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IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: INJECTAFER PRODUCTS LIABILITY LITIGATION

LAROSA JONES
230 Ohio Street
Racine, WI 53405

Plaintiff,

vs.

LUITPOLD PHARMACEUTICALS, INC
5 Ramsey Rd, Shirley, NY 11967
800 Adams Ave # 1, Norristown, PA 19403,
and
AMERICAN REGENT, INC.
5 Ramsey Rd, Shirley, NY 11967
and
DAIICHI SANKYO, INC.
211 Mt Airy Rd, Basking Ridge, NJ 07920
and
DAIICHI SANKYO US HOLDINGS, INC.
211 Mt Airy Rd, Basking Ridge, NJ 07920
and
VIFOR (INTERNATIONAL) AG
Rechenstrasse 37 CH-9014 St. Gallen, Switzerland

Defendants.

SEPTEMBER 2022

NO:

JURY TRIAL DEMAND

PETITION FOR DAMAGES

NOTICE TO DEFEND

NOTICE:

You have been sued in court. If you wish to defend against the claim set forth in the following pages, you must take action within twenty (20) days after this Complaint and Notice are served, by entering a written appearance personally or by attorney, and filing in writing with the Court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the Court without further notice for any money claimed in the Complaint or for any other claims or relief requested by the Plaintiff. You may lose money or property or other rights important to you.

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AVISO:

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas en las paginas siguientes, usted tiene veinte dias de plazo al partir de la fecha de la demanda y la notificacion. Hace falta ascentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomara medidas y puede continuar la demanda en contra suya sin previo aviso o notificacion. Ademas, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puede perder dinero o sus propiedades u otros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICIO, VAYA EN PERSONA O LLAME POR TELEFONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

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COMPLAINT – CIVIL ACTION
PRODUCT LIABILITY

PLAINTIFF, LaRosa Jones, by and through undersigned counsel, files this Complaint against Defendants, Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., Daiichi Sankyo U.S. Holdings, Inc., and Vifor (International) AG (collectively "Defendants"), and in support thereof, makes the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, LaRosa Jones, is a resident of Racine, Wisconsin.

American Regent Defendants

2. Luitpold Pharmaceuticals, Inc. (hereinafter "Luitpold") was a for-profit corporation incorporated in the state of New York. At all relevant times, Luitpold maintained its principal offices in Norristown, PA and Shirley, NY. Luitpold was a subsidiary and member of the Daiichi Sankyo Group and was the parent company to its own subsidiary, American Regent, Inc. In addition to maintaining an office in the Commonwealth of Pennsylvania, Luitpold was registered to do business throughout the state as well as in the county of Philadelphia, specifically. Luitpold has at all relevant times engaged in the business of researching, developing, testing, designing, licensing, manufacturing, distributing, selling, labeling, promoting, and marketing the Injectafer (*ferric* carboxymaltose) product.

3. American Regent, Inc. (hereinafter "American Regent") is a for-profit corporation incorporated in the state of New York. At all relevant times, American Regent appears to operate its principal office out of Shirley, NY, sharing an office address with Luitpold.[1] Upon information

[1] Upon information and belief, prior to December 31, 2018 when Luitpold merged American Regent into itself, American Regent existed as a corporation that was extensively involved with Injectafer. Therefore, at all times

and belief, American Regent also operates out of its Norristown, PA office and is registered to do business in the Commonwealth. American Regent was originally a subsidiary of Luitpold and the Daiichi Sankyo Group. American Regent is the manufacturer listed on the Injectafer label. Along with Defendant Luitpold, American Regent is and was at all relevant times engaged in the business of researching, developing, testing, designing, licensing, manufacturing, promoting, labeling, distributing, selling, and marketing the Injectafer product.

4. Upon information and belief, on or about December 31, 2018, Luitpold merged American Regent into itself, and the surviving entity – Luitpold – was renamed American Regent, Inc. The new entity of American Regent is wholly owned by Daiichi Sankyo, Inc.

Daiichi Sankyo Defendants

5. Daiichi Sankyo, Inc. (hereinafter "DSI") is a for-profit corporation incorporated in the state of Delaware with its principal office in Basking Ridge, New Jersey. Upon information and belief, DSI is or was also known as Sankyo USA Development, Sankyo Pharma Development, Sankyo Pharma Inc., Daiichi Sankyo Pharma Development, Daiichi Pharmaceuticals, Inc., Daiichi Medical Research, Inc., Daiichi Sankyo Group, and Daiichi Pharma Holdings, Inc. The below allegations are attributable to all such entities now represented by DSI.

6. DSI is the United States subsidiary of Daiichi Sankyo Co., Ltd. (hereinafter "DSC"), located in Tokyo, Japan, and is a member of the Daiichi Sankyo Group. Upon information and belief, both Defendants Luitpold and American Regent are and were members of the Daiichi Sankyo Group.

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relevant to this case, whether before, during, or after December 31, 2018, American Regent was an active party in the development, design, manufacture, labeling, promotion, marketing, pharmacovigilance, testing, studying, distribution, and sale of Injectafer.

7. DSI is wholly owned by Defendant, Daiichi Sankyo U.S. Holdings, Inc.

8. DSI is and was at all times engaged in the business of researching, developing, designing, licensing, manufacturing, and distributing, and selling the Injectafer product. Additionally, DSI specifically assumed the roles of promoting and marketing Injectafer in or around January 2017.

9. Upon information and belief, DSI operates as the U.S. headquarters of DSC.

10. Upon information and belief, DSI at all relevant times exercised control over the DSI subsidiaries, Luitpold and American Regent, and had control over all relevant decisions, policies, and conduct with regard to the researching, developing, designing, licensing, manufacturing, and distributing, and marketing, promoting and selling of the Injectafer product.

11. Daiichi Sankyo U.S. Holdings, Inc. (hereinafter "DS Holdings") wholly owns Daiichi Sankyo, Inc. and is located in Basking Ridge, New Jersey.

12. Upon information and belief, DS Holdings is a subsidiary of DSC.

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

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

15. 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,

the Daiichi Defendants does not exist and has never existed. Each of them is an alter ego of the other.

16. Because of the unity of operations and ownership, DSI and DS Holdings are hereto after referred to as the "Daiichi Defendants."

Vifor

17. Vifor (International) AG a/k/a Vifor (International) Inc. (hereinafter "Vifor International") is a for-profit corporation headquartered in Switzerland with an office location at Rechenstrasse 37 CH-9014 St. Gallen.

18. Vifor International is a wholly owned subsidiary of Vifor Pharma Participations Ltd. (hereinafter "Vifor Participations"), a for-profit corporation headquartered in Switzerland.

19. Vifor Participations is a wholly owned subsidiary of Vifor Pharma Ltd. (hereinafter "Vifor Pharma"), a for-profit corporation also headquartered in Switzerland.

20. Vifor International is a wholly owned subsidiary of Vifor Participations, which is wholly owned by Vifor Pharma.

21. Vifor International is also a corporate affiliate of Relypsa Inc. (hereinafter "Relypsa"), a for-profit corporation incorporated in the state of Delaware with its principal office located in California.

22. Relypsa is a wholly owned subsidiary of Vifor Pharma.

23. Vifor Pharma is the parent company to Vifor Participations, Vifor International, and Relypsa. At all relevant times, Vifor Pharma is and was a corporation organized and existing under the laws of Switzerland.

24. Because of the unity of operations and ownership among the Vifor entities, Vifor International, Vifor Pharma, Vifor Participations, and Relypsa, will collectively be referred to as "Vifor" and/or the "Vifor entities."

25. Vifor International was and is the agent for the Vifor entities for purposes of this lawsuit. Vifor International is responsible for all references and allegations herein attributed to the collective Vifor entities as well as all allegations specifically attributed to Vifor International.

26. The Vifor entities 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.

27. Upon information and belief, the Vifor entities, by and through Vifor International, are engaged in a licensing deal with Luitpold that permits Luitpold to design, manufacture, market, supply, promote, label, distribute, and sell Injectafer in the United States. 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 regard to Injectafer sales in the United States.

28. Upon information and belief, the Vifor entities and Vifor International were responsible for the original design and development of the bioequivalent ferric carboxymaltose product, Ferinject.

29. Upon information and belief, the Vifor Entities, by and through Vifor International, licensed that ferric carboxymaltose design to Luitpold, which in turn designed, manufactured, marketed, supplied, distributed, and sold the bioequivalent Injectafer product to the United States market.

30. Pursuant to the aforementioned licensing deal and other agreements, the Vifor entities and Vifor International assumed a role in the conducting and management of the clinical trials, marketing, promotion, marketing sales organization, and safety reporting for Injectafer.

31. Upon information and belief, the Vifor entities and Vifor International provide support to American Regent and DSI, on the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer in the United States.

32. 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. The Vifor entities' Registered Agent in the United States is American Regent.

33. Additionally, since initially introducing ferric carboxymaltose into the world market, the Vifor entities and Vifor International 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.

34. Each of the above entities and the named Vifor International Defendant played a role in the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer. Plaintiff's injuries were caused by the conduct of one or various combinations of Defendants, and through no fault of Plaintiff.

JURISDICTION AND VENUE

35. This Court has original jurisdiction over this matter pursuant to 28 U.S.C.S. § 1332 because the matter in controversy exceeds the sum of $75,000.00 and because it is between a citizen of Wisconsin and Defendant pharmaceutical companies that at all relevant times, have engaged in continuous and systematic business activities in the Commonwealth of Pennsylvania.

See 28 U.S.C.S. § 1332(a)(1).

General Personal Jurisdiction

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

37. This Court also 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, per 42 Pa. C.S. § 5301 and 42 Pa. C.S § 5322. DS Holdings, as the parent and alter ego to DSI and the Daiichi Sankyo Group, thus has inextricable ties to Pennsylvania.

38. This Court also has general personal jurisdiction over the Vifor entities, which do business in Pennsylvania. Specifically, the Vifor entities, by and through Vifor International, engaged in a licensing deal for its ferric carboxymaltose product that would see the continuous and systematic sale of Injectafer in the Commonwealth. Additionally, the Vifor entities, by and through the Vifor affiliates including, but not limited to, Relypsa, manage the sale of Injectafer in the United States, including in the Commonwealth, 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. The Vifor entities thus have inextricable ties to Pennsylvania.

39. This Court has additional grounds for general personal jurisdiction as Luitpold and American Regent operate an office and principal place of business at 800 Adams Street,

Norristown (*also referred to as Eagleville or Audubon*), PA 19403, which is located in the Eastern District of Pennsylvania. *See* 28 U.S.C.S. § 1391(b)(1)&(2).

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

Specific Personal Jurisdiction

41. This Court has specific personal jurisdiction over the Defendants due to the Injectafer-specific business activities, 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.

42. Upon information and belief, Luitpold headquartered its Clinical Division at its Norristown, Pennsylvania office.[2] Norristown, PA was also home to Luitpold's Clinical Research and Development Department, to the extent that group existed separately from the Clinical Division.

43. 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 Project Manager responsible for Injectafer.

44. Upon information and belief, Luitpold's Regulatory Affairs Department also operated out of the Norristown, PA office. Specifically, Marsha E. Simon, Director of Regulatory Affairs, was employed in the Norristown, PA office and used the Norristown, PA address when

[2] Given the December 31, 2018 corporate merger that resulted in Luitpold no longer existing, it is believed that American Regent would now continue to be the sole operating corporate entity at the Norristown, PA location. Therefore, any allegation throughout the Complaint specific to Luitpold also applies to its successor, American Regent.

making regulatory submissions on behalf of Luitpold and Injectafer to the Food and Drug Administration (FDA).

45. Additionally, the Luitpold Norristown PA office served as either the monitoring hub, 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."

46. Upon information and belief, the Norristown, PA office also was the location at which Luitpold conducted its pharmacovigilance and safety reporting functions for the Injectafer product. Specifically, Luitpold employed its Senior Medical Director, Clinical Quality Assurance, Senior Clinical Project Manager, and Clinical Research Associate positions, among other pharmacovigilance and safety positions, all in the Norristown, PA office.

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

48. Pursuant to the licensing and safety agreements between Vifor International and Luitpold, the Vifor entities directly participated in the registration and clinical trials, marketing, promotion and marketing sales organization, safety reporting, 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, PA location.

49. Additionally, the Vifor entities, by and through the Vifor Affiliates including, but not limited to, Relypsa, 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, PA location.

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

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

52. 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.

53. Venue is proper in the Eastern District of Pennsylvania because Defendants American Regent and Luitpold operate an office out of Norristown, Pennsylvania. *See* 28 U.S.C.S. § 1391(b)(1)&(2).

54. Venue is also proper in the Eastern District because substantial, specific conduct by the Luitpold Defendant, the American Regent Defendant, and the Vifor entities that gave rise to this claim including the design, creation, testing, labeling, development, pharmacovigilance, and sale of Injectafer originated and occurred in Defendants' Philadelphia region office. *See* 28 U.S.C.S. § 1391(b)(2).

INTRODUCTION AND NATURE OF CASE

55. 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, and in adult patients with non-dialysis dependent chronic kidney disease."

56. Injectafer entered the United States market in 2013, brought to market by Luitpold Defendants and American Regent Defendants, at the direction and under the control of their parent, the Daiichi Sankyo Defendants. Prior to 2013, the compound "ferric carboxymaltose" was available on the European and other markets under the brand name of Ferinject. Ferinject was designed, manufactured, promoted, and sold by the Vifor entities, by and through Vifor International. Defendant Vifor International licensed and continues to license ferric carboxymaltose to all other Defendants who in turn have designed, manufactured, and sold the product in the United States. The Vifor entities provide support to American Regent and DSI on

the design, manufacture, distribution, marketing, promotion, pharmacovigilance, and/or sale of Injectafer in the United States.

57. Iron deficiency anemia (hereinafter "IDA") is, put simply, insufficient levels of iron in an individual's body. Iron is a mineral that is essential for the body to produce a healthy amount of red blood cells. Red blood cells work to carry oxygen throughout the body to tissues and organs. Normally, people ingest iron from the foods they eat. When people have poor nutrition or poor absorption of food, this can lead to a shortage of iron and in turn a shortage of red blood cells. When the body does not have enough red blood cells, it is hard to maintain good health.

58. For years, IDA was treated with oral iron supplements. The pharmaceutical industry recently began to develop and introduce intravenous iron supplements for those unwilling or unable to take oral iron supplements. Injectafer is a member of the class of intravenous iron products available in the United States.

59. Injectafer is to be administered intravenously in two doses separated by at least 7 days. Each dose should be for 750 mg, for a total cumulative dose of 1500 mg of iron per course.

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

61. Unlike the other intravenous iron products available, FCM causes a condition called "Severe Hypophosphatemia" (hereinafter "Severe HPP") and potentially "persistent hypophosphatemia" (hereinafter "Persistent HPP") after use, the condition suffered by Plaintiff in this lawsuit that caused a number of other injuries to be specific in the below sections.

62. Hypophosphatemia (hereinafter "HPP") is defined as an electrolyte disturbance in which blood tests reveal that there is an abnormally low level of phosphate in the patient's blood. Phosphorous, or serum phosphate, is critically important and vital to several of the body's physiological processes. Phosphorous helps with bone growth, energy storage, and nerve and muscle production.

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

64. Additionally, there is a condition that has been coined as "persistent hypophosphatemia" in which an individual can suffer from hypophosphatemia or severe hypophosphatemia for a sustained period of time.

65. There are clinically significant differences between mild hypophosphatemia (2.0 – 2.5 mg/dl) and severe hypophosphatemia (less than 1.5, 1.3, or 1.0 mg/dl). While moderate HPP may occur with or without symptomatology or injury, Severe HPP is a dangerous diagnosis that carries with it muscle weakening, fatigue (potentially severe), severe nausea, and can also lead to serious medical complications including osteomalacia, arrhythmias, cardiac arrest, respiratory failure, and/or potentially rhabdomyolysis.

66. 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 hypophosphatemia.

67. Defendants have known for years, even before the pursuit of a New Drug Application (NDA) for Injectafer, that ferric carboxymaltose – and by extension, Injectafer – causes Severe HPP.

68. During ferric carboxymaltose's presence on the European and United States markets, dozens of case reports and important pieces of medical literature emerged revealing the dangers of Severe HPP and linked the ferric carboxymaltose compound to Severe HPP.

69. This includes, but is not limited to, studies which have identified the following findings of which Defendants were on notice:

(a) An increasing number of case reports and case series that suggest that some intravenous-iron patients develop severe and symptomatic hypophosphatemia. Diagnosis of iron-induced hypophosphatemia requires clinical suspicion, with treatment guided by the severity of hypophosphatemia;

(b) A comparison between ferric carboxymaltose (Injectafer) and another iron intravenous drug, iron isomaltoside (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].” Moreover, the “prevalence of hypophosphatemia increased from 11% to 32.1% after treatment with [any] intravenous iron.” **However, “[t]he hypophosphatemia risk was greater after [ferric carboxymaltose] (45.5%). And cases of “[s]evere hypophosphatemia occurred exclusively after [ferric carboxymaltose] (32.7%).” In conclusion, “[t]reatement with [ferric carboxymaltose] is associated with a high risk of developing severe and prolonged hypophosphatemia and should therefore be monitored”;**

(c) A separate comparison of ferric carboxymaltose to another intravenous iron drug, isomaltoside 1000 (Monofer) found significantly more HPP events when ferric carboxymaltose was administered to the patient at a rate of 64-9 (64 patients treated with ferric carboxymaltose contracted HPP and only 9 treated with isomaltoside 1000 contracted HPP). The study found that HPP “occurred in up to 50% of patients who received [ferric carboxymaltose]” **and also found cases of severe HPP only with ferric carboxymaltose administration**;

(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";

(e) More recently, a comparison between Injectafer and ferumoxytol (Feraheme) found that **58.8% 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**.

70. In addition to the aforementioned reports and literature, Luitpold had knowledge of the link between Injectafer and Severe HPP from its own clinical studies, some of which it never warned the general public via its labeling.

71. Most recently, in February 2020, a comparison between ferric carboxymaltose (Injectafer) and iron isomaltoside (Monofer) published in the Journal of the American Medical Association (JAMA) 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**."

72. An original New Drug Application (NDA) submitted by Luitpold to Food and Drug Administration (FDA) in July 2006 received a non-approvable letter in response due to clinical safety concerns. An additional NDA application for Injectafer was submitted in September 2007 and 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.

73. Despite FDA's own assessment that Injectafer caused "clinically important hypophosphatemia" and the multiple reports, adverse event reports, and published studies linking Injectafer to Severe HPP, Luitpold brought Injectafer to the United States market in 2013 without any adequate warnings on the product labeling or to the medical community.

74. **Injectafer's label omits, and has at all relevant times since its introduction into the United States market, any reference to Severe HPP** or "clinically important hypophosphatemia." The labeling makes no attempt to inform the user and medical community of the clinical differences between the varying levels of hypophosphatemia. At the time of Plaintiff's prescription, the labeling did not inform the user or medical community how to monitor serum phosphorous levels so as to be on alert for severely decreasing levels that may result in Severe HPP or additional injury.

75. At the time of Plaintiff's prescription, the label only made passing references to the potential occurrence of hypophosphatemia, downplayed its risk, and made **no reference at all to Severe HPP**. Inadequate to sufficiently warn the user and medical community, hypophosphatemia (not qualified as moderate or Severe) was not listed in the "Warnings or Precautions" section or in

a prominently placed "Black Box" warning, but instead was merely listed as an "Adverse Reaction" occurring in greater than 2% of users.

76. When the label did reference the potential adverse reaction of regular hypophosphatemia, it significantly downplayed the risk and potential for injury thus confusing and nullifying the nature of any potential warning:

(a) From introduction into the market in July 2013 through January 2018, the "Patient Information" leaflet section of the labeling refers to "**asymptomatic** reductions in blood phosphorous";

(b) In January 2018, Defendants removed the "asymptomatic" reference in the Patient Information leaflet and simply listed "low levels of phosphorous in your blood," still without reference to Severe HPP or any explanation as to the clinical significance of low levels of blood phosphorous. Additionally, no portions of the Prescribing Information were adjusted to reflect a potential increase in warning as to the symptoms and injuries that can accompany even a diagnosis of mild or moderate hypophosphatemia;

(c) In the "Adverse Reactions in Clinical Trials" section of the 2013 and 2018 labeling, Defendants refer only to "*transient* decreases in laboratory blood phosphorous levels (< 2 mg/dl)";

77. The aforementioned references to "transient" or "asymptomatic" reductions of blood phosphorous grossly mischaracterize the known, sharp decrease in blood phosphorous that can result in Severe HPP and persist over a time period of weeks or months, carrying with it dangerous, prolonged, and potentially permanent injuries. The injuries and conditions caused by

Severe HPP can have permanent effects, none of which are conveyed to the medical community via Injectafer's labeling.

78. The labeling made no reference to the following clinical conditions associated with Severe HPP: rhabdomyolysis, cardiac arrest, cardiac arrhythmia, or respiratory failure. The labeling only made passing, inadequate reference in the Post-marketing experience to hypophosphatemic osteomalacia that was reported in *one* individual.

79. In April 2018 or thereabouts, Defendants removed the reference to "asymptomatic" reductions in blood phosphorous from the labeling.

80. Most recently, in February 2020, the FDA approved revised labeling for Injectafer that includes the following changes allegedly related to hypophosphatemia:

(a) Addition of Section 2.3, entitled "Repeat Treatment Monitoring Safety Assessment," under "Dosage and Administration" that states: "Injectafer treatment may be repeated if iron deficiency anemia reoccurs. **Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment** [see Warnings and Precautions (5.2)]";

(b) Addition of Section 5.2, entitled "Symptomatic Hypophosphatemia," under "Warnings and Precautions" that states: "Symptomatic hypophosphatemia requiring clinical intervention has been reported in patients at risk of low serum phosphate in the postmarketing setting. These cases have occurred mostly after repeated exposure to Injectafer in patients with no reported history of renal impairment. Possible risk factors for hypophosphatemia

include 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. In most cases, hypophosphatemia resolved within three months.

Monitor serum phosphate levels in patients at risk for low serum phosphate who require a repeat course of treatment. [see Dosage and Administration (2.3)]";

(c) In Section 6, "Adverse Reactions," Hypophosphatemia was added as a bulleted adverse reaction;

(d) In Section 6.2, "Postmarketing Experience," the following was added: "Metabolism and nutrition disorders: Hypophosphatemia";

(e) In Section 10, "Overdosage", the following was added: "A patient who received Injectafer 18,000 mg over 6 months developed hemosiderosis with multiple joint disorder, walking disability, and asthenia."

81. Failure to warn of Severe HPP, along with the injuries it can cause – osteomalacia, rhabdomyolysis, cardiac arrest, cardiac arrhythmia, or respiratory failure – given their clinical significance and Defendants' knowledge of the frequency at which they occur in Injectafer users, is a complete derogation of Defendants' responsibilities to properly warn of Injectafer's known dangers in violation of all relevant state and federal laws.

82. In addition to the omission of any reference to Severe HPP, the labeling also omits any reference in the Clinical Pharmacology section to ferric carboxymaltose's known effect on the FGF23 hormone, which in turn is associated with a decrease in blood phosphorous.

83. Defendants have long known that ferric carboxymaltose increases the levels of the hormone fibroblast growth factor 23 ("FGF23") at a rate far greater than any other iron drug. Additionally, Defendants have long known that increases in FGF23 can induce hypophosphatemia, possibly through reduction of phosphate reabsorption in the body. Despite these accepted and known facts, Defendants at no place in the Injectafer labeling, nor via any other means of communication to the medical community, notified potential users and physicians of Injectafer's propensity to increase FGF23 levels far beyond the capacity of any other iron drug. Defendants have been aware of these risks since and before Injectafer's entrance into the United States market.

84. Defendants, as the entities responsible for the Injectafer product and labeling, had a duty to warn potential users of Injectafer's known risks of Severe HPP, as well as the injuries that can result from Severe HPP, and also Injectafer's known propensity to increase FGF23 which in turn can cause both acute and potentially prolonged Severe HPP.

85. Defendants at no times have attempted to warn users of these risks and have therefore violated their duties to warn and not misrepresent the benefits of a drug.

86. Defendants also have a duty to explain to the medical community how to properly investigate and monitor a sharp drop in phosphorous levels. Defendants at no time have provided such warnings.

87. Defendants additionally have a duty to not manufacture, market, and sell a product with so unreasonably dangerous that its potential harms far outweigh any potential benefits.

Defendants have failed their duty to ensure safe, well-tested, well-monitored, and properly labeled products are entered into the pharmaceutical market.

PLAINTIFF'S USE OF INJECTAFER

88. Plaintiff incorporates by reference the factual portion of this Complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, alleges as follows.

89. Plaintiff, LaRosa Jones, is a resident of Racine, Wisconsin.

90. Plaintiff suffers from Iron Deficiency Anemia (IDA). In April 2016, Plaintiff was prescribed Injectafer iron injection for treatment of her IDA.

91. Plaintiff received her first Injectafer injection on or around May 2, 2016. Thereafter, Plaintiff received Injectafer infusions on June 23, 2016, and November 30, 2016.

92. Subsequent to Plaintiff's Injectafer use, Plaintiff suffered symptoms indicative of severe and/or symptomatic hypophosphatemia.

93. As a result of her use of Injectafer, Plaintiff has suffered, and will likely suffer in the future, severe and permanent injuries and damages, including, but not limited to: chronic foot pain, neuropathy, poor balance, leg numbness, fibromyalgia, neck pain, sleep disturbance due to pain, stress and anxiety.

94. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of 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, for the purpose of obtaining delay on Plaintiff's filing of their causes of action. The Defendants' fraudulent concealment did result in such delay.

95. 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 care 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.

96. 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.

97. As pled below, Plaintiff seeks 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, Plaintiff reserves the right to recover under the laws of that state.

COUNT I – NEGLIGENCE
(The American Regent Defendants, The Daiichi Sankyo Defendants, and Vifor)

98. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

99. At all times relevant, the American Regent Defendants, Daiichi Sankyo Defendants, and Vifor (hereinafter "Defendants") 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.

100. Each of the Defendants played a role in the design and testing of Injectafer, either by virtue of the Defendants' control of the Injectafer product and labeling, ownership of the entity which controlled in the product and labeling, or involvement in contractual agreements that required participation and engagement in the design and testing of the Injectafer product.

101. 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.

102. Defendants breached their duty of care to the Plaintiff and her physicians, in the testing, monitoring, and pharmacovigilance of Injectafer.

103. 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.

104. At the time of the development and design of Injectafer, Defendants knew or should have known that ferric carboxymaltose, the active ingredient in Injectafer, was designed in such a manner as to cause 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 ferric carboxymaltose due to information and scientific evidence that existed from ferric carboxymaltose's time on the European and world markets in the form of Injectafer's bioequivalent, Ferinject.

105. At the time of the development and design of Injectafer, Defendants knew or should have known that ferric carboxymaltose 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 formulation. Defendants knew or should have known of the problems and defects with ferric carboxymaltose and FGF23 due to information and scientific evidence that existed from ferric carboxymaltose's time on the European and world markets in the form of Injectafer's bioequivalent, Ferinject.

106. At the time of the development and design of Injectafer, Defendants knew or should have known from the available adverse event reports, literature, clinical studies, and case studies, that using ferric carboxymaltose 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 diagnosis of Severe Hypophosphatemia and the injuries that result consequent to severely low levels of blood phosphorous.

107. At the time of the manufacture and sale of Injectafer to Plaintiff, Defendants knew or should have known from the available adverse event reports, literature, clinical studies, and case studies that had built up over years of ferric carboxymaltose and, specifically, Injectafer use in the European and US marketplaces, that the active ingredient in Injectafer could cause Severe Hypophosphatemia and the injuries that result consequent to severely low levels of blood phosphorous.

108. 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.

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

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

111. Defendants had a duty to place a product into the United States marketplace that was adequately tested to avoid the potential to decrease blood phosphorous to the life-threatening levels experienced by Plaintiff.

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

(a) Failing to perform reasonable and adequate 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 Hypophosphatemia;

(b) 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 the FDA;

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

(d) 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;

(e) 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 prolonged Severe Hypophosphatemia;

(f) 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.

113. 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 both at the time of development and ingestion.

114. As a direct and proximate result of the Defendants' negligent testing, monitoring, and pharmacovigilance of Injectafer (ferric carboxymaltose), Defendants introduced a product into the United States marketplace that is known to cause Severe Hypophosphatemia at the recommended dosing, and 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.

115. 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, LaRosa Jones, 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.

116. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Wisconsin common law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT II – NEGLIGENT FAILURE TO WARN
(The American Regent Defendants, The Daiichi Sankyo Defendants, and Vifor)

117. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

118. Defendants had a duty to exercise reasonable care and comply with existing standards of care in the marketing, promotion, labeling, packaging, and sale of Injectafer.

119. Defendants failed to exercise reasonable care and failed to comply with existing standards of care in the marketing, promotion, labeling, packaging, and sale of Injectafer. Defendants knew or should have known that using Injectafer as instructed in the labeling created an unreasonable risk of harm.

120. Defendants, its agents, servants, partners, and/or employees, failed to exercise reasonable care and failed to comply with existing standards of care in the following acts and/or omissions, among others:

(a) Promoting and marketing Injectafer while knowing at the time of its NDA approval and prior that Injectafer caused Severe Hypophosphatemia;

(b) Failing to warn in all Injectafer labeling that Injectafer and ferric carboxymaltose caused Severe Hypophosphatemia;

(c) Failing to warn in all Injectafer promotions, Continuing Medical Education (CME), symposia, luncheons, seminars, advertising, publications, and other means of communication to medical community and targeted patient populations that Injectafer caused Severe Hypophosphatemia;

(d) Failing to warn of the true incident rates of Severe Hypophosphatemia and Hypophosphatemia from all clinical studies completed by Defendants;

(e) Failing to warn of the accurate and known long-term effects of hypophosphatemia and Severe Hypophosphatemia;

(f) Failing to warn of the differences in severity between mild, moderate, and severe hypophosphatemia;

(g) Failing to warn physicians and users of need to monitor serum phosphorous levels after administration of Injectafer;

(h) Failing to warn physicians and consumers of need to supplement phosphorous levels after administration of Injectafer;

(i) Failing to instruct physician and consumers of available treatments for injuries, including but not limited to Severe Hypophosphatemia, caused by Injectafer; and,

(j) Failing to disclose their knowledge that Injectafer was known to increase the hormone FGF23 which was known to be associated with a decrease in levels of serum phosphate.

121. Defendants' failure to warn of the above was the proximate cause of Plaintiff's injuries, harm, and economic loss, which Plaintiff continue to suffer.

122. 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, LaRosa Jones, 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.

123. Defendants are liable in tort to Plaintiff for their negligent failure to warn pursuant to Wisconsin common law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT III – NEGLIGENT DESIGN DEFECT
(The American Regent Defendants, The Daiichi Sankyo Defendants, and Vifor)

124. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

125. Defendants are liable to Plaintiff for the injuries and damages sustained by her due to Defendants negligent design and/or formulation of Injectafer.

126. 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. The Defendants' duties included, but were not limited to, carefully and properly designing, testing, studying, and manufacturing Injectafer.

127. The Defendants negligently and carelessly breached the above-described 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 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 and necessary break in time between administrations.

128. The Injectafer that was designed, 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.

129. 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, more dangerous than an ordinary consumer would expect, and more dangerous than other iron injection drugs.

130. Despite Defendants' knowledge of the foreseeable risks and unreasonably dangerous nature of Injectafer at all times relevant, Defendants designed and brought the product to market and continued to market the drug when there were safer alternatives available and in actual use in the United States, including but not limited to other intravenous iron products utilized in a similar fashion and for similar indications as Injectafer.

131. As a result of Defendants' negligent and reckless design of Injectafer, Plaintiff sustained life-threatening and potentially permanent injuries.

132. 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.

133. Defendants are liable in tort to Plaintiff for their negligent acts and design of Injectafer pursuant to Wisconsin common law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT IV – NEGLIGENT MISREPRESENTATION
(The American Regent Defendants, The Daiichi Sankyo Defendants, and Vifor)

134. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

135. At all relevant times, Defendants negligently provided Plaintiff, 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.

136. 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.

137. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff 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 provider to request, recommend, purchase, and prescribe Injectafer.

138. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical device manufacturers, Plaintiff, her healthcare providers and the public, the known risks of Injectafer involving its propensity to cause Severe Hypophosphatemia.

139. Defendants made continued misrepresentations in the Injectafer labeling, including but not limited to:

(a) Decrease 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 failing to warn of Severe Hypophosphatemia while only referencing in passing an adverse effect of hypophosphatemia, which was interpreted by Plaintiff, Plaintiff's treaters, and the medical community to not rise to the level of Severe Hypophosphatemia;

(e) Advertising, promoting, and marketing Injectafer as a safe and superior iron injection drug to the other iron injection drugs on the market that were not known to cause Severe Hypophosphatemia.

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

141. Defendants misrepresented and overstated the benefits of Injectafer to Plaintiff, Plaintiff's treaters, and the medical community without properly advising of the known risks related to decreases in serum phosphorous.

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

143. 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.

144. 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.

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

146. 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.

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

148. 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.

149. 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.

150. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

151. 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.

152. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Wisconsin common law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in

excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT V – FRAUD
(The American Regent Defendants and The Daiichi Sankyo Defendants)

153. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

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

155. The representations made by the Defendants American Regent, Luitpold, and Daiichi Sankyo 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.

156. These representations were made by the Defendants American Regent, Luitpold, and Daiichi Sankyo with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public, to recommend, prescribe, dispense, and purchase Injectafer for use as a treatment for Iron Deficiency Anemia (IDA) while concealing the drug's known propensity to cause Severe Hypophosphatemia and the consequent injuries that occur from low levels of blood phosphorous.

157. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's prescribing physician, Dr. David Knight, the Defendants American Regent, Luitpold, and Daiichi Sankyo fraudulently stated on the Injectafer product labeling in existence at the time Plaintiff was prescribed Injectafer in April 2016, specifically the Injectafer (ferric carboxymaltose) labeling revised July 2013 and April 2018:

(a) Decreases in serum phosphorous are simply "transient" (Section 6.1 in July 2013 and April 2018 labeling);

(b) Decreases in serum phosphorous are "asymptomatic" (July 2013 Patient Information labeling);

(c) Misrepresenting the total number of incidences of low blood phosphorous findings in the multiple clinical studies completed by Defendants (Section 6.1 in July 2013 and April 2018 labeling);

(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.

158. In representations to Plaintiff and/or to her healthcare providers, including Plaintiff's prescribing physician, Dr. David Knight, the Defendants American Regent, Luitpold, and Daiichi Sankyo fraudulently concealed and intentionally omitted the following material information from the Injectafer product labeling in existence at the time Plaintiff was prescribed Injectafer in April 2016, specifically the Injectafer (ferric carboxymaltose) labeling revised July 2013 and April 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;

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

(f) 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;

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

(h) That Injectafer was negligently designed as set forth in the Negligent Defective Design Count.

159. The American Regent, Luitpold, and Daiichi Sankyo Defendants were under a duty to disclose to Plaintiff and her physicians the defective nature of Injectafer, including but not limited to, the risk of Severe Hypophosphatemia and its ability to cause debilitating and/or permanent injuries.

160. The Defendants American Regent, Luitpold, and Daiichi Sankyo had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

161. 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.

162. 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.

163. 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, Plaintiff's physicians, surgeons and healthcare providers and to induce them to purchase, prescribe, and/or use Injectafer.

164. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians used Injectafer, Plaintiff and/or her physicians were unaware of the falsehood of these representations.

165. In reliance upon these false representations, Plaintiff was induced to, and did use Injectafer, thereby causing severe, debilitating, and potentially permanent personal injuries and damages to Plaintiff. The 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.

166. In comporting with the standard of care for prescribing physicians, Plaintiff's prescribing physician relied on the labeling for Injectafer in existence at the April 2016 date of prescription that included the aforementioned fraudulent statements and omissions.

167. These representations made by American Regent, Luitpold, and Daiichi Sankyo 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.

168. 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 Daiichi Sankyo, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendants' misrepresentations at the time when Injectafer was prescribed to her.

169. As a proximate result of the Defendants' fraudulent statements and omissions, Plaintiff has been seriously injured, and sustained severe and permanent injury, pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

170. 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.

171. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to Wisconsin common law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

COUNT VI – STRICT LIABILITY FAILURE TO WARN
(The American Regent Defendants, The Daiichi Sankyo Defendants, and Vifor)

172. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

173. Defendants designed, set specifications, manufactured, prepared, marketed, promoted, labeled, distributed and sold Injectafer, including the product prescribed to and injected in Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

174. At the time Defendants designed set specifications, manufactured, prepared, marketed, promoted, labeled, distributed and sold Injectafer into the stream of commerce, Defendants knew or should have known that the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

175. Specifically, Defendants knew or should have known that Injectafer posed a significant risk of Severe Hypophosphatemia, which could lead to debilitating and long-term injuries as fully set forth in the Complaint, above.

176. Defendants had a duty to warn of the risk of harm associated with the use of Injectafer, especially given the lack of any such risk of harm with the other iron injection products on the market and available for treatment of IDA, and to provide adequate warnings concerning the risk that Injectafer caused Severe Hypophosphatemia.

177. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of Injectafer, and the complete lack of an effective remedy to the Severe Hypophosphatemia brought on by Injectafer.

178. The risks associated with Injectafer are of such a nature that health care providers and users were not generally aware and were not able to recognize the potential harm, given the product's deficient labeling and lack of understanding of the condition of Severe

Hypophosphatemia in the medical community. Plaintiff and her physicians would not have been able to recognize the potential harm of Injectafer prior to Plaintiff's use of the product.

179. Injectafer was unreasonably dangerous at the time of its release into the stream of commerce, including the specific injection prescribed to Plaintiff, due to the inadequate warnings, labeling and/or instructions accompanying the product.

180. The Injectafer administered to Plaintiff and prescribed by Plaintiff's physicians was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by the Defendants.

181. Defendants are strictly liable for their deficient Injectafer labeling and conduct in promoting and marketing the drug for the following, non-exhaustive reasons:

(a) Promoting and marketing Injectafer while knowing at the time of its NDA approval and prior that Injectafer caused Severe Hypophosphatemia;

(b) Failing to warn in all Injectafer labeling that Injectafer and ferric carboxymaltose caused Severe Hypophosphatemia;

(c) Failing to warn in all Injectafer promotions, Continuing Medical Education (CME), symposia, luncheons, seminars, advertising, publications, and other means of communication to medical community and targeted patient populations that Injectafer caused Severe Hypophosphatemia;

(d) Failing to warn of the true incident rates of Severe Hypophosphatemia and Hypophosphatemia from all clinical studies completed by Defendants;

(e) Failing to warn of the accurate and known long-term effects of hypophosphatemia;

(f) Failing to warn of the differences in severity between mild, moderate, and severe hypophosphatemia;

(g) Failing to warn physicians and users of need to monitor serum phosphorous levels after administration of Injectafer;

(h) Failing to warn physicians and consumers of need to supplement phosphorous levels after administration of Injectafer;

(i) Failing to instruct physician and consumers of available treatments for injuries, including but not limited to Severe Hypophosphatemia, caused by Injectafer; and,

(j) Failing to disclose their knowledge that Injectafer was known to increase the hormone FGF23 which was known to be associated with a decrease in levels of serum phosphate.

182. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

183. As a proximate result of the Defendants' marketing, promotion, labeling, sale and/or distribution of Injectafer, Plaintiff has been catastrophically injured, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

184. Defendants are strictly liable for their reckless and wrongful conduct to Plaintiff pursuant to Wisconsin common and statutory law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VII – STRICT LIABILITY DEFECTIVE DESIGN
(The American Regent Defendants, The Daiichi Sankyo Defendants, and Vifor)

185. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

186. 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.

187. 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.

188. The Injectafer administered to Plaintiff 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.

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

190. 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 and necessary break in time between administrations.

191. 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 the Defendants.

192. 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 April 2016 injection of the drug.

193. As a result of the foregoing design defects, Injectafer created risks to the health and safety of its users, including Plaintiff, 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.

194. 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.

195. 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.

196. As a proximate result of the 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.

197. Defendants are strictly liable in tort to Plaintiff as a result of their wrongful and reckless conduct pursuant to Wisconsin common and statutory law.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

COUNT VIII – GROSS NEGLIGENCE
(The American Regent Defendants, The Daiichi Sankyo Defendants, and Vifor)

198. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

199. Defendants' aforementioned conduct was 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 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 Plaintiff.

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

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

202. Given the Defendants' knowledge and awareness of the extensive body of information available on ferric carboxymaltose, and its propensity to cause Severe Hypophosphatemia, Defendants' failure 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 Plaintiff and others.

203. Plaintiff and her physicians relied on the Defendants to introduce into the marketplace a safe and adequately tested iron drug, and Plaintiff suffered her catastrophic injuries as a result of Defendants' failure to do so.

204. Plaintiff 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.

205. Plaintiff will seek to assert claims for exemplary damages to the extent available under all applicable Pennsylvania and Wisconsin laws.

206. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused Plaintiff's injuries. In that regard, Plaintiff 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.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of $75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands judgment against all Defendants and each of them, individually, jointly and severally, and requests compensatory damages, together with

interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A) compensatory damages for past, present, and future damages, including, but not limited to, great pain and suffering and emotional distress and anguish, for personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B) for all ascertainable economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial;

C) for specific damages according to proof;

D) for Punitive and Exemplary damages according to proof;

E) for pre-judgment interest and post-judgment interest as allowed by law;

F) for reasonable attorneys' fees;

G) for the costs of these proceedings; and

H) for such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial with regards to all claims.

DATED: September 26, 2022

Respectfully submitted,

POGUST GOODHEAD, LLC

Michael G. Daly – PA Bar No. 309911
Joshua M. Neuman – PA Bar No. 322648
POGUST GOODHEAD, LLC
161 Washington Street, Suite 250
Conshohocken, PA 19428
Counsel for Plaintiff

VERIFICATION

I, Michael G. Daly, verify that upon my knowledge or information and belief the facts set forth in the foregoing Complaint are true and correct to the best of my knowledge. This statement is made subject to the penalties of 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities.

DATED: September 26, 2022

Michael G. Daly - PA Bar No. 309911
POGUST GOODHEAD, LLC
161 Washington Street, Suite 250
Conshohocken, PA 19428
Counsel for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on this date I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to receive copies in this case.

Michael G. Daly - PA Bar No. 309911
POGUST GOODHEAD, LLC
161 Washington Street, Suite 250
Conshohocken, PA 19428
Counsel for Plaintiff