UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

KATHERINE CROCKETT, **PLAINTIFF,** v. **LUITPOLD PHARMACEUTICALS, INC.; AMERICAN REGENT, INC.; DAIICHI SANKYO, INC.; DAIICHI SANKYO CO., LTD.; VIFOR PHARMACEUTICALS MANAGEMENT LTD., and VIFOR PHARMA – ASPEREVA PHARMACEUTICALS, INC.,** **DEFENDANTS.**	**CASE NO. _____**

NOTICE OF REMOVAL

TO: COURT OF COMMON PLEAS OF PHILADELPHIA
Office of the Prothonotary
First Judicial District of Pennsylvania
Room 284 City Hall
Philadelphia, PA 19107

Michael G. Daly, Esq.
Tobias L. Millrood, Esq.
Kara Hill, Esq.
POGUST MILLROOD, LLC
161 Washington Street
Conshohocken, PA 19428

PLEASE TAKE NOTICE that pursuant to 28 U.S.C. §§ 1332, 1441, and 1446, Defendants Luitpold Pharmaceuticals, Inc. ("Luitpold"), American Regent, Inc. ("American Regent"), and Daiichi Sankyo, Inc. ("DSI") (collectively, "Removing Defendants") timely remove this action titled *Crockett v. Luitpold Pharmaceuticals, Inc., et al.,* from the Court of Common Pleas of Philadelphia County to the United States District Court for the Eastern District of Pennsylvania.[1] This Court has original jurisdiction under 28 U.S.C. §§ 1332 and 1441, *et seq*. Complete diversity of citizenship exists between the parties, and it is facially evident from the Complaint that the amount in controversy exceeds $75,000.00, exclusive of interest and costs. Thus, the action unquestionably is removable.[2] In support of removal, Removing Defendants further state as follows:

1. On December 19, 2018, Plaintiff Katherine Crockett filed a lawsuit in the Court of Common Pleas of Philadelphia County titled *Crockett v. Luitpold Pharmaceuticals, Inc., et al.,*, November Term 2018, No. 02043. *See* Complaint ("Compl.") (attached as Exhibit A).

2. Plaintiff alleges that she was injured following injection with Injectafer, an iron replacement injection medication allegedly manufactured and sold by Removing Defendants and indicated for the treatment of iron deficiency anemia. *See* Compl. ¶¶ 2–3, 4, 6, 43, 75–78. Based on her alleged injuries, Plaintiff asserts eleven claims against Removing Defendants as well as Defendants Daiichi Sankyo Co., Ltd., Vifor Pharmaceuticals Management Ltd., and Vifor

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[1] The American Regent entity named as a defendant in Plaintiff's Complaint no longer exists. As explained below, American Regent was a wholly-owned subsidiary of Luitpold. To streamline its business, Luitpold merged American Regent into itself on December 31, 2018, and the surviving entity, Luitpold, was renamed American Regent, Inc. *See infra* Part II.D.

[2] By removing this action to this Court, Removing Defendants do not waive any defenses, objections, or motions available under state or federal law. Removing Defendants expressly reserve the right to move for dismissal of some or all of Plaintiff's claims and/or seek dismissal based on lack of personal jurisdiction, improper venue, and/or the doctrine of *forum non conveniens*.

Pharma – Aspreva Pharmaceuticals, Inc.[3] In particular, Plaintiff asserts claims for negligence (Count 1), negligent failure to warn (Count 2), negligent design defect (Count 3), negligent misrepresentation (Count 4), fraud (Count 5), strict liability failure to warn (Count 6), strict liability design defect (Count 7), breach of express warranty (Count 8), breach of implied warranty (Count 9), violation of consumer protection laws (Count 10), and gross negligence (Count 11).

I. REMOVAL IS PROPER BECAUSE THIS COURT HAS ORIGINAL SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. § 1332(A)

3. This Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332(a) because this is a civil action between citizens of different states in which the amount in controversy exceeds $75,000, exclusive of interest and costs. That being so, Removing Defendants have a constitutional right to remove this action to federal court. *See, e.g.*, *Terral v. Burke Constr. Co.*, 257 U.S. 529, 532–33 (1922) (holding that foreign corporations have a "federal constitutional right . . . to resort to the federal courts" through exercise of their federal right of removal).

A. Complete Diversity Of Citizenship Exists Between The Parties.

4. Diversity jurisdiction requires that the controversy be between citizens of different states. *See* 28 U.S.C. § 1332(a)(1). Specifically, the statute requires "complete diversity." *Lincoln Prop. Co. v. Roche*, 546 U.S. 81, 84 (2005). Complete diversity exists if no plaintiff is "'a citizen of the same state as any of the defendants.'" *Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337, 346 (3d Cir. 2013) (quoting *Grand Union Supermarkets of the Virgin Islands, Inc. v. H.E. Lockhart Mgmt., Inc.*, 316 F.3d 408, 410 (3d Cir. 2003)); *see also Enza v. We the People, Inc.*, 838 F. Supp. 975, 977 (E.D. Pa. 1993) ("[A]ll of the parties on one

[3] Defendant Daiichi Sankyo Co., Ltd. has not been served in this action and intends to file a motion to strike Plaintiff's affidavit of service as improper. In addition, the named defendants "Vifor Pharmaceuticals Management Ltd.," and "Vifor Pharma – Aspereva Pharmaceuticals, Inc.," as they are named in the Complaint, have not been served in this action.

side of the controversy must be citizens of a different state from all of the parties on the other side.").

5. An individual's citizenship "is determined by her domicile, and the domicile of an individual is his true, fixed and permanent home and place of habitation." *Washington v. Hovensa LLC*, 652 F.3d 340, 344 (3d Cir. 2011) (internal quotation marks omitted); *see also Reid v. Albizem*, 2014 WL 2915883, at *2 (E.D. Pa. June 25, 2014) ("Individuals are deemed to be citizens of the State wherein they reside.").

6. A corporation is deemed to be a citizen of the state or states where it is incorporated and maintains "its principal place of business." 28 U.S.C. § 1332(c)(1). Because section 1332(c)(1) refers to a "principal place of business" in the singular, it is clear that a corporation can have only *one* principal place of business. *See Hertz Corp. v. Friend*, 559 U.S. 77, 93 (2010) ("The word 'place' is in the singular, not the plural. The word 'principal' requires us to pick out the 'main, prominent' or 'leading' place.") (quoting 12 Oxford English Dictionary 495 (2d ed. 1989) (def.(A)(I)(2))); *Murray v. Commercial Union Ins. Co.*, 782 F.2d 432, 434 (1986) ("A corporation may have 'literally dozens of important places of business *one of which we must pick out as the principal one because the statute says so.*'") (quoting *Kelly v. United States Steel Corp.*, 284 F.2d 850, 853 (3d Cir. 1960) (emphasis added)); *see also Wachovia Bank v. Schmidt*, 546 U.S. 303, 318 (2006) (explaining that a corporation "is not deemed a citizen of every State in which it conducts business or is otherwise amenable to personal jurisdiction").

7. In *Hertz*, the United States Supreme Court held that a corporation's principal place of business for purposes of section 1332(c)(1) is determined by the "nerve center" test. *See* 559 U.S. at 92–95. Under that test, a corporation's principal place of business is "the actual center of direction, control, and coordination." *Id.* at 93. As the Supreme Court explained, "[a] corporation's 'nerve center,' usually its main headquarters, is a single place." *Id.*; *see also*

Bullion Monarch Mining, Inc. v. Barrick Goldstrike Mines, Inc., 2018 WL 5777484, at *2 (D. Nev. Nov. 1, 2018) ("A corporation can have only one nerve center—it is a single place within a single state."); *Munoz v. Allstate Ins. Co.*, 2016 WL 10907057, at *2 (C.D. Cal. Mar. 3, 2016) ("[C]orporations have only one nerve center."); *Johnson v. SmithKline Beecham Corp.*, 853 F. Supp. 2d 487, 490 (E.D. Pa. 2012) (confirming that "[a] corporation may have only one nerve center"), *affirmed*, 724 F.3d 337 (3d Cir. 2013).

8. Applying these principles, it is clear that complete diversity of citizenship exists between the parties.

9. Plaintiff alleges that she resides in Pennsylvania. *See* Compl. ¶ 74. For purposes of 28 U.S.C. § 1332(a)(1), Plaintiff is therefore deemed to be a citizen of Pennsylvania. *See, e.g.*, *Washington*, 652 F.3d at 344; *Reid*, 2014 WL 2915883, at *2.

10. Plaintiff alleges that Luitpold is incorporated in New York and has "principal offices" in Norristown, Pennsylvania and Shirley, New York. Compl. ¶ 2. In addition, Plaintiff alleges that American Regent is incorporated in New York, "appears to operate its principal office" out of Shirley, New York, and "may also operate out of Luitpold's Norristown, PA office." *Id.* ¶ 3. Contrary to Plaintiff's implicit suggestion, however, neither Luitpold nor American Regent ever maintained its principal place of business in Pennsylvania, but rather only in Shirley, New York.

11. As explained in the accompanying Affidavit of Joseph Boyle (attached as Exhibit B), Luitpold was a corporation organized under the laws of the state of New York, with its principal place of business in Shirley, New York. *See* Boyle Aff. ¶ 2. The company formerly known as American Regent, Inc. was a wholly owned subsidiary of Luitpold organized under the laws of the state of New York, with its principal place of business in Shirley, New York. *See id.* To streamline its business, on December 31, 2018, Luitpold merged its subsidiaries, including the

former American Regent, Inc., into itself. *See id.* ¶ 3. On January 2, 2019, the surviving entity, Luitpold, was renamed American Regent, Inc. since that was the customer-facing corporate brand name. *See id.* Thus, the company now referred to as American Regent is the entity formerly known as Luitpold. *See id.*

12. American Regent (formerly known as Luitpold) never maintained its principal place of business anywhere other than Shirley, New York. *See id.* ¶ 4. The majority of the company's employees and executives, including the Chief Executive Officer and President, have worked out of the corporate headquarters in Shirley, New York for more than twenty-five years. *See id.* ¶ 5. Further, "[d]irection, control, coordination, and strategic decision-making activities concerning the Company's products, are based out of the New York headquarters." *Id.* ¶ 6. Accordingly, American Regent's nerve center, and thus its principal place of business, is in Shirley, New York, where the company maintains its headquarters. *See, e.g.*, *Hertz*, 559 U.S. at 96 (explaining that if a corporation's officers direct its business activities from New York, the corporation's "'principal place of business' is New York").

13. Based on the foregoing, Luitpold and American Regent are deemed to be citizens of New York for purposes of 28 U.S.C. § 1332(c)(1).

14. Plaintiff alleges that DSI is incorporated in Delaware and maintains its principal place of business in New Jersey. *See* Compl. ¶ 4. For purposes of 28 U.S.C. § 1332(c)(1), DSI is therefore deemed to be a citizen of Delaware and New Jersey.

15. Plaintiff alleges that Defendant Daiichi Sankyo Co., Ltd. ("DSC") is incorporated in Japan and maintains its principal place of business in Japan. *See* Compl. ¶ 7. For purposes of 28 U.S.C. § 1332(c)(1), DSC is therefore deemed to be a citizen of Japan.

16. Plaintiff named as a defendant "Vifor Pharmaceuticals Management Ltd." ("Vifor Pharma") and alleges that it is a corporation that maintains its principal place of business in

Switzerland. *See* Compl. ¶ 14. On information and belief, Vifor Pharmaceuticals Management Ltd. is the incorrect name of the entity and has not been served to date. For purposes of 28 U.S.C. § 1332(c)(1), Vifor Pharma is deemed to be a citizen of Switzerland.

17. Plaintiff named as a defendant "Vifor Pharma – Aspreva Pharmaceuticals, Inc." ("Aspreva") and alleges that it is a corporation with its principal place of business in New Jersey. *See* Compl. ¶ 20. On information and belief, Vifor Pharma – Aspreva Pharmaceuticals, Inc. is the incorrect name of an entity that no longer exists and has not been served to date. For purposes of 28 U.S.C. § 1332(c)(1), Aspreva is therefore deemed to be a citizen of New Jersey.

18. Based on the foregoing, there is complete diversity of citizenship between the parties.

B. The Amount-In-Controversy Requirement Is Satisfied.

19. Pursuant to 28 U.S.C. § 1446(c)(2)(B), removal is proper if the court finds, by a preponderance of the evidence, that the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

20. Under section 1446(a), a defendant seeking to remove an action must include in its notice of removal "a short and plain statement of the grounds for removal." The Supreme Court has explained that "by borrowing the familiar 'short and plain statement' standard" from Rule 8(a) of the Federal Rules of Civil Procedure, Congress "intended to 'simplify the pleading requirements for removal' and to clarify that courts should 'apply the same liberal rules [to removal allegations] that are applied to other matters of pleading.'" *Dart Cherokee Basin Operating Co. v. Owens*, 135 S. Ct. 547, 553 (2014) (quoting H.R. Rep. No. 100-889, p. 71 (1988)) (internal quotation marks omitted). To satisfy the "short and plain statement" requirement, the removal notice must allege the amount in controversy "plausibly" but "need not contain evidentiary submissions" to support the allegation. *Id.* at 551 (quoting *Ellenburg v.*

Spartan Motors Chassis Inc., 519 F.3d 192, 200 (4th Cir. 2008), for the proposition that "a removing party's notice of removal need not 'meet a higher pleading standard than the one imposed on a plaintiff in drafting an initial complaint'").[4]

21. The amount in controversy generally is determined by the complaint itself. *See Horton v. Liberty Mut. Ins. Co.*, 367 U.S. 348, 353 (1961); *Spectacor Mgmt. Grp. v. Brown*, 131 F.3d 120, 122 (3d Cir. 1997); *Angus v. Shiley, Inc.*, 989 F.2d 142, 145 (3d Cir. 1993); *Hocker v. Kurfeld*, 2015 WL 8007463, at *2 (E.D. Pa. Dec. 7, 2015). "When a complaint does not limit its request to a precise monetary amount, the court must independently appraise the claim's value to determine if it satisfies the amount in controversy requirement." *Hocker*, 2015 WL 8007463 at *2 (citing *Angus*, 989 F.2d at 146).

22. Here, Plaintiff alleges that following her treatment with Injectafer, she was "diagnosed with Severe Hypophosphatemia and, as a result, suffered from multiple hospitalizations, severe nausea, severe weakness and pain, and severe and constant fatigue." *Id.* ¶ 78. Plaintiff also alleges that she was diagnosed with "renal phosphate wasting" as a result of her treatment with Injectafer. *Id.* In addition, Plaintiff alleges that she "had to take a leave of absence from her place of employment and was only able to return after several months on limited duties." *Id.* Based on these alleged "severe and ongoing injuries," Plaintiff seeks compensatory damages "for past, present, and future damages," including, but not limited to,

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[4] If a court questions a defendant's amount-in-controversy allegation, the court *must* give the parties an opportunity to present evidence relating to the allegation and only then decide whether the preponderance of that evidence shows that the amount in controversy is met. *See Dart*, 135 S. Ct. at 554 ("Evidence establishing the amount *is required* . . . when . . . the court questions[] the defendant's allegation." (emphasis added)). In other words, a court may not *sua sponte* remand a removed case based on a deficient amount-in-controversy allegation before giving the defendant an opportunity to cure the alleged deficiency. *See, e.g.*, *Ellenburg*, 519 F.3d at 194, 197–98; *Corporate Mgmt. Advisors, Inc. v. Artjen Complexus, Inc.*, 561 F.3d 1294, 1295–96, 1298 (11th Cir. 2009); *accord Harmon v. OKI Systems*, 115 F.3d 477, 479 (7th Cir. 1997) (failure to allege amount in controversy constitutes a "procedural defect" that does not undermine jurisdiction).

"great pain and suffering and emotional distress and anguish," "personal injuries," and "health and medical care costs." *Id.* at p. 53 (paragraph A of Prayer for Relief).

23. Based on these allegations, it is plain that the amount in controversy with respect to Plaintiff's claims exceeds the $75,000 jurisdictional threshold. *See, e.g.*, *Hocker*, 2015 WL 8007463, at *2 (finding amount in controversy exceeded $75,000 where complaint alleged serious medical injuries and medical costs); *see also McPhail v. Deere Co.*, 529 F.3d 947, 955 (10th Cir. 2008) (concluding that amount in controversy was established by plaintiff's "alleged damages for property, travel expenses, and emergency ambulance trip, a six day stay in the hospital, pain and suffering, humiliation and her temporary inability to do housework") (citing *Luckett v. Delta Airlines, Inc.*, 171 F.3d 295, 298 (5th Cir. 1999)); *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 296 (S.D.N.Y. 2001) (finding that complaint alleging various injuries from taking a prescription drug "obviously asserts a claim exceeding $75,000").

24. In addition, Plaintiff seeks punitive damages. *See* Compl. at p. 53 (paragraph D of Prayer for Relief); *see also id.* at pps. 26, 28, 30, 34, 38, 41, 43, 46, 48, 51, 52 (Wherefore clauses). It is well-established that punitive damages are part of the amount in controversy in a civil action. *See Packard v. Provident Nat'l Bank*, 994 F.2d 1039, 1046 (3d Cir. 1993) ("When both actual and punitive damages are recoverable, punitive damages are properly considered in determining whether the jurisdictional amount has been satisfied.").

25. Based on the nature of the alleged injuries and claims as well as the alleged entitlement to recover compensatory damages for economic and noneconomic losses in addition to punitive damages, it is facially evident from the allegations in the Complaint that Plaintiff seeks recovery in excess of $75,000, exclusive of interests and costs. *See, e.g.*, *Hocker*, 2015 WL 8007463, at *2; *see also McPhail*, 529 F.3d at 955; *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d at 296.

II. REMOVING DEFENDANTS HAVE SATISFIED THE PROCEDURAL AND VENUE REQUIREMENTS FOR REMOVAL.

26. The Court of Common Pleas of Philadelphia County, Pennsylvania, is located within the Eastern District of Pennsylvania, *see* 28 U.S.C. § 118(a), and venue for this action is proper in this Court under 28 U.S.C. § 1441(a) because the Eastern District of Pennsylvania is the "district and division embracing the place where such action is pending."

27. Pursuant to 28 U.S.C. § 1446(a), a copy of all process, pleadings, and orders served upon and by Defendants related to this action is attached as Exhibit C.

28. Luitpold, American Regent, and DSI received the Complaint on December 20, 2018. Neither DSC, Vifor Pharma, nor Aspreva has been served with the Complaint. Therefore, removal is timely pursuant to 28 U.S.C. § 1446(b).

29. Since DSC, Vifor Pharma, and Aspreva have not been served, their consent to removal under 28 U.S.C. § 1446(b) is unnecessary. *See, e.g.*, *Brown v. Jevic*, 575 F.3d 322, 327 (3d Cir. 2009) ("[A] defendant who has not been served need not consent to removal.") (citing *Lewis v. Rego Co.*, 757 F.2d 66, 68–69 (3d Cir. 1985)).

30. Immediately following the filing of this Notice of Removal, written notice of the filing of this Notice will be delivered to counsel for all adverse parties, as required by 28 U.S.C. § 1446(d).

31. Defendants will promptly file a copy of this Notice with the Prothonotary of the Court of Common Pleas of Philadelphia County, as required by 28 U.S.C. § 1446(d).

WHEREFORE, Removing Defendants give notice that the civil action docketed *Crockett v. Luitpold Pharmaceuticals, Inc., et al.,*, November Term 2018, No. 02043 in the Court of Common Pleas of Philadelphia County, Pennsylvania, is removed to this Court pursuant to 28 U.S.C. §§ 1332, 1441, and 1446.

Respectfully submitted,

Dated: January 18, 2019

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Attorneys for Defendants Luitpold Pharmaceuticals, Inc., American Regent, Inc., and Daiichi Sankyo, Inc.

CERTIFICATE OF SERVICE

I hereby certify that, on January 18, 2019, I filed the foregoing Notice of Removal and caused a true and correct copy of the same to be sent via United States Mail, postage prepaid, to the following counsel of record:

Michael G. Daly, Esq.
Tobias L. Millrood, Esq.
Kara Hill, Esq.
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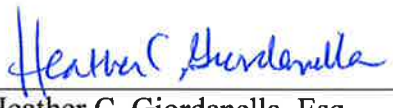
Attorneys for Plaintiff



Heather C. Giordanella, Esq.

EXHIBIT A

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KATHERINE CROCKETT
1830 Lombard Street, Apt 714
Philadelphia, PA 19146,

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 CO., LTD. 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan
and
VIFOR PHARMACEUTICALS MANAGEMENT LTD. Flughofstrasse 61 CH-8152 Glattbrugg, Switzerland
and
VIFOR PHARMA – ASPEREVA PHARMACEUTICALS INC. 106 Allen Road Basking Ridge, NJ 07920

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

NOVEMBER TERM, 2018

NO: 02043

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.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Philadelphia Bar Association
Lawyer Referral and Information Center
1101 Market Street, 10th Floor
Philadelphia, PA 19107

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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Filadelfia, PA 19107
(215) 238-6300 (Telefono)

COMPLAINT – CIVIL ACTION
PRODUCT LIABILITY

PLAINTIFF, Katherine Crockett, by and through undersigned counsel, files this Complaint against Defendants, Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Vifor Pharmaceuticals Management Ltd., and Vifor Pharma – Aspereva Pharmaceuticals Inc. (collectively "Defendants") and in support thereof make the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, Katherine Crockett, is a resident of Philadelphia, PA.

Luitpold Defendants

2. Luitpold Pharmaceuticals, Inc. (hereinafter "Luitpold") is 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 is a subsidiary and member of the Daiichi Sankyo Group and is the parent company to its own subsidiary, American Regent, Inc. In addition to maintaining an office in the Commonwealth of Pennsylvania, Luitpold is registered to do business throughout the state as well as in the county of Philadelphia, specifically. Luitpold has at all relevant times and continues to be engaged in the business of researching, developing, 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. Upon information and belief, American Regent may also operate out of Luitpold's Norristown, PA office, and is registered to do business in the Commonwealth. American Regent is a

subsidiary of Luitpold and the Daicchi 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, designing, licensing, manufacturing, promoting, labeling, distributing, selling, and marketing the Injectafer product. .

Daiichi Sankyo Defendants

4. 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 or Daiichi Sankyo Co., Ltd.

5. DSI is the United States subsidiary of Daiichi Sankyo Co., Ltd, located in Tokyo, Japan, and is a member of the Daiichi Sankyo Group. Upon information and belief, both Defendants Luitpold and American Regent are members of the Daiichi Sankyo Group.

6. 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.

7. Daiichi Sankyo Co., Ltd. (hereinafter "DSC") is the parent company to DSI and the Daiichi Sankyo Group of companies. At all relevant times, DSC is and was a corporation organized and existing under the laws of Japan, having its principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan.

8. DSC is in the business of designing and manufacturing prescription drugs, including that used by Plaintiff, across the world, including in the United States, and specifically in the Commonwealth of Pennsylvania.

9. Upon information and belief, DSC at all relevant times exercised control over DSI and the DSI subsidiaries, Luitpold and American Regent.

10. Upon information and belief, the agreements between and among the Daiichi defendants, and their affiliates and subsidiaries, provides for DSC to have ultimate control over all relevant decisions, policies, and conduct, and therefore is liable for any and all tort liabilities of Defendants DSI, Luitpold, and American Regent.

11. Upon information and belief, DSI operates as the U.S. headquarters of DSC. At least four of the principals, members, directors, or officers of DSI are also members of DSC. In addition, DSC operates several research and development facilities across the world, including collaborating with DSC to oversee operations for its U.S. subsidiaries.

12. Upon information and belief, there existed at all relevant times a unity of interest in ownership between DSC and DSI such that independence from, or separation between, the Daiichi Defendants does not exist and has never existed. Each of them are alter egos of the other.

13. Because of the unity of operations and ownership, DSI and DSC are heretoafter referred to as the "Daiichi Defendants."

The Vifor Defendants

14. Vifor Pharmaceuticals Management Ltd. (hereinafter "Vifor Pharma") is a for-profit corporation headquartered in Switzerland with an office location at Flughofstrasse 61, CH-81542 Glattbrugg.

15. Vifor Pharma is 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.

16. Upon information and belief, Vifor Pharma is 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 Pharma was the international "partner" of Luitpold in the sale of Injectafer. The licensing agreement between Vifor Pharma and Luitpold awards Vifor Pharma a "share of partner sales" in regards to Injectafer sales in the United States.

17. Upon information and belief, Vifor Pharma was responsible for the original design and development of the bioequivalent ferric carboxymaltose product, Ferinject.

18. Upon information and belief, Vifor Pharma 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.

19. Additionally, since initially introducing ferric carboxymaltose into the world market, Vifor pharma has 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.

20. Vifor Pharma – Aspreva Pharmaceuticals, Inc., (hereinafter "Vifor – Aspreva") is a for-profit corporation with its principal place of business located at 106 Allen Road, Basking Ridge, New Jersey 07920.

21. Vifor – Aspreva is a wholly owned subsidiary of Vifor Pharma. Vifor – Aspreva is and was at all relevant times engaged in the business of researching, developing, designing,

licensing, manufacturing, distributing, selling, and marketing pharmaceutical products on behalf of Vifor Pharma in the United States.

22. Each of the above Defendants 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

23. This Court has personal jurisdiction over Plaintiff, Katherine Crockett, who is a resident of Philadelphia, Pennsylvania. Additionally, Plaintiff was administered the Injectafer product in Philadelphia, Pennsylvania, suffered her injuries caused by the drug in Philadelphia, Pennsylvania, and received and continues to receive substantial medical treatment for her injuries in Philadelphia, Pennsylvania.

General Personal Jurisdiction

24. 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.

25. This Court also has general personal jurisdiction over the Luitpold, American Regent, an 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. DSC, as the parent to DSI and the Daiichi Sankyo Group, thus has inextricable ties to Pennsylvania. Additionally, the Vifor Defendants do business in Pennsylvania and engaged in a licensing deal for its ferric carboxymaltose product that would see the continuous and systematic sale of Injectafer in the Commonwealth.

26. This Court has additional grounds for general personal jurisdiction as Luitpold operates an office and principal place of business at 800 Adams Street, Norristown (*also referring to as Eagleville or Audobon*), PA 19403.

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

Specific General Jurisdiction

28. 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 the Commonwealth of Pennsylvania.

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

30. 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.

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

32. 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."

33. 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.

34. 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.

35. 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.

36. Additionally, the Injectafer product was promoted, marketed, distributed, and sold to Plaintiff's medical treaters in Philadelphia and King of Prussia, Pennsylvania, and administered to Plaintiff in her Philadelphia, Pennsylvania home.

37. Jurisdiction is proper under 28 U.S.C. § 1441(b)(2) and 28 U.S.C § 1446(d) because Luitpold is a properly joined and served forum defendant.

38. Defendants regularly conduct substantial business in Philadelphia County, Pennsylvania.

39. Injectafer is marketed, promoted, distributed, and sold to hospitals, medical facilities, infusion centers, home health care agencies, and consumers in the Philadelphia region.

40. Venue is proper in this Court, pursuant to PA R. Civ. P. 1006 & 2179, as Pennsylvania is where the Luitpold Defendant is a citizen and where it regularly conducts business.

41. Venue is additionally proper in this Court because Philadelphia, Pennsylvania is where Plaintiff's cause of action arose and/or where a transaction or occurrence took place out of which this cause of action arose.

42. Venue is further proper in this Court because substantial, specific conduct by the Luitpold Defendant in relation to the design, creation, testing, labeling, development, pharmacovigilance, and sale of Injectafer originated in Luitpold's Philadelphia region office.

INTRODUCTION AND NATURE OF CASE

43. 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."

44. 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 Defendant Vifor Pharmaceuticals. The Vifor Defendants licensed and continue to license ferric carboxymaltose to all other Defendants who in turn have designed, manufactured, and sold the product in the United States.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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

51. 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.

52. 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.

53. 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 can occur 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.

54. 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.

55. 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.

56. 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.

57. 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 (*measures 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**.

58. 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.

59. 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.

60. 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.

61. **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. The labeling does 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.

62. The label only makes passing references to the potential occurrence of hypophosphatemia and **no reference at all to Severe HPP.** Inadequate to sufficiently warn the user and medical community, hypophosphatemia (not qualified as moderate or Severe) is not

listed in the "Warnings or Precautions" section or in a prominently placed "Black Box" warning, but instead is merely listed as an "Adverse Reaction" occurring in greater than 2% of users.

63. When the label does reference the potential adverse reaction of regular hypophosphatemia, it significantly downplays 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 labeling, Defendants refer only to "*transient* decreases in laboratory blood phosphorous levels (< 2 mg/dl)";

64. 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.

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

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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

73. 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, allege as follows.

74. Plaintiff, Katherine Crockett, is a resident of Philadelphia, PA.

75. On May 3, 2017, Plaintiff was prescribed Injectafer iron injection for treatment of her IDA at the Mayo Clinic in Rochester, Minnesota.

76. Plaintiff received the first injection at the Mayo Clinic on May 5, 2017. Plaintiff received her second injection in Philadelphia, PA on May 16, 2017.

77. Following Plaintiff's first Injectafer injection, her blood phosphorous levels sharply dropped. At one measurement on May 11, 2017, her blood phosphorous dropped to 1.6

mg/dl. Following her second Injectafer administration, laboratory tests on May 19, 2017 revealed a blood phosphorous level in the Severe Hypophosphatemia range of 1.2 mg/dl. These tests do not necessarily represent the lowest levels of Plaintiff's blood phosphorous following the Injectafer administration.

78. Plaintiff was subsequently diagnosed with Severe Hypophosphatemia and, as a result, suffered from multiple hospitalizations, severe nausea, severe weakness and pain, and severe and constant fatigue. Plaintiff was additionally diagnosed with renal phosphate wasting that Plaintiff alleges was caused by Injectafer. As a result of Plaintiff's severe and ongoing injuries, Plaintiff had to take a leave of absence from her place of employment and was only able to return after several months on limited duties.

79. 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 keep 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.

80. 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.

81. As plead below, Plaintiff reserves the right to seek application of the law of the forum state, Pennsylvania, which is also home to Defendant Luitpold. 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

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

83. At all times relevant, the Defendants were in the business of designing, developing, manufacturing, marketing, promoting, monitoring, labeling, selling and/or distributing Injectafer, including the product administered to Plaintiff.

84. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, monitoring, promotion, and distribution of Injectafer so as to avoid exposing others to foreseeable and unreasonable risks of harm.

85. Defendants breached their duty of care to the Plaintiff and her physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, and distribution of Injectafer.

86. 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.

87. At the time of the manufacture and sale of Injectafer, Defendants knew or should have known that Injectafer was designed in such a manner so as to cause Severe Hypophosphatemia and the additional injuries that are known to stem from that diagnosis.

88. At the time of the manufacturer and sale 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.

89. At the time of the manufacturer and sale of Injectafer, Defendants knew or should have known 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 diagnosis of Severe Hypophosphatemia and the injuries that result consequence to severely low levels of blood phosphorous.

90. 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.

91. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, pharmacovigilance, labeling, promotion, distribution and sale of Injectafer in, among others, the following ways:

(a) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

(b) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

(c) Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

(d) Failing to use reasonable care to warn or instruct, including pre-and post-sale, Plaintiff, Plaintiff's healthcare providers and/or the general health care community about Injectafer's substantially dangerous condition or about facts making the product likely to be dangerous;

(e) Failing to warn of Injectafer's known ability to cause Severe Hypophosphatemia and consequent injuries such as osteomalacia, cardiac arrest, heart arrhythmia, cardiopulmonary injury, and rhabdomyolysis, and other injuries listed in the sections above and incorporated by reference herein;

(f) Failing to perform reasonable pre-and post-market testing of the product to investigate Injectafer's propensity to cause Severe Hypophosphatemia;

(g) Failing to adequately monitor the adverse events related to Injectafer known to Defendants from published case reports, study, and reports submitted to Defendants and FDA;

(h) Failing to provide adequate instructions, guidelines, and safety precautions, including pre-and post-sale, to those persons to whom it was reasonably foreseeable would recommend, prescribe, and use Injectafer;

(i) Failing to provide adequate instructions regarding how users and treaters should properly monitor user's serum phosphorous levels following administration of Injectafer;

(j) Representing that Injectafer was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

(k) Continuing the manufacture, promotion, marketing, and sale of Injectafer with the knowledge that Injectafer was dangerous, carried a deficient warning, and not reasonably safe;

(l) Failing to use reasonable and prudent care in the design, research, manufacture, and development of Injectafer so as to avoid the risk of serious harm associated with ferric carboxymaltose;

(m) Promoting, marketing, and selling Injectafer to patient populations who were beyond the approved indicated populations;

(n) Promoting, marketing, and selling Injectafer to physicians for the purposes of off-label uses;

(o) Marketing a product known to Defendants to cause Severe Hypophosphatemia;

(p) Misrepresenting the effects of hypophosphatemia as "transient" or "asymptomatic" in the product labeling and marketing; and

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

92. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

93. As a direct and proximate result of the Defendants' design, manufacture, marketing, pharmacovigilance, monitoring, labeling, promotion, sale and/or distribution 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.

94. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

95. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to New York 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 $50,000.00, 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

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

97. 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.

98. 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.

99. 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.

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

101. Defendants are liable in tort to Plaintiff for their negligent failure to warn under Pennsylvania common law.

102. Defendants are liable in tort to Plaintiff for their negligent failure to warn under New York 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 $50,000.00, 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

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

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

105. 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.

106. 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) 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;

(e) Designing a product without taking into consideration the proper dosage and necessary break in time between administrations;

(f) Utilizing false and misleading claims, including ghost-writing, in advertisements, professional meetings, medical journal articles,

advisory meetings, promotional speaking, CMEs, leave-behinds at prescriber offices, detailing, and by other methods and materials in the design and formulation of Injectafer.

107. The Injectafer that was 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.

108. 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.

109. 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 and in actual use in the United States.

110. As a direct and proximate result of the Defendants' negligent acts and design of Injectafer, Plaintiff suffered injuries and damages as set forth in this Complaint.

111. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania 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 $50,000.00, 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

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

113. 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.

114. 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.

115. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiffs' 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.

116. 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.

117. 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.

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

119. 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.

120. 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.

121. 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.

122. 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.

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

124. 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.

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

126. 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.

127. 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.

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

129. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to New York common law.

130. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania 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 $50,000.00, 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

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

132. The Defendants 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.

133. The representations made by the 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.

134. These representations were made by the Defendants 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.

135. In representations to Plaintiff and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted or misrepresented the following material information (*non-exhaustive*):

(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 the risk of incidences of hypophosphatemia in adverse events and clinical studies was marginal and/or non-existent;

(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 and Strict Liability Design Defect Count.

136. The 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.

137. The 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.

138. 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.

139. In reliance upon these false representations, Plaintiff and her physicians were 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 and her physicians and other healthcare providers 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.

140. The Defendants 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.

141. The information distributed to the public, the medical community, Plaintiff and her physicians by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of Injectafer.

142. These representations, and others made by the 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.

143. 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, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when Injectafer was prescribed to her.

144. Plaintiff and her physicians relied on the misrepresentations and omissions of Defendants, unaware of the falsity of the statements. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Injectafer.

145. As a proximate result of the Defendants' design, manufacture, marketing, sale, promotion, labeling, and/or distribution of Injectafer, 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.

146. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to Pennsylvania common law.

147. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to New York 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 $50,000.00, 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

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

149. 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.

150. 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.

151. 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.

152. 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.

153. 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.

154. 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.

155. 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.

156. 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.

157. 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.

158. 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.

159. As a proximate result of the Defendants' marketing, promotion, labeling, sale and/or distribution 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.

160. Defendants are strictly liable for their reckless and wrongful conduct to Plaintiff pursuant to New York 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 $50,000.00, 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

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

162. 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.

163. 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.

164. 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.

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

166. 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.

167. 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 May 2017 injection of the drug.

168. 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 products and procedures available to treat Iron Deficiency Anemia (IDA), and which far outweigh the utility of Injectafer.

169. 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.

170. 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.

171. Defendants are strictly liable in tort to Plaintiff as a result of their wrongful and reckless conduct pursuant to New York 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 $50,000.00, 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 – BREACH OF EXPRESS WARRANTY

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

173. At all relevant times, the Defendants intended that Injectafer be used in the manner that Plaintiff used it and they expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for IDA, and that they were adequately tested and fit for their intended use.

174. At all relevant times, the Defendants were aware that consumers, including Plaintiff, would use Injectafer; which is to say that Plaintiff was a foreseeable user of the product.

175. Plaintiff and/or her physicians were at all relevant times in privity with the Defendants.

176. Injectafer was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her physicians, without substantial change in the condition in which it was manufactured, labeled, and sold by the Defendants.

177. The Defendants breached various express warranties with respect to Injectafer including the following particulars:

(a) The Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, continuing education, and regulatory submissions that the Injectafer was safe and therefore fraudulently withheld and concealed information about the substantial risks of serious injury associated with Injectafer; and

(b) The Defendants represented to Plaintiff and her physicians and healthcare providers that Injectafer was as safe, and/or safer than other alternative products used to treat IDA, and therefore fraudulently concealed information which demonstrated that Injectafer was a cause of Severe Hypophosphatemia and not safer than alternatives available on the market.

178. In reliance upon the Defendants' express warranties, Plaintiff used Injectafer as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

179. At the time of making such express warranties, the Defendants knew or should have known that Injectafer does not conform to these express representations because the Injectafer was not safe and had numerous side effects, many of which the Defendants did not accurately warn about, including but not limited to Severe Hypophosphatemia and the injuries that are subsequently caused by low levels of blood phosphorous, thus making Injectafer unreasonably unsafe for their intended purpose.

180. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of the Defendants in connection with the prescription, dosage, administration, and treatment of and with Injectafer.

181. The Defendants breached their express warranties to Plaintiff in that Injectafer was not of merchantable quality, safe and fit for its intended uses, nor was it adequately tested.

182. The Defendants' breach constituted violations of Pennsylvania common law principles and 13 Pa. Stat. Ann. §2313, *et seq*.

183. The Defendants' breach constituted violations of New York common and statutory law.

184. As a proximate result of the Defendants' design, manufacture, marketing, labeling, promotion, sale and/or distribution 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.

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 $50,000.00, 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 IX – BREACH OF IMPLIED WARRANTY

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

186. At all relevant and material times, Defendants manufactured, designed, monitored, labeled, distributed, advertised, promoted, and sold Injectafer.

187. At all relevant times, Defendants intended that Injectafer be used for the purposes and in the manner that Plaintiff or her physicians used/prescribed it and the Defendants impliedly warranted that each Injectafer product to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

188. Defendants were aware that consumers, including Plaintiff and her physicians would use/prescribe Injectafer in the manner instructed in the labeling and that Plaintiff was a foreseeable user of Injectafer.

189. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

190. Injectafer was expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

191. Defendants breached various implied warranties with respect to Injectafer, including the following particulars:

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, continuing education, medical literature, and regulatory submissions that Injectafer was safe and therefore fraudulently withheld and concealed information about the substantial risks of serious injury associated with Injectafer; and,

(b) Defendants represented that the Injectafer was safe, and/or safer than other alternative products available for the treatment of IDA, and fraudulently concealed information which demonstrated that Injectafer was not as safe and/or safer than alternatives available on the market.

192. In reliance upon Defendants' implied warranties, Plaintiff and/or her physicians prescribed/used Injectafer in the foreseeable manner normally intended, recommended, instructed, promoted, and marketed by Defendants.

193. Defendants breached their implied warranties to Plaintiff and/or her physicians in that Injectafer was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of common law principles and the following statutory provision: 13 Pa. Stat. Ann. §§2314 *et seq*.

194. Defendants breached their implied warranties to Plaintiff and/or her physicians in that Injectafer was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of New York common and statutory law.

195. As a proximate result of the Defendants' design, manufacture, marketing, labeling, promotion, sale and/or distribution of Injectafer, Plaintiff has been injured

catastrophically, and sustained severe and permanent damages, including pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

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 $50,000.00, 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 X – VIOLATION OF CONSUMER PROTECTION LAWS

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

197. Plaintiff purchased and used Injectafer primarily for personal use and thereby suffered ascertainable losses as a result of the Defendants' actions in violation of the consumer protection laws.

198. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for Injectafer, and would not have incurred related medical costs and injury.

199. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for Injectafer, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

200. Unfair methods of competition of deceptive acts or practices that were proscribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

201. Plaintiff was injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, physicians and consumers, including the Plaintiff and her physicians, was to create demand for and sell Injectafer. Each aspect of the Defendants' conduct combined to artificially create sales of the Injectafer.

202. The Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Injectafer.

203. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for Injectafer, and would not have incurred related medical costs.

204. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq*., and any and all New York consumer protection statutes.

205. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state

consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq*, and any and all New York consumer protection statutes.

206. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

207. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Injectafer was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations made in uniform promotional materials and product labeling.

208. The actions and omissions of the Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

209. The Defendants had actual knowledge of the defective and dangerous condition of Injectafer and failed to take any action to cure such defective and dangerous conditions.

210. Plaintiff and her physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product to use.

211. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

212. By reason of the unlawful acts engaged by the Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

213. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution 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.

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 $50,000.00, 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 XI – GROSS NEGLIGENCE

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

215. The 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 a 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 .

216. Plaintiff and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

217. 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.

218. Plaintiff will seek to assert claims for exemplary damages to the extent available under all applicable Pennsylvania and New York law.

219. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused that injuries to Plaintiff. 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 $50,000.00, 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 this 19th day of December, 2018.

Respectfully submitted,

POGUST MILLROOD, LLC

/s/ Michael G. Daly

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161 Washington Street, Suite 940
Conshohocken, PA 19428

Counsel for Plaintiff

VERIFICATION

I, Katherine Crocket, hereby state:

1. I am the plaintiff in this action.

2. I verify that the statements made in the foregoing COMPLAINT AND JURY DEMAND are true and correct to the best of my knowledge, information and belief; and

3. I understand that the statements in said COMPLAINT AND JURY DEMAND are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsifications to authorities.

Dated: 12/19/18

Katherine Crockett
Plaintiff

EXHIBIT B

AFFIDAVIT OF JOSEPH BOYLE

Joseph Boyle, being duly sworn, deposes and says:

1. I have been the Chief Financial Officer of American Regent, Inc. (formerly known as Luitpold Pharmaceuticals, Inc.) since February 21, 2017, the company's Treasurer since June 1, 2017, and a member of the company's Board of Directors since June 5, 2017.

2. Luitpold Pharmaceuticals, Inc. ("Luitpold") was a corporation organized under the laws of the state of New York, with its principal place of business in Shirley, New York. Luitpold developed, manufactured, distributed, and sold injectable pharmaceutical products for humans and for animals. The company formerly known as American Regent, Inc. was a wholly owned subsidiary of Luitpold organized under the laws of the State of New York, with its principal place of business in Shirley, New York. The American Regent, Inc. subsidiary of Luitpold was responsible for all commercial aspects of the human-health pharmaceutical products of Luitpold.

3. To streamline its business, on December 31, 2018, Luitpold merged its subsidiaries, including the former American Regent, Inc. and a subsidiary based in Ohio, PharmaForce, Inc., into itself. On January 2, 2019, the surviving entity, Luitpold, was renamed American Regent, Inc. since that was the customer-facing corporate brand name. (Hereinafter, the company referred to as "American Regent" or "Company" is the entity formerly known as Luitpold.)

4. In addition to its headquarters in Shirley, New York, American Regent also maintains locations in Ohio, as well as a smaller location in Norristown, Pennsylvania. American Regent never maintained its principal place of business anywhere other than Shirley, New York.

5. For more than twenty-five years, American Regent has employed hundreds of employees, the majority of whom have worked out of the Company's headquarters in Shirley, New York. The Chief Executive Officer & President, as well as the majority of executives, have worked out of the Shirley, New York headquarters throughout this time period.

6. Direction, control, coordination, and strategic decision-making activities concerning the Company's products are based out of the New York headquarters, where functions such as Commercial Operations, Finance, Medical Affairs, Information Technology, and Legal are based. Although there are a number of personnel in the Manufacturing, Quality, and Human Resources functions in the Company's Ohio locations, those functions are run primarily out of New York, and the majority of employees in each function are located in Shirley, New York. Clinical and pharmacovigilance activities take place in Pennsylvania; however, all such activity is reported to headquarters in Shirley, New York, where ultimate decision-making authority resides.

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7. The corporate officers of American Regent, including the Chief Executive Officer & President, the Treasurer, and the Corporate Secretary work out of the Company's headquarters in Shirley, New York, as do all members of the Company's Board of Directors.

FURTHER AFFIANT SAYETH NAUGHT

Dated: 1/17/19

Joseph Boyle

SWORN TO and subscribed in my presence this 17TH January, 2019.

Sworn to and subscribed
before me this
17 day of JAN, 20 19

NOTARY PUBLIC

PAMELA HERFORTH
NOTARY PUBLIC OF NEW JERSEY
Comm. # 50058014
My Commission Expires 4/5/2022

EXHIBIT C

Court of Common Pleas of Philadelphia County
Trial Division

Civil Cover Sheet

For Prothonotary Use Only (Docket Number)
NOVEMBER 2018 002043
E-Filing Number: 1811038775

PLAINTIFF'S NAME	DEFENDANT'S NAME
KATHERINE CROCKETT	LUITPOLD PHARMACEUTICALS, INC
PLAINTIFF'S ADDRESS 1830 LOMBARD STREET APT 714 PHILADELPHIA PA 19146	DEFENDANT'S ADDRESS 800 ADAMS AVE #1 NORRISTOWN PA 19403
PLAINTIFF'S NAME	DEFENDANT'S NAME AMERICAN REGENT, INC
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS 5 RAMSEY ROAD SHIRLEY NY 11967
PLAINTIFF'S NAME	DEFENDANT'S NAME DAIICHI SANKYO, INC
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS 211 MT AIRY RD BASKING RIDGE NJ 07920

TOTAL NUMBER OF PLAINTIFFS	TOTAL NUMBER OF DEFENDANTS	COMMENCEMENT OF ACTION
1	6	☐ Complaint ☐ Petition Action ☐ Notice of Appeal ☒ Writ of Summons ☐ Transfer From Other Jurisdictions

AMOUNT IN CONTROVERSY
☐ $50,000.00 or less
☒ More than $50,000.00

COURT PROGRAMS

☐ Arbitration	☐ Mass Tort	☐ Commerce	☐ Settlement
☒ Jury	☐ Savings Action	☐ Minor Court Appeal	☐ Minors
☐ Non-Jury	☐ Petition	☐ Statutory Appeals	☐ W/D/Survival
☐ Other:			

CASE TYPE AND CODE
2P - PRODUCT LIABILITY

STATUTORY BASIS FOR CAUSE OF ACTION

RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)

FILED
PRO PROTHY
NOV 19 2018
A. SILIGRINI

IS CASE SUBJECT TO COORDINATION ORDER?
YES NO

TO THE PROTHONOTARY:

Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: KATHERINE CROCKETT

Papers may be served at the address set forth below.

NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY
MICHAEL G. DALY

ADDRESS
161 WASHINGTON ST SUITE 940
CONSHOHOCKEN PA 19428

PHONE NUMBER
(610)941-4204

FAX NUMBER
(610)941-4245

SUPREME COURT IDENTIFICATION NO.
309911

E-MAIL ADDRESS
mdaly@pogustmillrood.com

SIGNATURE OF FILING ATTORNEY OR PARTY
MICHAEL DALY

DATE SUBMITTED
Monday, November 19, 2018, 02:02 pm

COMPLETE LIST OF DEFENDANTS:

1. LUITPOLD PHARMACEUTICALS, INC
   800 ADAMS AVE #1
   NORRISTOWN PA 19403
2. AMERICAN REGENT, INC
   5 RAMSEY ROAD
   SHIRLEY NY 11967
3. DAIICHI SANKYO, INC
   211 MT AIRY RD
   BASKING RIDGE NJ 07920
4. DAIICHI SANKYO CO., LTD
   3-5-1, NIHONBASHI-HONCHO, CHUO-KU, 103-8426
   TOKYO
5. VIFOR PHARMACEUTICALS MANAGEMENT LTD.
   FLUGHOFSTRASSE 61 CH-8152
   GLATTBRUGG
6. VIFOR PHARMA - ASPEREVA PHARMACEUTICALS INC.
   106 ALLEN ROAD
   BASKING RIDGE NJ 07920

POGUST MILLROOD, LLC
Michael G. Daly, Esq., ID No. 309911
Tobias L. Millrood, Esq., ID No. 77764
Eight Tower Bridge, Suite 940
161 Washington Street
Conshohocken, PA 19428
Phone: (610) 941-4204
Fax: (610) 941-4245
Attorneys for Plaintiff

THIS IS NOT AN ARBITRATION CASE. AN ASSESSMENT OF DAMAGES HEARING IS REQUIRED.
JURY TRIAL DEMANDED

Katherine Crockett **1830 Lombard Street, Apt 714** **Philadelphia, PA 19146** **Plaintiff,** **vs.** **Luitpold Pharmaceuticals, Inc** **5 Ramsey Rd** **Shirley, NY 11967** **800 Adams Ave # 1,** **Norristown, PA 19403** ------AND--------- **SEE ATTACHED SHEET FOR ADDITIONAL DEFENDANTS** **Defendants.**	: : : : : : : : : : : : : : : : :	**PHILADELPHIA COUNTY** **TRIAL DIVISION** **COURT OF COMMON PLEAS** **NOVEMBER TERM, 2018** **DOCKET NO: #_____** **JURY TRIAL DEMANDED**

PRAECIPE TO ISSUE WRIT OF SUMMONS
Product Liability Action

TO THE PROTHONOTARY:

Kindly issue a Writ of Summons – Civil Action to Defendants Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Vifor Pharmaceuticals Management Ltd. and Vifor Pharma – Aspereva Pharmaceuticals Inc.

Dated: November 19, 2018

By: /s/ *Michael G. Daly*

Michael G. Daly, Esquire

ATTACHED SHEET FOR ADDITIONAL DEFENDANTS

American Regent, Inc.
5 Ramsey Rd,
Shirley, NY 11967

Daiichi Sankyo, Inc.
211 Mt Airy Rd
Basking Ridge, NJ 07920

Daiichi Sankyo Co., Ltd.
3-5-1, Nihonbashi-honcho, Chuo-ku
Tokyo 103-8426, Japan

Vifor Pharmaceuticals Management Ltd.
Flughofstrasse 61
CH-8152 Glattbrugg, Switzerland

Vifor Pharma – Aspereva Pharmaceuticals Inc.
106 Allen Road
Basking Ridge, NJ 07920

C.P.97

Commonwealth of Pennsylvania

CITY AND COUNTY OF PHILADELPHIA

SUMMONS
CITACION

COURT OF COMMON PLEAS

_____ Term, 20_____

No. _____

vs.

To[1]

You are notified that the Plaintiff[2]
Usted esta avisado que el demandante[2]

Has (have) commenced an action against you.
Ha (han) iniciado una accion en contra suya.

JOSEPH H. EVERS
Prothonotary

By _____

Date _____

[1] Name(s) of Defendant(s)
[2] Name(s) of Plaintiff(s)

10-208 (Rev. 6/00)

COURT OF COMMON PLEAS

_____Term, 20 ____ No. _____

vs.

SUMMONS

POGUST MILLROOD, LLC
Michael G. Daly, Esq., ID No. 309911
Tobias L. Millrood, Esq., ID No. 77764
Kara Hill, Esq., ID No. 324171
Eight Tower Bridge, Suite 940
161 Washington Street
Conshohocken, PA 19428
Phone: (610) 941-4204
Fax: (610) 941-4245
Attorneys for Plaintiffs

KATHERINE CROCKETT
1830 Lombard Street, Apt 714
Philadelphia, PA 19146,

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 CO., LTD. 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan
and
VIFOR PHARMACEUTICALS MANAGEMENT LTD. Flughofstrasse 61 CH-8152 Glattbrugg, Switzerland
and
VIFOR PHARMA – ASPEREVA PHARMACEUTICALS INC. 106 Allen Road Basking Ridge, NJ 07920

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

NOVEMBER TERM, 2018

NO: 02043

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.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Philadelphia Bar Association
Lawyer Referral and Information Center
1101 Market Street, 10th Floor
Philadelphia, PA 19107

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.

Asociacion De Licenciados De Filadelfia
Servicio De Referencia E Informacion Legal
1101 Market Street, 10th Floor
Filadelfia, PA 19107
(215) 238-6300 (Telefono)

COMPLAINT – CIVIL ACTION
PRODUCT LIABILITY

PLAINTIFF, Katherine Crockett, by and through undersigned counsel, files this Complaint against Defendants, Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Vifor Pharmaceuticals Management Ltd., and Vifor Pharma – Aspereva Pharmaceuticals Inc. (collectively "Defendants") and in support thereof make the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, Katherine Crockett, is a resident of Philadelphia, PA.

Luitpold Defendants

2. Luitpold Pharmaceuticals, Inc. (hereinafter "Luitpold") is 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 is a subsidiary and member of the Daiichi Sankyo Group and is the parent company to its own subsidiary, American Regent, Inc. In addition to maintaining an office in the Commonwealth of Pennsylvania, Luitpold is registered to do business throughout the state as well as in the county of Philadelphia, specifically. Luitpold has at all relevant times and continues to be engaged in the business of researching, developing, 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. Upon information and belief, American Regent may also operate out of Luitpold's Norristown, PA office, and is registered to do business in the Commonwealth. American Regent is a

subsidiary of Luitpold and the Daicchi 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, designing, licensing, manufacturing, promoting, labeling, distributing, selling, and marketing the Injectafer product. .

Daiichi Sankyo Defendants

4. 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 or Daiichi Sankyo Co., Ltd.

5. DSI is the United States subsidiary of Daiichi Sankyo Co., Ltd, located in Tokyo, Japan, and is a member of the Daiichi Sankyo Group. Upon information and belief, both Defendants Luitpold and American Regent are members of the Daiichi Sankyo Group.

6. 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.

7. Daiichi Sankyo Co., Ltd. (hereinafter "DSC") is the parent company to DSI and the Daiichi Sankyo Group of companies. At all relevant times, DSC is and was a corporation organized and existing under the laws of Japan, having its principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan.

8. DSC is in the business of designing and manufacturing prescription drugs, including that used by Plaintiff, across the world, including in the United States, and specifically in the Commonwealth of Pennsylvania.

9. Upon information and belief, DSC at all relevant times exercised control over DSI and the DSI subsidiaries, Luitpold and American Regent.

10. Upon information and belief, the agreements between and among the Daiichi defendants, and their affiliates and subsidiaries, provides for DSC to have ultimate control over all relevant decisions, policies, and conduct, and therefore is liable for any and all tort liabilities of Defendants DSI, Luitpold, and American Regent.

11. Upon information and belief, DSI operates as the U.S. headquarters of DSC. At least four of the principals, members, directors, or officers of DSI are also members of DSC. In addition, DSC operates several research and development facilities across the world, including collaborating with DSC to oversee operations for its U.S. subsidiaries.

12. Upon information and belief, there existed at all relevant times a unity of interest in ownership between DSC and DSI such that independence from, or separation between, the Daiichi Defendants does not exist and has never existed. Each of them are alter egos of the other.

13. Because of the unity of operations and ownership, DSI and DSC are heretoafter referred to as the "Daiichi Defendants."

The Vifor Defendants

14. Vifor Pharmaceuticals Management Ltd. (hereinafter "Vifor Pharma") is a for-profit corporation headquartered in Switzerland with an office location at Flughofstrasse 61, CH-81542 Glattbrugg.

15. Vifor Pharma is 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.

16. Upon information and belief, Vifor Pharma is 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 Pharma was the international "partner" of Luitpold in the sale of Injectafer. The licensing agreement between Vifor Pharma and Luitpold awards Vifor Pharma a "share of partner sales" in regards to Injectafer sales in the United States.

17. Upon information and belief, Vifor Pharma was responsible for the original design and development of the bioequivalent ferric carboxymaltose product, Ferinject.

18. Upon information and belief, Vifor Pharma 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.

19. Additionally, since initially introducing ferric carboxymaltose into the world market, Vifor pharma has 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.

20. Vifor Pharma – Aspreva Pharmaceuticals, Inc., (hereinafter "Vifor – Aspreva") is a for-profit corporation with its principal place of business located at 106 Allen Road, Basking Ridge, New Jersey 07920.

21. Vifor – Aspreva is a wholly owned subsidiary of Vifor Pharma. Vifor – Aspreva is and was at all relevant times engaged in the business of researching, developing, designing,

licensing, manufacturing, distributing, selling, and marketing pharmaceutical products on behalf of Vifor Pharma in the United States.

22. Each of the above Defendants 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

23. This Court has personal jurisdiction over Plaintiff, Katherine Crockett, who is a resident of Philadelphia, Pennsylvania. Additionally, Plaintiff was administered the Injectafer product in Philadelphia, Pennsylvania, suffered her injuries caused by the drug in Philadelphia, Pennsylvania, and received and continues to receive substantial medical treatment for her injuries in Philadelphia, Pennsylvania.

General Personal Jurisdiction

24. 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.

25. This Court also has general personal jurisdiction over the Luitpold, American Regent, an 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. DSC, as the parent to DSI and the Daiichi Sankyo Group, thus has inextricable ties to Pennsylvania. Additionally, the Vifor Defendants do business in Pennsylvania and engaged in a licensing deal for its ferric carboxymaltose product that would see the continuous and systematic sale of Injectafer in the Commonwealth.

26. This Court has additional grounds for general personal jurisdiction as Luitpold operates an office and principal place of business at 800 Adams Street, Norristown (*also referring to as Eagleville or Audobon*), PA 19403.

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

Specific General Jurisdiction

28. 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 the Commonwealth of Pennsylvania.

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

30. 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.

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

32. 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."

33. 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.

34. 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.

35. 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.

36. Additionally, the Injectafer product was promoted, marketed, distributed, and sold to Plaintiff's medical treaters in Philadelphia and King of Prussia, Pennsylvania, and administered to Plaintiff in her Philadelphia, Pennsylvania home.

37. Jurisdiction is proper under 28 U.S.C. § 1441(b)(2) and 28 U.S.C § 1446(d) because Luitpold is a properly joined and served forum defendant.

38. Defendants regularly conduct substantial business in Philadelphia County, Pennsylvania.

39. Injectafer is marketed, promoted, distributed, and sold to hospitals, medical facilities, infusion centers, home health care agencies, and consumers in the Philadelphia region.

40. Venue is proper in this Court, pursuant to PA R. Civ. P. 1006 & 2179, as Pennsylvania is where the Luitpold Defendant is a citizen and where it regularly conducts business.

41. Venue is additionally proper in this Court because Philadelphia, Pennsylvania is where Plaintiff's cause of action arose and/or where a transaction or occurrence took place out of which this cause of action arose.

42. Venue is further proper in this Court because substantial, specific conduct by the Luitpold Defendant in relation to the design, creation, testing, labeling, development, pharmacovigilance, and sale of Injectafer originated in Luitpold's Philadelphia region office.

INTRODUCTION AND NATURE OF CASE

43. 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."

44. 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 Defendant Vifor Pharmaceuticals. The Vifor Defendants licensed and continue to license ferric carboxymaltose to all other Defendants who in turn have designed, manufactured, and sold the product in the United States.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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

51. 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.

52. 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.

53. 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 can occur 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.

54. 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.

55. 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.

56. 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.

57. 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 (*measures 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**.

58. 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.

59. 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.

60. 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.

61. **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. The labeling does 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.

62. The label only makes passing references to the potential occurrence of hypophosphatemia and **no reference at all to Severe HPP.** Inadequate to sufficiently warn the user and medical community, hypophosphatemia (not qualified as moderate or Severe) is not

listed in the "Warnings or Precautions" section or in a prominently placed "Black Box" warning, but instead is merely listed as an "Adverse Reaction" occurring in greater than 2% of users.

63. When the label does reference the potential adverse reaction of regular hypophosphatemia, it significantly downplays 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 labeling, Defendants refer only to "*transient* decreases in laboratory blood phosphorous levels (< 2 mg/dl)";

64. 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.

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

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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

73. 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, allege as follows.

74. Plaintiff, Katherine Crockett, is a resident of Philadelphia, PA.

75. On May 3, 2017, Plaintiff was prescribed Injectafer iron injection for treatment of her IDA at the Mayo Clinic in Rochester, Minnesota.

76. Plaintiff received the first injection at the Mayo Clinic on May 5, 2017. Plaintiff received her second injection in Philadelphia, PA on May 16, 2017.

77. Following Plaintiff's first Injectafer injection, her blood phosphorous levels sharply dropped. At one measurement on May 11, 2017, her blood phosphorous dropped to 1.6

mg/dl. Following her second Injectafer administration, laboratory tests on May 19, 2017 revealed a blood phosphorous level in the Severe Hypophosphatemia range of 1.2 mg/dl. These tests do not necessarily represent the lowest levels of Plaintiff's blood phosphorous following the Injectafer administration.

78. Plaintiff was subsequently diagnosed with Severe Hypophosphatemia and, as a result, suffered from multiple hospitalizations, severe nausea, severe weakness and pain, and severe and constant fatigue. Plaintiff was additionally diagnosed with renal phosphate wasting that Plaintiff alleges was caused by Injectafer. As a result of Plaintiff's severe and ongoing injuries, Plaintiff had to take a leave of absence from her place of employment and was only able to return after several months on limited duties.

79. 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 keep 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.

80. 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.

81. As plead below, Plaintiff reserves the right to seek application of the law of the forum state, Pennsylvania, which is also home to Defendant Luitpold. 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

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

83. At all times relevant, the Defendants were in the business of designing, developing, manufacturing, marketing, promoting, monitoring, labeling, selling and/or distributing Injectafer, including the product administered to Plaintiff.

84. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, monitoring, promotion, and distribution of Injectafer so as to avoid exposing others to foreseeable and unreasonable risks of harm.

85. Defendants breached their duty of care to the Plaintiff and her physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, and distribution of Injectafer.

86. 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.

87. At the time of the manufacture and sale of Injectafer, Defendants knew or should have known that Injectafer was designed in such a manner so as to cause Severe Hypophosphatemia and the additional injuries that are known to stem from that diagnosis.

88. At the time of the manufacturer and sale 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.

89. At the time of the manufacturer and sale of Injectafer, Defendants knew or should have known 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 diagnosis of Severe Hypophosphatemia and the injuries that result consequence to severely low levels of blood phosphorous.

90. 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.

91. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, pharmacovigilance, labeling, promotion, distribution and sale of Injectafer in, among others, the following ways:

(a) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

(b) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

(c) Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

(d) Failing to use reasonable care to warn or instruct, including pre-and post-sale, Plaintiff, Plaintiff's healthcare providers and/or the general health care community about Injectafer's substantially dangerous condition or about facts making the product likely to be dangerous;

(e) Failing to warn of Injectafer's known ability to cause Severe Hypophosphatemia and consequent injuries such as osteomalacia, cardiac arrest, heart arrhythmia, cardiopulmonary injury, and rhabdomyolysis, and other injuries listed in the sections above and incorporated by reference herein;

(f) Failing to perform reasonable pre-and post-market testing of the product to investigate Injectafer's propensity to cause Severe Hypophosphatemia;

(g) Failing to adequately monitor the adverse events related to Injectafer known to Defendants from published case reports, study, and reports submitted to Defendants and FDA;

(h) Failing to provide adequate instructions, guidelines, and safety precautions, including pre-and post-sale, to those persons to whom it was reasonably foreseeable would recommend, prescribe, and use Injectafer;

(i) Failing to provide adequate instructions regarding how users and treaters should properly monitor user's serum phosphorous levels following administration of Injectafer;

(j) Representing that Injectafer was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

(k) Continuing the manufacture, promotion, marketing, and sale of Injectafer with the knowledge that Injectafer was dangerous, carried a deficient warning, and not reasonably safe;

(l) Failing to use reasonable and prudent care in the design, research, manufacture, and development of Injectafer so as to avoid the risk of serious harm associated with ferric carboxymaltose;

(m) Promoting, marketing, and selling Injectafer to patient populations who were beyond the approved indicated populations;

(n) Promoting, marketing, and selling Injectafer to physicians for the purposes of off-label uses;

(o) Marketing a product known to Defendants to cause Severe Hypophosphatemia;

(p) Misrepresenting the effects of hypophosphatemia as "transient" or "asymptomatic" in the product labeling and marketing; and

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

92. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

93. As a direct and proximate result of the Defendants' design, manufacture, marketing, pharmacovigilance, monitoring, labeling, promotion, sale and/or distribution 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.

94. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

95. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to New York 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 $50,000.00, 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

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

97. 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.

98. 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.

99. 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.

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

101. Defendants are liable in tort to Plaintiff for their negligent failure to warn under Pennsylvania common law.

102. Defendants are liable in tort to Plaintiff for their negligent failure to warn under New York 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 $50,000.00, 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

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

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

105. 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.

106. 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) 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;

(e) Designing a product without taking into consideration the proper dosage and necessary break in time between administrations;

(f) Utilizing false and misleading claims, including ghost-writing, in advertisements, professional meetings, medical journal articles,

advisory meetings, promotional speaking, CMEs, leave-behinds at prescriber offices, detailing, and by other methods and materials in the design and formulation of Injectafer.

107. The Injectafer that was 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.

108. 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.

109. 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 and in actual use in the United States.

110. As a direct and proximate result of the Defendants' negligent acts and design of Injectafer, Plaintiff suffered injuries and damages as set forth in this Complaint.

111. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania 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 $50,000.00, 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

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

113. 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.

114. 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.

115. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiffs' 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.

116. 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.

117. 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.

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

119. 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.

120. 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.

121. 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.

122. 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.

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

124. 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.

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

126. 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.

127. 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.

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

129. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to New York common law.

130. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania 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 $50,000.00, 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

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

132. The Defendants 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.

133. The representations made by the 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.

134. These representations were made by the Defendants 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.

135. In representations to Plaintiff and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted or misrepresented the following material information (*non-exhaustive*):

(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 the risk of incidences of hypophosphatemia in adverse events and clinical studies was marginal and/or non-existent;

(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 and Strict Liability Design Defect Count.

136. The 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.

137. The 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.

138. 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.

139. In reliance upon these false representations, Plaintiff and her physicians were 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 and her physicians and other healthcare providers 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.

140. The Defendants 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.

141. The information distributed to the public, the medical community, Plaintiff and her physicians by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of Injectafer.

142. These representations, and others made by the 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.

143. 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, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when Injectafer was prescribed to her.

144. Plaintiff and her physicians relied on the misrepresentations and omissions of Defendants, unaware of the falsity of the statements. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Injectafer.

145. As a proximate result of the Defendants' design, manufacture, marketing, sale, promotion, labeling, and/or distribution of Injectafer, 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.

146. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to Pennsylvania common law.

147. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to New York 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 $50,000.00, 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

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

149. 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.

150. 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.

151. 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.

152. 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.

153. 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.

154. 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.

155. 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.

156. 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.

157. 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.

158. 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.

159. As a proximate result of the Defendants' marketing, promotion, labeling, sale and/or distribution 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.

160. Defendants are strictly liable for their reckless and wrongful conduct to Plaintiff pursuant to New York 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 $50,000.00, 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

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

162. 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.

163. 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.

164. 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.

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

166. 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.

167. 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 May 2017 injection of the drug.

168. 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 products and procedures available to treat Iron Deficiency Anemia (IDA), and which far outweigh the utility of Injectafer.

169. 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.

170. 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.

171. Defendants are strictly liable in tort to Plaintiff as a result of their wrongful and reckless conduct pursuant to New York 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 $50,000.00, 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 – BREACH OF EXPRESS WARRANTY

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

173. At all relevant times, the Defendants intended that Injectafer be used in the manner that Plaintiff used it and they expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for IDA, and that they were adequately tested and fit for their intended use.

174. At all relevant times, the Defendants were aware that consumers, including Plaintiff, would use Injectafer; which is to say that Plaintiff was a foreseeable user of the product.

175. Plaintiff and/or her physicians were at all relevant times in privity with the Defendants.

176. Injectafer was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her physicians, without substantial change in the condition in which it was manufactured, labeled, and sold by the Defendants.

177. The Defendants breached various express warranties with respect to Injectafer including the following particulars:

(a) The Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, continuing education, and regulatory submissions that the Injectafer was safe and therefore fraudulently withheld and concealed information about the substantial risks of serious injury associated with Injectafer; and

(b) The Defendants represented to Plaintiff and her physicians and healthcare providers that Injectafer was as safe, and/or safer than other alternative products used to treat IDA, and therefore fraudulently concealed information which demonstrated that Injectafer was a cause of Severe Hypophosphatemia and not safer than alternatives available on the market.

178. In reliance upon the Defendants' express warranties, Plaintiff used Injectafer as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

179. At the time of making such express warranties, the Defendants knew or should have known that Injectafer does not conform to these express representations because the Injectafer was not safe and had numerous side effects, many of which the Defendants did not accurately warn about, including but not limited to Severe Hypophosphatemia and the injuries that are subsequently caused by low levels of blood phosphorous, thus making Injectafer unreasonably unsafe for their intended purpose.

180. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of the Defendants in connection with the prescription, dosage, administration, and treatment of and with Injectafer.

181. The Defendants breached their express warranties to Plaintiff in that Injectafer was not of merchantable quality, safe and fit for its intended uses, nor was it adequately tested.

182. The Defendants' breach constituted violations of Pennsylvania common law principles and 13 Pa. Stat. Ann. §2313, *et seq*.

183. The Defendants' breach constituted violations of New York common and statutory law.

184. As a proximate result of the Defendants' design, manufacture, marketing, labeling, promotion, sale and/or distribution 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.

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 $50,000.00, 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 IX – BREACH OF IMPLIED WARRANTY

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

186. At all relevant and material times, Defendants manufactured, designed, monitored, labeled, distributed, advertised, promoted, and sold Injectafer.

187. At all relevant times, Defendants intended that Injectafer be used for the purposes and in the manner that Plaintiff or her physicians used/prescribed it and the Defendants impliedly warranted that each Injectafer product to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

188. Defendants were aware that consumers, including Plaintiff and her physicians would use/prescribe Injectafer in the manner instructed in the labeling and that Plaintiff was a foreseeable user of Injectafer.

189. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

190. Injectafer was expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

191. Defendants breached various implied warranties with respect to Injectafer, including the following particulars:

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, continuing education, medical literature, and regulatory submissions that Injectafer was safe and therefore fraudulently withheld and concealed information about the substantial risks of serious injury associated with Injectafer; and,

(b) Defendants represented that the Injectafer was safe, and/or safer than other alternative products available for the treatment of IDA, and fraudulently concealed information which demonstrated that Injectafer was not as safe and/or safer than alternatives available on the market.

192. In reliance upon Defendants' implied warranties, Plaintiff and/or her physicians prescribed/used Injectafer in the foreseeable manner normally intended, recommended, instructed, promoted, and marketed by Defendants.

193. Defendants breached their implied warranties to Plaintiff and/or her physicians in that Injectafer was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of common law principles and the following statutory provision: 13 Pa. Stat. Ann. §§2314 *et seq*.

194. Defendants breached their implied warranties to Plaintiff and/or her physicians in that Injectafer was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of New York common and statutory law.

195. As a proximate result of the Defendants' design, manufacture, marketing, labeling, promotion, sale and/or distribution of Injectafer, Plaintiff has been injured

catastrophically, and sustained severe and permanent damages, including pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

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 $50,000.00, 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 X – VIOLATION OF CONSUMER PROTECTION LAWS

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

197. Plaintiff purchased and used Injectafer primarily for personal use and thereby suffered ascertainable losses as a result of the Defendants' actions in violation of the consumer protection laws.

198. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for Injectafer, and would not have incurred related medical costs and injury.

199. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for Injectafer, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

200. Unfair methods of competition of deceptive acts or practices that were proscribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

201. Plaintiff was injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, physicians and consumers, including the Plaintiff and her physicians, was to create demand for and sell Injectafer. Each aspect of the Defendants' conduct combined to artificially create sales of the Injectafer.

202. The Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Injectafer.

203. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for Injectafer, and would not have incurred related medical costs.

204. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq*., and any and all New York consumer protection statutes.

205. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state

consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq*, and any and all New York consumer protection statutes.

206. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

207. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Injectafer was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations made in uniform promotional materials and product labeling.

208. The actions and omissions of the Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

209. The Defendants had actual knowledge of the defective and dangerous condition of Injectafer and failed to take any action to cure such defective and dangerous conditions.

210. Plaintiff and her physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product to use.

211. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

212. By reason of the unlawful acts engaged by the Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

213. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution 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.

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 $50,000.00, 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 XI – GROSS NEGLIGENCE

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

215. The 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 a 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 .

216. Plaintiff and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

217. 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.

218. Plaintiff will seek to assert claims for exemplary damages to the extent available under all applicable Pennsylvania and New York law.

219. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused that injuries to Plaintiff. 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 $50,000.00, 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 this 19th day of December, 2018.

Respectfully submitted,

POGUST MILLROOD, LLC

/s/ Michael G. Daly
Michael G. Daly - PA Bar No. 309911
Tobias L. Millrood – PA Bar No. 77764
Kara Hill – PA Bar No. 324171
Eight Tower Bridge
161 Washington Street, Suite 940
Conshohocken, PA 19428

Counsel for Plaintiff

VERIFICATION

I, Katherine Crocket, hereby state:

1. I am the plaintiff in this action.

2. I verify that the statements made in the foregoing COMPLAINT AND JURY DEMAND are true and correct to the best of my knowledge, information and belief; and

3. I understand that the statements in said COMPLAINT AND JURY DEMAND are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsifications to authorities.

Dated: 12/19/18

Katherine Crockett
Plaintiff

Michael G. Daly, Esquire
161 Washington Street, Suite 940
Conshohocken, PA 19428
(610) 941-4204

Commonwealth of Pennsylvania
In the Court of Common Pleas
Philadelphia County

Katherine Crockett

v.

Luitpold Pharmaceuticals, Inc., et al.

_____ /

Case No.:18-11-2043

Commonwealth of Pennsylvania
County of Philadelphia ss

AFFIDAVIT OF CORPORATE SERVICE

I, **Thomas J. Crean, Jr.,** being duly sworn according to the law upon my oath, depose and say, that I am not a party to this action, am over 18 years of age, and have no direct personal interest in this litigation.

PARTY SERVED:	**Daiichi Sankyo, Inc.**
DOCUMENTS SERVED:	**Complaint**
BY LEAVING WITH:	**Albert McCormick, Assoc. General Counsel**
DATE & TIME OF SERVICE:	**12/20/2018 12:32 PM**
PHYSICAL DESCRIPTION:	**Age: 58** **Weight: 175** **Hair: Gray** **Sex: Male** **Height: 5'9** **Race: Caucasian**
SERVED ADDRESS:	**211 Mount Airy Road** **Basking Ridge, NJ 07920**

I hereby affirm that the information contained in the Affidavit of Service is true and correct. This affirmation is made subject to the penalties of 18 PA C.S. 4904 relating to unsworn falsification to authorities.

Subscribed and sworn before me, a Notary Public, this 20th day of December, 2018

Regina A. Richman, Notary Public
Falls Twp., Bucks County
My Commission expires on: 12/12/2021

Thomas J. Crean, Jr.
Dennis Richman's Services for the Professional, Inc
1500 John F. Kennedy Blvd. Suite #1315,
Philadelphia, PA 19102
(215) 977-9393

GPS: [illegible]7157;-74.57838013294561

Case ID: 181102043

Order #P163745

Michael G. Daly, Esquire
161 Washington Street, Suite 940
Conshohocken, PA 19428
(610) 941-4204

Commonwealth of Pennsylvania
In the Court of Common Pleas
Philadelphia County

Katherine Crockett

v.

Luitpold Pharmaceuticals, Inc., et al.

Case No.:18-11-2043

Commonwealth of Pennsylvania
County of Philadelphia ss

AFFIDAVIT OF NON-SERVICE

I, **Thomas J. Crean, Jr.,** being duly sworn according to the law upon my oath, depose and say, that I am not a party to this action, am over 18 years of age, and have no direct personal interest in this litigation.

PARTY: **Vifor Pharma-Aspereva Pharmaceuticals, Inc.**

DOCUMENTS: **Complaint**

DATE & TIME: **12/20/2018 12:10 PM**

ADDRESS: **106 Allen Road**
Basking Ridge, NJ 07920

I hereby certify and return that I completed due and diligent attempts to servee Vifor Pharma-Aspereva Pharmaceuticals, Inc.. I therefore return this Complaint without service on Vifor Pharma-Aspereva Pharmaceuticals, Inc..

Diligent attempts were made per the following notations:

12/20/2018 12:10 PM Results: No longer here, moved 6 months ago.

I hereby affirm that the information contained in the Affidavit of Non-Service is true and correct. This affirmation is made subject to the penalties of 18 PA C.S. 4904 relating to unsworn falsification to authorities.

Thomas J. Crean, Jr.
Dennis Richman's Services for the Professional, Inc
1500 John F. Kennedy Blvd. Suite #1315,
Philadelphia, PA 19102
(215) 977-9393
Ref #
Order #P163746

Subscribed and sworn before me, a Notary Public, this 21st day of December, 2018

Regina A. Richman, Notary Public
Falls Twp., Bucks County
My Commission expires on: 12/12/2021

GPS: 0.0;0.0

Michael G. Daly, Esquire
161 Washington Street, Suite 940
Conshohocken, PA 19428
(610) 941-4204

Commonwealth of Pennsylvania
In the Court of Common Pleas
Philadelphia County

Katherine Crockett
v.
Luitpold Pharmaceuticals, Inc., et al.

Case No.:18-11-2043

Commonwealth of Pennsylvania
County of Philadelphia ss

AFFIDAVIT OF NON-SERVICE

I, **Thomas J. Crean, Jr.,** being duly sworn according to the law upon my oath, depose and say, that I am not a party to this action, am over 18 years of age, and have no direct personal interest in this litigation.

PARTY: **Vifor Pharmaceuticals Management, Ltd.**

DOCUMENTS: **Complaint**

DATE & TIME: **1/2/2019 12:32 PM**

ADDRESS: **106 Allen Road**
Basking Ridge, NJ 07920

I hereby certify and return that I completed due and diligent attempts to servee Vifor Pharmaceuticals Management, Ltd.. I therefore return this Complaint without service on Vifor Pharmaceuticals Management, Ltd..

Diligent attempts were made per the following notations:

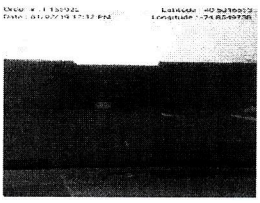
1/2/2019 12:32 PM Results: Defendant is unknown at this location.

I hereby affirm that the information contained in the Affidavit of Non-Service is true and correct. This affirmation is made subject to the penalties of 18 PA C.S. 4904 relating to unsworn falsification to authorities.

Thomas J. Crean, Jr.
Dennis Richman's Services for the Professional, Inc
1500 John F. Kennedy Blvd. Suite #1315,
Philadelphia, PA 19102
(215) 977-9393
Ref #
Order #P163924

Subscribed and sworn before me, a Notary Public, this 2nd day of January, 2019

Regina A. Richman, Notary Public
Falls Twp., Bucks County
My Commission expires on: 12/12/2021



POGUST MILLROOD, LLC
Kara D. Hill, Esquire
Attorney I.D. Nos. 324171
khill@pogustmillrood.com
Eight Tower Bridge, Suite 940
161 Washington Street
Conshohocken, PA 19428
Tel: (610) 941-4204
Attorney for Plaintiff

Katherine Crockett Plaintiff, v. Luitpold Pharmaceuticals, Inc; American Regent, Inc.; Daiichi Sankyo, Inc.; Daiichi Sankyo Co., Ltd.; Vifor Pharmaceuticals Management Ltd.; Vifor Pharma – Aspreva Pharmaceuticals Inc. Defendants.	:	**PHILADELPHIA COUNTY** **TRIAL DIVISION** **COURT OF COMMON PLEAS** **NOVEMBER TERM, 2018** **No. 02043**

ENTRY OF APPEARANCE

To the Prothonotary:

Kindly enter my appearance as counsel for Plaintiff, Katherine Crockett, in the above-captioned action.

Dated: 1/9/2019

By: **/s/** Kara D. Hill
Kara D. Hill, Esquire
Attorney for Plaintiff

CERTIFICATE OF SERVICE

I, Kara D. Hill, hereby certify that a true and correct copy of the Entry of Appearance was served via the First Judicial District Electronic Filing System (EFS) upon all counsel of record.

Dated: 1/9/2019

By: /s/ Kara D. Hill
Kara D. Hill, Esquire
Attorney for Plaintiff

AFFIDAVIT OF SERVICE

Long Island Timely Process Servers
117 Paul's Path # 204
Coram, New York

December 20, 2018

File # 002043

Court of Common Pleas of Philadelphia County
Trial Division

KATHERINE CROCKET
1830 Lombard Street Apt. 714
Philadelphia, Pa 19146

-against-

LUITPOLD PHARMACEUTICALS, INC
5 Ramsey Road
Shirley, NY 11967

The undersigned being duly sworn, deposes and says:

Thomas Thompson is not a party to the action, is over 18 years of age and resides at 117 Paul's Path # 204 Coram, New York 11727 served Alyssa Vetrano Senior Administrative Assistant of Luitpold Pharmaceuticals Inc. on December 20, 2018 @ 8:55 am @ 5 Ramsey Road Shirley, New York 11967.

She is described as follows

Race	Gender	Age	Ht	Wt	Hair
W	F	29	5'2	150	Blonde

Thomas Thompson

DEC 24 2018

Sworn to before me this _____

day of _____

Notary Public

BLANCA ELSY MOLINA
NOTARY PUBLIC, State of New York
No. 01MO6329115
Qualified in Nassau County
Commission Expires 08/17/2019

Michael G. Daly, Esquire
161 Washington Street, Suite 940
Conshohocken, PA 19428
(610) 941-4204

Commonwealth of Pennsylvania
In the Court of Common Pleas
Philadelphia County

Katherine Crockett

v.

Luitpold Pharmaceuticals, Inc., et al.

Case No.:18-11-2043

Commonwealth of Pennsylvania
County of Philadelphia ss

AFFIDAVIT OF CORPORATE SERVICE

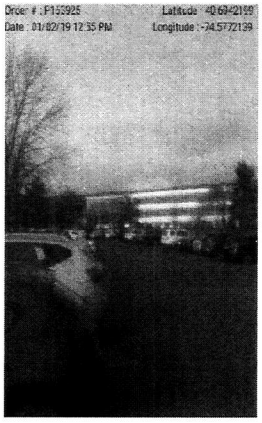
I, **Thomas J. Crean, Jr.,** being duly sworn according to the law upon my oath, depose and say, that I am not a party to this action, am over 18 years of age, and have no direct personal interest in this litigation.

PARTY SERVED:	**Daiichi Sankyo Co., LTD**
DOCUMENTS SERVED:	**Complaint**
BY LEAVING WITH:	**Amy Kluge, Legal Department**
DATE & TIME OF SERVICE:	**1/2/2019 12:54 PM**
PHYSICAL DESCRIPTION:	**Age: 34** **Weight: 150** **Hair: Blonde** **Sex: Female** **Height: 5'8"** **Race: Caucasian**
SERVED ADDRESS:	**211 Mount Airy Road** **Basking Ridge, NJ 07920**

I hereby affirm that the information contained in the Affidavit of Service is true and correct. This affirmation is made subject to the penalties of 18 PA C.S. 4904 relating to unsworn falsification to authorities.

Subscribed and sworn before me, a Notary Public, this 2nd day of January, 2019

Regina A. Richman, Notary Public
Falls Twp., Bucks County
My Commission expires on: 12/12/2021



Thomas J. Crean, Jr.
Dennis Richman's Services for the Professional, Inc
1500 John F. Kennedy Blvd. Suite #1315,
Philadelphia, PA 19102
(215) 977-9393

Order #P163923

Kenneth A. Murphy (I.D. No. 58162)
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Attorneys for Defendants
Luitpold Pharmaceuticals, Inc.
American Regent, Inc.
Daiichi Sankyo, Inc.
Daiichi Sankyo Co., Ltd.

KATHERINE CROCKETT, Plaintiff, v. LUITPOLD PHARMACEUTICALS, INC., et al., Defendants.	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY** **NOVEMBER TERM 2018** **No. 2043**

ENTRY OF APPEARANCE

TO THE PROTHONOTARY:

Kindly enter the appearance of Kenneth A. Murphy on behalf of Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd. in the above-entitled action.

Dated: January 17, 2019

Respectfully Submitted,
/s/ Kenneth A. Murphy
Kenneth A. Murphy
Heather C. Giordanella
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996

Attorneys for Defendants
Luitpold Pharmaceuticals, Inc.
American Regent, Inc.
Daiichi Sankyo, Inc.
Daiichi Sankyo Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that, on January 17, 2019, I caused a true and correct copy of the foregoing Entry of Appearance to be served on counsel of record via electronic case filing and first class mail:

Michael G. Daly, Esq.
Kara D. Hill, Esq.
POGUST MILLROOD
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161 Washington Street
Conshohocken, PA 19428

Attorneys for Plaintiff

/s/ Kenneth A. Murphy
Kenneth A. Murphy

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Daiichi Sankyo, Inc.
Daiichi Sankyo Co., Ltd.

KATHERINE CROCKETT, Plaintiff, v. LUITPOLD PHARMACEUTICALS, INC., et al., Defendants.	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY** **NOVEMBER TERM 2018** **No. 2043**

ENTRY OF APPEARANCE

TO THE PROTHONOTARY:

Kindly enter the appearance of Heather C. Giordanella on behalf of Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., and Daiichi Sankyo Co., Ltd. in the above-entitled action.

Dated: January 17, 2019

Respectfully Submitted,
/s/ Heather C. Giordanella
Kenneth A. Murphy
Heather C. Giordanella
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996

Attorneys for Defendants
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Daiichi Sankyo, Inc.
Daiichi Sankyo Co., Ltd.

CERTIFICATE OF SERVICE

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Attorneys for Plaintiff

/s/ Heather C. Giordanella
Heather C. Giordanella

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Attorneys for Defendants
Luitpold Pharmaceuticals, Inc.;
American Regent, Inc.;
Daiichi Sankyo, Inc.; and
Daiichi Sankyo Co., Ltd.

KATHERINE CROCKETT, Plaintiff, v. LUITPOLD PHARMACEUTICALS, INC., et al., Defendants.	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY** **NOVEMBER TERM 2018** **No. 2043**

DEFENDANT DAIICHI SANKYO CO., LTD.'S PRELIMINARY OBJECTION TO STRIKE THE CORPORATE AFFIDAVIT OF SERVICE AND PLAINTIFF'S COMPLAINT

Defendant Daiichi Sankyo Co., Ltd. ("DSC"), through its undersigned counsel, hereby files this Preliminary Objection to Strike the Corporate Affidavit of Service and Plaintiff's Complaint as to DSC and in support thereof states as follows:

I. FACTS

1. On November 19, 2018, Plaintiff Katherine Crockett ("Plaintiff") filed a Complaint in this matter against several Defendants including Daiichi Sankyo, Inc. ("DSI") and DSC. *See* Pl.'s Compl. (attached hereto as Exhibit A).

2. DSI is a United States subsidiary of DSC, a Japanese corporation with its principal place of business in Japan. *See* Pl.'s Compl. ¶¶ 5, 7; *see also* Aff. of Amy Todd Klug ¶ 2 ("Klug Aff.") (attached hereto as Exhibit B).

3. On January 2, 2019, Thomas J. Crean, Jr. ("Mr. Crean"), a process server, hand delivered a copy of Plaintiff's Complaint to "Amy Kluge"[1] at DSI's office in Basking Ridge, New Jersey. *See* Klug Aff. ¶ 3; *see also* Aff. of Corporate Service (attached hereto as Exhibit C).

4. When delivering the copy of Plaintiff's Complaint on January 2, 2019, Mr. Crean stated that he was serving the same papers that he had served before the holiday, which referred to the service of process that was made on DSI at its Basking Ridge, New Jersey office on December 20, 2018. *See* Klug Aff. ¶ 4.

5. Mr. Crean did not state or otherwise indicate that he was attempting to serve Plaintiff's Complaint on DSC by delivering a copy of the Complaint to DSI's Basking Ridge, New Jersey office. *Id.* ¶ 5.

6. Mr. Crean also did not ask Ms. Klug if Ms. Klug or DSI had authority to accept service on behalf of DSC. *Id.* ¶¶ 6, 7.

7. Furthermore, the copy of Plaintiff's Complaint that was delivered to Ms. Klug on January 2, 2019, did not include a Summons directed to DSC. *Id.* ¶ 8.

8. After Mr. Crean delivered the Complaint at issue, Ms. Klug noticed, on subsequent pages of the delivered multi-page package, that "Daiichi Sankyo Co., Ltd." and DSC's address in Japan were circled in ink in the caption of the Complaint and on a list of additional defendants. *Id.* ¶ 9.

[1] Mr. Crean actually delivered the Complaint to Amy Todd Klug ("Ms. Klug"), but misspelled her name in the Affidavit of Corporate Service.

9. After noticing these markings, Ms. Klug immediately returned the Complaint to Plaintiff's counsel, Michael Daly, Esquire, via overnight mail along with a note stating that neither she nor DSI is authorized to accept service on behalf of DSC and that Plaintiff would need to attempt service of the Complaint on DSC through the Hague Convention on the Service of Judicial and Extrajudicial Documents in Civil and Commercial Matters ("Hague Convention"). *Id.* ¶ 10.

10. Ms. Klug is neither an executive officer, partner or trustee of DSC nor an agent that has been authorized by DSC in writing to accept service on its behalf. *Id.* ¶¶ 11, 13.

11. In addition, DSI is not a regular place of business or activity of DSC. *Id.* ¶ 12.

12. On January 3, 2019, Ms. Klug tried contacting Mr. Daly to discuss the attempted service of Plaintiff's Complaint by Mr. Crean on DSC and, on January 4, 2019, actually spoke with Mr. Daly. *Id.* ¶ 14.

13. During her January 4, 2019 telephone call with Mr. Daly, Ms. Klug explained that she was not authorized to accept service on behalf of DSC and she would have advised Mr. Crean that she was not authorized to accept service if he had identified the party he sought to serve either verbally or through delivery of a Summons directed to DSC. *Id.* ¶ 15.

14. While Mr. Daly stated that he understood Ms. Klug's position, Mr. Daly refused to acknowledge that the attempted service on DSC at DSI's office in Basking Ridge, New Jersey was improper and ineffective. *Id.* ¶ 16.

15. On or about January 10, 2019, Mr. Daly then caused to be filed in this matter a Corporate Affidavit of Service, which purports to show that Ms. Klug accepted service of Plaintiff's Complaint on behalf of DSC. *Id.* ¶ 17; *see also* Aff. of Corporate Service.

II. ARGUMENT

A. Legal Standard.

16. Pursuant to Pennsylvania Rule of Civil Procedure 1028(a)(1), a party may file a preliminary objection for "improper form or service of a writ of summons or a complaint." Pa. R. Civ. P. 1028(a)(1); *see, e.g.*, *Salas v. Wal-Mart Stores East, Inc.*, No. 1101137, 2014 WL 12606282 (Berks Cnty. Com. Pls. Oct. 24, 2014) (sustaining preliminary objection pursuant to Rule 1028(a)(1) and striking affidavit/return of service from the record), *aff'd*, *Salas v. Wal-Mart Stores East, Inc.*, No. 1954 MDL 2014, 2015 WL 6737591 (Pa. Super. Ct. Aug. 7, 2015); *see also Salas v. Wal-Mart Stores, East, Inc.*, Case No. 11-1137, slip op. (Berks Cty. Com. Pls. Jan. 29, 2015) (attached hereto as Exhibit D).

17. "Service of process is a mechanism by which a court obtains jurisdiction of a defendant, and therefore, the rules concerning service of process must be strictly followed. Without valid service, a court lacks personal jurisdiction of a defendant and is powerless to enter judgment against him or her." *Cintas Corp. v. Lee's Cleaning Servs.*, 700 A.2d 915, 917 (Pa. 1997) (citations omitted).

18. Pennsylvania Rule of Civil Procedure 424 governs the service of original process on corporations and provides, in pertinent part, that:

> Service of original process upon a corporation or similar entity *shall* be made by handing a copy to any of the following persons . . . (1) an executive officer, partner or trustee of the corporation or similar entity, or (2) the manager, clerk or other person for the time being in charge of any regular place of business or activity of the corporation or similar entity, or (3) an agent authorized by the corporation or similar entity in writing to receive service of process for it.

Pa. R. Civ. P. 424 (emphasis added).[2]

[2] Pennsylvania Rule of Civil Procedure 404 further provides, in pertinent part, that proper service on a corporation outside of the Commonwealth can only be accomplished "in the manner provided by treaty." Pa. R. Civ. P. 404(4).

19. Because Plaintiff attempted to serve DSC by hand delivery, Rule 424 governs whether DSC was effectively served by delivery of Plaintiff's Complaint to DSI's office in Basking Ridge, New Jersey.

B. The Improper Corporate Affidavit of Service and Plaintiff's Complaint Should Be Stricken As to DSC Pursuant to Rule of Civil Procedure 1028(a)(1).

20. Ms. Klug is neither an executive officer, partner or trustee of DSC nor an agent that is authorized by DSC in writing to accept service of process on its behalf. *See* Klug Aff. ¶ 11; *see also id.* ¶ 13 ("I am not, nor have I ever been, authorized to accept service on behalf of DSC.").

21. In addition, when Mr. Crean attempted to serve Plaintiff's Complaint on DSC by delivering it to Ms. Klug at DSI's office, he did not ask Ms. Klug if she or anyone at DSI was authorized to accept service on behalf of DSC and the copy of the Complaint delivered by Mr. Crean did not include a Summons directed to DSC. *Id.* ¶¶ 6–8.

22. Moreover, DSC is a Japanese corporation with its principal place of business in Japan and DSI's office at 211 Mt. Airy Road, Basking Ridge, New Jersey is not a regular place of business or activity of DSC. *See* Pl.'s Compl. ¶¶ 5, 7; Klug Aff. ¶¶ 2, 12.

23. Finally, Mr. Crean did not advise Ms. Klug that he was attempting to serve Plaintiff's Complaint on DSC by delivering a copy of the Complaint to DSI's office. *Id.* ¶ 5. It was only after Mr. Crean left that Ms. Klug noticed that "Daiichi Sankyo Co., Ltd." and DSC's

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In these circumstances, the Hague Convention, which is a multi-national treaty that establishes a uniform procedure for service of process in foreign countries, is applicable. *See* 20 U.S.T. 361; T.I.A.S. No. 6638; Fed. R. Civ. P. 4, Note; *see also, e.g.*, *Arco Elec. Control Ltd. v. Core Intern.*, 794 F. Supp. 1144, 1146 (S.D. Fla. 1992) ("As a ratified treaty, the Hague Convention is of equal dignity with acts of Congress and enjoys the constitutional status of ' supreme Law of the Land.'"). Plaintiff did not attempt to serve DSC with her Complaint through the Hague Convention.

address in Japan were circled in ink in the caption of the Complaint and on a list of additional defendants. *Id.* ¶ 9.

24. For the foregoing reasons, Plaintiff failed to effectuate proper service on DSC pursuant to Pennsylvania Rule of Civil Procedure 424 because Plaintiff did not serve DSC by either handing a copy to an executive officer, partner or trustee of DSC or an agent of DSC that is authorized in writing to accept such service, or by handing a copy to a manager, clerk or other person in charge at a regular place of business or activity of DSC.

25. Thus, due to the improper and ineffective service of the Complaint by Plaintiff, this Court does not have personal jurisdiction over DSC. *See Cintas Corp.*, 700 A.2d at 917; *U.K. LaSalle, Inc. v. Lawless*, 618 A.2d 447, 449 (Pa. Super. Ct. 1992).

26. Accordingly, DSC's preliminary objection should be sustained and the Corporate Affidavit of Service and Plaintiff's Complaint as to DSC should be stricken.

WHEREFORE, Defendant Daiichi Sankyo Co., Ltd. respectfully requests that this Honorable Court sustain its Preliminary Objection to Strike the Corporate Affidavit of Service and Plaintiff's Complaint.

Dated: January 18, 2019

Respectfully Submitted,

/s/ Heather C. Giordanella
Kenneth A. Murphy
Heather C. Giordanella
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996

Luitpold Pharmaceuticals, Inc.;
American Regent, Inc.;
Daiichi Sankyo, Inc.; and
Daiichi Sankyo Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that, on January 18, 2019, I caused a true and correct copy of the foregoing Defendant Daiichi Sankyo Co., Ltd.'s Preliminary Objection to Strike the Corporate Affidavit of Service and Plaintiff's Complaint to be served on counsel of record via electronic case filing and first class mail:

Michael G. Daly, Esq.
Kara D. Hill, Esq.
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161 Washington Street
Conshohocken, PA 19428

Attorneys for Plaintiff

/s/ Heather C. Giordanella
Heather C. Giordanella

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Attorneys for Defendants
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American Regent, Inc.;
Daiichi Sankyo, Inc.; and
Daiichi Sankyo Co., Ltd.

KATHERINE CROCKETT, Plaintiff, v. LUITPOLD PHARMACEUTICALS, INC., et al., Defendants.	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY** **NOVEMBER TERM 2018** **No. 2043**

DEFENDANT DAIICHI SANKYO CO., LTD.'S MEMORANDUM OF LAW IN SUPPORT OF ITS PRELIMINARY OBJECTION TO STRIKE THE CORPORATE AFFIDAVIT OF SERVICE AND PLAINTIFF'S COMPLAINT

Defendant Daiichi Sankyo Co., Ltd. ("DSC"), through its undersigned counsel, hereby files this Memorandum of Law in Support of its Preliminary Objection to Strike the Corporate Affidavit of Service and Plaintiff's Complaint as to DSC.

I. MATTER BEFORE THE COURT

Pursuant to Pennsylvania Rule of Civil Procedure 1028(a)(1), DSC has filed a Preliminary Objection to Strike the Corporate Affidavit of Service and Plaintiff's Complaint as to DSC due to improper and ineffective service.

II. ISSUE PRESENTED

Should DSC's Preliminary Objection pursuant to Pennsylvania Rule of Civil Procedure 1028(a)(1) be sustained where Plaintiff Katherine Crockett ("Plaintiff") attempted to serve DSC by hand delivering a copy of the Complaint but failed to serve DSC by either handing a copy to an executive officer, partner or trustee of DSC or an agent of DSC that is authorized in writing to accept such service, or by handing a copy to a manager, clerk or other person in charge at a regular place of business or activity of DSC, as required by Pennsylvania Rule of Civil Procedure 424?

Suggested Answer: Yes.

III. FACTS

The relevant facts regarding Plaintiff's attempted service on DSC plainly reveal that Plaintiff has failed to effectuate proper service and, therefore, the Court does not have personal jurisdiction over DSC. On November 19, 2018, Plaintiff Katherine Crockett ("Plaintiff") filed a Complaint against several Defendants including Daiichi Sankyo, Inc. ("DSI") and DSC. *See* Pl.'s Compl. (attached as Exhibit A to Def. Daiichi Sankyo Co., Ltd.'s Preliminary Obj. to Strike the Corporate Aff. of Service and Pl.'s Compl. ("DSC's Preliminary Obj.")). As Plaintiff is aware, DSI is a United States subsidiary of DSC, a Japanese corporation with its principal place of business in Japan. *See* Pl.'s Compl. ¶¶ 5, 7; *see also* Aff. of Amy Todd Klug ¶ 2 ("Klug Aff.") (attached as Exhibit B to DSC's Preliminary Obj.).

On January 2, 2019, Thomas J. Crean, Jr. ("Mr. Crean"), a process server, hand delivered a copy of Plaintiff's Complaint to "Amy Kluge"[1] at DSI's office in Basking Ridge, New Jersey. *See* Klug Aff. ¶ 3; *see also* Aff. of Corporate Service (attached as Exhibit C to DSC's

[1] Mr. Crean actually delivered the Complaint to Amy Todd Klug ("Ms. Klug"), but misspelled her name in the Affidavit of Corporate Service.

Preliminary Obj.). When delivering this copy, Mr. Crean stated that he was serving the same papers that he had served before the holiday, which referred to the service of process that was made on DSI at its Basking Ridge, New Jersey office on December 20, 2018. *See* Klug Aff. ¶ 4. Importantly, Mr. Crean did not state that he was attempting to serve Plaintiff's Complaint on DSC by delivering a copy of the Complaint to DSI's office. *Id.* ¶ 5. Nor did he ask Ms. Klug if Ms. Klug or DSI had authority to accept service on behalf of DSC. *Id.* ¶¶ 6, 7. The copy of Plaintiff's Complaint that was delivered by Mr. Crean to Ms. Klug on January 2, 2019, also did not include a Summons directed to DSC. *Id.* ¶ 8.

After Mr. Crean delivered the Complaint, Ms. Klug noticed, on subsequent pages of the delivered multi-page package, that "Daiichi Sankyo Co., Ltd." and DSC's address were circled in ink in the caption of the Complaint and on a list of additional defendants. *Id.* ¶ 9. Ms. Klug then immediately returned the Complaint to Plaintiff's counsel, Michael Daly, Esquire, via overnight mail along with a note stating that neither she nor DSI had authority to accept service on behalf of DSC and that Plaintiff would need to attempt service of the Complaint on DSC through the Hague Convention on the Service of Judicial and Extrajudicial Documents in Civil and Commercial Matters ("Hague Convention"). *Id.* ¶ 10. Ms. Klug is neither an executive officer, partner or trustee of DSC nor an agent that has been authorized by DSC in writing to accept service on its behalf. *Id.* ¶¶ 11, 13. In addition, DSI is not a regular place of business or activity of DSC. *Id.* ¶ 12.

On January 3, 2019, Ms. Klug also tried contacting Mr. Daly to discuss the attempted service of Plaintiff's Complaint on DSC. *Id.* ¶ 14. On January 4, 2019, Ms. Klug actually spoke with Mr. Daly by telephone and explained to him that she was not authorized to accept service on behalf of DSC and she would have advised Mr. Crean that she was not so authorized if he had

identified the party he sought to serve either verbally or through delivery of a Summons directed to DSC. *Id.* ¶ 15. While Mr. Daly stated that he understood Ms. Klug's position, and despite being aware that DSC is a Japanese corporation with its principal place of business in Japan as alleged by Plaintiff in her Complaint, he refused to acknowledge that the attempted service on DSC at DSI's office was improper and ineffective. *Id.* ¶ 16. On or about January 10, 2019, Mr. Daly then filed a Corporate Affidavit of Service, which purportedly shows that Ms. Klug accepted service of Plaintiff's Complaint on behalf of DSC. *Id.* ¶ 17; *see also* Aff. of Corporate Service.

IV. ARGUMENT

A. Legal Standard.

Pursuant to Pennsylvania Rule of Civil Procedure 1028(a)(1), a party may file a preliminary objection for "improper form or service of a writ of summons or a complaint." Pa. R. Civ. P. 1028(a)(1); *see, e.g.*, *Salas v. Wal-Mart Stores East, Inc.*, No. 1101137, 2014 WL 12606282 (Berks Cnty. Com. Pls. Oct. 24, 2014) (sustaining preliminary objection pursuant to Rule 1028(a)(1) and striking affidavit/return of service from the record), *aff'd*, *Salas v. Wal-Mart Stores East, Inc.*, No. 1954 MDL 2014, 2015 WL 6737591 (Pa. Super. Ct. Aug. 7, 2015); *see also Salas v. Wal-Mart Stores, East, Inc.*, Case No. 11-1137, slip op. (Berks Cty. Com. Pls. Jan. 29, 2015) (attached hereto as Exhibit D to DSC's Preliminary Obj.). As the Pennsylvania Supreme Court has recognized, "[s]ervice of process is a mechanism by which a court obtains jurisdiction of a defendant, and therefore, the rules concerning service of process must be strictly followed. Without valid service, a court lacks personal jurisdiction of a defendant and is powerless to enter judgment against him or her." *Cintas Corp. v. Lee's Cleaning Servs.*, 700 A.2d 915, 917 (Pa. 1997) (citations omitted).

Pennsylvania Rule of Civil Procedure 424 governs the service of original process on corporations and provides, in pertinent part, that:

> Service of original process upon a corporation or similar entity *shall* be made by handing a copy to any of the following persons . . . (1) an executive officer, partner or trustee of the corporation or similar entity, or (2) the manager, clerk or other person for the time being in charge of any regular place of business or activity of the corporation or similar entity, or (3) an agent authorized by the corporation or similar entity in writing to receive service of process for it.

Pa. R. Civ. P. 424 (emphasis added).[2] Because Plaintiff attempted to serve DSC by hand delivery, Rule 424 governs whether DSC was effectively served by delivery of Plaintiff's Complaint to DSI's office in Basking Ridge, New Jersey.

B. The Improper Corporate Affidavit of Service and Plaintiff's Complaint Should Be Stricken As to DSC Pursuant to Rule of Civil Procedure 1028(a)(1).

There is no doubt that Plaintiff failed to properly serve her Complaint on DSC. Ms. Klug is neither an executive officer, partner or trustee of DSC nor an agent that is authorized by DSC in writing to accept service of process on its behalf. *See* Klug Aff. ¶ 11; *see also id.* ¶ 13 ("I am not, nor have I ever been, authorized to accept service on behalf of DSC."). In addition, when Mr. Crean attempted to serve Plaintiff's Complaint on DSC by delivering it to Ms. Klug at DSI's office, he did not ask Ms. Klug if she or anyone at DSI was authorized to accept service on behalf of DSC and the copy of the Complaint delivered by Mr. Crean did not include a Summons directed to DSC. *Id.* ¶¶ 6–8.

[2] Pennsylvania Rule of Civil Procedure 404 further provides, in pertinent part, that proper service on a corporation outside of the Commonwealth can only be accomplished "in the manner provided by treaty." Pa. R. Civ. P. 404(4). In these circumstances, the Hague Convention, which is a multi-national treaty that establishes a uniform procedure for service of process in foreign countries, is applicable. *See* 20 U.S.T. 361; T.I.A.S. No. 6638; Fed. R. Civ. P. 4, Note; *see also, e.g.*, *Arco Elec. Control Ltd. v. Core Intern.*, 794 F. Supp. 1144, 1146 (S.D. Fla. 1992) ("As a ratified treaty, the Hague Convention is of equal dignity with acts of Congress and enjoys the constitutional status of ' supreme Law of the Land.'"). Plaintiff did not attempt to serve DSC with her Complaint through the Hague Convention.

Moreover, DSC is a Japanese corporation with its principal place of business in Japan and DSI's office at 211 Mt. Airy Road, Basking Ridge, New Jersey is not a regular place of business or activity of DSC. *See* Pl.'s Compl. ¶¶ 5, 7; Klug Aff. ¶¶ 2, 12. Mr. Crean did not advise Ms. Klug that he was attempting to serve Plaintiff's Complaint on DSC by delivering a copy of the Complaint to DSI's office. *Id.* ¶ 5. It was only after Mr. Crean left that Ms. Klug noticed that "Daiichi Sankyo Co., Ltd." and DSC's address in Japan were circled in ink in the caption of the Complaint and on a list of additional defendants. *Id.* ¶ 9.

Due to Plaintiff's failure to meet the strict requirements of Pennsylvania Rule of Civil Procedure 424, Plaintiff's attempt to serve DSC was ineffective. It is undisputed that Plaintiff did not serve DSC by either handing a copy to an executive officer, partner or trustee of DSC or an agent of DSC authorized in writing to accept such service. Plaintiff also did not hand a copy to a manager, clerk or other person in charge at a regular place of business or activity of DSC. Thus, this Court does not have personal jurisdiction over DSC. *See Cintas Corp.*, 700 A.2d at 917; *U.K. LaSalle, Inc. v. Lawless*, 618 A.2d 447, 449 (Pa. Super. Ct. 1992). Accordingly, DSC's preliminary objection should be sustained and the Corporate Affidavit of Service and Plaintiff's Complaint as to DSC should be stricken.

V. RELIEF REQUESTED

For all of the foregoing reasons, Defendant Daiichi Sankyo Co., Ltd. respectfully requests that the Court enter an Order sustaining its Preliminary Objection to Strike the Corporate Affidavit of Service and Plaintiff's Complaint.

Dated: January 18, 2019

Respectfully Submitted,

/s/ Heather C. Giordanella

Kenneth A. Murphy
Heather C. Giordanella
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996

Attorneys for Defendants
Luitpold Pharmaceuticals, Inc.;
American Regent, Inc.;
Daiichi Sankyo, Inc.; and
Daiichi Sankyo Co., Ltd.

KATHERINE CROCKETT, Plaintiff, v. LUITPOLD PHARMACEUTICALS, INC., et al., Defendants.	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY** **NOVEMBER TERM 2018** **No. 2043**

ORDER

AND NOW, this ___ day of _____, 2019, upon consideration of Defendant Daiichi Sankyo Co., Ltd.'s ("DSC") Preliminary Objection to Strike the Corporate Affidavit of Service and Plaintiff's Complaint as to DSC, and all papers submitted in support thereof and in opposition thereto, it is hereby ORDERED that DSC's Preliminary Objection is SUSTAINED. It is further ORDERED that the Corporate Affidavit of Service and Complaint filed by Plaintiff as to DSC are STRICKEN.

BY THE COURT:

_____
J.

EXHIBIT A

Court of Common Pleas of Philadelphia County
Trial Division

Civil Cover Sheet

For Prothonotary Use Only (Docket Number)
NOVEMBER 2018 002043
E-Filing Number: 1811038775

PLAINTIFF'S NAME KATHERINE CROCKETT	DEFENDANT'S NAME LUITPOLD PHARMACEUTICALS, INC
PLAINTIFF'S ADDRESS 1830 LOMBARD STREET APT 714 PHILADELPHIA PA 19146	DEFENDANT'S ADDRESS 800 ADAMS AVE #1 NORRISTOWN PA 19403
PLAINTIFF'S NAME	DEFENDANT'S NAME AMERICAN REGENT, INC
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS 5 RAMSEY ROAD SHIRLEY NY 11967
PLAINTIFF'S NAME	DEFENDANT'S NAME DAIICHI SANKYO, INC
PLAINTIFF'S ADDRESS	DEFENDANT'S ADDRESS 211 MT AIRY RD BASKING RIDGE NJ 07920

TOTAL NUMBER OF PLAINTIFFS	TOTAL NUMBER OF DEFENDANTS	COMMENCEMENT OF ACTION
1	6	☐ Complaint ☐ Petition Action ☐ Notice of Appeal ☒ Writ of Summons ☐ Transfer From Other Jurisdictions

AMOUNT IN CONTROVERSY
☐ $50,000.00 or less
☒ More than $50,000.00

COURT PROGRAMS

☐ Arbitration	☐ Mass Tort	☐ Commerce	☐ Settlement
☒ Jury	☐ Savings Action	☐ Minor Court Appeal	☐ Minors
☐ Non-Jury	☐ Petition	☐ Statutory Appeals	☐ W/D/Survival
☐ Other:			

CASE TYPE AND CODE
2P - PRODUCT LIABILITY

STATUTORY BASIS FOR CAUSE OF ACTION

RELATED PENDING CASES (LIST BY CASE CAPTION AND DOCKET NUMBER)

FILED
PRO PROTHY
NOV 19 2018
A. SILIGRINI

IS CASE SUBJECT TO COORDINATION ORDER?
YES NO

TO THE PROTHONOTARY:

Kindly enter my appearance on behalf of Plaintiff/Petitioner/Appellant: KATHERINE CROCKETT

Papers may be served at the address set forth below.

NAME OF PLAINTIFF'S/PETITIONER'S/APPELLANT'S ATTORNEY MICHAEL G. DALY	ADDRESS 161 WASHINGTON ST SUITE 940 CONSHOHOCKEN PA 19428
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SIGNATURE OF FILING ATTORNEY OR PARTY *MICHAEL DALY*	DATE SUBMITTED Monday, November 19, 2018, 02:02 pm

FINAL COPY (Approved by the Prothonotary Clerk)

Case ID: 181102043
Control No.: 19012741

COMPLETE LIST OF DEFENDANTS:

1. LUITPOLD PHARMACEUTICALS, INC
   800 ADAMS AVE #1
   NORRISTOWN PA 19403
2. AMERICAN REGENT, INC
   5 RAMSEY ROAD
   SHIRLEY NY 11967
3. DAIICHI SANKYO, INC
   211 MT AIRY RD
   BASKING RIDGE NJ 07920
4. DAIICHI SANKYO CO., LTD
   3-5-1, NIHONBASHI-HONCHO, CHUO-KU, 103-8426
   TOKYO
5. VIFOR PHARMACEUTICALS MANAGEMENT LTD.
   FLUGHOFSTRASSE 61 CH-8152
   GLATTBRUGG
6. VIFOR PHARMA - ASPEREVA PHARMACEUTICALS INC.
   106 ALLEN ROAD
   BASKING RIDGE NJ 07920

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Attorneys for Plaintiffs

KATHERINE CROCKETT
1830 Lombard Street, Apt 714
Philadelphia, PA 19146,

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 CO., LTD. 3-5-1, Nihonbashi-
honcho, Chuo-ku, Tokyo 103-8426, Japan
and
VIFOR PHARMACEUTICALS MANAGEMENT
LTD. Flughofstrasse 61 CH-8152
Glattbrugg, Switzerland
and
VIFOR PHARMA – ASPEREVA
PHARMACEUTICALS INC. 106 Allen Road
Basking Ridge, NJ 07920

Defendants.

COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

NOVEMBER TERM, 2018

NO: 02043

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.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

Philadelphia Bar Association
Lawyer Referral and Information Center
1101 Market Street, 10th Floor
Philadelphia, PA 19107

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.

Asociacion De Licenciados De Filadelfia
Servicio De Referencia E Informacion Legal
1101 Market Street, 10th Floor
Filadelfia, PA 19107
(215) 238-6300 (Telefono)

COMPLAINT – CIVIL ACTION
PRODUCT LIABILITY

PLAINTIFF, Katherine Crockett, by and through undersigned counsel, files this Complaint against Defendants, Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., Daiichi Sankyo Co., Ltd., Vifor Pharmaceuticals Management Ltd., and Vifor Pharma – Aspereva Pharmaceuticals Inc. (collectively "Defendants") and in support thereof make the following allegations:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff, Katherine Crockett, is a resident of Philadelphia, PA.

Luitpold Defendants

2. Luitpold Pharmaceuticals, Inc. (hereinafter "Luitpold") is 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 is a subsidiary and member of the Daiichi Sankyo Group and is the parent company to its own subsidiary, American Regent, Inc. In addition to maintaining an office in the Commonwealth of Pennsylvania, Luitpold is registered to do business throughout the state as well as in the county of Philadelphia, specifically. Luitpold has at all relevant times and continues to be engaged in the business of researching, developing, 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. Upon information and belief, American Regent may also operate out of Luitpold's Norristown, PA office, and is registered to do business in the Commonwealth. American Regent is a

subsidiary of Luitpold and the Daicchi 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, designing, licensing, manufacturing, promoting, labeling, distributing, selling, and marketing the Injectafer product. .

Daiichi Sankyo Defendants

4. 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 or Daiichi Sankyo Co., Ltd.

5. DSI is the United States subsidiary of Daiichi Sankyo Co., Ltd, located in Tokyo, Japan, and is a member of the Daiichi Sankyo Group. Upon information and belief, both Defendants Luitpold and American Regent are members of the Daiichi Sankyo Group.

6. 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.

7. Daiichi Sankyo Co., Ltd. (hereinafter "DSC") is the parent company to DSI and the Daiichi Sankyo Group of companies. At all relevant times, DSC is and was a corporation organized and existing under the laws of Japan, having its principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo, 103-8426, Japan.

8. DSC is in the business of designing and manufacturing prescription drugs, including that used by Plaintiff, across the world, including in the United States, and specifically in the Commonwealth of Pennsylvania.

9. Upon information and belief, DSC at all relevant times exercised control over DSI and the DSI subsidiaries, Luitpold and American Regent.

10. Upon information and belief, the agreements between and among the Daiichi defendants, and their affiliates and subsidiaries, provides for DSC to have ultimate control over all relevant decisions, policies, and conduct, and therefore is liable for any and all tort liabilities of Defendants DSI, Luitpold, and American Regent.

11. Upon information and belief, DSI operates as the U.S. headquarters of DSC. At least four of the principals, members, directors, or officers of DSI are also members of DSC. In addition, DSC operates several research and development facilities across the world, including collaborating with DSC to oversee operations for its U.S. subsidiaries.

12. Upon information and belief, there existed at all relevant times a unity of interest in ownership between DSC and DSI such that independence from, or separation between, the Daiichi Defendants does not exist and has never existed. Each of them are alter egos of the other.

13. Because of the unity of operations and ownership, DSI and DSC are heretoafter referred to as the "Daiichi Defendants."

The Vifor Defendants

14. Vifor Pharmaceuticals Management Ltd. (hereinafter "Vifor Pharma") is a for-profit corporation headquartered in Switzerland with an office location at Flughofstrasse 61, CH-81542 Glattbrugg.

15. Vifor Pharma is 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.

16. Upon information and belief, Vifor Pharma is 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 Pharma was the international "partner" of Luitpold in the sale of Injectafer. The licensing agreement between Vifor Pharma and Luitpold awards Vifor Pharma a "share of partner sales" in regards to Injectafer sales in the United States.

17. Upon information and belief, Vifor Pharma was responsible for the original design and development of the bioequivalent ferric carboxymaltose product, Ferinject.

18. Upon information and belief, Vifor Pharma 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.

19. Additionally, since initially introducing ferric carboxymaltose into the world market, Vifor pharma has 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.

20. Vifor Pharma – Aspreva Pharmaceuticals, Inc., (hereinafter "Vifor – Aspreva") is a for-profit corporation with its principal place of business located at 106 Allen Road, Basking Ridge, New Jersey 07920.

21. Vifor – Aspreva is a wholly owned subsidiary of Vifor Pharma. Vifor – Aspreva is and was at all relevant times engaged in the business of researching, developing, designing,

licensing, manufacturing, distributing, selling, and marketing pharmaceutical products on behalf of Vifor Pharma in the United States.

22. Each of the above Defendants 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

23. This Court has personal jurisdiction over Plaintiff, Katherine Crockett, who is a resident of Philadelphia, Pennsylvania. Additionally, Plaintiff was administered the Injectafer product in Philadelphia, Pennsylvania, suffered her injuries caused by the drug in Philadelphia, Pennsylvania, and received and continues to receive substantial medical treatment for her injuries in Philadelphia, Pennsylvania.

General Personal Jurisdiction

24. 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.

25. This Court also has general personal jurisdiction over the Luitpold, American Regent, an 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. DSC, as the parent to DSI and the Daiichi Sankyo Group, thus has inextricable ties to Pennsylvania. Additionally, the Vifor Defendants do business in Pennsylvania and engaged in a licensing deal for its ferric carboxymaltose product that would see the continuous and systematic sale of Injectafer in the Commonwealth.

26. This Court has additional grounds for general personal jurisdiction as Luitpold operates an office and principal place of business at 800 Adams Street, Norristown (*also referring to as Eagleville or Audobon*), PA 19403.

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

Specific General Jurisdiction

28. 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 the Commonwealth of Pennsylvania.

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

30. 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.

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

32. 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."

33. 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.

34. 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.

35. 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.

36. Additionally, the Injectafer product was promoted, marketed, distributed, and sold to Plaintiff's medical treaters in Philadelphia and King of Prussia, Pennsylvania, and administered to Plaintiff in her Philadelphia, Pennsylvania home.

37. Jurisdiction is proper under 28 U.S.C. § 1441(b)(2) and 28 U.S.C § 1446(d) because Luitpold is a properly joined and served forum defendant.

38. Defendants regularly conduct substantial business in Philadelphia County, Pennsylvania.

39. Injectafer is marketed, promoted, distributed, and sold to hospitals, medical facilities, infusion centers, home health care agencies, and consumers in the Philadelphia region.

40. Venue is proper in this Court, pursuant to PA R. Civ. P. 1006 & 2179, as Pennsylvania is where the Luitpold Defendant is a citizen and where it regularly conducts business.

41. Venue is additionally proper in this Court because Philadelphia, Pennsylvania is where Plaintiff's cause of action arose and/or where a transaction or occurrence took place out of which this cause of action arose.

42. Venue is further proper in this Court because substantial, specific conduct by the Luitpold Defendant in relation to the design, creation, testing, labeling, development, pharmacovigilance, and sale of Injectafer originated in Luitpold's Philadelphia region office.

INTRODUCTION AND NATURE OF CASE

43. 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."

44. 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 Defendant Vifor Pharmaceuticals. The Vifor Defendants licensed and continue to license ferric carboxymaltose to all other Defendants who in turn have designed, manufactured, and sold the product in the United States.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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.

50. 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

51. 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.

52. 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.

53. 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 can occur 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.

54. 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.

55. 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.

56. 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.

57. 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 (*measures 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.**

58. 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.

59. 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.

60. 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.

61. **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. The labeling does 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.

62. The label only makes passing references to the potential occurrence of hypophosphatemia and **no reference at all to Severe HPP.** Inadequate to sufficiently warn the user and medical community, hypophosphatemia (not qualified as moderate or Severe) is not

listed in the "Warnings or Precautions" section or in a prominently placed "Black Box" warning, but instead is merely listed as an "Adverse Reaction" occurring in greater than 2% of users.

63. When the label does reference the potential adverse reaction of regular hypophosphatemia, it significantly downplays 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 labeling, Defendants refer only to "*transient* decreases in laboratory blood phosphorous levels (< 2 mg/dl)";

64. 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.

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

66. 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.

67. 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.

68. 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.

69. 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.

70. 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.

71. 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.

72. 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

73. 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, allege as follows.

74. Plaintiff, Katherine Crockett, is a resident of Philadelphia, PA.

75. On May 3, 2017, Plaintiff was prescribed Injectafer iron injection for treatment of her IDA at the Mayo Clinic in Rochester, Minnesota.

76. Plaintiff received the first injection at the Mayo Clinic on May 5, 2017. Plaintiff received her second injection in Philadelphia, PA on May 16, 2017.

77. Following Plaintiff's first Injectafer injection, her blood phosphorous levels sharply dropped. At one measurement on May 11, 2017, her blood phosphorous dropped to 1.6

mg/dl. Following her second Injectafer administration, laboratory tests on May 19, 2017 revealed a blood phosphorous level in the Severe Hypophosphatemia range of 1.2 mg/dl. These tests do not necessarily represent the lowest levels of Plaintiff's blood phosphorous following the Injectafer administration.

78. Plaintiff was subsequently diagnosed with Severe Hypophosphatemia and, as a result, suffered from multiple hospitalizations, severe nausea, severe weakness and pain, and severe and constant fatigue. Plaintiff was additionally diagnosed with renal phosphate wasting that Plaintiff alleges was caused by Injectafer. As a result of Plaintiff's severe and ongoing injuries, Plaintiff had to take a leave of absence from her place of employment and was only able to return after several months on limited duties.

79. 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 keep 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.

80. 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.

81. As plead below, Plaintiff reserves the right to seek application of the law of the forum state, Pennsylvania, which is also home to Defendant Luitpold. 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

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

83. At all times relevant, the Defendants were in the business of designing, developing, manufacturing, marketing, promoting, monitoring, labeling, selling and/or distributing Injectafer, including the product administered to Plaintiff.

84. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, monitoring, promotion, and distribution of Injectafer so as to avoid exposing others to foreseeable and unreasonable risks of harm.

85. Defendants breached their duty of care to the Plaintiff and her physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, and distribution of Injectafer.

86. 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.

87. At the time of the manufacture and sale of Injectafer, Defendants knew or should have known that Injectafer was designed in such a manner so as to cause Severe Hypophosphatemia and the additional injuries that are known to stem from that diagnosis.

88. At the time of the manufacturer and sale 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.

89. At the time of the manufacturer and sale of Injectafer, Defendants knew or should have known 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 diagnosis of Severe Hypophosphatemia and the injuries that result consequence to severely low levels of blood phosphorous.

90. 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.

91. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, pharmacovigilance, labeling, promotion, distribution and sale of Injectafer in, among others, the following ways:

(a) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

(b) Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

(c) Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

(d) Failing to use reasonable care to warn or instruct, including pre-and post-sale, Plaintiff, Plaintiff's healthcare providers and/or the general health care community about Injectafer's substantially dangerous condition or about facts making the product likely to be dangerous;

(e) Failing to warn of Injectafer's known ability to cause Severe Hypophosphatemia and consequent injuries such as osteomalacia, cardiac arrest, heart arrhythmia, cardiopulmonary injury, and rhabdomyolysis, and other injuries listed in the sections above and incorporated by reference herein;

(f) Failing to perform reasonable pre-and post-market testing of the product to investigate Injectafer's propensity to cause Severe Hypophosphatemia;

(g) Failing to adequately monitor the adverse events related to Injectafer known to Defendants from published case reports, study, and reports submitted to Defendants and FDA;

(h) Failing to provide adequate instructions, guidelines, and safety precautions, including pre-and post-sale, to those persons to whom it was reasonably foreseeable would recommend, prescribe, and use Injectafer;

(i) Failing to provide adequate instructions regarding how users and treaters should properly monitor user's serum phosphorous levels following administration of Injectafer;

(j) Representing that Injectafer was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

(k) Continuing the manufacture, promotion, marketing, and sale of Injectafer with the knowledge that Injectafer was dangerous, carried a deficient warning, and not reasonably safe;

(l) Failing to use reasonable and prudent care in the design, research, manufacture, and development of Injectafer so as to avoid the risk of serious harm associated with ferric carboxymaltose;

(m) Promoting, marketing, and selling Injectafer to patient populations who were beyond the approved indicated populations;

(n) Promoting, marketing, and selling Injectafer to physicians for the purposes of off-label uses;

(o) Marketing a product known to Defendants to cause Severe Hypophosphatemia;

(p) Misrepresenting the effects of hypophosphatemia as "transient" or "asymptomatic" in the product labeling and marketing; and

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

92. A reasonable manufacturer, designer, distributor, promotor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

93. As a direct and proximate result of the Defendants' design, manufacture, marketing, pharmacovigilance, monitoring, labeling, promotion, sale and/or distribution 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.

94. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania common law.

95. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to New York 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 $50,000.00, 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

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

97. 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.

98. 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.

99. 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.

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

101. Defendants are liable in tort to Plaintiff for their negligent failure to warn under Pennsylvania common law.

102. Defendants are liable in tort to Plaintiff for their negligent failure to warn under New York 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 $50,000.00, 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

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

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

105. 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.

106. 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) 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;

(e) Designing a product without taking into consideration the proper dosage and necessary break in time between administrations;

(f) Utilizing false and misleading claims, including ghost-writing, in advertisements, professional meetings, medical journal articles,

advisory meetings, promotional speaking, CMEs, leave-behinds at prescriber offices, detailing, and by other methods and materials in the design and formulation of Injectafer.

107. The Injectafer that was 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.

108. 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.

109. 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 and in actual use in the United States.

110. As a direct and proximate result of the Defendants' negligent acts and design of Injectafer, Plaintiff suffered injuries and damages as set forth in this Complaint.

111. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania 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 $50,000.00, 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

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

113. 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.

114. 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.

115. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiffs' 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.

116. 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.

117. 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.

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

119. 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.

120. 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.

121. 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.

122. 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.

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

124. 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.

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

126. 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.

127. 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.

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

129. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to New York common law.

130. Defendants are liable in tort to Plaintiff for their wrongful conduct pursuant to Pennsylvania 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 $50,000.00, 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

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

132. The Defendants 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.

133. The representations made by the 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.

134. These representations were made by the Defendants 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.

135. In representations to Plaintiff and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted or misrepresented the following material information (*non-exhaustive*):

(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 the risk of incidences of hypophosphatemia in adverse events and clinical studies was marginal and/or non-existent;

(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 and Strict Liability Design Defect Count.

136. The 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.

137. The 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.

138. 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.

139. In reliance upon these false representations, Plaintiff and her physicians were 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 and her physicians and other healthcare providers 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.

140. The Defendants 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.

141. The information distributed to the public, the medical community, Plaintiff and her physicians by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of Injectafer.

142. These representations, and others made by the 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.

143. 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, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when Injectafer was prescribed to her.

144. Plaintiff and her physicians relied on the misrepresentations and omissions of Defendants, unaware of the falsity of the statements. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Injectafer.

145. As a proximate result of the Defendants' design, manufacture, marketing, sale, promotion, labeling, and/or distribution of Injectafer, 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.

146. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to Pennsylvania common law.

147. Defendants are liable in tort to Plaintiff for their fraudulent conduct pursuant to New York 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 $50,000.00, 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

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

149. 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.

150. 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.

151. 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.

152. 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.

153. 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.

154. 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.

155. 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.

156. 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.

157. 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.

158. 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.

159. As a proximate result of the Defendants' marketing, promotion, labeling, sale and/or distribution 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.

160. Defendants are strictly liable for their reckless and wrongful conduct to Plaintiff pursuant to New York 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 $50,000.00, 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

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

162. 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.

163. 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.

164. 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.

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

166. 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.

167. 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 May 2017 injection of the drug.

168. 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 products and procedures available to treat Iron Deficiency Anemia (IDA), and which far outweigh the utility of Injectafer.

169. 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.

170. 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.

171. Defendants are strictly liable in tort to Plaintiff as a result of their wrongful and reckless conduct pursuant to New York 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 $50,000.00, 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 – BREACH OF EXPRESS WARRANTY

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

173. At all relevant times, the Defendants intended that Injectafer be used in the manner that Plaintiff used it and they expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for IDA, and that they were adequately tested and fit for their intended use.

174. At all relevant times, the Defendants were aware that consumers, including Plaintiff, would use Injectafer; which is to say that Plaintiff was a foreseeable user of the product.

175. Plaintiff and/or her physicians were at all relevant times in privity with the Defendants.

176. Injectafer was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her physicians, without substantial change in the condition in which it was manufactured, labeled, and sold by the Defendants.

177. The Defendants breached various express warranties with respect to Injectafer including the following particulars:

(a) The Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, continuing education, and regulatory submissions that the Injectafer was safe and therefore fraudulently withheld and concealed information about the substantial risks of serious injury associated with Injectafer; and

(b) The Defendants represented to Plaintiff and her physicians and healthcare providers that Injectafer was as safe, and/or safer than other alternative products used to treat IDA, and therefore fraudulently concealed information which demonstrated that Injectafer was a cause of Severe Hypophosphatemia and not safer than alternatives available on the market.

178. In reliance upon the Defendants' express warranties, Plaintiff used Injectafer as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

179. At the time of making such express warranties, the Defendants knew or should have known that Injectafer does not conform to these express representations because the Injectafer was not safe and had numerous side effects, many of which the Defendants did not accurately warn about, including but not limited to Severe Hypophosphatemia and the injuries that are subsequently caused by low levels of blood phosphorous, thus making Injectafer unreasonably unsafe for their intended purpose.

180. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of the Defendants in connection with the prescription, dosage, administration, and treatment of and with Injectafer.

181. The Defendants breached their express warranties to Plaintiff in that Injectafer was not of merchantable quality, safe and fit for its intended uses, nor was it adequately tested.

182. The Defendants' breach constituted violations of Pennsylvania common law principles and 13 Pa. Stat. Ann. §2313, *et seq*.

183. The Defendants' breach constituted violations of New York common and statutory law.

184. As a proximate result of the Defendants' design, manufacture, marketing, labeling, promotion, sale and/or distribution 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.

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 $50,000.00, 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 IX – BREACH OF IMPLIED WARRANTY

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

186. At all relevant and material times, Defendants manufactured, designed, monitored, labeled, distributed, advertised, promoted, and sold Injectafer.

187. At all relevant times, Defendants intended that Injectafer be used for the purposes and in the manner that Plaintiff or her physicians used/prescribed it and the Defendants impliedly warranted that each Injectafer product to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

188. Defendants were aware that consumers, including Plaintiff and her physicians would use/prescribe Injectafer in the manner instructed in the labeling and that Plaintiff was a foreseeable user of Injectafer.

189. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

190. Injectafer was expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

191. Defendants breached various implied warranties with respect to Injectafer, including the following particulars:

(a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, continuing education, medical literature, and regulatory submissions that Injectafer was safe and therefore fraudulently withheld and concealed information about the substantial risks of serious injury associated with Injectafer; and,

(b) Defendants represented that the Injectafer was safe, and/or safer than other alternative products available for the treatment of IDA, and fraudulently concealed information which demonstrated that Injectafer was not as safe and/or safer than alternatives available on the market.

192. In reliance upon Defendants' implied warranties, Plaintiff and/or her physicians prescribed/used Injectafer in the foreseeable manner normally intended, recommended, instructed, promoted, and marketed by Defendants.

193. Defendants breached their implied warranties to Plaintiff and/or her physicians in that Injectafer was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of common law principles and the following statutory provision: 13 Pa. Stat. Ann. §§2314 *et seq*.

194. Defendants breached their implied warranties to Plaintiff and/or her physicians in that Injectafer was not of merchantable quality, safe and fit for its intended use, or adequately tested, in violation of New York common and statutory law.

195. As a proximate result of the Defendants' design, manufacture, marketing, labeling, promotion, sale and/or distribution of Injectafer, Plaintiff has been injured

catastrophically, and sustained severe and permanent damages, including pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

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 $50,000.00, 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 X – VIOLATION OF CONSUMER PROTECTION LAWS

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

197. Plaintiff purchased and used Injectafer primarily for personal use and thereby suffered ascertainable losses as a result of the Defendants' actions in violation of the consumer protection laws.

198. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for Injectafer, and would not have incurred related medical costs and injury.

199. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for Injectafer, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

200. Unfair methods of competition of deceptive acts or practices that were proscribed by law, including the following:

(a) Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

(b) Advertising goods or services with the intent not to sell them as advertised; and

(c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

201. Plaintiff was injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at patients, physicians and consumers, including the Plaintiff and her physicians, was to create demand for and sell Injectafer. Each aspect of the Defendants' conduct combined to artificially create sales of the Injectafer.

202. The Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Injectafer.

203. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for Injectafer, and would not have incurred related medical costs.

204. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq*., and any and all New York consumer protection statutes.

205. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state

consumer protection statutes, including but not limited to 79 Pa. Stat. §§201-1 *et seq*, and any and all New York consumer protection statutes.

206. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

207. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Injectafer was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations made in uniform promotional materials and product labeling.

208. The actions and omissions of the Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

209. The Defendants had actual knowledge of the defective and dangerous condition of Injectafer and failed to take any action to cure such defective and dangerous conditions.

210. Plaintiff and her physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product to use.

211. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

212. By reason of the unlawful acts engaged by the Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

213. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution 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.

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 $50,000.00, 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 XI – GROSS NEGLIGENCE

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

215. The 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 a 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 .

216. Plaintiff and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

217. 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.

218. Plaintiff will seek to assert claims for exemplary damages to the extent available under all applicable Pennsylvania and New York law.

219. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused that injuries to Plaintiff. 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 $50,000.00, 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 this 19th day of December, 2018.

Respectfully submitted,

POGUST MILLROOD, LLC

/s/ Michael G. Daly

Michael G. Daly - PA Bar No. 309911
Tobias L. Millrood – PA Bar No. 77764
Kara Hill – PA Bar No. 324171
Eight Tower Bridge
161 Washington Street, Suite 940
Conshohocken, PA 19428

Counsel for Plaintiff

VERIFICATION

I, Katherine Crocket, hereby state:

1. I am the plaintiff in this action.
2. I verify that the statements made in the foregoing COMPLAINT AND JURY DEMAND are true and correct to the best of my knowledge, information and belief; and
3. I understand that the statements in said COMPLAINT AND JURY DEMAND are made subject to the penalties of 18 Pa. C.S. § 4904 relating to unsworn falsifications to authorities.

Dated: 12/19/18

Katherine Crockett
Plaintiff

EXHIBIT B

KATHERINE CROCKETT Plaintiff, vs. LUITPOLD PHARMACEUTICALS, INC Defendants	)	COURT OF COMMON PLEAS PHILADELPHIA COUNTY NOVEMBER TERM, 2018 NO: 02043

MELANIE ATKINSON Plaintiff, vs. LUITPOLD PHARMACEUTICALS, INC Defendants	)	COURT OF COMMON PLEAS PHILADELPHIA COUNTY NOVEMBER TERM, 2018 NO: 02049

Affidavit of Amy Todd Klug

I, Amy Todd Klug, under penalty of perjury, depose and state the following:

1. I am over 18 years of age and am an Associate General Counsel at Daiichi Sankyo, Inc. (DSI), located at 211 Mt. Airy Road, Basking Ridge, New Jersey.
2. DSI is a U.S. subsidiary of Daiichi Sankyo Company, Ltd. (DSC),a Japanese corporation with its principal place of business in Japan.

3. On January 2, 2019, a process server hand delivered copies of two complaints – Melanie Atkinson v. Luitpold Pharmaceuticals, Inc. et al. (Case No. 18-11-2049) and Katherine Crockett v. Luitpold Pharmaceuticals, Inc. et al. (Case No. 18-11-2043) – at the DSI offices in Basking Ridge, New Jersey.

4. The process server advised that he simply was serving the "same papers [he] served before the holiday" –a reference to service of process made on DSI at this location on December 20, 2018.

5. On January 2, 2019, the process server did not state or otherwise indicate that he was seeking to serve DSC.

6. The process server did not inquire whether I was authorized to accept service on behalf of DSC.

7. The process server did not inquire whether DSI was authorized to accept service on behalf of DSC.

8. The papers presented by the process server were devoid of any Summons directed to DSC.

9. Only after the process server left the premises did I notice that "Daiichi Sankyo Co., Ltd.", along with its address in Japan, was circled in ink on subsequent pages of the multi-page packages – in the caption of the complaints and on a list of additional defendants.

10. I immediately returned the complaints to Plaintiffs' counsel, Michael Daly, via overnight mail, with a note advising that neither I nor DSI are authorized to accept service on behalf of DSC and that Plaintiffs must follow the Hague Convention to effect service on DSC.

11. I am neither an executive officer, partner or trustee of DSC or an agent that has been authorized by DSC in writing to accept service on its behalf.

12. DSI is not a regular place of business or activity of DSC.

13. I am not, nor have I ever been, authorized to accept service on behalf of DSC.

14. On January 3, 2019, I contacted Mr. Daly to discuss the attempted service on DSC. Mr. Daly and I ultimately spoke live on January 4, 2019.

15. I explained to Mr. Daly that I am not authorized to accept service on behalf of DSC, and that I would have so advised the process server had he identified the party whom he sought to serve either verbally or with a properly executed summons directed to the defendant being served.

16. Mr. Daly indicated that he understood my position, but he refused to acknowledge that the attempted service on DSC was improper and ineffective.

17. On or about January 10, 2019, Mr. Daly caused to be filed in the Philadelphia Court of Common Pleas Affidavits of Service, purporting that I had accepted service of complaints on behalf of DSC in the Atkinson and Crockett matters referenced above. Copies of the Affidavits of Service are attached hereto as Exhibit A.

Dated: Jan 17 2019

Amy Todd Klug

Sworn and subscribed to before me
This 17 day of January, 2019

Notary Public

CANDY MINGST
NOTARY PUBLIC OF NEW JERSEY
ID # 50003504
My Commission Expires 9/19/2019

EXHIBIT C

Michael G. Daly, Esquire
161 Washington Street, Suite 940
Conshohocken, PA 19428
(610) 941-4204

Commonwealth of Pennsylvania
In the Court of Common Pleas
Philadelphia County

Katherine Crockett

v.

Luitpold Pharmaceuticals, Inc., et al.

Case No.:18-11-2043

Commonwealth of Pennsylvania
County of Philadelphia ss

AFFIDAVIT OF CORPORATE SERVICE

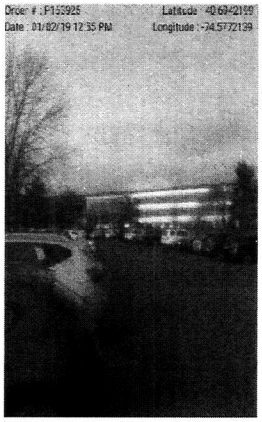
I, **Thomas J. Crean, Jr.,** being duly sworn according to the law upon my oath, depose and say, that I am not a party to this action, am over 18 years of age, and have no direct personal interest in this litigation.

PARTY SERVED:	**Daiichi Sankyo Co., LTD**
DOCUMENTS SERVED:	**Complaint**
BY LEAVING WITH:	**Amy Kluge, Legal Department**
DATE & TIME OF SERVICE:	**1/2/2019 12:54 PM**
PHYSICAL DESCRIPTION:	**Age: 34** **Weight: 150** **Hair: Blonde** **Sex: Female** **Height: 5'8"** **Race: Caucasian**
SERVED ADDRESS:	**211 Mount Airy Road** **Basking Ridge, NJ 07920**

I hereby affirm that the information contained in the Affidavit of Service is true and correct. This affirmation is made subject to the penalties of 18 PA C.S. 4904 relating to unsworn falsification to authorities.

Subscribed and sworn before me, a Notary Public, this 2nd day of January, 2019

Regina A. Richman, Notary Public
Falls Twp., Bucks County
My Commission expires on: 12/12/2021



Thomas J. Crean, Jr.
Dennis Richman's Services for the Professional, Inc
1500 John F. Kennedy Blvd. Suite #1315,
Philadelphia, PA 19102
(215) 977-9393

EXHIBIT D

2/9/2015
2/9/2015

JORGE SALAS,
Plaintiff

VS.

WAL-MART STORES, EAST, INC.,
Defendant

: IN THE COURT OF COMMON PLEAS
: OF BERKS COUNTY, PENNSYLVANIA
:
: CIVIL ACTION - LAW
:
:
: No. 11-1137

Eric Winter, Esquire,
Attorney for plaintiff

Marc R. Kamin, Esquire
Attorney for defendant

OPINION, JEFFREY K. SPRECHER, J. **JANUARY 29, 2015**

Plaintiff appeals the Order dated October 20, 2014, which sustained defendant's preliminary objections to the complaint and dismissed the action with prejudice. This Opinion is filed pursuant to Pa. R.A.P. 1025.

FACTS

Plaintiff, Jorge Salas, initiated the above captioned case by filing a Writ of Summons on January 24, 2011. The action stems from an alleged slip and fall that occurred on January 23, 2009 at a Wal-Mart retail store located in Temple, Berks County, Pennsylvania. On December 17, 2012, the Prothonotary of Berks County issued a Notice of Proposed Termination of the above captioned case. On February 15, 2013, plaintiff filed a Notice of Intention to Proceed.

On July 17, 2014, plaintiff finally filed his complaint. Plaintiff named Wal-Mart Stores East, Inc., as the defendant. Defendant is a Delaware corporation with its principal place of business in Bentonville, Arkansas. Defendant has a registered mailing office address in Harrisburg, Pennsylvania.

Defendant filed preliminary objections based on improper service. Plaintiff's Affidavit/Return of Service states that the summons was served on Phaedra Miller Asset Protection/Person in Charge at the Wal-Mart retail store (hereinafter, Store) in Temple. Defendant contended that Store is maintained and operated by Wal-Mart Stores East, **L.P.** Defendant has never owned, operated, or controlled Store. Defendant also asserted that it does not regularly conduct business or have anyone authorized to accept service on its behalf at Store.

After consideration of the record and argument, this court sustained defendant's preliminary objections, struck the Affidavit/Return of Service from the record, and dismissed the action with prejudice. Plaintiff appealed this Order.

ISSUES

Plaintiff's Concise Statement of Errors Complained of on Appeal stated the following issue.

Whether this court erred in striking the return of service and sustaining the preliminary objections to dismiss the action, where the individual served was a security supervisor for defendant at the location where plaintiff was injured, and that service was timely made.

DISCUSSION

Plaintiff submits that this court erred in striking the return of service and sustaining the preliminary objections to dismiss the action because the individual served was a security supervisor for defendant at the Store where plaintiff was injured and service was timely made. These contentions are without merit.

Pursuant to Pa. R.C.P. 424, service upon a corporation is made by handing a copy to any of the following persons:

(1) An executive officer, partner or trustee of the corporation or similar entity, or

(2) The manager, clerk or other person for the time being in charge of any regular place of business or activity of the corporation or similar entity, or

(3) An agent authorized by the corporation or similar entity in writing to receive service of process for it.

In the case *sub judice*, Ms. Miller is clearly not an individual permitted to be served under paragraph (1). No writing has been produced to show that there is any written authorization for her to receive service of process for defendant pursuant to paragraph (3). The service of process states that she is the person in charge of Store; however, she works in the asset protection division of Store. Therefore, she is not a manager or anyone in charge of the entire Store; a security worker or manager does not qualify as the person in charge of the Store. Defendant has a local corporate address in Harrisburg, Pennsylvania where it could have been served.

Furthermore, defendant does not own, operate, or control Store, so Ms. Miller does not work for defendant. Store is maintained and operated by Wal-Mart Stores East, **L.P.** Plaintiff contends that pursuant to Pa. R.C.P. 2176, Wal-Mart Stores East, L.P. is the same as Wal-Mart Stores East, Inc. This rule defines "corporation or similar entity" as follows:

> Includes any public, quasi-public or private corporation, insurance association or exchange, joint stock company or association, limited liability company, professional association, business trust, or any other association which is regarded as an entity distinct from the members composing the association. . .

Thus, this definition establishes a distinction between a corporation and the individuals who run it.

Under this same rule "corporate name" is defined as "any name, real or fictitious, under which a corporation or similar entity was organized, or conducts

business, whether or not such name has been filed or registered." Therefore, a corporate name does not have to be registered or filed.

These definitions do not mean that as long as the names are similar, as plaintiff suggests, that two separate entities are interchangeable. If plaintiff wanted to file a complaint against Store, he filed a complaint against the wrong defendant. If plaintiff wanted to file a complaint against the defendant that he did, he served the wrong defendant. For these reasons, this court sustained the preliminary objections.

This court dismissed this case because plaintiff has demonstrated a lack of due diligence throughout the history of this lawsuit. He initiated it with a writ of summons on January 24, 2011, the last day before the statute of limitations would run on his tort claim. Plaintiff finally filed his complaint on July 17, 2014. Defendant filed timely preliminary objections to the service. Plaintiff argues that service is good and refers to Exhibit A to refute defendant's preliminary objections. There is no Exhibit A attached to his pleading.

Even assuming *arguendo*, that plaintiff is correct and the two entities are the same, he still did not serve the summons correctly. A security person is not the person in charge of a corporation; plaintiff had to know that a corporate defendant would have a corporate office where the summons could have been properly served. Plaintiff simply did not execute proper service in the case *sub judice*. Now, it is more than six years since plaintiff's alleged accident, and service is still not perfected. At this time, plaintiff cannot cure the service within the time period prescribed by the statute of limitations. Therefore, this court dismissed the action with prejudice.

2/5/2015

In accordance with the foregoing Opinion, this court submits that this court's order should be sustained and plaintiff's appeal denied.

JEFFREY K. SPRECHER, J.

2/9/2015

JEFFREY K. SPRECHER, JUDGE

No. ~~GD-15-001~~ 11-1137 **Date:** 01-30-15

Prothonotary, please File the original Order and distribute copies as follows:

- ☒ Prothonotary (original)
- ☒ Computer
- ☒ Attorney for the Plaintiff Eric E. Winter, Esq.
- ☐ Attorney for the Plaintiff _____, Esq.
- ☐ Attorney for the Plaintiff _____, Esq.
- ☐ Attorney for the Plaintiff _____, Esq.
- ☐ Attorney for the Plaintiff _____, Esq.
- ☐ Attorney for the Plaintiff _____, Esq.
- ☐ Plaintiff _____
- ☐ Plaintiff _____
- ☐ Plaintiff _____
- ☐ Plaintiff _____
- ☒ Attorney for the Defendant Marc R. Kamin, Esq.
- ☐ Attorney for the Defendant _____, Esq.
- ☐ Attorney for the Defendant _____, Esq.
- ☐ Attorney for the Defendant _____, Esq.
- ☐ Attorney for the Defendant _____, Esq.
- ☐ Attorney for the Defendant _____, Esq.
- ☐ Defendant _____
- ☐ Defendant _____
- ☐ Defendant _____
- ☐ Defendant _____
- ☒ Other Law Library
- ☐ Other _____
- ☐ Other _____

PROTHONOTARY	BY		DATE
Order sent to Judge			
Copies Sent	MB		2-6-15
Forwarded for Processing			
Forwarded for Processing			
Entered in Hearing Book			ENTERED 2-6-15
Forwarded to Comp. Room	MB		
Forwarded to File Room			
File Located			
Filing Completed			
Returned to:	Person:		
Request			

A Certified Copy of this Opinion & Notice
was issued to Marc B Kamin
Eric F Winter
Law Library

by first class mail by MB
Deputy Prothonotary on 2-6-15
and to

by Inter Office Mail.

2/6/15 Opinion Filed

JS 44 (Rev. 06/17)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

Katherine Crockett

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Pogust Millrood, LLC; Eight Tower Bridge, Ste. 940; 161 Washington Street; Conshohocken, PA 19428; 610-941-4204

DEFENDANTS

Luitpold Pharmaceuticals, Inc.; American Regent, Inc.; Daiichi Sankyo, Inc.; Daiichi Sankyo Co., Ltd.; Vifor Pharmaceuticals Managem

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

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

Attorneys *(If Known)*

Drinker, Biddle & Reath LLP; One Logan Square, Ste. 2000; Philadelphia, PA 19103; 215-988-2700

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

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

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

Click here for: Nature of Suit Code Descriptions.

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

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

TORTS

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

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

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

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

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

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

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

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

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

☐ 1 Original Proceeding ☒ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

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

Brief description of cause:
Plaintiff alleges personal injury tort claims related to a prescription medication.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 01/18/2019

SIGNATURE OF ATTORNEY OF RECORD Heather C. Giordanella

FOR OFFICE USE ONLY

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

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: Katherine Crockett, 1830 Lombard Street, Apt. 714; Philadelphia, Pa. 19146

Address of Defendant: Luitpold Pharmaceuticals, Inc.; 5 Ramsey Rd., Shirley, NY 11967

Place of Accident, Incident or Transaction: Pennsylvania

RELATED CASE, IF ANY:

Case Number: _____ Judge: _____ Date Terminated: _____

Civil cases are deemed related when ***Yes*** is answered to any of the following questions:

1.	Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?	Yes ☐	No ☑
2.	Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?	Yes ☐	No ☑
3.	Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?	Yes ☐	No ☑
4.	Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual?	Yes ☐	No ☑

I certify that, to my knowledge, the within case ☐ **is** / ☉ **is not** related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 01/18/2019 Heather C. Giordanella PA - 82754

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

CIVIL: (Place a √ in one category only)

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Patent
- ☐ 6. Labor-Management Relations
- ☐ 7. Civil Rights
- ☐ 8. Habeas Corpus
- ☐ 9. Securities Act(s) Cases
- ☐ 10. Social Security Review Cases
- ☐ 11. All other Federal Question Cases
  (Please specify): _____

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury *(Please specify):* _____
- ☑ 7. Products Liability
- ☐ 8. Products Liability – Asbestos
- ☐ 9. All other Diversity Cases
  (Please specify): _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration.)

I, Heather C. Giordanella, counsel of record *or* pro se plaintiff, do hereby certify:

☑ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs:

☐ Relief other than monetary damages is sought.

DATE: 01/18/2019 Heather C. Giordanella PA - 82754

Attorney-at-Law / Pro Se Plaintiff *Attorney I.D. # (if applicable)*

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

Civ. 609 (5/2018)

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

CASE MANAGEMENT TRACK DESIGNATION FORM

KATHERINE CROCKETT
v.
LUITPOLD PHARMACEUTICALS, INC., ET AL.

CIVIL ACTION

NO. 2:19-CV-00276-WB

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) (X)

(f) Standard Management – Cases that do not fall into any one of the other tracks. ( )

1/24/2019	KENNETH A. MURPHY	LUITPOLD PHARMACEUTICALS, INC. AMERICAN REGENT, INC. DAIICHI SANKYO, INC.
Date	**Attorney-at-law**	**Attorney for**
215·988·2700	215·988·2757	KENNETH.MURPHY@DBR.COM
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02