UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

JAMES D. "BUDDY" CALDWELL,
ET AL

CIVIL ACTION

VERSUS

NUMBER 11-542-BAJ-SCR

ABBOTT LABORATORIES, INC.,
ET AL

NOTICE

Please take notice that the attached Magistrate Judge's Report has been filed with the Clerk of the U. S. District Court.

In accordance with 28 U.S.C. §636(b)(1), you have 14 days after being served with the attached report to file written objections to the proposed findings of fact, conclusions of law, and recommendations set forth therein. Failure to file written objections to the proposed findings, conclusions and recommendations within 14 days after being served will bar you, except upon grounds of plain error, from attacking on appeal the unobjected-to proposed factual findings and legal conclusions accepted by the District Court.

ABSOLUTELY NO EXTENSION OF TIME SHALL BE GRANTED TO FILE WRITTEN OBJECTIONS TO THE MAGISTRATE JUDGE'S REPORT.

Baton Rouge, Louisiana, March 5, 2012.

Stephen C. Riedlinger

STEPHEN C. RIEDLINGER
UNITED STATES MAGISTRATE JUDGE

UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

JAMES D. "BUDDY" CALDWELL, ET AL	CIVIL ACTION
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MAGISTRATE JUDGE'S REPORT

Before the court is the State's Motion to Remand filed by plaintiff James D. "Buddy" Caldwell, Attorney General of the State of Louisiana. Record document number 8. The motion is opposed.[1]

Careful consideration of the allegations in the plaintiff's Original Petition for Civil Penalties and Damages and Jury Demand and the applicable law supports the conclusion that the defendants failed to satisfy their burden of establishing federal question jurisdiction, and that the State's Motion to Remand should be granted.

Background

Plaintiff filed an Original Petition for Civil Penalties and Damages and Jury Demand (hereafter, "Petition"), in state court against defendants Abbott Laboratories, Abbott Laboratories, Inc., (hereafter, collectively "Abbott") and one hundred John Doe

[1] Record document number 9. Plaintiff filed a reply memorandum. Record document number 13.

defendants.[2] Plaintiff generally alleged that the defendant is liable for deceptive, false, misleading, reckless and fraudulent acts and practices in the marketing, promotion, pricing and selling of Depakote products[3] in Louisiana. Plaintiff sued to collect damages, restitution, civil fines and penalties, interest, costs and attorney's fees from the defendant under five state law provisions and theories of recovery: (1) Count One - Louisiana's Medical Assistance Programs Integrity Law ("MAPIL"), LSA-R.S. 46:437.1, et seq.;[4] (2) Count Two - Louisiana's Unfair Trade Practices and Consumer Protection Law ("LUTPCPL"), LSA-R.S. 51:1401, et seq.;[5] (3) Count Four - Redhibition under Louisiana Civil Code Article 2520;[6] (4) Count Five - Fraud under Louisiana Civil Code Article 1953;[7] and (5) Count Six - Unjust Enrichment

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[2] Plaintiff alleged that the John Doe defendants are all past and present individuals, corporations, limited liability companies and other business entities, who or which conspired with Abbott in the unlawful, fraudulent marketing schemes alleged in the Petition. Record document number 1-6, Exhibit F, Petition, ¶ 36-38. Since these defendants are unidentified, the rest of this report only refers to defendant Abbott.

[3] Plaintiff alleged that the defendant sold divalproex sodium under the trade names Depakote, Depakote DR, Depakote ER, Depacon, and Depakote Sprinkles. *Id.*, ¶ 2.

[4] *Id.*, ¶ 372-388.

[5] *Id.*, ¶ 389-398.

[6] *Id.*, ¶ 399-406.

[7] *Id.*, ¶ 407-416.

under Louisiana Civil Code Article 2298.[8] Plaintiff alleged that the claims are based exclusively on Louisiana law and no claims arising under the law of the United States were asserted.[9]

Defendant removed the case and asserted federal question jurisdiction under 28 U.S.C. § 1331. In the Notice of Removal the defendant acknowledged that the five claims alleged by the plaintiff are all brought under state law.[10] Defendant argued that removal is nonetheless proper because the allegations underlying the state law claims demonstrate the existence of an embedded federal issue that is actually disputed and substantial and warrants the exercise of federal question jurisdiction. Plaintiff moved to remand for lack of subject matter jurisdiction under § 1331.

Applicable Law

The party invoking removal jurisdiction bears the burden of establishing federal jurisdiction over the state court suit. *Frank v. Bear Stearns & Company*, 128 F.3d 919, 921-22 (5th Cir. 1997). To support removal the defendant must locate the basis of federal jurisdiction in the allegations necessary to support the

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[8] *Id.*, ¶ 417-423. In Count Three the plaintiff alleged equitable tolling of any applicable prescriptive periods. In Counts Seven through Twelve the plaintiff asserted the same claims and allegations against the John Doe defendants that were alleged against Abbott in Counts One through Six.

[9] *Id.*, ¶ 9.

[10] Record document number 1, Notice of Removal, ¶ 6.

plaintiff's claims, ignoring the defendant' own pleadings and notice of removal. *Gully v. First National Bank*, 299 U.S. 109, 111, 57 S.Ct. 96, 97 (1936).

Absent diversity of jurisdiction, removal is appropriate only for those claims within the federal question jurisdiction of the district courts. 28 U.S.C. § 1331. It is well established that the "arising under" language of § 1331 has a narrower meaning than the corresponding language in Article III of the Constitution which defines the limits of the judicial power of the United States. Federal question jurisdiction is generally invoked by plaintiff pleading a cause of action created by federal law. However, another well-established but less frequently encountered form of federal "arising under" jurisdiction, is that in certain cases federal-question jurisdiction will lie over state law claims that implicate significant federal issues. *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 125 S.Ct. 2363 (2005).

Thus, a federal question exists only in "those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law." *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 27-28, 103 S.Ct. 2841 (1983); *Singh v. Duane Morris LLP*, 538 F.3d 334, 337-38 (5th Cir. 2008). However, as the Fifth Circuit observed in *Singh*, the Supreme court has subsequently

warned that *Franchise Tax Board's* "necessary-resolution" language is no automatic test, and should be read as part of a carefully nuanced standard rather than a broad, simplistic rule.

> The fact that a substantial federal question is necessary to the resolution of a state-law claim is not sufficient to permit federal jurisdiction: *Franchise Tax Board* ... did not purport to disturb the long-settled understanding that the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction. Likewise, the presence of a disputed federal issue is never necessarily dispositive. Instead, far from creating some kind of automatic test, *Franchise Tax Board* thus candidly recognized the need for careful judgments about the exercise of federal judicial power in an area of uncertain jurisdiction. (internal quotations and citations omitted).

Singh, 538 F.3d at 338.

The Supreme Court's most recent summation of the standard for determining whether an embedded federal issue in a state law claim raises a substantial question of federal law is set forth in *Grable.* The Court stated: "[] 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." *Grable*, 545 U.S. at 314, 125 S.Ct. at 2368. The lack of a private cause of action is relevant to, but not dispositive of, the question of whether the right is substantial enough to satisfy the exercise of federal jurisdiction. The federal issue must be a substantial one that indicates a serious federal interest in claiming the advantages inherent in a federal

forum. However, the presence of a disputed federal issue and the importance of a federal forum are never dispositive. The court must always assess whether the exercise of federal jurisdiction would be consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331. *Grable*, 545 U.S. at 313, 125 S.Ct. at 2367, 2370.

The Parties' Arguments

Plaintiff argued that the state law claims alleged do not require resolution of any federal issue, much less a disputed and substantial one. Plaintiff acknowledged that the Petition contains multiple references to the federal Food and Drug Administration ("FDA") and the federal Food Drug and Cosmetic Act ("FDCA"), but argued that the Petition does not challenge federal law or regulations or the federally approved labeling of Depakote. Plaintiff maintained that the defendant's liability under state law does not depend on the violation of a federal statute or regulation or any federally approved label. Plaintiff argued that neither the federal interest in the basic subject matter of the suit, nor the fact that federal funds comprised a large part of the money paid for the Depakote products, is sufficient to confer federal question jurisdiction under *Grable*.

Plaintiff also maintained that exercising federal jurisdiction over the state law claims would interfere with congressional

judgment about the division and balance of responsibilities between state and federal courts. Plaintiff argued that principles of federal-state comity dictate that claims alleged exclusively under state law and brought by the state to protect its citizens and consumers should be heard in state court; to conclude otherwise would deny the police powers of the state. In support of its position the plaintiff also pointed out that: (1) Congress did not establish a private right of action or preemption under federal law for the types of claims alleged, which are traditionally adjudicated in state court; (2) the majority of federal courts have remanded similar cases; and, (3) this case requires a fact-bound and situation-specific analysis and does not fall into the slim category defined by *Grable*, where resolution of the case turned on deciding a pure issue of federal law.

Defendant argued that the numerous references to federal law in the Petition are not incidental. Rather, the allegations demonstrate that the plaintiff has invoked the FDCA and FDA regulations as the sole basis for its claims of false or fraudulent promotion under state law. According to the defendant, the alleged state law claims turn on the resolution of a fundamental federal question, that is, whether promoting Depakote for uses not approved or indicated by the FDA violated federal law and regulations. Thus, the defendant remained steadfast in the position that the plaintiff's state law claims raise significant federal issues that

are not merely relevant to the elements of the claims, but are a necessary predicate to proving those claims.

Analysis

The allegations of the Petition determine whether federal question jurisdiction exists in this case. Defendant appeared to rely on a quantitative approach, that is, reciting the number of times the Petition refers to the FDA, "off-label" and "off-label marketing." Defendant argued:

> The centrality of the federal issues involved in this case is evident from even a cursory review of the State's Petition. The State references "off-label" marketing in 16 of the 21 headings of the Petition and the term "off-label" appears a total of 257 times throughout its 125 page Petition, an average of more than twice per page. Plaintiff likewise references the FDA by name over 50 times, and spends pages of its Petition detailing the federal FDA approval process for drugs and for federally-approved product labeling. (Pet. ¶¶ 63, 65-66, 69-71) Because the entire Petition is based on allegations of "off-label" promotion, which can only mean promotion that violates a federal statute and federal regulations, federal law issues form the entire foundation of the State's claims.[11]

Contrary to the defendant's argument, the number of references to "off-label" and the FDA is not controlling or necessarily determinative. The references may be indicative of an actually disputed and substantial federal question, or only the mere presence of a federal issue. It is the substance of the allegations necessary to support the plaintiff's claims which

[11] Record document number 9, pp. 7 and 12.

determines whether any federal issues embedded in the state law claims raise a substantial question of federal law.

Citing paragraphs 63-71 of the Petition, the defendant argued that at the core of the plaintiff's claims is the allegation that Abbott engaged in off-label promotion of Depakote, and that resolution of this issue requires a determination of whether the drug was marketed in a manner inconsistent with the federally-approved uses described in the federally-approved label. But in paragraph 65 the plaintiff specifically alleged that a physician "may prescribe a drug for uses that are different than those indicated on the label." Plaintiff alleged further that in contemplating "on- or off-label use" a physician relies on patient-specific evidence, and that much of the other information the physician relies on is provided by drug company sales representatives and drug-company-sponsored medical education courses, speaker programs and clinical trials.

The remaining allegations demonstrate that the core of the Petition is the allegation that Abbott unlawfully influenced the off-label prescribing decisions of physicians and providers by intentionally supplying them with false, fraudulent and misleading information about the appropriateness and effectiveness of prescribing Depakote in those situations not covered by the FDA labeling and information. The following act and omissions by

Abbott are detailed in the Petition:[12] (1) knowingly misrepresented evidence concerning the effectiveness and safety of the off-label uses of Depakote products; (2) knowingly marketed and promoted Depakote products for uses that were not effective and/or safe, i.e. not supported by demonstrable scientific facts or substantial and reliable medical and scientific opinion; (3) knowingly created off-label consensus guidelines on the use of Depakote products in a way that made them appear to be written by independent researchers, but were in fact sponsored or ghost-written by Abbott and/or its agents; (4) improperly sent these publications out to physicians and providers through requests by sales representatives that were made to appear to be requests from the physicians and

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[12] See record document number 1-6, Petition, ¶ 5. The Petition has 478 numbered paragraphs. It is not necessary to list or summarize all of the plaintiff's allegations here. Viewing the Petition as a whole, paragraph 5 gives a fair summary of the alleged false, fraudulent and misleading actions the defendant used to market and promote the off-label uses of Depakote to physicians and other providers.

Paragraph 62 of the Petition also summarized at least three illegal schemes which resulted in false claims being submitted to Louisiana Medicaid and medical assistance programs. These include: (1) marketing off-label uses of Depakote to Louisiana government-pay prescribers and providers in violation of MAPIL; (2) using misrepresentations and deceptive, false and/or fraudulent records and/or statements to persuade physicians and health care providers to prescribe Depakote ER for off-label purposes, to write new prescriptions for Depakote ER and to prescribe Depakote ER instead of Depakote DR to increase its profits in violation of MAPIL, LUTPCPL, and other state laws and statutes; and, (3) using illegal remuneration, including kickbacks, honoraria, gifts and rebates to induce physicians and healthcare providers to prescribe Depakote in violation of MAPIL, LUTPCPL, and other Louisiana laws and statutes.

providers; (5) paid financial inducements to key opinion leaders who gave presentations concerning the off-label uses at promotional speaker or continuing medical education programs, despite the lack of scientific facts or substantial and reliable medical and scientific opinion to support the off-label uses of Depakote products, and also funded the creation and dissemination of standing orders for off-label uses so that patients would be treated with Depakote products without a physician having to write a prescription; (6) knowingly funded and disseminated consensus guidelines to promote the off-label use of Depakote products for the treatment of agitation and aggression associated with dementia, representing that they were prepared by unbiased experts when in fact the preparers were paid by Abbott for the purpose of increasing sales of Depakote products.

This summary demonstrates that the gravamen of the plaintiff's alleged violations of state law is not that Abbott simply promoted and marketed Depakote products for off-label uses, but that they did so by false, fraudulent and misleading practices. As alleged in the Petition, these types of practices resulted in misbranding Depakote in violation of the Louisiana Food Drug and Cosmetic Act (LFDCA). LSA-R.S. 40:601, et seq.[13] The alleged violation of the

[13] Under LSA-R.S. 40:617A a drug or device is "misbranded" if it has been found to be such by any department of the United States government, or:

(1) If its labeling is false or misleading in any

(continued...)

LFDCA resulted in the submission of false claims to Louisiana Medicaid and medical assistance programs to pay for Depakote products which would not have been prescribed or administered but for the defendant's false, fraudulent and misleading conduct in the marketing and promotion of Depakote.[14] This, the "misbranding" in violation of state law is the basis for the state law claims on for which the plaintiff seeks relief.

Depakote products are prescription drugs. Therefore, general references to federal law, regulations and labeling do not necessarily indicate the presence of a disputed, substantial federal issue. Review of the Petition shows that the numerous references to the FDA, FDCA and off-label are either alleged as background information or as facts relevant to describing the

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[13](...continued)
particular. Any representation concerning any effect of a drug or device is considered false for purposes of this Paragraph if the representation is not supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion.
(2) If it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof.
The LFDCA also defines "advertisement" to include all representations of fact or opinion disseminated to the public in any manner or by any means other than by the labeling, and "labeling" includes all labels and other written, printed and graphic matter, in any form whatsoever that accompanies any food, drug, device or cosmetic. LSA-R.S. 40:602(1) and (8).

[14] Plaintiff alleged that between 1997 and 2008 the defendant's fraudulent and misleading promotion and marketing of Depakote products caused Louisiana Medicaid and medical assistance programs to reimburse providers over $35 million dollars. Record document number 1-6, Petition, ¶ 18.4.

defendant's fraudulent, false and misleading scheme to convince physicians and providers to prescribe or administer Depakote.[15] This conclusion is supported by a fair reading of the allegations in the Petition as a whole rather than only focusing on specific words and phrases scattered throughout its 478 paragraphs.

In determining whether the defendant's actions violated state law, the federally-approved label will be examined and compared to the uses being promoted and marketed. But liability will not depend on this inquiry. Liability will turn on whether the defendant's conduct was false or misleading, as defined by the LFDCA. Thus, the allegations in the Petition do not indicate that the violation of any federal law or regulation will be an actually disputed and substantial issue in determining whether the defendant's actions violated state law.

Defendant argued that the entire Petition rests on allegations of off-label promotion, which can only mean promotion that violates federal statutes and regulations:

> Thus, the State's claims turn on the resolution of a fundamental federal question: whether Abbott violated the *federal* Food Drug and Cosmetic Act ("FDCA") and associated *federal* regulations by promoting Depakote for uses not approved or indicated by the *federal* Food and Drug Administration ("FDA")."[16]

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[15] See, e.g. record document number 1-6, Petition, ¶¶ 50, 52-58, 63, 66, 68-71, 74, 93, 147, 160, 162, 165, 171, 174, 175, 188, 218, 220, 226, 239, 241, 245, 248, 265, 269, 272.

[16] Record document number 9, pp. 1-2 (emphasis in original).

But Abbott failed to persuasively explain why the state law claims turn on the resolution of this question, or why off-label promotion can only mean promotion that violates federal law and regulations. Nor did the defendant cite any specific federal statute or regulation that would be violated if the plaintiff merely establishes that Depakote was marketed and promoted for uses not approved or indicated by the FDA.

Defendant relied in part on copies of the pleadings filed against Abbott and others in federal False Claims Act cases involving the off-label marketing of Depakote.[17] The district court in Virginia has original federal question jurisdiction in these actions based on the False Claims Act, and has supplemental jurisdiction over the claims by the various states, including Louisiana's MAPIL claims alleged in three of the consolidated cases. Defendant pointed out that the allegations of off-label marketing and violations of the FDA and FDCA support both the False Claims Act and Louisiana cause of action, and that the Petition here simply copied the identical language from the federal suits and inserted a few more allegations and references to Louisiana law. Therefore, Abbott argued, the uniformity of the allegations

[17] Copies of the complaints were filed with the Notice of Removal. Record document number 1-2, Exhibit B; record document number 1-4, Exhibit D; record document number 1-5, Exhibit E. These three actions along with another case are consolidated in the Western District of Virginia. Record document number 1-1, Exhibit A. There is no question of federal jurisdiction in these cases.

and legal issues contained in the consolidated federal cases and the Petition illustrates the importance of the federal issues and the need for a consistent resolution in the federal courts.

This argument is unpersuasive. Defendant did not cite the specific allegations it claims were actually or essentially copied, nor did the defendant cite any legal authority for its argument that similarity between the allegations in a state court suit and a False Claims Act case supports finding a substantial federal issue in a suit alleging only violations of state law.

Defendant also argued that the *Grable* standard is met in this case because the plaintiff's claims are predicated on violations of federal law. Defendant argued that *Grable* is binding, on-point authority supporting the finding that federal jurisdiction exists in this case.[18] The *Grable* standards are binding, but the circumstances in *Grable* are not on-point. The factual and legal basis for concluding that there was federal question jurisdiction in *Grable* are easily distinguished. In *Grable*, whether the plaintiff was given proper notice within the meaning of the federal tax statute was an essential element of the plaintiff's claim, and the only contested issue in the case. Contrary to the defendant's assertion, the plaintiff here has not elected to invoke the FDA or FDCA or federal regulations as the sole basis for its claims. Rather, the allegations here show that the plaintiff's claims (that

[18] Record document number 9, p. 2.

the defendant marketed and promoted Depakote for conditions, symptoms and patients that were not approved or indicated by the FDA) are just part of the alleged factual basis for proving the defendant violated the state laws cited in the Petition.

Plaintiff argued that the decision in *Merrell Dow Pharmaceuticals, Inc. v. Thompson*[19] supports the conclusion that any federal issues embedded in the Petition are not substantial. Defendant argued that the plaintiff's reliance on *Merrell Dow* is misplaced. Defendant's argument is unpersuasive.

Defendant asserted that *Merrell Dow* does not warrant remand for two main reasons.[20] First, the defendant noted that the case predated *Grable*, and that in *Grable* the Court stated that *Merrell Dow* did not overturn decades of precedent, and did not establish a bright-line rule for determining whether a case alleging state law claims involves substantial federal issues. Defendant failed to explain how this shows *Merrell Dow* does not support remand. Review of the *Grable* court's entire discussion of *Merrell Dow* actually supports the conclusion that the federal issues in this Petition are not substantial.

In *Grable* the Court did not retreat from the holding and

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[19] 478 U.S. 804, 106 S.Ct. 3229 (1986). *Merrell Dow* involved the removal of a state court petition that alleged only state law claims of negligence, breach of warranty, strict liability, fraud and gross negligence against the manufacturer/distributor of the prescription drug Bendectin.

[20] Record document number 9, p. 13.

reasoning in *Merrell Dow*. It clarified that the case "should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the 'sensitive judgments about congressional intent' that § 1331 requires." *Grable*, 545 U.S. at 318, 125 S.Ct. at 2370. The Court explained that in *Merrell Dow* it was the combination of no federal cause action and no preemption of state remedies for misbranding that provided an important indication that Congress would not have intended the exercise of federal question jurisdiction in circumstances which would have resulted in a potentially "enormous shift of traditionally state cases into federal courts." *Id.* 319, 125 S.C. at 2371.

The circumstances of this case are not any different. This case also involves a prescription drug. Abbott did not claim, and there has been no showing, that there is a private cause of action for violations of any FDCA/FDA law or regulations implicated by the plaintiff's allegations. Nor has the defendant argued or shown that federal law preempts any of the state law claims and remedies alleged in the Petition.[21]

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[21] Defendant argued that the plaintiff alleged off-label promotion because proving off-label promotion is the only way the plaintiff can make a case without going against substantial precedent holding that fraud claims based on promotion that complies with federally-approved labeling is preempted by federal law.

None of the cases cited by the defendant involved prescription drugs. Record document number 9, p. 12. They involved federal

(continued...)

Second, the defendant argued that *Merrell Dow* does not support a finding that a substantial federal question is lacking in this case because *Merrell Dow* involved a conventional personal injury claim, and the alleged FDCA violation was only one standard by which the plaintiff could prove his negligence claim. The defendant argued that "[b]y contrast the FDCA issues in this case are central, necessary elements of the State's claims because proving off-label promotion is the State's only avenue for proving its case."[22] This assertion is unsupported. Moreover, the *Merrell Dow* decision itself and the Court's discussion of it in *Grable* demonstrate that there is no substantial federal issue present bases on the allegations in the state court Petition.

In *Merrell Dow* the plaintiff alleged that because the Bendectin labeling did not adequately warn that its use was potentially dangerous, it was misbranded in violation of the FDCA.; and the violation of the FDCA in the promotion of the drug created a rebuttable presumption of negligence under state law. The Court concluded that where Congress did not create a private federal remedy for violation of the FDCA, a complaint alleging a violation of the FDCA as an element of a state law cause of action did not

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[21] (...continued)
laws that have preemption provisions - laws that apply to over-the-counter medications and medical devices. Nevertheless, through this argument the defendant essentially acknowledges that preemption of state law claims is not a factor in this case.

[22] Record document number 9, p. 13.

give rise to a federal claim under § 1331. The *Grable* Court explained that other important factors were at work in *Merrell Dow*: (1) the absence of federal preemption of state remedies for misbranding; (2) if alleging the violation of federal labeling standards could get a state claim into federal court, so could alleging the violation of any other federal standard without a federal cause of action; and, (3)the result would attract a large number of original filings and removed cases raising other state claims with embedded federal issues to the federal courts.

Like *Merrell Dow*, the federal labeling standards will be an issue in this case. But that is true simply because the alleged fraudulent scheme which violated the LFDCA involved the marketing and promoting of off-label uses of the prescription drug Depakote. To prove that the scheme involved off-label uses, evidence of what was "on-label", i.e. the federally approved label, will be relevant to proving the fraudulent scheme. However, unlike *Merrell Dow*, the plaintiff in this case has not alleged any violation of the FDCA, other federal law or regulations as proof of its state law claims. Plaintiff only alleged violations of the state misbranding law, which is an element of the state law claims under which the plaintiff is seeking relief. This makes the federal issues embedded in this Petition even less substantial than those present in *Merrell Dow*. To the extent the Petition can be construed to allege violations of the FDA or FDCA provisions governing off-label

marketing, as evidence to establish a violation of state law, the presence of such an issue would be similar to and no more substantial than the issue in *Merrell Dow*.

Finally, what the *Grable* court observed about *Merrell Dow* is also true in this case: if the need to introduce evidence of the federal labeling standards warrants exercising federal jurisdiction over purely state law claims, then this could potentially result in a significant shift to the federal courts of traditional state cases alleging fraud, redhibition and violation of state consumer protection laws. Such a shift would breach "Congress's intended division of labor between state and federal courts." *Grable*, 545 U.S. at 319, 125 S.Ct. at 2371.

Conclusion

Defendant has the burden of establishing the existence of jurisdiction under § 1331. The Petition alleges only state law claims. Application of the legal standards established by the Supreme Court in *Franchise Tax Board*, *Merrell Dow* and *Grable* leads to the conclusion that the defendant failed to demonstrate that the Petition alleges claims which involve actually disputed and substantial federal issues a federal court may entertain without disturbing the congressionally-approved balance of federal and state judicial responsibilities. Defendant failed to satisfy its burden of establishing federal question jurisdiction. The State's Motion to Remand should be granted.

Recommendation

It is the recommendation of the magistrate judge that the State's Motion to Remand be granted.

Baton Rouge, Louisiana, March 5, 2012.

STEPHEN C. RIEDLINGER
UNITED STATES MAGISTRATE JUDGE