UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF IDAHO

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

Plaintiffs,

v.

NOVARTIS PHARMACEUTICALS CORPORATION, a Delaware Corporation; ALCAMI CAROLINAS CORPORATION fka AAIPHARMA SERVICES CORP., a Delaware Corporation; GENUS LIFESCIENCES INC. dba LEHIGH VALLEY TECHNOLOGIES, a Pennsylvania Corporation; LANNETT COMPANY, INC., a Delaware Corporation; IMPAX LABORATORIES, INC., a Delaware Corporation; ST. LUKE'S REGIONAL MEDICAL CENTER, LTD., an Idaho Non-Profit Corporation; GLEN LOVELACE, M.D., an Individual; and DOES INDIVIDUAL/ENTITIES I through XX,

Defendants.

Case No. 1:18-CV-00436-DCN

MEMORANDUM DECISION AND ORDER

I. INTRODUCTION

This matter comes before the Court on Plaintiffs' Motion to Remand. Dkt. 30. Having reviewed the record and briefs, the Court finds that the facts and legal arguments are adequately presented. Accordingly, in the interest of avoiding further delay, and because the Court finds that the decisional process would not be significantly aided by oral argument, the Court will address the motion without oral argument. Dist. Idaho Loc.

Civ. R. 7.1(d)(2)(ii). For the reasons outlined below, the Court finds good cause to GRANT the motion.

II. BACKGROUND

In this case, Plaintiffs contend that Defendants' negligently and/or fraudulently marketed, labeled, and/or prescribed the drug Terbutaline Sulfate (a generic version of the brand name drug Brethine) to Plaintiff Michelle Stirling while she was pregnant. Dkt. 1-4, at 9-11. Terbutaline Sulfate is used for tocolytic purposes (i.e. to suppress premature labor). According to Plaintiffs, the potential risks of this medication to an unborn fetus "include, but are not limited to, higher rates of psychiatric disorders and psychopathology and decreased cognitive development." Dkt. 1-4, at 9.

In October 2007, Michelle was approximately twenty-five weeks pregnant with her son B.S., who is now eleven years old. *Id.* On October 26, 2007, Michelle began experiencing contractions, cramping, and abdominal pain, and was admitted to Defendant St. Luke's Regional Medical Center, Ltd. ("Saint Luke's") in Boise, Idaho. Defendant Glen Lovelace served as Michelle's doctor. Upon learning of her symptoms, Dr. Lovelace administered a subcutaneous injection of Terbutaline Sulfate, and gave Michelle a prescription for Terbutaline Sulfate to use as a maintenance tocolytic.

Michelle used the medication as prescribed, which included taking the drug multiple times a day, for over ninety (90) consecutive days. *Id.* at 15. Plaintiffs contend that "[a]t no time prior to or during the period of time that [Michelle] was prescribed Terbutaline Sulfate were Plaintiffs informed that the ingestion of the drug could potentially have adverse effects on B.S.'s brain development or his cognitive and

neuropsychiatric condition." Dkt. 30-1, at 3. They further allege that "none of the labels on the bottles of Terbutaline Sulfate had warnings about possible adverse side effects to their developing fetus, nor were those bottles accompanied by any such written warnings." *Id.*

Plaintiffs' son, B.S., was born on February 18, 2008. Dkt. 1-4, at 11. While B.S. did not initially exhibit signs or symptoms of cognitive or neuropsychiatric disorders, this began to change as he grew older. In September of 2014, B.S. was diagnosed with Anxiety Disorder and Oppositional Defiant Disorder. *Id.* In October 2014, B.S. was diagnosed with Disruptive Mood Dysregulation Disorder. *Id.* In August 2016, B.S. was diagnosed with Bipolar Disorder, Separation Anxiety Disorder, and Social Anxiety Disorder of Childhood. *Id.* at 11-12. Shortly thereafter, B.S. was diagnosed with Autism Spectrum Disorder. *Id.*

Plaintiffs filed this lawsuit in the Fourth Judicial District of the State of Idaho on March 12, 2018. Dkt. 1-3. A primary contention underlying Plaintiffs' claims is that Defendants knew, or should have known, the risks associated with the tocolytic drugs at issue in this case (Brethine and Terbutaline Sulfate). Their Amended Complaint includes the following eight claims: I. negligent failure to warn (against Defendants Novartis, Alcami, Genus, and Does I-X [brand-name manufacturers]); II. fraud (against Defendants Novartis, Alcami, Genus, Lannett, Impax, and Does I-XX [generic and brand-name manufacturers]); III. negligence *per se* (against Defendants Novartis, Alcami, Genus, and Does I-X [brand-name manufacturers]); IV. breach of the implied warranty of merchantability (against Defendants Novartis, Alcami, Genus, and Does I-X [brand-name

manufacturers]); V. medical malpractice (against Defendants St. Luke's and Lovelace); VI. failure to obtain informed consent (against Defendants St. Luke's and Lovelace); VII. intentional infliction of emotional distress (against all Defendants); and VIII. negligent infliction of emotional distress (against all Defendants).

On October 9, 2018, Defendant Genus Lifesciences Inc. ("Genus") removed the case to this court, citing 28 U.S.C. § 1441(c). On November 8, 2018, Plaintiffs filed their Motion to Remand the action back to state court. Dkt. 30.

III. LEGAL STANDARD

Federal district courts are courts of limited jurisdiction and are "presumed to lack subject matter jurisdiction until the contrary affirmatively appears." *Dragovich v. United States Dep't of Treasury*, 764 F.Supp.2d 1178, 1184 (N.D. Cal. 2011). When an action is removed to federal district court from state court, the district court has "broad discretion" to remand the removed claim or cause of action. 28 U.S.C. § 1452(b); *see also* 28 U.S.C. § 1446(c)(4) (noting that if a court finds "that removal should not be permitted, the court shall make an order for summary remand").

The "burden of establishing federal jurisdiction is on the party seeking removal, and the removal statute is strictly construed against removal jurisdiction." *Prize Frize, Inc. v. Matrix Inc.*, 167 F.3d 1261, 1265 (9th Cir. 1999). Any doubt as to the right of removal is resolved in favor of remand. *Gaus v. Miles, Inc.*, 980 F.2d 564, 566 (9th Cir. 1992).

A defendant may remove any civil action from state court to federal district court if the district court has original jurisdiction over the matter. 28 U.S.C. § 1441(a). 28

U.S.C. § 1331 explains that "district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331.

The Supreme Court has found that a case "arises under" the Constitution in two circumstances. First, and "most often, federal jurisdiction attaches when federal law creates the cause of action asserted." *Hornish v. King Cty.*, 899 F.3d 680, 687 (9th Cir. 2018). However, even if a claim originates under state law, federal jurisdiction may still exist in "a special and small category of cases." *Id.* In this second category, a federal court may exercise jurisdiction over a state law claim if the claim "necessarily raises a stated federal issue, [that is] actually disputed and substantial" and that a federal court "may entertain without disturbing any congressionally approved balance of federal and state power." *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Manning*, 136 S. Ct. 1562, 1565 (2016) (quoting *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005)). In other words, federal jurisdiction over a state law claim exists if a "federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn v. Minton*, 568 U.S. 251, 258 (2013).

"Federal question jurisdiction lies . . . only if it appears from the face of the complaint that determination of the suit depends upon a question of federal law." *Manning*, 136 S. Ct. at 1565 (citations and punctuation omitted). "[T]he controversy must be disclosed upon the face of the complaint, *unaided by the answer or by the petition for removal*." *Pan Am. Petroleum Corp. v. Superior Court of Del.*, 366 U.S. 656, 663 (1961)

(emphasis added).

Importantly, cases "may not be removed to federal court on the basis of a federal defense." *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 393 (1987). This is true even when the federal defense is one that can be readily anticipated by the Plaintiff. *Franchise Tax Bd. of Calif. v. Construction Laborers Vacation Trust of S. Cal.*, 463 U.S. 1, 10 (1983).

IV. ANALYSIS

Only state law claims are present in this case, and it is undisputed that federal law does not create the causes of action involved. Accordingly, federal jurisdiction is proper only if the case falls into the second category mentioned above.[1] Thus, the Court asks whether the case involves a federal issue that is (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress. *Gunn*, 568 U.S. at 258. All four of these factors must exist for the Court to exercise jurisdiction. *Id.*

Plaintiffs' Amended Complaint frequently refers to the federal Food, Drug, and Cosmetic Act (FDCA). *See* Dkt. 1-4, at 5-7, 13, 17, 18, 20, 21, 22. Under the FDCA, "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." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011).

In 1984, Congress passed a related Act (the Drug Price Competition and Patent Term Restoration Act), commonly referred to as the Hatch-Waxman Amendments.

[1] In its Notice of Removal, Genus states that "complete preemption" provides another basis for removal. Dkt. 1. However, Genus has since conceded that a "federal preemption defense, alone, does not suffice for [federal] jurisdiction" in this case. Dkt. 44, at 2.

"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." *Id.* These amendments allow "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.'" *Id.* at 612-13 (quoting 21 U.S.C. § 355(j)(2)(A)(v)). This standard is often referred to as the "duty of sameness."

Additionally, an FDA regulation known as the "changes being effected" regulation ("CBE"), allows brand name drug manufacturers to update labels—without waiting for FDA preapproval—to add or strengthen a contraindication, warning, precaution, or adverse reaction. *See Wyeth v. Levine*, 555 U.S. 555, 569 (2009) (quoting 21 CFR §§ 314.70(c)(6)(iii)(A), (C)). However, "a CBE supplement is appropriate . . . only to reflect newly acquired information." 73 FR 49603.

Clearly the FDCA regime is relevant here. But the Court must ask whether the four factors discussed above are met. Based on the record before the Court, it appears Michelle Stirling never took tocolytic medications produced by brand-name manufacturers. Instead, she only took generic brand Terbutaline Sulfate. The Defendants claim that there is no Idaho state law analog to the federal duty of sameness—nor is the Court aware of any such standard. Thus, absent the federal duty of sameness, Plaintiffs would likely have no logical basis for linking the brand-name manufacturers to this case. Accordingly, the Court assumes—without deciding—that the FDCA regime was

necessarily raised.

However, the Court still finds it proper to remand this case because the federal issues involved are not substantial. "Substantial," in this context, does not mean "significant to the particular parties in the immediate suit; that will always be true when the state claim 'necessarily raise[s]' a disputed federal issue." *Gunn*, 568 U.S. at 260. Instead, "the substantiality inquiry . . . looks [] to the importance of the issue to the federal system as a whole." *Id.*

Without the duty of sameness, Plaintiffs would have a difficult time connecting their claims to the brand-name manufacturers at all. Thus, the FDCA regime is undoubtably substantial in this case under the traditional meaning of the word. However, the Court does not find the relevant federal issues substantial *to the federal system as a whole*, as required for "arising under" jurisdiction.

Based upon the Amended Complaint, it appears this dispute has less to do with the general application or interpretation of FDCA requirements, and more to do with whether research regarding the relevant tocolytic medications warranted updated labelling. While that issue is important (and involves questions about the FDCA regime), the impact and relevance of this case will largely be confined to manufacturers of specific tocolytic medications. Thus, it is less important to the federal system *as a whole*. *See Gunn*, 568 U.S. at 262 (explaining that "if [a question] does not arise frequently, it is unlikely to implicate substantial federal interests" and that a case is more likely to be substantial to the federal system as a whole when the "court's resolution of the federal question would be controlling in numerous other cases.") (citation and punctuation omitted).

Defendants disagree, and rely heavily on *Bowdrie v. Sun Pharm. Indus.*, 909 F. Supp. 2d 179 (E.D.N.Y. 2012), a non-binding decision in which a district court found that the FDCA was necessarily raised and presented substantial questions of federal law. The Court acknowledges that there are similarities between *Bowdrie* and this case. However, there are also key differences.

Bowdrie involved a brand-name manufacturer that changed its label through a CBE amendment and generic drug manufacturers that did not immediately change their labels in response. Although it is not entirely clear from the court's decision, it appears the plaintiffs claimed that, pursuant to the duty of sameness, the generic manufacturers should have immediately updated their labels to match the brand name manufacturer's label, even if the brand-name manufacturer's changes were implemented via the CBE process. This federal issue (determining whether the duty of sameness requires generic manufacturers to immediately match CBE updates made by brand name manufacturers) is arguably applicable to generic drug manufacturers nationwide, regardless of the type of drugs they manufacture. Thus, it is understandable why the *Bowdrie* court found the issue substantial to the federal system as a whole.

Here, however, the dispute appears much more confined to manufacturers of certain tocolytic medications. As noted above, the key[2] federal issue in this case appears

[2] The Court understands that there may be other disputed federal issues involved in this case. For example, Defendant Impax Laboratories, LLC (a generic drug manufacturer) has filed a Motion to Dismiss (Dkt. 28) that argues the state law claims against it are preempted by the FDCA. Whether that is true is likely a disputed federal issue that must be resolved. However, the Court finds that this (and any other potential federal issues) do not trigger federal jurisdiction in this case either because (1) the issue is not apparent from the face of the Complaint (as required by *Manning*, 136 S. Ct. at 1565); (2) the issue is raised as a federal defense, which cannot be used to confer federal jurisdiction; or (3) the issues are not substantial to the federal system as a whole. Ultimately, Defendants bear the burden of showing removal

to be whether available research warranted updated labelling for Brethine.[3] Regardless of the outcome of this case, it is unlikely to be controlling—or even impactful—in "numerous other cases," because the dispute is so specific to research regarding a certain type of medication. Accordingly, the Court finds that the federal issue in this case is not substantial to the federal system as a whole.

Finally, "[r]egarding the FDCA regime in particular, the Supreme Court has put great weight on Congress's decisions (1) not to create a federal remedy for violations of the FDCA . . . while (2) selectively declining to pre-empt most state causes of action based on FDCA standards" *Or. ex rel. Kroger v. Johnson & Johnson*, 832 F. Supp. 2d 1250, 1257 (D. Ore. 2011) (citing *Wyeth*, 555 U.S. at 574-75; *Grable*, 545 U.S. at 318)). "That is, Congress has affirmatively decided to keep such actions out of federal courts while tolerating overlapping regulation and litigation in state forums. All of this strongly

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was proper, and here, the Court finds that burden has not been met. Rather than seeking to conceive of every possible federal issue that may manifest itself in this case, the Court's analysis is centered on the primary federal issue the parties address in their briefing for this Motion to Remand, and that is readily apparent from the face of the Complaint.

[3] In its Notice of Removal, Genus explains that the FDA rejected a petition to add warnings similar to those that Plaintiffs allege should have been included on Brethine's labelling. This fact could arguably present a substantial federal issue under different circumstances, because the outcome of such a case could have implications for drug manufactures nationwide (i.e. whether brand-name manufacturers should still update their labelling even if the FDA denies such a petition). This fact does not warrant federal jurisdiction in this case, however, because Genus states that the FDA received this petition in June 2008—months after B.S. was born. Accordingly, the FDA's denial of this petition—while likely relevant to this case in some manner—does not require a determination of whether labelling changes should still be made even if the FDA denies a petition to add warnings. Instead, Plaintiffs argue that—in light of available research—the brand-name manufacturers should have utilized a CBE supplement to update their labels long before June 2008. Additionally, even if the facts of this case did require a determination of the above question, this potential federal issue becomes clear only upon reading Genus' Notice of Removal. As noted above, "[f]ederal question jurisdiction lies . . . only if it appears from the face of the complaint that determination of the suit depends upon a question of federal law," *Manning*, 136 S. Ct. at 1565, "unaided by the answer or by the petition for removal." *Pan Am. Petroleum Corp.*, 366 U.S. at 663.

suggests there is no need in drug-related consumer protection cases for the 'experience, solicitude, and hope of uniformity that a federal forum offers.'" *Kroger*, 832 F. Supp 2d, at 1257 (quoting *Grable*, 545 U.S. at 312). "Within the context of the FDCA regime in particular, the Supreme Court has therefore concluded 'that the presence of a claimed violation of the [FDCA] statute as an element of a state cause of action is insufficiently 'substantial' to confer federal-question jurisdiction.'" *Kroger*, 832 F. Supp 2d, at 1257. (quoting *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 814 (1986)).[4]

Simply put, without a more persuasive showing by Defendants, the Court must remand. Any doubt as to the right of removal is resolved in favor of remand, *see Gaus*, 980 F.2d at 566, and here, doubt still lingers over whether federal jurisdiction exists. As such, the Court GRANTS Plaintiffs' Motion (Dkt. 30) and REMANDS this action back to state court.

V. ORDER

The Court HEREBY ORDERS:

1. Plaintiffs' Motion to Remand (Dkt. 30) is **GRANTED**.
2. This case is **REMANDED** back to the Fourth Judicial District of the State of Idaho.

[4] The Court does not mean to imply that a claimed violation of the FDCA as an element of a state cause of action could never involve a federal issue substantial enough to confer federal-question jurisdiction. The Court's discussion of the *Bowdrie* case shows that the Court does not interpret *Merrell Dow* in this manner. In *Merrell Dow*, the Supreme Court recognized the need for "principled, pragmatic distinctions" and "careful judgments about the exercise of federal judicial power in an area of uncertain jurisdiction." 478 U.S. at 814 (citing *Franchise Tax Bd.*, 463 U.S. at 20-21). Here, the Court simply seeks to do as the Supreme Court directs—make a careful judgment about the exercise of federal judicial power. In doing so, the Court finds that the federal issues in this case are not sufficiently substantial to warrant federal jurisdiction.

3. All other motions currently pending in this case (Dkt. 7; Dkt. 19; Dkt. 28) are **DISMISSED** as **MOOT**.

DATED: March 25, 2019

David C. Nye
Chief U.S. District Court Judge