adverse effect of hypophosphatemia, which was interpreted by Plaintiff, Plaintiff's healthcare providers, and the medical community to not rise to the level of Severe Hypophosphatemia; and

e. Advertising, promoting, and marketing Injectafer as a safe and superior iron infusion product compared to the other iron infusion products drugs

on the market that were not known to cause Severe Hypophosphatemia.

200. Defendants have made additional misrepresentations beyond the product labeling by representing Injectafer as a safe and superior intravenous iron product with only minimal risks.

201. Upon information and belief, Defendants also made these misrepresentations via a robust sales and marketing detailing program starting in about 2015 via phone or in person to Plaintiff's prescribing physicians—Drs. Cynthia Rutherford and Matthew Meeneghan, both of whom Defendants American Regent, Luitpold, and DSI targeted as potential and actual prescribing doctors.

202. Defendants misrepresented and overstated the benefits of Injectafer to Plaintiff Barbara Kessler, Plaintiff's healthcare providers, and the medical community without properly advising of the known risks related to decreases in serum phosphorous.

203. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff Barbara Kessler and Plaintiff's healthcare providers were induced to, and did use Injectafer, thereby causing Plaintiff to endure severe and permanent injuries.

204. Dr. Rutherford, who originally prescribed Injectafer to Plaintiff Barbara Kessler, relied on a number of misrepresentations and omissions. For example, she relied on the misrepresentation that only 2% of Injectafer patients suffer from an adverse reaction related to low phosphate; that the drug's design and dosing schedule was a benefit to use that did not raise any additional serious safety concerns over the competitor products; and that the drug was adequately tested before it was put on the market and adequately studied and monitored after it was put on the market.

205. Similarly, upon information and belief, Dr. Meeneghan relied on the same misrepresentations and omissions.

206. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's healthcare providers were unable to associate the injuries sustained by Plaintiff with her Injectafer use, and therefore unable to provide adequate treatment.

207. Defendants knew and had reason to know that the Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

208. Plaintiff and her healthcare providers would not have used or prescribed Injectafer had the true facts not been concealed by the Defendants.

209. Defendants had sole access to many of the material facts concerning the defective nature of Injectafer and its propensity to cause serious and dangerous side effects.

210. At the time Plaintiff Barbara Kessler was prescribed and administered Injectafer, Plaintiff and her healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

211. The Defendants failed to exercise ordinary care in making representations concerning Injectafer while they were involved in their manufacture, design, sale, testing, quality assurance, quality control, promotion, marketing, labeling, and distribution in interstate commerce, because the Defendants negligently misrepresented Injectafer's high risk of unreasonable and dangerous adverse side effects.

212. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by the Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Injectafer.

213. Plaintiff Barbara Kessler and Plaintiff's healthcare providers' reliance on the

foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

214. The aforementioned misrepresentations and wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

COUNT IV—GROSS NEGLIGENCE

215. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further alleges as follows:

216. Defendants' negligent conduct, including their negligent failure to test and negligent defective design, was aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiffs, for which the law would allow, and which Plaintiff will seek at the appropriate time under the governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiffs; or when viewed objectively from Defendants' standpoint at the time

of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious disregard to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiffs.

217. Defendants ignored or disregarded years of data and reports on the relationship between ferric carboxymaltose and Severe Hypophosphatemia.

218. Defendants' ignorance of the safety data was ongoing through the date Plaintiff was prescribed and ingested the Injectafer product.

219. Given Defendants' knowledge and awareness of the extensive body of information available on ferric carboxymaltose, and its propensity to cause Severe Hypophosphatemia, Defendants failure to conduct adequate testing and failure to design the product to minimize safety risks in order to ensure the version of ferric carboxymaltose that made its way to the United States marketplace was safe for recommended use amounts to gross negligence, malice, and a reckless disregard for the safety of Plaintiffs and others.

220. Plaintiff Barbara Kessler and her healthcare providers relied on the Defendants to introduce into the marketplace a safe and adequately tested iron drug, and Plaintiff suffered injuries as a result of Defendants' failure to do so.

221. Plaintiff Barbara Kessler therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

222. Plaintiff will seek to assert claims for exemplary damages to the extent available

under all applicable Pennsylvania and Texas laws.

223. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately cause Plaintiffs' injuries. In that regard, Plaintiffs will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT V—FRAUD

224. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further alleges as follows:

225. The Defendants, specifically American Regent, Luitpold, and the Daiichi Sankyo Defendants, falsely and fraudulently have represented and continue to represent to the medical and healthcare community, to Plaintiff Barbara Kessler and her healthcare providers, and/or the public that Injectafer has been appropriately tested, was being appropriately monitored, and was found to be safe and effective.

226. The representations made by Defendants American Regent, Luitpold, and the Daiichi Sankyo Defendants were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of Injectafer.

227. These representations were made by Defendants American Regent, Luitpold, and the Daiichi Sankyo Defendants with the intent of defrauding and deceiving the medical community, Plaintiff Barbara Kessler, Plaintiff's healthcare providers, and/or the public. These representations were intended to induce the medical community, Plaintiff, Plaintiff's healthcare

providers, and/or the public, to recommend, prescribe, dispense, purchase, and/or use Injectafer to treat Iron Deficiency Anemia (IDA) while concealing the drug's known propensity to cause Severe or Persistent Hypophosphatemia and the consequent injuries that occur from low levels of blood phosphorous.

228. Defendants made these misrepresentations via its sales and marketing program, which in representations to Plaintiff Barbara Kessler and/or to her healthcare providers, including Plaintiff's prescribing physicians—Drs. Cynthia Rutherford and Matthew Meeneghan—Defendants American Regent, Luitpold, and the Daiichi Sankyo Defendants fraudulently stated on the Injectafer product labeling in existence at the time Plaintiff was prescribed Injectafer in February 2016, specifically the Injectafer (ferric carboxymaltose) labeling in effect beginning in July 2013 and revised in January 2018:

a. Decreases in serum phosphorous are simply "transient" (Section 6.1);

b. Decreases in serum phosphorous are "asymptomatic" (Patient Information);

c. Misrepresenting the total number of incidences of low blood phosphorous findings in the multiple clinical studies completed by Defendants (Section 6.1);

d. That Injectafer was safe and efficacious for adult Patients regardless of pre-existing conditions related to blood phosphorous disease or deficiency, or FGF23 disease or deficiency.

229. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's prescribing physicians Drs. Cynthia Rutherford and Matthew Meeneghan, Defendants American Regent, Luitpold, and the Daiichi Sankyo Defendants fraudulently concealed and

intentionally omitted the following material information from the Injectafer product labeling in existence at the time Plaintiff was prescribed Injectafer in February 2016, specifically the Injectafer (ferric carboxymaltose) labeling in effect beginning in July 2013 and revised in January 2018:

a. That Injectafer causes Severe Hypophosphatemia and potentially long-term and permanent injuries that result from low blood phosphorous including but not limited to osteomalacia, rhabdomyolysis, respiratory failure, cardiac arrest, cardiac arrhythmia;

b. That Injectafer was known to increase the hormone FGF23 which in turn is associated with the decreased of blood phosphorus levels;

c. That Injectafer was considerably less safe than the other iron supplement and iron injection products on the market given its unique propensity to cause Severe Hypophosphatemia;

d. That Injectafer was not adequately tested following the Defendants' knowledge that the drug was causing Severe Hypophosphatemia at increased and alarming levels;

e. That Defendants deliberately failed to follow up on the adverse results from clinical studies and formal and informal reports from physicians and other healthcare providers and either ignored, concealed and/or misrepresented those findings;

f. That there is a clinically important difference between mild, moderate hypophosphatemia, and Severe Hypophosphatemia, the latter of which is a serious harm caused by Injectafer use; and

g. That Injectafer was negligently designed as set forth in the Negligent Defective Design Count.

230. Upon information and belief, Defendants also made these misrepresentations via a robust sales and marketing detailing program starting in about 2015 via phone or in person to Plaintiff's prescribing physicians—Drs. Cynthia Rutherford and Matthew Meeneghan, both of whom Defendants American Regent, Luitpold, and DSI targeted as potential and actual prescribing doctors.

231. The American Regent, Luitpold, and Daiichi Sankyo Defendants knew or had reason to know that incidences of decreased in blood phosphorous were not temporary, transient, or asymptomatic, as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Injectafer, as well as at the time of Plaintiff's Injectafer prescription.

232. The American Regent, Luitpold, and Daiichi Sankyo Defendants knew or had reason to know that Injectafer caused Severe Hypophosphatemia and related conditions as a result of information from case studies, clinical trials, literature, and adverse event reports available to the Defendants at the time of the development and sale of Injectafer, as well as at the time of Plaintiff's Injectafer prescription.

233. The American Regent, Luitpold, and Daiichi Sankyo Defendants' concealment and omissions of material facts concerning the safety of the Injectafer were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff and Plaintiff's healthcare providers and to induce them to purchase, prescribe, and/or use Injectafer.

234. At the time these representations were made by Defendants, and at the time Plaintiff and/or her healthcare providers used Injectafer, Plaintiff and/or her healthcare providers were

unaware of the falsehood of these representations.

235. In reliance upon these false representations and omissions, Plaintiff was induced to, and did use Injectafer, thereby causing severe, debilitating, and potentially permanent personal injuries and damages to Plaintiff. Defendants knew or had reason to know that the Plaintiff had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of Injectafer, as described in detail herein.

236. In comporting with the standard of care for prescribing physicians, Plaintiff's prescribing physician relied on the labeling for Injectafer in existence at Plaintiff's date of prescription that included the aforementioned fraudulent statements and omissions.

237. These representations made by American Regent, Luitpold, and the Daiichi Sankyo Defendants were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

238. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of the Defendants American Regent, Luitpold, and the Daiichi Sankyo Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendants' misrepresentations at the time when Injectafer was prescribed to her.

239. As a proximate result of the Defendants' fraudulent statements and omissions, Plaintiff Barbara Kessler has suffered injuries, harm, and economic damages.

240. The aforementioned fraudulent statements and omissions and wrongs done by the Defendants were aggravated by the kind of malice and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at

the appropriate time under governing law for the imposition of exemplary (or, punitive) damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants knowing that they was false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff .

COUNT VI—STRICT LIABILITY DESIGN DEFECT

241. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

242. Injectafer is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectations of patients and their health care providers in that the side effects caused by Injectafer nullify any possible benefit.

243. Here, the Injectafer injection was expected to, and did, reach its intended consumer without substantial change in the condition in which it was in when it left Defendants' possession.

244. The Injectafer administered to Plaintiff Barbara Kessler was defective in design because it failed to perform as safely as persons who ordinarily use the products would have expected at time of use.

245. The Injectafer administered to Plaintiff was defective in design in that the product's risks of harm clearly exceeded its claimed benefits.

246. The Defendants are strictly liable in the above-described duties to Plaintiff by,

among other acts and omissions:

a. Failing to use ordinary care in designing, testing, and manufacturing Injectafer:

b. Failing to design Injectafer as to properly minimize the effects on the hormone FGF23 that was known when increased to in turn decrease serum phosphorous;

c. Failing to counteract in the design the known effects of ferric carboxymaltose that result in an increase in FGF23 and decrease of serum phosphorus;

d. Failing to counteract in the design the known effects of ferric carboxymaltose that result in the condition of renal phosphate wasting;

e. Designing a product with excessive amounts of iron where the benefits of additional iron were greatly outweighed by the risks of excessive iron injected into the body;

f. Designing a product without taking into consideration the proper dosage, dosage frequency, or duration of dose administration.

247. Plaintiff and her healthcare providers used Injectafer consistent with the instructions provided in the product labeling and in a manner that was reasonably foreseeable to Defendants.

248. Neither Plaintiff nor her healthcare providers could have by the exercise of reasonable care discovered the extent of Injectafer's defective condition or perceived its unreasonable dangers prior to her first injection of the drug.

249. As a result of the foregoing design defects, Injectafer created risks to the health and

safety of its users, including Plaintiff Barbara Kessler, that were far more significant and devastating than the risks posed by other intravenous iron products and procedures available to treat Iron Deficiency Anemia (IDA), and which far outweigh the utility of Injectafer.

250. At the time Injectafer was developed and designed, there existed safer alternative intravenous iron medications that were known to Defendants and available on the marketplace and comparatively safer than the Injectafer product.

251. Defendants have intentionally and recklessly designed and developed Injectafer with wanton and willful disregard for the rights and health of the Plaintiff and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

252. As a proximate result of Defendants' design and development of Injectafer, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT VII—LOSS OF CONSORTIUM

253. Plaintiffs incorporate the factual allegations set forth above as if fully set forth herein and further allege as follows:

254. At all times relevant hereto, Plaintiff Thomas Kessler, the spouse of Plaintiff Kessler suffered injuries and losses as a result of Plaintiff Barbara Kessler's injuries.

255. As a further direct result of Defendants' breach of duties as described and alleged above, Plaintiff Thomas Kessler has lost and will in the future lose his spouse's companionship, aid, comfort, society, services, protection and consortium, all to his damage in an amount greater than $75,000.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against all Defendants and each of them, individually, jointly and severally, on each of the above-referenced claims and Causes of Action and requests damages as follows:

256. For general damages in a sum in excess of the jurisdictional minimum of this Court;

257. For medical, incidental, and hospital expenses according to proof;

258. For all ascertainable economic and non-economic damages in an amount as provided by law and according to proof;

259. For pre-judgment and post-judgment interest as provided by law;

260. For consequential damages in excess of the jurisdictional minimum of this Court;

261. For compensatory damages in excess of the jurisdictional minimum of this Court;

262. For punitive and exemplary damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

263. For attorneys' fees, expenses and costs of this action; and

264. For such further and other relief as this Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment to the U.S. Constitution on all of the triable issues within this Complaint.

Dated: February 18, 2021

Respectfully submitted,

ROBINS KAPLAN LLP

By: *s/Rayna E. Kessler*
Rayna E. Kessler, Esq.
PA ID No. 309607
399 Park Avenue, Suite 3600
New York, New York 10022
Telephone: (212) 980-7431
Facsimile: (212) 980-7499
E-mail: RKessler@RobinsKaplan.com

Kate Jaycox, Esq.*
Matthew Leighton, Esq.*
2800 LaSalle Plaza
800 LaSalle Avenue
Minneapolis, MN 55402-2015
Telephone: 612-349-8500
Facsimile: 612-339-4181
Email: KJaycox@RobinsKaplan.com
MLeighton@RobinsKaplan.com

**Pro Hac Vice Motion to be Filed*

Attorneys for Plaintiffs Barbara and Thomas Kessler