Not for Publication

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

RODERICK DEVINE,	:	
Plaintiff,	:	**Hon. Joseph H. Rodriguez**
v.	:	**Civil Action No. 08-859**
NOVARTIS PHARMACEUTICALS CORPORATION, et al.,	:	**OPINION**
Defendants.	:	

This matter was originally filed in the Superior Court of New Jersey, Law Division, Atlantic County. Defendant Novartis Pharmaceuticals Corporation ("Defendant") filed a Notice of Removal to remove the case to this Court pursuant to 28 U.S.C. §§ 1331, 1367, 1441, 1446. Pending resolution of Wyeth v. Levine, 555 U.S. - - - , 129 S. Ct. 1187 (2009), the parties consented to a stay, which was lifted on April 6, 2009.

Presently before the Court is the Motion to Remand [23] of Plaintiff Roderick Devine ("Plaintiff") filed on April 13, 2009, predicated upon lack of federal subject matter jurisdiction pursuant to 28 U.S.C. § 1447(c). The Court has reviewed the written submissions of the parties and heard oral argument on July 1, 2009. For the reasons expressed on the record on that date and for the reasons that follow, Plaintiff's Motion to Remand is granted.

I. Factual Background

In ruling on whether a cause of action should be remanded to the state court from which it was removed, the court must assume as true all factual allegations in the

plaintiff's complaint. See Steel Valley Auth. v. Union Switch & Signal Div., 809 F.2d 1006, 1010 (3d Cir. 1987), cert. dismissed sub nom. Am. Standard, Inc. v. Steel Valley Auth., 484 U.S. 1021 (1988) (internal citations omitted);[1] see also Abels v. State Farm Fire & Cas. Co., 770 F.2d 26, 29 (3d Cir. 1985) (citing Pullman Co. v. Jenkins, 305 U.S. 534, 537 (1939) (stating that defendant's right to remove is determined from the plaintiff's pleading at the time of removal)). Plaintiff commenced this action against Defendants Novartis Pharmaceuticals Corporation, Novartis Pharma GmbH, and Novartis AG ("Defendants") for damages allegedly incurred from Defendants' product, Elidel.

Elidel is the product name for the drug known as pimecrolimus, used in the treatment of various skin diseases. (See Compl. ¶ 14.) On December 13, 2001, Defendants received Food and Drug Administration ("FDA") approval for pimecrolimus for the treatment of dermatitis (i.e. eczema), including certain restrictions that it should not be prescribed for long term use and should only be used when first-line treatments cannot be used. (Id. ¶ 20.) In December 2001, the FDA notified Defendants that pediatric patients who intermittently use pimecrolimus could develop systemic malignancies. (Id. ¶ 23.) The FDA's approval of the drug was therefore conditioned on Defendants' commitment to conduct a study assessing the risk of the development of malignancies in pediatric patients who are treated with pimecrolimus. (Id. ¶ 24.) On

[1] Steel Valley was later superseded by statute on other grounds. See Shaw v. Unum Life Ins. Co. of Am., Inc., No. 88-4637, 1989 WL 52713, at *6 (D.N.J. May 15, 1989) (internal citations omitted).

October 30, 2003, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee recommended a Black Box Warning for the use of pimecrolimus indicating the risk of malignancies in pediatric patients, but Defendants did not provide the warning at this time. (Id. ¶ 27.) Defendants affixed the warning to the pimecrolimus label in January 2006 following the FDA's requirement of such warning in March 2005, based upon pimecrolimus' adverse effects. (Id. ¶¶ 30-31.)

Beginning in 2001, Defendants sold and distributed pimecrolimus throughout the United States. (Id. ¶ 32.) Through such activities, Defendants controlled the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supply, promotion, sales, and issuance of product warnings. (Id. ¶ 34.) Defendants represented the drug as safe and effective for the treatment of dermatitis through a widespread marketing and advertising campaign. (Id. ¶ 43.) Although Defendants were aware of the risk of developing malignancies from using pimecrolimus, Defendants did not inform the FDA, medical community, or consumer public of such risk. (Id. ¶¶ 51, 107.) In 2004, Plaintiff's physician prescribed Elidel for treating his dermatitis. (Id. ¶ 57.) Plaintiff applied Elidel in accordance with his physician's instructions. (Id.) As a result, Plaintiff was diagnosed in 2005 with Stage One malignant melanoma. (Id. ¶ 58.)

II. Standard of Review

A case must be remanded if, at any time before final judgment, the district court discovers that it lacks subject matter jurisdiction to hear the case. See 28 U.S.C. § 1447(c). As the party removing the case, the defendant has the burden to prove that federal court jurisdiction is proper at all stages of the litigation. See Samuel-Bassett v. KIA Motors Am., Inc., 357 F.3d 392, 396 (3d Cir. 2004); Boyer v. Snap-On Tools Corp.,

913 F.2d 108, 111 (3d Cir. 1990); Abels, 770 F.2d at 29. The district court must resolve all contested issues of fact and uncertainties of law in favor of the plaintiff. See Boyer, 913 F.2d at 111. Moreover, the court should strictly construe removal statutes and resolve all doubts in favor of remand. See Abels, 770 F.2d at 29. The strict construction of removal statutes honors Congress' power to determine the contours of the federal court's limited subject matter jurisdiction. See Bowles v. Russell, 551 U.S. 205, 212-13 (2007) (internal citation omitted) ("Because Congress decides whether federal courts can hear cases at all, it can also determine when, and under what conditions, federal courts can hear them.").

In order for removal to be proper, the federal court must have original jurisdiction to hear the case. See 28 U.S.C. § 1441(a); U.S. Express Lines, Ltd. v. Higgins, 281 F.3d 383, 389 (3d Cir. 2002). One basis of original jurisdiction is federal question jurisdiction. See 28 U.S.C. § 1331; U.S. Express, 281 F.3d at 389. Federal question jurisdiction applies to "all civil actions arising under the Constitution, laws, or treatises of the United States." 28 U.S.C. § 1331. If the federal court has original jurisdiction based upon federal question, the case may be removed without regard to the citizenship of the parties. See 28 U.S.C. § 1441(b). One claim conferring federal question jurisdiction is sufficient for the entire case to be removed to federal court. See id. § 1441(c). The district court, however, may exercise its discretionary powers to remand all matters to state court in which state law predominates. See id.

Next, the well-pleaded complaint rule requires that the face of the plaintiff's complaint provide the basis for federal question jurisdiction by raising issues of federal

law. See City of Chicago v. Int'l Coll. of Surgeons, 522 U.S. 156, 163 (1997). Federal jurisdiction cannot arise from a defense that raises a federal question. See Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804, 808 (1986). The basis for federal question jurisdiction must exist within the four corners of the complaint. See id. In light of the presumption in favor of remand, district courts should remand close or doubtful cases to the state courts from which they were removed. See Abels, 770 F.2d at 29; Glenmede Trust Co. v. Dow Chem. Co., 384 F. Supp. 423, 433 (E.D.Pa. 1974). Remand to state court avoids a later determination that the federal court is without jurisdiction, and places the case in a forum having clear jurisdiction over the case. See id. (internal citation omitted).

When a federal issue is embedded in a state law claim, the federal court has jurisdiction over the claim when it "necessarily raise[s] 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." See Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 314 (2005). Only a "slim category" of state law claims satisfy this two-part test. See Empire Healthchoice Assurance, Inc. v. McVeigh, 547 U.S. 677, 701 (2006). The federal interest must be substantial enough to justify turning a state law claim "into a discrete and costly 'federal case.'" See id.

III. Discussion

As the removing party bears the burden to prove federal subject matter jurisdiction exists, the appropriate starting point in considering a motion to remand is

the defendant's contentions supporting removal. See Samuel-Bassett, 357 F.3d at 396; Boyer, 913 F.2d at 111; Abels, 770 F.2d at 29. In its Notice of Removal, Defendant asserts that Plaintiff's Complaint raises three main federal issues that warrant federal question jurisdiction under 28 U.S.C. § 1331: (1) Defendants' alleged commission of fraud under the New Jersey Consumer Fraud Act ("CFA claim"); (2) Defendants' alleged failure to warn under the New Jersey Products Liability Act ("NJPLA"), involving a violation of the Food, Drug, and Cosmetic Act ("FDCA") by failing to provide adequate warnings and labels regarding Elidel ("failure to warn claim"); and (3) Plaintiff's claim for punitive damages under the NJPLA, requiring proof that Defendants committed fraud on the FDA ("punitive damages claim").[2]

At oral argument, Defendant conceded that both the CFA claim and failure to warn claim do not provide federal question jurisdiction. (R. at 16; 14-21.) The sole consideration on this motion, therefore, is whether the presence of a federal element in New Jersey's Products Liability Act, as plead in Plaintiff's punitive damages claim, constitutes a substantial and/or significant federal issue meriting resolution in federal court. Several judges in this district have addressed this issue; all have declined to find that the punitive damages claim presents a substantial federal question.[3] Defendant

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[2] In his Complaint, Plaintiff alleges six counts, three of which are relevant for this motion: Count I ("Products Liability Act-Failure to Warn"), Count III ("New Jersey Consumer Fraud Act") and Count VII ("Punitive Damages Under Common Law and the Products Liability Act").

[3] See Sullivan I, 602 F. Supp. 2d 527; Sullivan II, 575 F. Supp. 2d at 653; Reilly v. Novartis Pham. Corp., 2009 WL 3010540 (D.N.J. September 18, 2009); D'Anna v. Novartis Pharm. Corp., 2009 WL 1662174 (D.N.J. June 15, 2009); Brown v. Organon Int'l Inc., No. 07-3092, 2008 WL 2833294, at *4 (D.N.J. July 21, 2008); Fields v. Organon USA Inc., No. 07-2922, 2007 WL 4365312, at *9 (D.N.J. Dec. 12, 2007);

ardently attempts to escape this conclusion and petitions this Court for a different result.

A. Punitive Damages Claim

Plaintiff's punitive damages claim does not provide this Court with federal question jurisdiction. The punitive damages claim alleges Defendants knowingly withheld material information from the FDA, medical community, and consumer public regarding Elidel's safety. (See Compl. ¶ 107.) The NJPLA states in relevant part that "where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded." See N.J. Stat. Ann. § 2a:58C-5(c). According to Defendant, because success on this state claim hinges on proof that it violated federal law in its submission of materials to the FDA, a substantial federal question is raised warranting federal jurisdiction. (See Notice of Remov. ¶ 10.)

The determination of whether a state law claim sufficiently implicates a federal question meriting federal jurisdiction requires satisfaction of a two part test. See Grable, 545 U.S. at 314. Firstly, the state law claim must "necessarily raise a stated federal issue, actually disputed and substantial." Id. Secondly, the federal court must be

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DeAngelo-Shuayto v. Organon USA Inc., No. 07-2923, 2007 WL 4365311, at *9 (D.N.J. Dec. 12, 2007); Von Essen v. C.R. Bard, Inc., No. Civ.A. 06-4786, 2007 WL 2086483, at *5 (D.N.J. June 18, 2007); see also In re Aredia and Zometa Prods. Liab. Litig., No. 3:06-MD-1760, 2007 WL 649266, at *10 (M.D.Tenn. Feb. 27, 2007). All of these decisions similarly found that the NJPLA punitive damages claim is better suited for state court because its adjudication does not require the resolution of substantial federal issues and would disrupt the balance between the federal and state workload.

able to hear the claim "without disturbing any congressionally approved balance of federal and state judicial responsibilities." Id.

This test was formulated by the Supreme Court in Grable which considered the propriety of the removal of a state law quiet title claim to federal court. Id. The claim in Grabel centered on whether the Internal Revenue Service gave the corporation adequate notice of the seizure. The Internal Revenue Service's notice obligations with respect to the seizure were statutory. See id. at 315. Applying the two-part test, the Supreme Court ruled that the corporation's state law quiet title claim was properly removed to federal court on the basis of federal question jurisdiction because the claim turned on the interpretation of a federal statute. See id. at 316. With respect to the second prong of the test, the Supreme Court concluded that the "rare state title case," would only have a "microscopic effect" on the federal/state workload balance. See id.

But the finding of federal jurisdiction in Grable was the exception, rather than the rule, as clarified by the Supreme Court in McVeigh. See 547 U.S. at 700-01. Stating that there is only a "slim category" of cases containing state law claims that merit federal question jurisdiction, the Court explained that federal jurisdiction is appropriate in cases where "[t]he dispute center[s] on the action of a federal agency and its compatibility with a federal statute, the question qualifie[s] as 'substantial,' and its resolution [is] both dispositive of the case and would be controlling in numerous other cases." See id.

Applying the Grable analysis, federal jurisdiction is not appropriate in this case. Unlike Grable, the federal issue in Plaintiff's state law punitive damages claim is not

dispositive of the case and does not justify a federal court hearing Plaintiff's entire case. See McVeigh, 547 U.S. at 700-01. Under the NJPLA, proof of fraud on the FDA is merely a prerequisite to and not dispositive of a punitive damages award. See N.J. Stat. Ann. § 2a:58C-5(c)(upon a showing of fraud,"punitive damages may be awarded.")(emphasis added); see also, Sullivan v. Novartis Pharm. Corp., 602 F. Supp. 2d 527, 534-35 (D.N.J. 2009) ("Sullivan I"); see also See Sullivan v. Novartis Pharm. Corp., 575 F. Supp. 2d 640, 653 (D.N.J. 2008) ("Sullivan II")(stating that the punitive damages claim, however, may not require the court to find fraud on the FDA).[4] An award of punitive damages in New Jersey also requires "circumstances of aggravation or outrage, such as a spite or 'malice', or a fraudulent or evil motive on the part of the defendant, or such a conscious and deliberate disregard of the interests of others that his conduct may be called wilful or wanton." Di Giovanni, 260 A.2d at 511. Thus, the federal element in Plaintiff's punitive damages claim presents a stark contrast to the dispositive federal issue in the quiet title claim in Grable in which the resolution of the case depended upon the interpretation of a federal statute. See 545 U.S. at 315. Here, the federal element is only a prerequisite and does appear to require a sophisticated understanding of the FDA rules and regulations.

This conclusion reflects the consensus of the courts in this district that have addressed the present issue. Particularly, the decision in Sullivan I, bears a strikingly similarity to the case at hand. 602 F. Supp. 2d at 529. In Sullivan I, the plaintiff

[4] The plaintiff in this case has the same surname as a plaintiff in a case mentioned later in this opinion. For the sake of clarity, the cases are hereinafter referred to as "Sullivan I" and "Sullivan II," although the plaintiffs in the two cases are two different individuals.

consumer sought damages from same Defendants for bodily harm caused by the use of Elidel for the treatment of eczema. See id. The plaintiff pursued, among other claims, a punitive damages claim under the NJPLA. See id. The court, *sua sponte*, issued an Order to Show Cause why the case should not be remanded to state court, and upon hearing the arguments, concluded that the case should be remanded to state court for lack of federal subject matter jurisdiction. See id. The Sullivan I court reasoned that although 28 U.S.C. § 1331 appears to grant broad federal jurisdiction to all cases containing a federal element, the "statutory grant of federal question is more limited in scope." See id. at 531 (citing Merrell Dow, 478 U.S. at 807). While not binding on this Court, there exists no reason to reject the sound reasoning employed in Sullivan I or its ultimate conclusion that resolution of Plaintiff's claim does not necessarily implicate federal law.

In an attempt to garner a different result, the crux of Defendant's argument is that the fraud on the FDA component of the claim arises in Plaintiff's "case in chief" and is not merely an affirmative defense to the damages claim. See Def.'s Br. In Opp. P. 8. According to Defendant, Plaintiff "interjected a disputed, necessary, and substantial federal issue into this case" by electing to pursue the punitive damages claim. Id. At pp. 5, 11. In support, Defendant contends that the absence of a punitive damages limitation under the "defenses" heading in N.J.Stat. Ann. § 2a:58C-3 indicates that the federal element is part of Plaintiff's affirmative punitive damages claim, not part of Defendants' affirmative defense. Defendant also relies on several cases that measure the federal interest in a fraud on the FDA punitive damages claim as greater than the state interests. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001); Grange v. mylan

Labs., Inc., 2008 WL 4813311 (D. Utah Oct. 31, 2008); Henderson v. Merck & Co., No. 04-CV-05987-LDD, 2005 WL 2600220, at *11 (E.D.Pa. Oct. 11, 2005); Kobar ex rel. Kobar v. Novartis Corp., 378 F. Supp. 2d 1166, 1171-73 (D. Ariz. 2005) (applying Buckman and finding that products liability statutes containing a fraud on the FDA element implicate federal law.); see also, Rowe v. Hoffman-LaRoche, Inc., 189 N.J. 615, 626 (2007).

The above aforementioned cases are unpersuasive and do not directly counsel on the present issue. Notably, Rowe involved a state choice of law question. 189 N.J. 615. The New Jersey Supreme Court, in ruling that the State of Michigan held a greater interest in having the matter adjudicated in its forum, reasoned that the punitive damages provision of the NJPLA "along with the rebuttable-presumption contained in N.J.S.A. 2A:58C-4, cede to FDA regulation some of this State's interest in policing local pharmaceutical manufacturers, thereby reducing New Jersey's interest in applying its law to this case." Id. at 626. The Supreme Court was measuring New Jersey's interest in a matter involving a Michigan Plaintiff; the question of whether the NJPLA punitive damages claim presents a "substantial" federal claim warranting federal jurisdiction was not before the Court. This statement, therefore, is taken out of context and does not inform the analysis of whether the punitive damages claim satisfies the strictures of Grable.

Likewise, Defendant's reliance on Buckman, is also misplaced. In Buckman, the plaintiffs claimed that a consulting company that assisted a manufacturer made fraudulent representations to the FDA while obtaining approval to market orthopedic

bone screws. See 531 U.S. at 343. Essentially, the plaintiffs were affirmatively making an express fraud on the FDA claim. See id. at 348. The Supreme Court held that such claim conflicted with, and therefore was impliedly preempted by, the FDCA, as amended by the Medical Device Amendments of 1976 ("MDA"). See id. at 344, 348 (internal citations omitted). Buckman, Defendant argues, demonstrates the federal nature of Plaintiff's punitive damages claim, as the claim requires proof of fraud on the FDA and is therefore "inherently federal in character." (See Def.'s Opp'n Br. p. 1.)

Defendant's reliance on Buckman has been uniformly rejected in this district for the following reasons. Firstly, the plaintiffs in Buckman made a direct fraud on the FDA claim, while here fraud on the FDA is merely a prerequisite to Plaintiff's recovery of punitive damages. See Sullivan I, 602 F. Supp. 2d at 535; Sullivan II, 575 F. Supp. 2d at 652. Secondly, Buckman held that state law fraud on the FDA claims are preempted by federal law, but did not "make any holding with regard to the existence of federal question jurisdiction over a case by virtue of a state law claim that incorporates federal law as setting forth the standard of offending conduct." See Sullivan I, 602 F. Supp. 2d at 535; Sullivan II, 575 F. Supp. 2d at 651; DeAngelo-Shuayto, 2007 WL 4365311, at *7. Here, the issue is whether Plaintiff's claim provides federal question jurisdiction, not whether or not there is federal preemption. See Sullivan I, 602 F. Supp. 2d at 535; Sullivan II, 575 F. Supp. 2d at 651. Buckman simply did not address whether a punitive damages claim with a fraud on the FDA prerequisite warrants removal to federal court. See Sullivan II, 575 F. Supp. 2d at 653.

Thirdly, Buckman's decision was guided by the MDA. See Sullivan I, 602 F.

Supp. 2d at 535. Federal medical device regulation has set forth an express preemption clause, 21 U.S.C. § 360k, that "reflects a legislative prerogative to displace certain state causes of action in the realm of medical devices." See Sullivan I, 602 F. Supp. 2d at 535-36. The "ethical drug arena," on the other hand, is an area in which Congress has implicitly approved the concurrent operation of state tort liability and federal regulation. See id. at 536 (citing Wyeth, 129 S. Ct. at 1199-1200). The Court agrees that Buckman, therefore, is inapplicable and does not provide grounds for federal question jurisdiction based on the federal element in Plaintiff's punitive damages claim.[5] See Sullivan I, 602 F. Supp. 2d at 536.

The district court's decision in Grange is also unpersuasive. Defendant contends that in Grange, the district court considered whether Utah's product's liability punitive damages statute implicated federal law. In holding that it did, the court stated that "a state court will have to interpret what information is required under FDA regulations. Such a review will implicate . . . the Buckman concerns." 2008 WL 4813311, at *7 n.4. But Grange, like Buckman, only addressed whether the Utah statute was preempted by federal law and did not opine on the merits of federal question jurisdiction. On the issue of preemption, the court ruled that the Utah statute did "not predicate liability on fraud on the FDA" and was not preempted "where a plaintiff invokes Utah Code Ann. § 78B-8-203(2) to seek punitive damages in cases where the FDA itself has found that

[5] Besides Buckman, Defendant relied at oral argument on a case cited in a footnote of its Opposition Brief among a list of citations containing parentheticals. See Broder v. Cablevision Sys. Corp., 418 F.3d 187 (2d Cir. 2005); (Def.'s Opp'n Br. p. 4 n.5.) Although the Second Circuit upheld federal jurisdiction in Broder, the state law claim, importantly, alleged that the defendants violated a federal statute, 47 U.S.C. § 543(d). See 418 F.3d at 191. No such allegation exists here. See id.

there was fraud in the application process." Id. at *7. Plainly, Grange did not measure whether the embedded federal issue would cause the state law punitive damages claim to fall within the "slim category" of cases contemplated by the Supreme Court in McVeigh.

For all of these reasons, while there may be a federal component embedded in Plaintiff's state law punitive damages claim, the Court finds that the federal issue is neither dispositive of the claim nor sufficiently substantial so as to merit consideration in federal court. In addition, even if Plaintiff's punitive damages claim satisfied the first prong of the Grable standard, entertaining Plaintiff's state law claims in federal court would disrupt the balance between federal and state judicial responsibilities. See Grable, 545 U.S. at 314.

Defendant contends that the state has ceded some of its interest in regulating pharmaceutical manufacturers to the FDA through N.J. Stat. Ann. § 2a:58C-5. See Rowe, 917 A.2d at 774. Further, Defendant contends that regulation of fraud against federal agencies is not a field traditionally occupied by states, pursuant to Buckman. See 531 U.S. at 347. In contrast to the claim in Merrell Dow,[6] the exceptional nature of a punitive damages claim based upon fraud on the FDA, Defendant asserts, would not

[6] If federal jurisdiction had been upheld in Merrell Dow, Defendant contends, any claim alleging a defendant's presumptive negligence under state law due to a violation of federal law could be brought to federal court. Merrell Dow adopted the contextual analysis of Smith v. Kansas City Title & Trust Co., 255 U.S. 180 (1921), to consider the particular federal interest in each determination of federal question jurisdiction. Defendant cites to a case from the Eastern District of New York to make the point that jurisdiction may be appropriate in cases similar to, but jurisdictionally different, from Merrell Dow. See In re Zyprexa Prods. Liab. Litig., 375 F. Supp. 2d 170, 172 (E.D.N.Y. 2005) ("The specific allegations and subtle distinctions in pleadings among pharmaceutical cases may require exercise of jurisdiction in cases which appear close to, but jurisdictionally different from, Merrell Dow.").

attract an enormous amount of cases into federal court. For all of these reasons, Defendant contends that the exercise of federal jurisdiction over Plaintiff's claims would not upset the balance between federal and state judicial responsibilities. The Court disagrees.

Although "punitive damages are reserved for 'exceptional cases'", Di Giovanni, 260 A.2d at 511, the volume of cases that would gain entry into the federal court by way of the NJPLA punitive damages claim is significant. Plaintiff's claim for punitive damages is not unique; there are over twenty cases pending in this district regarding Elidel's link to the onset of cancer. See D'Anna, No. 08-1119, 2009 U.S. Dist. LEXIS 49750, at *2, n.1 (noting that twenty-two cases are currently pending in the District of New Jersey alleging Elidel's link to cancer). Thus, "there is ample proof that federal jurisdiction over NJPLA punitive damages claims would markedly increase the volume of such cases in federal courts." See Sullivan I, 602 F. Supp. 2d at 537; see also Sullivan II, 575 F. Supp. 2d at 653 ("opening the federal forum in this case would have the effect of shifting to federal court an enormous volume of state law claims in which manufacturers are protected from punitive damages so long as they have made no misrepresentations to the FDA.").

Moreover, the federal issue embedded in the punitive damages claim is not the type of claim that would further congressional purpose. See Sullivan I, 602 F. Supp. 2d at 537. Defendants' violation of FDA regulations, albeit a question of federal law, is not sufficiently substantial, "such that it would require a sophisticated inquiry into the meaning of FDA regulations." See D'Anna, 2009 U.S. Dist. LEXIS 49750, at *7.

Instead, Plaintiff's claims sound in state law. And for Plaintiff to be awarded punitive damages, proof of fraud on the FDA is not enough; Plaintiff would still have to satisfy New Jersey's prescription for an award of punitive damages. See id. (". . . it is a substantial body of New Jersey law that determines when a jury may award punitive damages."); see also Di Giovanni, 260 A.2d at 511 (An award of punitive damages in New Jersey requires "circumstances of aggravation or outrage, such as a spite or 'malice', or a fraudulent or evil motive on the [part of the defendant, or such a conscious and deliberate disregard of the interests of others that his conduct may be called wilful or wanton.") State courts have a strong interest in handling cases where state law predominates.

Given the consensus among the well-reasoned courts in this District,[7] Plaintiff's punitive damages claim would upset the balance between federal and state judicial responsibilities. See Grable, 545 U.S. at 314. Further, upholding federal jurisdiction over Plaintiff's claim would have considerable implications for federalism, running afoul of the standard set forth in Grable. See 545 U.S. at 314. Ultimately, Defendant cannot overcome the presumption in favor of remand and Plaintiff's Motion for Remand is granted. See Abels, 770 F.2d at 29.

[7] Defendant asks this Court to rule differently from the other District Court of New Jersey opinions that held adversely to Defendant with regard to federal question jurisdiction over punitive damages claims like Plaintiff's. Defendant is correct that these decisions are not binding on this Court and that there is no "law of the district." See Gasperini v. Ctr. for Humanities, Inc., 518 U.S. 415, 430 n.10 (1996); Threadgill v. Armstrong World Indus., Inc., 928 F.2d 1366, 1371 (3d Cir. 1991); (Def.'s Opp'n Br. p. 8 n.13.) However, when district court opinions, representing the same or similar facts, are well-reasoned, this Court is not barred from being persuaded by the analysis presented in those cases.

IV. Conclusion

For the reasons stated herein, Plaintiff's case is remanded to the Superior Court of New Jersey, Law Division, Atlantic County. In light of the absence of a substantial, disputed, and necessary federal question, coupled with the disruption of the balance between federal and state judicial responsibilities, Plaintiff's Motion to Remand is granted. An appropriate order will issue.

Dated: October 19, 2009

/s/ Joseph H. Rodriguez
JOSEPH H. RODRIGUEZ,
United States District Judge