IN THE DISTRICT COURT OF THE FOURTH JUDICIAL DISTRICT OF THE STATE OF IDAHO, IN AND FOR THE COUNTY OF ADA

MICHELLE STIRLING and BRANDON STIRLING, individually and as the natural parents of minor child B.S.,

Plaintiffs,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION, ALCAMI CAROLINAS CORPORATION fka AAIPHARMA SERVICES CORP., GENUS LIFESCIENCES INC. dba LEHIGH VALLEY TECHNOLOGIES, LANNETT COMPANY, INC., IMPAX LABORATORIES, INC., ST. LUKE'S REGIONAL MEDICAL CENTER, LTD., GLEN LOVELACE, M.D.,

Defendants.

Case No. CV01-18-4880

MEMORANDUM DECISION RE: NOVARTIS PHARMACEUTICALS MOTION TO DISMISS

I. INTRODUCTION

This matter is before the Court on the Motion to Dismiss filed by Defendant Novartis Pharmaceuticals Corporation ("Novartis"). Plaintiffs' Amended Complaint set out six causes of action against Novartis: (1) Count One—Negligent Failure to Warn; (2) Count Two—Fraud; (3) Count Three—Negligence Per Se; (4) Count Four—Breach of Implied Warranty of Merchantability; (5) Count Seven—intentional infliction of emotional distress ("IIED"); and (6) Count Eight—negligent infliction of emotional distress ("NIED"). Novartis requested the Court dismiss under I.R.C.P. 12(b)(2) for lack of personal jurisdiction and I.R.C.P. 12(b)(6) for failure of the Amended Complaint to state a claim for which relief can be granted. At the hearing Court on September 4, 2019 the Court declined to rule on the merits of the motion to dismiss for lack of jurisdiction pending Novartis responses to Plaintiffs' discovery directed to the jurisdictional facts. The Court took the 12(b)(6) portion of the motion under advisement.

Because this is a motion to dismiss, all facts are derived from the Amended Complaint. The Court announced at the hearing that it would not convert the motion into a motion for

summary judgment.[1] Consequently, the Court will not consider any additional evidentiary materials filed by the parties when reaching the decision on the Rule 12(b)(6) motion. *See Paslay v. A&B Irrigation Dist.*, 162 Idaho 866, 870, 406 P.3d 878, 882 (2017) ("[A] court can dismiss an action under Rule 12(b)(6) if it considers only the complaint, despite whether a party has submitted additional materials to the record.").

II. FACTS AS ALLEGED BY PLAINTIFFS

The facts alleged as concerns Defendant are summarized here. Other facts contained in the Amended Complaint pertaining to other Defendants not germane to the question under consideration are omitted.

Defendant Novartis is a pharmaceutical company that owned[2] the New Drug Application ("NDA") for the brand-name drug Brethine from sometime before until December 2001.[3] Brethine was originally developed by Draco, a Swedish company, and released for use as a bronchodilator to treat asthma. Terbutaline sulfate is the generic form of Brethine. In 1974, the FDA approved terbutaline sulfate as a treatment for asthma in the United States. In its capacity as the owner of the Brethine NDA, Novartis developed, manufactured, packaged, labeled, marketed and distributed Brethine until around December 2001 when it sold the rights to the Brethine NDA to Alcami Carolinas Corporation. Plaintiffs make no allegation that Novartis manufactured the drug taken by Plaintiff Michelle Stirling ("Michelle").[4] The Amended Complaint does not allege the name of the actual manufacturer of the drug ingested by Michelle. It is clear, however, that the manufacturer was not Novartis.

In late October 2007 Michelle was approximately twenty-five (25) weeks pregnant with her now ten-year-old son, B.S., when she began experiencing pre-mature labor contractions. She was prescribed an injection of the generic drug terbutaline sulfate as a tocolytic – a drug to suppress premature labor in pregnant women. Michelle continued the use of the drug in pill

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[1] If a party presents matters outside of the pleadings for consideration on a 12(b) motion, and the Court does not exclude the consideration of these materials, then the motion must be treated as though it were a motion for summary judgment under I.R.C.P. 56.

[2] At places in the Amended Complaint, Plaintiffs refer to Novartis as the owner of the rights to the drug. At other places, Plaintiffs refer to Novartis as the "holder" of the right so the drug. There does not appear to be any legal distinction. The Court will simply use the term "owner" to encompass both.

[3] The Amended Complaint does not allege a date Novartis acquired the rights to the drug, only the date it sold the rights to another company. Plaintiffs' brief refers to dates stated in the Novartis brief, but those statements are not facts to be considered as they are not set forth in the Amended Complaint.

[4] Where the context requires individual Plaintiffs be identified, first names will be used. No disrespect is intended.

form for 90 consecutive days from the original injection on October 26, 2007 into January 2008. B.S. was born on February 18, 2008. At birth B.S. did not have any objective manifestations that indicated he had any cognitive or neuropsychiatric impairments or disorders but was eventually diagnosed with and treated for cognitive and personality disorders. These cognitive and personality disorders were caused by the terbutaline sulfate ingested by Michelle during her pregnancy. Michelle and her husband Brandon suffered damages, including emotional distress, as a result of the injury to B.S.

In the Amended Complaint, Plaintiffs include incongruous factual allegations that the use of Brethine and the generic terbutaline sulfate for tocolytic was both on and off-label.[5] "On-label use" is when a drug or medical device is used in a manner approved by the FDA, including treatment for use on identified and specific conditions and diseases. In contrast, "off-label"

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[5] *See* Amended Complaint (emphasis added):

Paragraph 23: at no time during Alcami's ownership of the Brethine NDA, [2001-2007] including at the time it sold the rights to that NDA to Genus, did Alcami's label for Brethine contain any warning that use of the drug as a tocolytic posed a risk to fetal brain development, *even though the label allowed for administration for pre-term labor.*

Paragraph 24: at no time in 2007 or through February 18, 2008, when Genus owned the Brethine NDA, did Genus' label for Brethine contain any warning that use of the drug as a tocolytic posed a risk to fetal brain development, *even though the label allowed for administration for pre-term labor.*

Paragraph 25: At no time in late 2007 or early 2008 did the labels for these companies' respective terbutaline sulfate drugs contain any warning that use of the drug as a tocolytic posed a risk to fetal brain development, *even though the labels allowed for administration for pre-term labor.*

Paragraph 49: At all times relevant hereto, Defendants Novartis, Alcami, Genus, Lannett, Impax and Does I-XX (collectively the "Manufacturer Defendants") manufactured, marketed and distributed Brethine and/or its generic bioequivalent, terbutaline sulfate, with the intention that it be used in the *off-label manner as a tocolytic* by improperly promoting those drugs as safe and effective for that particular use.

Paragraph 50: the Manufacturer Defendants knew or reasonably should have known not only that Brethine and terbutaline sulfate *were not effective tocolytics*, but also that their use in such an *off-label manner* was not safe

Paragraph 56: Plaintiffs and their health care providers justifiably relied upon the Manufacturer Defendants' expertise and justifiably believed that … (4) not promote a drug for an **off-label use** that had been shown to be ineffective and dangerous.

Paragraph 63**:** At all times relevant hereto, the Brand-Name Manufacturer Defendants' Brethine drug products were misbranded under both the FDCA and the IFDCA in *that their labeling promoted the use of Brethine as a tocolytic* but failed to include any warning of the known risks to fetal brain development associated with such use.

Paragraph 78: At all times relevant hereto, the Brand-Name Manufacturer Defendants' *labeling* for Brethine was defective and deficient in that it *promoted and/or approved of the use of the drug as a tocolytic* …

usage is the "use of a device for some other purpose than that for which it has been approved by the FDA." *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350, 121 S. Ct. 1012, 1018, 148 L. Ed. 2d 854 (2001). The Supreme Court's observations regarding medical devices applies equally to drugs. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L.J. 71 (1998). The Court will accept that the use of the drug as a tocolytic was both on and off label because this is a 12(b)(6) motion.

III. STATUTORY SCHEME RELATED TO PHARMACEUTICAL DRUG LABELING

The Food, Drug, and Cosmetic Act (FDCA; 21 U.S.C. § 301 *et seq.*) prohibits the marketing of a new brand-name drug unless the manufacturer has submitted a new drug application ("NDA") and the Food and Drug Administration ("FDA") has approved the drug as safe and effective for its intended use. 21 U.S.C. § 355(a). The NDA must include an exemplar of the drug's proposed label (21 U.S.C. § 355(b)(1)(F)) describing the drug's indications and usage, contraindications, warnings and precautions, and adverse reactions. 21 C.F.R. § 201.56(e)(1).

The United States Supreme Court has outlined general drug labeling requirements, stating:

> Under the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act, 76 Stat. 780, 21 U.S.C. § 301 *et seq.,* a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate. See, *e.g.,* 21 U.S.C. §§ 355(b)(1), (d); *Wyeth v. Levine,* 555 U.S. 555, 567, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009). Meeting those requirements involves costly and lengthy clinical testing. §§ 355(b)(1)(A), (d); *see also* D. Beers, Generic and Innovator Drugs: A Guide to FDA Approval Requirements § 2.02[A] (7th ed. 2008).
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> Originally, the same rules applied to all drugs. In 1984, however, Congress passed the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly called the Hatch–Waxman Amendments. Under this law, "generic drugs" can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA. 21 U.S.C. § 355(j)(2)(A). As we use it here, "generic drug" refers to a drug designed to be a copy of a reference listed drug (typically a brand-name drug), and thus identical in active ingredients, safety, and efficacy. See, *e.g., United States v. Generix Drug Corp.,* 460 U.S. 453, 454–455, 103 S.Ct. 1298, 75 L.Ed.2d 198 (1983); 21 CFR § 314.3(b) (2006) (defining "reference listed drug"). This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials

> already performed on the equivalent brand-name drug. A generic drug application must also "show that the [safety and efficacy] labeling proposed ... is the same as the labeling approved for the [brand-name] drug." § 355(j)(2)(A)(v); see also § 355(j)(4)(G); Beers §§ 3.01, 3.03[A].

PLIVA, Inc. v. Mensing, 564 U.S. 604, 612–13, 131 S. Ct. 2567, 2574, 180 L. Ed. 2d 580 (2011) (relevant footnotes included in body of text).

> The FDA has created procedures by which manufacturers can make changes to a drug's approved labeling or other changes to an approved application. Drug manufacturers may submit either "Prior Approval Supplements," which require FDA approval before the proposed change may be implemented, or "Changes Being Effected" ("CBE") Supplements, under which the proposed change may be implemented before the FDA has acted on the supplemental application. 21 C.F.R. § 314.70(b), (c). While most changes to a drug's approved labeling must be requested through a Prior Approval Supplement, manufacturers may "add or strengthen a contraindication, warning, precaution, or adverse reaction" through a CBE supplement. *See* §§ 314.70(b)(1)(i), § 314.70(c)(6)(iii)(A).
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> Under current regulations, brand-name and generic manufacturers have different labeling responsibilities, even though both are authorized to use the label supplement procedures. 21 C.F.R. § 314.97.

In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig., 756 F.3d 917, 923 (6th Cir. 2014).

Thus, under the regulatory scheme, a brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label, (See, *e.g.,* 21 U.S.C. §§ 355(b)(1), (d); *Wyeth, supra,* at 570–571, 129 S.Ct. 1187), whereas a generic manufacturer is responsible for ensuring that its warning label is the same as the brand name label. *See, e.g.,* § 355(j)(2)(A)(v); § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7).

IV. APPLICABLE LAW

Pursuant to Idaho Rule of Civil Procedure 12(b)(6), a claim is properly dismissed when the complaint "[fails] to state a claim upon which relief can be granted." When reviewing a motion to dismiss for failure to state a claim, a court looks only to the pleadings and views all inferences in favor of the non-moving party. *Young v. City of Ketchum*, 137 Idaho 102, 104 (2002). Under this standard, the Court will determine whether a plaintiff has stated a claim for relief "after viewing all facts and inferences from the record in favor of the non-moving party." *Taylor v. McNichols*, 149 Idaho 826, 832 (2010). "The issue is not whether the plaintiff will ultimately prevail, but whether the party is entitled to offer evidence to support the claims." *BHA Investments, Inc. v. State*, 138 Idaho 348, 350-51 (2003) (citing *Orthman v. Idaho Power Co.*, 126 Idaho 960, 962 (1995), *quoting Scheuer v. Rhodes,* 416 U.S. 232, 236 (1974)). While the

Court "assumes that all *factual* allegations in the complaint are true . . . [it] is not obligated to assume that a plaintiff's *legal conclusions* or *arguments* are also true." *Owsley v. Idaho Indus. Comm'n*, 141 Idaho 129, 136 (2005).

V. DISCUSSION

i. Innovator Liability

Novartis asserts that Plaintiffs' claims against Novartis are premised on this Court's recognition of "innovator liability."[6] Plaintiffs' Amended Complaint does not have a count labeled "innovator liability." Plaintiffs define innovator liability as a theory under which a brand-name drug manufacturer may be held liable for injuries caused by an individual's ingestion of the generic version of its drug. *See*, *Plaintiffs' Memorandum in Opposition to Novartis Motion to Dismiss*, p. 1, footnote 2. The logic that underlies this theory of liability is that a generic manufacturer of a drug has no ability to control the content of the label. It is the brand name manufacturer that must ensure that the warning label for the drug is accurate and adequate under § 505 of the Federal Food, Drug, and Cosmetic Act. *See, e.g. Rafferty v. Merck & Co., Inc.*, 479 Mass. 141, 92 N.E.3d 1205 (2018); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010).

Plaintiffs acknowledge Idaho Courts have not recognized a cause of action for innovator liability, but argue Idaho courts have not considered the theory and this Court should allow Plaintiffs to raise a claim for innovator liability "because the theory is consistent with Idaho law, does not impose an undue burden upon brand-name manufacturers and promotes critical public policies."[7]

Novartis cites to contrary cases rejecting innovator liability. *See, e.g.*, *McNair v. Johnson & Johnson*, 241 W. Va. 26, 818 S.E.2d 852 (2018); *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013). Novartis argues that "[l]ike the vast majority of states, Idaho does not recognize a cause of action based on an innovator liability theory." Novartis does not cite, and the Court could not find, any Idaho case so holding. It is more accurate to say that the Idaho appellate courts have not considered the question.

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[6] "Plaintiffs' Complaint … fails to state any claim against [Novartis] upon which relief can be granted because it relies solely on an "innovator liability" theory that is not a viable cause of action under Idaho Law." *Novartis Motion to Dismiss*.

[7] Pls' Response, pp. 5–6.

A review of the allegations in count in Plaintiffs' Amended Complaint that pertain to Novartis reveals that all have a crucial fact in common. Novartis did not manufacture the drug that caused the injuries.

ii. Count One - Negligent Failure to Warn

A cause of action for common law negligence has four elements: "(1) a duty, recognized by law, requiring the defendant to conform to a certain standard of conduct; (2) a breach of that duty; (3) a causal connection between the defendant's conduct and the resulting injury; and (4) actual loss or damage. *Nation v. State, Dep't of Correction*, 144 Idaho 177, 189, 158 P.3d 953, 965 (2007) (quoting *O'Guin v. Bingham County,* 142 Idaho 49, 52, 122 P.3d 308, 311 (2005)). Count 1 of the Amended Complaint, albeit in a rather wordy fashion, sufficiently alleges these elements. The motion by Novartis essentially challenges whether a legal duty exists in the context of this case.[8] In other words, does Idaho law require the manufacturer of a product, in this case a drug, to warn the consumer of a similar product manufactured by another. The Court concludes it does not. A collection and succinct discussion of the cases and citation to the conflicting policy arguments is found in *In re Zofran (Ondansetron) Products Liab. Litig.*, 2018 WL 2317525 (D. Mass. May 21, 2018).

The Idaho Supreme Court in *Boots* outlined the basic rule for determining whether a duty will arise in a particular context, stating:

> In determining whether a duty will arise in a particular context, our Supreme Court has identified several factors to consider. The factors include the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved. Where the degree or result of harm is great, but preventing it is not difficult, a relatively low degree of foreseeability is required. Conversely, where the threatened injury is minor but the burden of preventing such injury is high, a higher degree of foreseeability may be required. We engage in a balancing of the harm only in those rare situations when we are called upon to extend a duty beyond the scope previously imposed or when a duty has not previously been recognized.

[8] Novartis makes much of the fact that there was a six-year gap between its alleged failure to act and the ingestion of the drug by Michelle. The time gap implicates the statute of limitations, not the existence of a duty to the Plaintiffs.

Boots ex rel. Boots v. Winters, 145 Idaho 389, 394, 179 P.3d 352, 357 (Ct. App. 2008) (internal citations removed).

It has long been the general law in Idaho that a company is not liable for the injuries caused by another company's products. *See e.g.*, *Garrett v. Nobles*, 102 Idaho 369, 372, 630 P.2d 656, 659 (1981); *see e.g.*, *Farmer v. Int'l Harvester Co.*, 97 Idaho 742, 746, 553 P.2d 1306, 1310 (1976).This Court finds persuasive the reasoning of the Supreme Court of Iowa in *Huck v. Wyeth, Inc.*,[9]:

> We are unwilling to make brand manufacturers the de facto insurers for competing generic manufacturers. (Deep pocket jurisprudence is law without principle.) It may well be foreseeable that competitors will mimic a product design or label. But, we decline Huck's invitation to step onto the slippery slope of imposing a form of innovator liability on manufacturers for harm caused by a competitor's product. Where would such liability stop? If a car seat manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design? Why not, under Huck's theory, if it is foreseeable others will copy the design?
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> In sum, we will not contort Iowa's tort law in order to create liability for brand manufacturers. The unfairness resulting from *Mensing* is best addressed by Congress or the FDA....
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> We will continue to apply the same long-standing causation rule ... which required Huck to prove the defendant manufactured or supplied the product that caused her injury, and we decline to extend the duty of product manufacturers to those injured by use of a competitor's product. We will not impose liability on the brand defendants for injuries to those using only the competing generic formulation.

Huck, 850 N.W.2d at 380-81 (quotation marks and citations omitted). *See, also* Part III of *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 612–14, (8th Cir. 2009), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 564 U.S. 604, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011), and *opinion vacated in part, reinstated in part,* 658 F.3d 867, (8th Cir. 2011).

iii. Count Two -Fraud

The discussion in *Huck* and *Mensing*, *supra*, applies as well to the fraud claims. In addition, a party claiming fraud must plead with particularity the factual circumstances constituting fraud *G & M Farms v. Funk Irr. Co.*, 119 Idaho 514, 518, 808 P.2d 851, 855 (1991). Those elements are (1) a representation; (2) its falsity; (3) its materiality; (4) the speaker's knowledge of its falsity or ignorance of its truth; (5) his intent that it should be acted on by the

[9] 850 N.W.2d 353 (Iowa 2014) (rejecting the argument that brand manufacturers owe a duty to consumers of generic drugs).

person and in the manner reasonably contemplated; (6) the hearer's ignorance of its falsity; (7) his reliance on the truth; (8) his right to rely thereon; and (9) his consequent and proximate injury. *Id.* Missing from Plaintiff's complaint are is the particularity required to allege fraud. There are general statements that Novartis made false statements that its drugs were safe and effective, but nothing more. One cannot tell when the statements were made, by whom made, or what words were used. The general statement that Novartis promoted, marketed, and distributed Brethine and terbutaline sulfate as a safe and effective tocolytic is not sufficiently specific.

The Amended Complaint does not state a claim for fraud.

iv. Count Three - Negligence Per Se

Negligence per se is simply a subset of negligence. The standard of conduct is defined by a statue or regulation. Proving violation of the statute or regulation, proves the violation of the standard of care. Before it can apply, a plaintiff must show membership in the class of persons the regulation was intended to protect. In other words, that the duty defined by the statute or regulation extends to plaintiff. Here the issue is the same as with common law negligence. The regulations protect the consumers of the manufacturer's product. Absent an allegation that Michelle took a drug made by Novartis, the complaint does not state a cause of action.

A collection and succinct discussion of the cases and citation to the conflicting policy arguments is found in *In re Zofran (Ondansetron) Products Liab. Litig.*, 2018 WL 2317525 (D. Mass. May 21, 2018). Ultimately this Court concludes that the traditional notion that the manufacturer of a product cannot be held liable where its product did not cause the alleged harm.

v. Count Four - Breach of Implied Warranty of Merchantability

In Idaho, strict products liability and negligent rendition of service are not mutually exclusive theories. *Chancler v. Am. Hardware Mut. Ins. Co.*, 109 Idaho 841, 846, 712 P.2d 542, 547 (1985). In Idaho, non-privity, breach of warranty claims against a manufacturer to recover for personal injuries caused by a defective product are treated as a strict liability claims. *Oats v. Nissan Motor Corp. in U.S.A.*, 126 Idaho 162, 172, 879 P.2d 1095, 1105 (1994). To prove such a claim, a plaintiff must show that (1) the manufacturer's product was defective; (2) the product was defective or unsafe when it left the manufacturer's control; and (3) the defect was a proximate cause of the plaintiff's injury. *Puckett v. Oakfabco, Inc.*, 132 Idaho 816, 821, 979 P.2d 1174, 1179 (1999); *Garrett v. Nobles*, 102 Idaho 369, 372, 630 P.2d 656, 659 (1981).

Once again, this Court will not deviate from traditional products liability law principles in order to extend the duty of brand manufacturers to those allegedly injured by a competitor's product. The reasoning of the Iowa Court in *Huck* is likewise applicable here. Even if one accepts that Brethine was a defective product when last produced by Novartis in December 2001, it was not the product that caused the injuries. Because Novartis did not manufacture the product that Michelle was given, there is no proximate cause, and no basis under which this Court can hold Novartis liable.

vi. Count Seven - intentional infliction of emotional distress

To prove intentional infliction of emotional distress, a plaintiff must prove (1) defendant's intentional or reckless conduct; (2) defendant's extreme and outrageous conduct; (3) a causal connection between the defendant's wrongful conduct and the plaintiff" s emotional distress; and (4) severe emotional distress. *James v. City of Boise*, 160 Idaho 466, 484, 376 P.3d 33, 51 (2016). Count Seven in Plaintiffs' Amended Complaint does not allege any additional facts. Rather it incorporates earlier allegations and characterizes Defendant's conduct as extreme and outrageous. Assuming, without deciding, that this is a proper characterization of Novartis's conduct, there is lacking a factual allegation linking the conduct to any harm suffered by Plaintiffs. The alleged outrageous conduct is apparently either the failing to properly label Brethine or promoting Brethine as a tocolytic. Because Michelle was not given Brethine, there is no causal connection to be made.

vii. Count Eight -negligent infliction of emotional distress

To prove negligent infliction of emotional distress, a plaintiff must prove (1) a legal duty recognized by law; (2) a breach of that duty; (3) a causal connection between the defendant's conduct and the plaintiff's injury; and (4) actual loss or damage. *Frogley v. Meridian Joint Sch. Dist. No. 2*, 155 Idaho 558, 569, 314 P.3d 613, 624 (2013). Again, the Amended Complaint incorporates earlier allegations and characterizes Defendant's conduct as a breach of Defendant's duty to exercise ordinary care to prevent harm to others. The alleged negligent conduct is apparently either the failing to properly label Brethine or promoting Brethine as a tocolytic. For the same reasons that the Amended Complaint fails to state a cause of action for negligence, it fails to state a claim for negligent infliction of emotional distress.

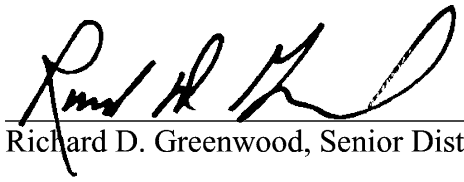
VI. PENDING JURISDICTIONAL QUESTION

As noted above, this Court declined to rule on the merits of the motion to dismiss for lack of jurisdiction pending discovery of the jurisdictional facts. The conclusion reached by the Court in this motion presents a procedural conundrum. If this Court has no jurisdiction, a still open question, this decision is essentially a void advisory opinion. But entering and order of dismissal moots the question of jurisdiction. Consequently, no Order dismissing this case will be entered unless and until there is a determination that this Court has jurisdiction over Novartis.

VII. CONCLUSION

The Court concludes Plaintiff's Amended Complaint fails to state a claim against Novartis as to each count in which Novartis is named. That conclusion is preliminary pending determination of whether this Court has jurisdiction over Novartis. The order dismissing the case will be held in abeyance pending determination of jurisdiction.

DATED: Signed: 9/25/2019 08:44 AM



Richard D. Greenwood, Senior District Judge

cc: All Counsel - emailed