IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF ILLINOIS
SPRINGFIELD DIVISION

ROBBY MOHR, as Administrator of Estate of Jolee Mohr,	)	
Plaintiff,	)	
v.	)	NO. 09-3170
TARGETED GENETICS, INC., ABBOTT LABORATORIES, INC., and WESTERN INSTITUTIONAL REVIEW BOARD, INC.,	)	
Defendants.	)	

OPINION

RICHARD MILLS, U.S. District Judge:

In sum: motion to dismiss denied; motion to remand allowed.

But first, the background.

ABBOTT'S MOTION TO DISMISS

I. INTRODUCTION

The Plaintiff's amended complaint purports to state two counts against Defendant Abbott Laboratories, Inc., strict products liability in

Count III and wrongful death in Count IV.[1]

The Plaintiff filed his initial complaint in the Circuit Court of Christian County, Illinois. Abbott, with the consent of the other Defendants, removed this case from state court on July 2, 2009. On August 13, 2009, Abbott moved to dismiss the Plaintiff's original complaint. That motion was granted. On December 14, 2009, the Plaintiff filed his first amended complaint, which Abbott now moves to dismiss.

Abbott contends that the complaint should be dismissed for three separate reasons: (1) the claims do not allege facts establishing a plausible claim for relief under the Ashcroft v. Iqbal[2] pleading standard; (2) the claims should be dismissed under the "learned intermediary" doctrine because the FDA-approved labels for Humira specifically warn of the risk of histoplasmosis and the risks from the concomitant use of Humira with other immunosuppressive therapies–the risks complained of in the amended

[1]Counts III and Count IV are also asserted against Targeted Genetics, Inc.. Count I is a survival action for negligence against Targeted Genetics and Western Industrial Review Board, Inc. Count II is for wrongful death against Targeted Genetics and Western Industrial Review Board.

[2]See Ashcroft v. Iqbal, __ U.S. __, 129 S. Ct. 1937 (2009)

complaint; and (3) the claims against Abbott should be dismissed under Illinois Supreme Court Rule 103(b) for failure to exercise reasonable diligence in effecting service of process because the Plaintiff delayed service for nearly one year after filing the complaint.

II. FACTS

The Plaintiff notes that the basic factual claims alleged against Abbott are as follows:

a. For seven years preceding her death, Jolee Mohr was treated for rheumatoid arthritis which was under control with various established treatments and drugs. (Amended Complaint at ¶ 6).

b. Ms. Mohr was treating with Humira for a period of time preceding her death as prescribed by her treating physician, Dr. Robert Trapp of Springfield, Illinois. (Amended Complaint at ¶¶ 7, 9).

c. Ms. Mohr's treating physician recommended that she enroll in the experiment involving a genetically modified virus containing a TNF inhibitor. (Amended Complaint at ¶¶ 10-11).

d. Patients on TNF inhibitors such as Humira should not be

placed on other TNF inhibitors. (Amended Complaint at ¶ 12).

e. On July 2, 2007, after receiving her second course of the experimental drug, Ms. Mohr experienced acute adverse symptoms consistent with the known adverse effects of TNF blockers, which escalated at an alarming rate until her death on July 24, 2007. Ms. Mohr died as a direct result of her participation in the experiment, or as a result of the experimental drug combined with prior intake of Humira. (Amended Complaint at ¶¶ 29-39).

f. Humira's label at the time failed to warn physicians of the serious risk of histoplasmosis; rather, the warnings section of the package insert solely mentioned the risk of infection, as follows:

> SERIOUS INFECTIONS, SEPSIS, TUBERCULOSIS AND RARE CASES OF OPPORTUNISTIC INFECTIONS, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF TNF BLOCKING AGENTS INCLUDING HUMIRA. MANY OF THE SERIOUS INFECTIONS HAVE OCCURRED IN PATIENTS ON CONCOMITANT IMMUNOSUPPRESSIVE THERAPY THAT, IN ADDITION TO THEIR RHEUMATOID ARTHRITIS, COULD PREDISPOSE THEM TO INFECTIONS.

(Amended Complaint at ¶ 41).

g. On September 4, 2008, in response to a number of deaths involving histoplasmosis in patients treating with TNF blockers, the FDA ordered Abbott to incorporate stronger warnings into Humira's label, in addition to the mandated black box warning regarding infection risk already in place, advising of the risk of fungal infections and histoplasmosis in particular. (Amended Complaint at ¶ 42).

Humira's label at the time Ms. Mohr took the drug did mention histoplasmosis, which the Plaintiff alleges is a potentially deadly fungal infection and a known adverse reaction to TNF blockers, such as Humira.[3] The label, which is attached to the Amended Complaint,[4] states in relevant part:

> PHYSICIANS SHOULD EXERCISE CAUTION WHEN CONSIDERING THE USE OF HUMIRA IN PATIENTS WITH A HISTORY OF RECURRENT INFECTION OR UNDERLYING CONDITIONS WHICH MAY PREDISPOSE THEM TO INFECTIONS, OR PATIENTS WHO HAVE

[3]The parties state that histoplasmosis is found mostly in Midwestern and Southeastern states and along the Ohio and Mississippi River Valleys.

[4]Documents which are attached to the complaint become part of the pleading and may be considered on a motion to dismiss under Rule 12(b)(6). See Int'l Marketing Ltd. v. Archer-Daniels-Midland Co., 192 F.3d 724, 729 (7th Cir. 1999) (citing Fed. R. Civ. P. 10(c)).

> RESIDED IN REGIONS WHERE TUBERCULOSIS AND HISTOPLASMOSIS ARE ENDEMIC.

(Amended Complaint, Ex. C at 13). The label included other warnings about infections:

> TUBERCULOSIS (FREQUENTLY DISSEMINATED OR EXTRAPULMONARY AT CLINICAL PRESENTATION), INVASIVE FUNGAL INFECTIONS, AND OTHER OPPORTUNISTIC INFECTIONS, HAVE BEEN OBSERVED IN PATIENTS RECEIVING HUMIRA. SOME OF THESE INFECTIONS HAVE BEEN FATAL.
>
> . . . .
>
> Some cases of opportunistic infections and tuberculosis have been fatal (see WARNINGS). In postmarketing experience, infections have been observed with various pathogens including viral, bacterial, fungal, and protozoal organisms. Infections have been noted in all organ systems and have been reported in patients receiving HUMIRA alone or in combination with immunosuppressive agents.
>
> . . . .
>
> Serious infections, including tuberculosis, have occurred in patients receiving HUMIRA. Some patients have died as a result of these infections. . . . HUMIRA can block the damage that too much TNF-alpha can cause, and it can also lower your body's ability to fight infections. Taking HUMIRA can make you more prone to getting infections or make any infection you have worse.

. . . .

> **Tell your doctor if you have or have had any of the following:** Any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from HUMIRA. If you are unsure, please ask your doctor.
>
> . . . .
>
> There have been rare cases where patients taking HUMIRA or other TNF-blocking agents have developed serious infections, including tuberculosis (TB) and infections caused by bacteria or fungi. Some patients have died when the bacteria that cause infections have spread throughout their body (sepsis).

(Amended Complaint Ex. C at 1, 18, 25, 26).

The Plaintiff alleges that dismissal is inappropriate, even under the heightened pleading standard. Sufficient facts have been alleged to establish plausible claims of negligence and wrongful death. The Plaintiff further contends that Abbott has failed to provide support for the other reasons it has advanced for dismissal.

III. ANALYSIS

A. Legal standard

In reviewing a motion to dismiss under Rule 12(b)(6), courts must

accept as true the facts alleged in the complaint, drawing all reasonable inferences in the plaintiff's favor. See Rodriguez v. Plymouth Ambulance Service, 577 F.3d 816, 820 (7th Cir. 2009). "The Supreme Court has stated that to survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Id. at 821 (internal quotations omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. The plausibility requirement does not equate to a "probability requirement," but it requires "more than a sheer possibility that a defendant has acted unlawfully." See Ashcroft v. Iqbal, __ U.S. __, 129 S. Ct. 1937, 1949 (2009). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. (internal quotation marks and citations omitted).

"A formulaic recitation" of the claim's elements is not enough to withstand a motion to dismiss. Reger Development, LLC v. National City

Bank, 592 F.3d 759, 764 (7th Cir. 2010) (internal quotations omitted). "[A]s the Court said in Iqbal, determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Cooney v. Rossiter, 583 F.3d 967, 971 (7th Cir. 2009) (internal quotation marks and citations omitted).

B. Sufficiency of allegations

Abbott alleges that, as in the original complaint, the Plaintiff simply recites the "magic words" of a strict liability claim:

a. selling a product it knew or should have known was in a defective condition by failing to adequately warn of the risk of histoplasmosis or the risks associated with taking Humira in conjunction with other TNF blockers;
b. selling a product which it knew or should have known was unreasonably dangerous to the user by failing to adequately warn of the risk of histoplasmosis or the risks associated with taking Humira in conjunction with other TNF blockers;
c. selling a product which it knew or should have known was not safe because of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;
d. supplying warnings with the product that it knew or should have known were inadequate by failing to adequately warn of the risk of histoplasmosis or the risks associated with taking Humira in conjunction with other TNF blockers;

e. providing instructions to be followed with regard to the prescribing of this product that it knew or should have known were not accurate and truthful;
f. failing to warn users of the dangers inherent in using this product by failing to adequately warn of the risk of histoplasmosis or the risks associated with taking Humira in connection with other TNF blockers;
g. selling a product wherein it was foreseeable that someone would be injured upon ingesting the medication in question because of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;
h. selling a product which it knew or should have known was not safe for its intended use because of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;
i. selling a product which it knew or should have known was lacking of one or more elements necessary to make it safe for its intended use because of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;
j. manufacturing a product which it knew or should have known was defective and which could cause injury to the user because of the known risk of histoplasmosis and/or the risks of taking Humira in conjunction with other TNF blockers;
k. designing a product which it knew or should have known was defective and which could cause injury to the user because of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;
l. distributing a product which it knew or should have known was defective and which could cause injury to the user because of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;
m. failing to see that ultimate users were advised of the dangers of said product by failing to warn of the known risk of

histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;

n. failing to exercise reasonable care in the design of this product by failing to warn of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;

o. failing to exercise reasonable care in the marketing of this product by failing to warn of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;

p. failing to adequately and properly test said product;

q. failing to use reasonable care under the circumstances by failing to adequately warn of the risk of histoplasmosis or the risks associated with taking Humira in conjunction with other TNF blockers;

r. delivering a product which it knew or should have known was defective and could cause injury to the user by failing to adequately warn of the risk of histoplasmosis or the risks associated with taking Humira in conjunction with other TNF blockers;

s. producing a product which it knew or should have known was defective and could cause injury to the user by failing to adequately warn of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;

t. producing a product with component parts that defendant knew or should have known increased the risk of harm to the user;

u. supplying a product which it knew or should have known was defective and could cause injury to the user by failing to adequately warn of the known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers;

v. violating applicable sections of the Restatement of Torts, 2d; and

w. engaging in other acts regarding the manufacturing, designing, preparing, producing, distributing, advising and selling of Humira as will be learned in discovery.

(Amended Complaint at ¶ 57). Abbott asserts that simply tacking on the phrase "known risk of histoplasmosis and/or the risks associated with taking Humira in conjunction with other TNF blockers" at the end of each conclusory allegation does not transform this "laundry list" of elements into "specific facts" necessary to satisfy the Iqbal standard.

(2)

It is true that many of the allegations directed against Abbott do consist primarily of formulaic recitations. In order to assert a strict liability claim based on a failure to warn, the plaintiff must allege "that defendant knew or should have known of the danger and this is tested on knowledge existing at the time of production." Smith v. Eli Lilly & Co., 137 Ill.2d 222, 266 (1990). Conditions of a person's mind, like knowledge, may be alleged generally, see Fed. R. Civ. P. 9(b), but a plaintiff must still assert a plausible grievance. See Burks v. Raemisch, 555 F.3d 592, 594 (7th Cir. 2009).

Abbott notes that the Amended Complaint does not allege facts establishing that it should have known from February to July of 2007, when Ms. Mohr was taking Humira, of the need for additional warnings. The Plaintiff alleges only that "on September 4, 2008, in response to a number of deaths involving histoplasmosis in patients treat[ed] with TNF blockers," the FDA ordered manufacturers of TNF-inhibitors to incorporate identical warnings "in addition to the mandated black box warning regarding infection risk already in place, advising of the risk of fungal infections and histoplasmosis in particular." (Amended Complaint at ¶ 42). Abbott states that it is not plausible that it could have known of the data upon which the FDA based its September 2008 determination before it existed.

The Plaintiff does not indicate how many deaths there were or when they occurred, in relation to Ms. Mohr's death. Thus, the complaint does not specify whether the facts establishing the data on which the FDA based its September 2008 determination to further highlight the warnings was known or knowable to Abbott fourteen months earlier during Ms. Mohr's participation in the clinical trial. This is information that likely would be

difficult for a plaintiff to obtain prior to discovery. The information exchanged during discovery may establish that the warnings were sufficient, based on what was known to Abbott at the time.

Based on a liberal reading of the Amended Complaint, however, the Court finds that Plaintiff has alleged just enough regarding Abbott's knowledge of the dangers of taking Humira to assert a plausible grievance, even under the heightened pleading standard. The Court concludes at this stage that these general allegations are sufficient to allege knowledge.

(3)

A plaintiff asserting a strict liability failure-to-warn claim must also establish causation. See Smith, 137 Ill.2d at 266. Abbott contends that Plaintiff alleges no facts establishing that the alleged failure-to-warn proximately caused the Plaintiff's injury. The Plaintiff alleges only, "Had Ms. Mohr been aware of the risk of histoplasmosis, she would have constantly monitored herself for signs of infection." (Amended Complaint at ¶ 55). The Plaintiff does not allege that Ms. Mohr would not have taken Humira, or that the monitoring would have prevented her injuries.

As Abbott contends, because the case involves prescription drugs, the critical causation element is what Ms. Mohr's physician, not Ms. Mohr, would have done differently with a different warning. See Kirk v. Michael Reese Hosp. & Medical Center, 117 Ill.2d 507, 519 (1987) (observing that because warnings related to drugs are generally communicated through package inserts, the learned intermediary doctrine applies and prescription drug manufacturers have no duty to directly warn patients). It is difficult to know, prior to discovery, whether Ms. Mohr's physician would have prescribed Humira if there were additional warnings. The causation element will be addressed in the Court's discussion pertaining to the learned intermediary doctrine.

C. Learned intermediary doctrine

(1)

Abbott asserts that Plaintiff's failure-to-warn claims should be dismissed under the learned intermediary doctrine because the FDA-approved labels for Humira specifically warned of the very risks complained-of in this case: (1) histoplasmosis; and (2) the concomitant use of Humira

with other immunosuppressants. At first glance, it appears that the labels warned of those risks. The Plaintiff contends, however, that the warnings were not sufficient based on the information known to Abbott at the time. In its reply brief, Abbott emphasizes that the label specifically warned physicians of the risk of histoplasmosis and other fungal infections, including fatalities.

Under the learned intermediary doctrine, "manufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients." Happel v. Wal-Mart Stores, Inc., 199 Ill.2d 179, 190-91 (2002) (quoting Kirk, 117 Ill.2d at 517). The court explained the rationale for the rule:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, and individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs

> are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Kirk, 117 Ill.2d at 518 (citations omitted).

"A corollary of that doctrine is the principle that a prescription medical device manufacturer need not provide a warning of risks already known to the medical community." Hansen v. Baxter Healthcare Corp., 198 Ill.2d 420, 430 (2002).

The Plaintiff contends that Abbott did not adequately warn physicians of the risk of histoplasmosis or the adverse reactions associated with concomitant use of Humira and other TNF blockers. Consequently, Dr. Trapp would not qualify as a learned intermediary. The Plaintiff alleges, moreover, that it is unclear whether any warnings were, in fact, communicated to Ms. Mohr by Dr. Trapp. Assuming the warnings were adequate, however, Abbott would not be responsible for the physician's failure to communicate them to the patient.

Citing Bautista v. Verson Allsteel Press Co., 152 Ill. App.3d 524 (1st Dist. 1987), the Plaintiff alleges that the adequacy of a particular warning is an issue to be resolved by a jury. See id. at 530-31. Bautista did not deal

with prescription drugs and the learned intermediary doctrine. It was a products liability action dealing with a machine that was alleged to be unreasonably dangerous. See id. The court in Bautista was reviewing a jury verdict. See id. at 531. The Court is not persuaded that Baustista stands for the proposition that a plaintiff is always entitled to a jury trial by simply disputing that the warnings were adequate. In this case, however, based solely on the allegations contained in the amended complaint, there appears to be a factual dispute as to the adequacy of the warnings and whether they informed the medical community of all risks known at the time.

The Plaintiff states that although Abbott refers to Humira's "FDA-approved label" and package insert, the label solely warns physicians of the risk of serious infections without any mention of the risk of histoplasmosis while taking Humira. The year after Ms. Mohr's death, the FDA found the warnings contained on TNF blockers, such as Humira, inadequate due to the failure to sufficiently warn of the risk of histoplasmosis. The FDA required the manufacturers of TNF blockers to include additional warnings regarding the risk of fungal infections and histoplasmosis in particular. The

Plaintiff notes that the only reference to histoplasmosis in the package insert warns physicians to exercise caution in considering the use of Humira in patients who have resided in regions where tuberculosis and histoplasmosis are endemic. According to the Plaintiff, that warning was not sufficient.

The Plaintiff further asserts that although the package insert warns that "You should not take HUMIRA with other TNF blockers," it does not provide any warning whatsoever regarding the risks associated with taking Humira in conjunction with other TNF blockers. According to the Plaintiff, moreover, the fact that Dr. Trapp saw fit to recommend that Ms. Mohr enroll in the clinic and the fact that he did not identify her symptoms as being associated with an adverse drug event, let alone histoplasmosis, also speaks to the inadequacy of Abbott's warnings.

Based on the foregoing, the Plaintiff contends that Dr. Trapp does not qualify as a learned intermediary because Abbott had not informed him of the material information necessary to save Ms. Mohr's life. The Plaintiff asserts that Abbott's motion, before fact discovery, is woefully premature.

(2)

In its Reply brief, Abbott highlights where the relevant warnings were contained on its label. Under "WARNING" and "RISK OF INFECTIONS," the label refers to "INVASIVE FUNGAL INFECTIONS, AND OTHER OPPORTUNISTIC INFECTIONS." It further warns that some infections have been "FATAL."

Under "WARNINGS" and "Serious Infections," the label indicates that "SERIOUS INFECTIONS . . . AND RARE OPPORTUNISTIC INFECTIONS, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH THE USE OF TNF BLOCKING AGENTS INCLUDING HUMIRA." The label goes on to warn physicians to "EXERCISE CAUTION WHEN CONSIDERING THE USE OF HUMIRA IN PATIENTS . . . WHO HAVE RESIDED IN REGIONS WHERE . . . HISTOPLASMOSIS [IS] ENDEMIC." The label further provides, "Some cases of opportunistic infections and tuberculosis have been fatal" and states that "[s]ome patients have died when the bacteria that cause infections have spread throughout their body (sepsis)."

Abbott disputes the Plaintiff's assertion that the package insert did not

warn of any of the "risks associated with taking Humira in conjunction with other TNF blockers." The label specifically provides that the **"INFECTIONS"** have included **"FATALITIES"** and that **"MANY OF THE SERIOUS INFECTIONS HAVE OCCURRED IN PATIENTS ON CONCOMITANT IMMUNOSUPPRESSIVE THERAPY."** The label also states, "Some cases of opportunistic infections . . . have been fatal." Moreover, infections "have been reported in patients receiving HUMIRA alone or in combination with immunosuppressive agents."

Citing Perkins v. Silverstein, 939 F.2d 463 (7th Cir. 1991), Abbott asserts that the Plaintiff cannot rely on these "inaccurate" allegations to survive dismissal. In assessing the sufficiency of the complaint, a court "must rely on the exhibits whenever the allegations of the complaint are materially inconsistent with those exhibits." Id. at 469 n.4. Relying on the Humira label which was attached as an exhibit to the Amended Complaint, Abbott contends that Plaintiff has failed to assert a "plausible" theory under Iqbal establishing that the warnings were not adequate.

At first glance, the Plaintiff's allegations do appear to be inconsistent

with the warnings that were included on the Humira label. The label warned physicians about the possibility of fungal infections. It stated that there had been fatalities. The label referred to histoplasmosis.[5] It warned of the potential for serious infections if a patient takes the drug while on concomitant immunosuppressive therapy.

Although this is a very close issue, the Court at this stage of the litigation is unable to conclude that the learned intermediary doctrine applies to bar the Plaintiff's claims. It is not yet apparent when Abbott learned of the information that prompted the FDA to require additional warnings regarding the risk of fungal infections and histoplasmosis. It may be that the package insert, which warned about fungal infections and, at least generally, histoplasmosis, was sufficient based on the information Abbott had at the time and dismissal is thus appropriate.

When the complaint's allegations are accepted as true, however, the

[5]The Plaintiff suggests that the warning is not adequate because physicians are warned only to exercise caution in considering the use of Humira in patients who have resided in regions where histoplasmosis is endemic. Although the warning could have been more clear, the Court observes that physicians constitute a fairly sophisticated audience. Consequently, it is at least arguable that the warning adequately conveys to physicians that Humira probably should not be prescribed for someone who suffers from histoplasmosis.

Court finds that Plaintiff has alleged enough facts to assert a plausible claim. Presumably, the discovery process will yield information as to the timing issue.[6] Until then, the Court cannot determine whether the warnings provided adequate information to physicians about the known or knowable risks of Humira. The Court will Deny Abbott's motion to dismiss as to causation.

D. Illinois Supreme Court Rule 103(b)

Illinois Supreme Court 103(b) provides that the plaintiff must be reasonably diligent in effecting service of process. Rule 103(b) provides, in relevant part, "If the plaintiff fails to exercise reasonable diligence to obtain service on a defendant prior to the expiration of the applicable statute of limitations, the action as to that defendant may be dismissed without

[6]Citing Iqbal, Abbott suggests that Plaintiff has not asserted enough facts to be entitled to discovery. 129 S. Ct. at 1953 ("We have held . . . that the question presented by a motion to dismiss a complaint for insufficient pleadings does not turn on the controls placed upon the discovery process"). However, a plaintiff cannot be expected to allege facts of which–through no fault of its own--it is not yet aware. Moreover, the Court must still draw all reasonable inferences in the Plaintiff's favor. See Rodriguez, 577 F.3d at 820. Based on the number of deaths involving histoplasmosis in patients who were using TNF blockers, it may be reasonable to infer that stronger warnings should have been incorporated into Humira's label before the FDA ordered such warnings in September 2008.

prejudice."

According to the Plaintiff, the ten-month delay between filing the complaint and effecting service of process on Abbott is because the Plaintiff wanted to wait until the United States Supreme Court rendered its decision in Wyeth v. Levine, 129 S. Ct. 1187 (2008), which the Plaintiff claimed "had the potential to dispose of this case." The Plaintiff alleges that he determined that judicial economy and the parties' interests would best be served by postponing service of the complaint until the Supreme Court rendered its decision. The decision was rendered on March 4, 2009. The Plaintiff notes that the Court in Wyeth rejected both of the drug manufacturer's preemption arguments. See Wyeth, 129 S. Ct. at 1196-98, 1204. On May 21, 2009, the Plaintiff sought to have the complaint served on Abbott, within the statute of limitations for the Plaintiff's claims.

Abbott does not dispute that Wyeth had the potential to dispose of this action. In such a case, waiting to effect service until the Supreme Court rendered a decision would seem like a good idea, as long as the delay did not implicate the statute of limitations. Citing Lewis v. Dillon, 352 Ill. App.3d

512 (1st Dist. 2004), Abbott asserts that Plaintiff's explanation does not qualify as "special circumstances" that might excuse the delay. In Lewis, the plaintiff waited to obtain the required health professional's report before serving the defendants and the statute of limitations ran in the period of time after the plaintiff filed the complaint and before plaintiff served the defendants. See id. at 514. Accordingly, the court affirmed the trial court's dismissal. See id. Because of the significantly different factual scenario, Lewis does not support Abbott's argument.

In this case, the Plaintiff's stated reason for the delay in effecting service is a reasonable explanation. Although the other Rule 103(b) factors may not favor the Plaintiff, the "special circumstances" present in this case tend to override those factors.[7] The Court declines to dismiss a case in which service was effected within the relevant statute of limitations.

For the foregoing reasons, the Court will DENY Abbott's motion to

[7]Other factors that courts may examine include: (1) the length of time used in serving the defendant; (2) the plaintiff's activities; (3) whether the plaintiff is aware of the defendant's location; (4) whether the defendant's location could be easily ascertained; (5) actual knowledge of the complaint on the part of the defendant; and (6) actual service on the defendant. See Segal v. Sacco, 136 Ill.2d 282, 287 (1990).

dismiss.

PLAINTIFF'S MOTION TO REMAND

I. FACTUAL BACKGROUND

The Plaintiff has moved to remand this action to the to the Circuit Court of the Fourth Judicial District in Christian County, Illinois. Abbott's Notice of Removal asserts that there is diversity of citizenship and that the matter in controversy exceeds the value of $75,000 and, in the alternative, the claims in the complaint raise a federal question. Abbott claims that the Court retains jurisdiction over the subject matter pursuant to 28 U.S.C. §§ 1331 & 1332. The Plaintiff, an Illinois citizen, disputes that diversity of citizenship exists based on the inclusion of Abbott, a domestic Defendant and an alleged indispensable party to this matter.

The Plaintiff notes that his claims arise out of his wife's use of the drug Humira and her participation in a clinical trial sponsored by Targeted Genetics ("TG") called "A Phase ½ Study of Repeat Intra-Articular Administration of tgAAC94, a Recombinant Adeno-Associated Vector Containing the TNFR:Fc Fusion Gene, an Inflammatory Arthritis Subjects

with and without Concurrent TNF-alpha Antagonists" ("the experiment"). The experiment involved gene transfer in which subjects were injected with millions of particles of tgAAC94, a genetically modified virus called "adeno-associated virus" containing Enbrel gene. Enbrel is also a TNF inhibitor. TgAAC94 was designed and manufactured by TG. The Plaintiff states that patients on a TNF inhibitor such as Humira should not be placed on any other TNF inhibitor such as Enbrel. The experiment was a double blink, placebo-controlled, multicenter study sponsored and designed by TG.

The Plaintiff alleges that TG contacted Defendant Western Institutional Review Board ("WIRB") to serve as the federally required institutional review board. TG and WIRB designated and approved Dr. Trapp to serve as Principal Investigator for the experiment conducted at his site, The Arthritis Center. The Protocol which governed the experiment, however, was designed and approved by TG and WIRB. Because the experiment involved gene transfer, it had originally been presented to the Recombinant DNA Activities Committee ("RAC"), a federal advisory committee established by the National Institute of Health.

The Plaintiff further alleges that TG and WIRB, against the recommendations of RAC, assigned Dr. Trapp the role of Principal Investigator and encouraged him to recruit and induce his longtime patients, such as Ms Mohr, into enrolling in the experiment and convincing them it was in their best therapeutic interest to do so. During the recruitment process, Dr. Trapp represented to Ms. Mohr that the experiment was what he called "gene therapy," a phrase which by itself denotes that it is therapeutic and beneficial. In fact, "gene therapy" is a purely experimental procedure which, despite its promise, has been proved neither safe nor effective for any human disease or ailment. The Plaintiff asserts that Ms. Mohr agreed to participate after being induced by various misrepresentations and falsehoods and believing that enrolling in the experiment was in her best therapeutic interest.

The Plaintiff alleges that the experiment was unethical because it presented significant risk to Ms. Mohr with no benefit whatsoever. Ms. Mohr would never have agreed to participate in the experiment had she known it presented a risk of death, even if it offered a potential cure for her

mild rheumatoid arthritis. Dr. Trapp injected her on two separate occasions as part of the protocol designed and controlled by TG and WIRB. The first time, on February 26, 2007, Ms. Mohr suffered no ill effects nor did she discern any benefit. Almost immediately after her second injection, on July 2, 2007, Ms. Mohr began to experience nausea and pain; by the next afternoon, she started vomiting and her temperature rose to 101 degrees. Although another patient injected by Dr. Trapp with the virus experienced the same acute symptoms after an injection, Dr. Trapp did not identify Ms. Mohr's reaction as being linked to the experiment and neither the FDA nor WIRB were notified of an adverse event.

The Plaintiff alleges that Ms. Mohr's condition continued to deteriorate, though Dr. Trapp still did not report the event to the FDA or WIRB. By July 9, 2007, physicians at St. John's Hospital in Springfield noted that her liver enzymes were elevated and that she had an elevated white blood count. By July 18, Ms. Mohr was critically ill. Though conscious, she was suffering from liver and kidney failure, loss of blood, and sepsis. She was transferred to the University of Chicago Hospital as a

potential liver and kidney transplant. By the time she arrived, all of Ms. Mohr's organs were failing; she was suffering from a severe internal hematoma. Her body was full of infection, while her immune system seemingly was ceasing to function.

The Plaintiff further alleges that, when the doctors at the University of Chicago learned Ms. Mohr had received gene transfer, they immediately suspected a connection between her condition and her participation in the experiment. On July 19, 2007, the physicians informed the FDA of a serious adverse event connected to a gene transfer trial. The following day, TG informed the FDA that Ms Mohr's critical condition was "possibly related" to the trial it was conducting at The Arthritis Center in Springfield. The night of July 22, 2007 was the last time that she was conscious. The Plaintiff asserts that on July 24, 2007, Ms. Mohr died as a direct and proximate result of her participation in the experiment, or as a result of the experimental drug combined with prior intake of Humira.

The Plaintiff further alleges that TG and WIRB were charged with the professional responsibility of conducting an ethical experiment in which the

risks did not greatly exceed the benefits, of determining the universe of harm through proper preclinical animal studies, of properly conducting the informed consent process, of rendering proper care and treatment to Ms. Mohr, of properly and carefully examining her in order to determine her condition and eligibility for the experiment, of properly and carefully designing and administering the experiment's protocol in a careful and prudent fashion, and of assuring that proper care and attention were provided during all periods of time during which she remained under the Defendants' care and treatment. The Plaintiff asserts that TG designed and manufactured the virus vector and Abbott manufactured, distributed and sold Humira, both of which Ms. Mohr took before her death and, as a direct and proximate result of TG and Abbott's negligence, Ms. Mohr was caused to sustain serious and excruciating personal injuries which ultimately led to her death.

The Plaintiff claims that remand to state court is appropriate as fraudulent joinder is not met when the Plaintiff has a viable cause of action against a resident Defendant. Moreover, Abbott's claim that there are

federal issues is unfounded under prevailing law.

II. ANALYSIS

A. Fraudulent joinder and diversity jurisdiction

The "fraudulent joinder" doctrine allows a district court considering removal "to disregard, for jurisdictional purposes, the citizenship of certain nondiverse defendants, assume jurisdiction over a case, dismiss the nondiverse defendants, and thereby retain jurisdiction." Schur v. L.A. Weight Loss Centers, Inc., 577 F.3d 752, 763 (7th Cir. 2009). The term "fraudulent joinder" is something of a misnomer, in that it requires neither fraud nor joinder. See id. at 763 n.9. The doctrine is often invoked when a plaintiff brings a claim against a nondiverse defendant "that simply has no chance of success, whatever the plaintiff's motives." Id.

Abbott's argument that there is diversity jurisdiction between the Plaintiff, an Illinois citizen, and TG and WIRB, Washington citizens, because the Plaintiff fraudulently joined Abbott in the complaint can be quickly addressed. In considering Abbott's motion to dismiss, the Court concluded that it was premature to dismiss the claims asserted against

Abbott. The Court cannot determine, prior to discovery, that Plaintiff is unable to establish a cause of action against Abbott. Accordingly, this action includes a Plaintiff who is an Illinois citizen and, at least at this stage of the litigation, a Defendant that is an Illinois citizen. The Court declines to hold that there is diversity jurisdiction because a citizen Defendant was fraudulently joined.

Having determined that diversity of citizenship jurisdiction is lacking, the Court will now consider whether there is federal question jurisdiction or whether the action must be remanded.

B. Federal question jurisdiction

(1)

The Plaintiff contends that removal was not appropriate because the complaint does not raise any substantial federal questions. The United States Supreme Court has long recognized that in certain cases, "federal-question jurisdiction will lie over state-law claims that implicate significant federal issues." Grable & Sons Metal Products, Inc. v. Darue Engineering & Manufacturing, 545 U.S. 308, 312 (2005) (citing Hopkins v. Walker,

244 U.S. 486, 490-91 (1917)); see also International Union Pacific of Operating Engineers, Local 150 AFL-CIO v. Ward, 563 F.3d 276, 282 n.5 (7th Cir. 2009) ("In certain situations . . . a state law cause of action may also raise a federal question sufficient to permit federal court jurisdiction"). The doctrine is based on the idea that federal courts should be able to hear state law claims that turn on substantial questions of federal law. See Grable & Sons, 545 U.S. at 312. "[F]ederal jurisdiction demands not only a contested federal issue, but a substantial one, indicating a serious federal interest in claiming the advantages thought to be inherent in a federal forum." Id. at 313. However, courts should avoid "upsetting the state-federal line drawn (or at least assumed) by Congress." Id. at 314.

Based on the above considerations, the Court for many years avoided announcing a particular test for jurisdiction when federal issues are embedded in state-law claims if diversity was lacking. Grable & Sons, 545 U.S. at 314. "[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of

federal and state judicial responsibilities." Id. Although the Seventh Circuit observed that "[a] private right of action is not a component of subject-matter jurisdiction," Bertrand ex rel. Bertrand v. Maram, 495 F.3d 452, 458 (7th Cir. 2007), the Supreme Court stated that the absence of such an action constitutes "evidence relevant to, but not dispositive of, the sensitive judgments about congressional intent that § 1331 requires." See Grable & Sons, 545 U.S. at 318 (internal quotation marks omitted).

"That some standards of care used in tort litigation come from federal law does not make the tort claim one 'arising under' federal law." Bennett v. Southwest Airlines Co., 484 F.3d 907, 912 (7th Cir. 2007) (citations omitted). For example, the fact that many aspects of air travel are nationally regulated does not mean that a tort claim following a plane crash "arises under" federal law. See id.

Abbott alleges that a complex federal statutory and administrative scheme under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), and the Public Health Service Act, 42 U.S.C. § 201 et seq. ("PHSA"), regulates clinical trials for investigational gene-therapy

agents. Consequently, it contends that the Court has subject matter jurisdiction.

(2)

In contending that the test is met for federal jurisdiction, Abbott notes that pursuant to the FDCA, the FDA is the "expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective." Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934. The FDCA and its implementing regulations direct the FDA to "make[] approval decisions based not on an abstract estimation of [a drug's] safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits." Id.

Abbott further asserts that applicants must submit, among other things, "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use." 21 U.S.C. § 355(b)(1). The formal approval process begins with the manufacturer's submission of an Investigational New Drug application

("IND") to conduct clinical trials. See 21 C.F.R. § 312.20. Before filing the IND, the applicant must have subjected biologically active agents of the proposed drug to comprehensive animal and human tissue testing. See 21 C.F.R. § 312.23(a). The applicant may commence human clinical trials if the FDA does not request more information or seek modifications to the testing protocols. See 21 C.F.R. §§ 312.21-23, 312.40(b)(1).

Abbott further states that, during the next stage of the approval process, there are three phases of clinical trials. See 21 C.F.R. § 312.21(a)(1), (b), & (c). By statute, the studies conducted must be "adequate and well-controlled." 21 U.S.C. § 355(d); see 21 C.F.R. § 314.126(b)(1)–(7). In reviewing the studies, the FDA conducts "an assessment of the scientific quality of the clinical investigations." 21 C.F.R. § 312.22(a). Moreover, the FDA may require additional testing or studies at any stage in the approval process. See 21 C.F.R. § 312.41(a). Throughout, the FDA "monitor[s] the progress of the conduct and evaluation of clinical trials" and is "involved in facilitating their appropriate progress." 21 C.F.R. § 312.87.

Abbott next notes that, after the successful completion of this testing regime, the applicant must submit a New Drug Application ("NDA") or, in the case of biologic products like gene therapies, a Biologics License Application ("BLA"). See 21 U.S.C. § 355(a)–(d); 21 C.F.R. § 314.50; 42 U.S.C. § 262(a) et seq.; 21 C.F.R. § 601.2. The NDA or BLA catalogues the history of the drug's development and testing. In seeking approval, the applicant must provide "substantial evidence" that the drug is safe and effective. See 21 C.F.R. § 314.125(b)(5). This means:

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed . . . .

21 U.S.C. § 355(d); see also 21 C.F.R. § 314.125(b).

Abbott next states that, in reviewing the scientific evidence regarding a proposed drug, the FDA is required to "establish panels of experts" consisting of "members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel

and who, to the extent feasible, possess skill and experience in the development, manufacture or utilization of such drugs." 21 U.S.C. § 355(n)(1) & (n)(3)(A). In determining whether a drug should be approved, the "FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards." 21 C.F.R. § 314.105(c).

Abbott next alleges that, significantly, the FDA is barred from approving a drug if it finds the manufacturing process deficient. The FDA "shall issue an order refusing to approve the application" if, among other things, "the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality and purity." 21 U.S.C. § 355(d). Moreover, FDA regulations set forth good manufacturing practices with which drug manufacturers must comply. See, e.g., 21 C.F.R. § 211.1 ("regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans and

animals").

Even after approving a drug, the FDA has a continuing obligation to evaluate its safety and efficacy. By law, manufacturers must report to the FDA "[a]ny adverse event associated with the use of a drug in humans, whether or not considered drug related." 21 C.F.R. § 314.80(a); 21 C.F.R. § 601.2. Prompt reporting of serious and unexpected adverse drug experiences is required, as is any increase in frequency of a particular adverse event. See 21 C.F.R. § 314.80(c)(1). Moreover the FDA, after due notice and opportunity for hearing to the applicant, is statutorily required to withdraw approval under specified circumstances. 21 U.S.C. § 355(e); see also 21 C.F.R. § 314.150.

Abbott further asserts that the FDA also closely regulates what information may and may not be disseminated by manufacturers about their drugs. Specifically, "[t]he centerpiece of risk management for prescription drugs generally is the labeling which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions

under which the product can be used safely and effectively." Requirements on Content and Format of Labeling, 71 Fed. Reg. at 3934; 21 C.F.R. §§ 314.70, 601.12(f). Provision is also made for the dissemination of information regarding drugs "in situations involving, in the opinion of the Secretary, imminent danger to [the] health or gross deception of the consumer." 21 U.S.C. § 375(b).

Abbott states that, in addition to the foregoing regulations that apply to all BLA applications, even more stringent regulations apply to gene-therapy applications. See 197 Fed. Reg. 53248-53251; 62 Fed. Reg. 9721. The Recombinant DNA Activities Committee ("RAC Committee"), a part of the National Institutes of Health ("NIH"), closely monitors investigational gene-therapy clinical trials and issues guidelines and recommendations.

(3)

Abbott further asserts that Plaintiff's product-defect and negligent-conduct claims necessarily raise numerous disputed federal issues regarding clinical trials of investigational gene therapy agents, including:

1. Testing requirements (21 C.F.R. § 312.23(a)). Plaintiff alleges Defendants were negligent in "determin[ing] the universe of harm through preclinical animal studies." (Complaint ¶¶ 21, 42)

2. FDA Approval of Study (21 C.F.R. §§ 312.22(a), 312.41(a), 312.87). Plaintiff challenges the FDA's approval of the study, alleging that the study was "unethical because it presented serious risk . . . with no benefit whatsoever." (Complaint ¶¶ 23, 42)

3. Informed Consent Process (21 C.F.R. § 50.25(a)(2)). Plaintiff challenges the FDA-approved consent form and related communications as "materially misleading and deceptive." (Complaint ¶¶ 20-21, 42)

4. Protocols (21 C.F.R. § 312.20). Plaintiff alleges defendants were negligent in "evaluat[ing] Ms. Mohr's condition and eligibility for the experiment," and in "designing and administering the experiment's protocol." (Complaint ¶¶ 15, 40, 42).

5. Definition of Gene Therapy (197 Fed. Reg. 53249). Plaintiff challenges defendants' use of the term "gene therapy" to describe the investigational agent to trial participants on the grounds that the phrase "denotes that it is therapeutic and beneficial," whereas gene therapy is "a purely experimental procedure which, despite its promise, has been proven neither safe nor effective for any human disease or ailment." (Complaint ¶¶ 19, 21)

6. Institutional Review Board (21 C.F.R. §§ 56.109, 312.66; 45 C.F.R. § 46.116). Plaintiff challenges the institutional review board's "federally required" approval of the study protocol. (Complaint ¶¶ 4, 13, 40-42)

7. **RAC Committee Approvals and Recommendations.** Plaintiff alleges that TG and WIRB were negligent in failing to follow RAC Committee recommendations regarding the study protocol. (Complaint ¶¶ 16-18)

8. **Adverse event reporting** (21 C.F.R. §§ 312.32(c)(1)(i)(A), 314.80(a)&(c)(1), 601.2). Plaintiff challenges Defendants' failure to report Ms. Mohr's adverse reaction to the FDA at an earlier date. (Complaint ¶ 35)

Based on the foregoing, Abbott alleges that Plaintiff's claims necessarily challenge the Defendants' compliance with numerous FDA regulations, as well as the adequacy of those regulations and FDA determinations themselves.

Abbott further asserts that the federal interest in the issues is substantial. The need for uniformity is compelling because the Plaintiff's lawsuit raises the potential for disparate requirements for the testing, approval, clinical trials, and adverse event reporting for gene therapies. Abbott contends that, when imposed by courts throughout the country, such disparate, fact-specific outcomes could conflict with and undermine the regulatory framework designed to provide a uniform standard for assuring the safety and efficacy of gene therapies. Moreover, the federal interests at

stake, including the need for uniformity, are particularly compelling here given the centrality of the allegations in the complaint that gene-therapy trials are inherently unbeneficial.

(4)

The Plaintiff notes that, although a defendant may remove certain matters to federal court, a "plaintiff is still the master of his own claim." Burns v. Windsor Ins. Co., 31 F.3d 1092, 1095 (11th Cir. 1994). However, many of the cases cited by the Plaintiff were decided before Grable & Sons and thus do not cite the precise legal standard. For example, the Plaintiff's argument, based on Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804 (1986), that there is not federal jurisdiction because there is no private cause of action is not persuasive because whether there is a private right of action is not the only factor courts assess in determining whether there is jurisdiction. Bertrand, 495 F.3d at 458. Consequently, the Plaintiff's reliance on Guckin v. Nagle, 259 F. Supp.2d 406 (E.D. Pa. 2003) is misplaced.

The Plaintiff acknowledges that he may attempt to use the

Defendants' alleged violations of the FDCA or PHSA to support state law claims of negligence, wrongful death and strict products liability, which is allowed under Illinois law. Relying on Sercye-McCollum v. Ravenswood Hospital Medical Center, 140 F. Supp.2d 944 (N.D. Ill. 2001), the Plaintiff alleges that a defendant cannot remove a case based on an allegation that there is a substantial question of federal law due to a violation of a federal statute. In certain instances, however, this is enough to establish federal jurisdiction, depending upon how substantial the federal interest is and other considerations. The Plaintiff's argument that it is not sufficient is based on the state of the law before Grable & Sons.

The Court must consider whether the Plaintiff's claims "necessarily raise a stated federal issue, actually disputed and substantial," which it may entertain without disturbing the congressionally approved balance of judicial responsibilities. See Grable & Sons, 545 U.S. at 314. Unlike this case, Grable & Sons did not involve extensive federal regulation over a particular industry. The plaintiff's quiet title action in that case depended on the interpretation of a provision in 26 U.S.C. § 6335(a), which required the

Internal Revenue Service to notify the plaintiff of the seizure of its property. See id. at 311. The dispute involved whether the plaintiff was notified in the exact manner provided by § 6335(a). See id.

The Court is of the view that there are many cases or potential cases which, at least arguably, raise federal issues that are as important as the notification provision in Grable & Sons. Examples might include claims arising from a plane crash or a claim which deals solely with whether the warnings on a prescription drug were consistent with federal standards. However, the Court must be concerned with the proper balance between judicial responsibilities. It is difficult to determine precisely where that line is. The Supreme Court suggested that problems could result, especially in certain areas of the law:

> The absence of any federal cause of action affected Merrell Dow's result two ways. The Court saw the fact as worth some consideration in the assessment of substantiality. But its primary importance emerged when the Court treated the combination of no federal cause of action and no preemption of state remedies for misbranding as an important clue to Congress's conception of the scope of jurisdiction to be exercised under § 1331. The Court saw the missing cause of action not as a missing federal door key, always required, but as a missing welcome mat, required in the circumstances, when exercising

> federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues. For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases.

Id. at 318. In observing that most state quiet title actions did not involve contested issues of federal law, the Supreme Court concluded that "jurisdiction over actions like Grable's would not materially affect, or threaten to affect, the normal currents of litigation." Id. at 319.

The Seventh Circuit stated that the Supreme Court in Grable & Sons "has greatly complicated the analysis," in concluding "that a contested federal issue in a state-law suit may allow jurisdiction under § 1331" because the Court has also held that even a significant federal issue is usually not enough for § 1331 jurisdiction. See Bennett, 484 F.3d at 909 (emphasis in original). In Bennett, the court considered whether the claims arose under federal law "because federal aviation standards play a major role in a claim that Southwest (as operator of the flight), Boeing (as manufacturer of the airframe), or Chicago (as operator of the airport) acted negligently." Id. at

908. "That some standards of care used in tort litigation come from federal law does not make the tort claim one "arising under" federal law." Id. at 912. Accordingly, the court held that these federal standards with respect to air travel were not enough to provide subject matter jurisdiction over this tort case in the wake of a plane crash. See id.

To the extent that there are many federal standards, the prescription drug industry is similar to the airline industry. The Seventh Circuit observed, however, that despite this extensive federal regulation, no court of appeals has held that is enough to provide subject matter jurisdiction. See Bennett, 484 F.3d at 912. Although Abbott's argument is bolstered by the fact that this case deals not only with prescription drugs, but also with investigational gene-therapy clinical trials, this Court is not aware of any federal courts of appeals that since Grable & Sons have found that the extent of federal regulation is enough to provide jurisdiction under § 1331.

There is no question that the Plaintiff's complaint raises some important federal issues. However, federalism concerns preclude the Court from finding that it has jurisdiction over the subject matter. Abbott

contends that the exercise of jurisdiction in this case will not disrupt any congressionally approved balance of federal and state judicial responsibilities, which was one of the Supreme Court's concerns. See Grable & Sons, 545 U.S. at 319-20. According to Abbott, routine state-law product liability claims that implicate federal standards will not become subject to federal jurisdiction.

Because the record does not seem to indicate how often investigational gene therapies are conducted, the Court is uncertain to what extent dockets would increase if federal courts retained jurisdiction over such cases. The Plaintiff does allege that TG and WIRB encouraged Dr. Trapp to recruit his longtime patients to enroll in the experiment. Based on the Plaintiff's allegations, it appears that there were at least a few others who were part of the experiment at The Arthritis Center. However, it is unclear how prevalent this type of treatment was on a national level. The Plaintiff does state that gene therapy is a purely experimental procedure, which has not been established to be therapeutic and beneficial. It has been proved neither safe nor effective for any human disease or ailment. Based on the

foregoing allegations, it appears that it is reasonable to believe that there may be a number of potential claims involving gene therapy or similar experimental procedures. Thus, a finding that the Court retains subject matter jurisdiction in this case could serve to upset the jurisdictional line intended by Congress.

Unlike the Supreme Court in Grable & Sons, however, this Court is not certain how a finding that there is jurisdiction in this case would affect the number of filings in federal court. See Grable & Sons, 545 U.S. at 319 ("Consequently, jurisdiction over actions like Grable's would not materially affect, or threaten to affect, the normal currents of litigation").

Obviously, there is extensive federal regulation of prescription drugs in general. The number of filings would likely increase significantly if federal subject matter jurisdiction pursuant to § 1331 is retained over such suits. Even if the number of potential claims involving investigational gene therapies is relatively low, however, it seems arbitrary to distinguish for jurisdictional purposes between such claims or other experimental treatments and the more typical claims involving prescription drugs. The

Court concludes that is not what the Supreme Court intended when it decided Grable & Sons. A finding that there is federal subject matter jurisdiction over cases involving experimental gene therapy treatments would disturb the "judicial federalism" line that Congress has drawn. Accordingly, the Court finds that it lacks jurisdiction under § 1331. The Plaintiff's motion to remand will be ALLOWED.

CONCLUSION

The Court has concluded that the Plaintiff's amended complaint contains just enough factual allegations to withstand Abbott's motion to dismiss. Based on that finding, the Court is unable to determine that Abbott was fraudulently joined and that there is jurisdiction pursuant to 28 U.S.C. § 1332. Because there is a dispute as to the adequacy of the drug's warnings, dismissal at this stage based on the learned intermediary doctrine would not be appropriate. Consequently, the Court will DENY Abbott's motion to dismiss.

Although the Plaintiff's amended complaint does raise some important federal issues, the Court finds that it lacks "arising under" jurisdiction

pursuant to 28 U.S.C. § 1331. A finding that the Court retains jurisdiction over the subject matter could potentially affect "the normal currents of litigation," which was a concern of the Supreme Court in Grable, 545 U.S. at 319. The Court will ALLOW the Plaintiff's motion to remand. The Court declines to award costs and expenses.

Ergo, the motion to dismiss the Plaintiff's First Amended Complaint filed by Defendant Abbott Laboratories, Inc. [d/e 31] is DENIED.

The Plaintiff's motion to remand [d/e 6] is ALLOWED.

This action is hereby remanded to the Circuit Court of the Fourth Judicial District in Christian County, Illinois.

ENTER: March 3, 2010

FOR THE COURT:

s/Richard Mills
United States District Judge