

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF KENTUCKY  
LOUISVILLE DIVISION**

**CIVIL ACTION NO. 3:13-CV-00624-JHM**

**COMMONWEALTH OF KENTUCKY *ex rel.*  
JACK CONWAY, ATTORNEY GENERAL,**

**PLAINTIFF**

**V.**

**JANSSEN PHARMACEUTICALS, INC., *et al.***

**DEFENDANTS**

**MEMORANDUM OPINION AND ORDER**

This matter is before the Court on the Commonwealth's Motion to Remand [DN 10]. Fully briefed, this matter is ripe for decision. For the following reasons, the motion is **GRANTED**.

**I. BACKGROUND**

This action focuses on Risperdal®, a prescription antipsychotic medicine which has been approved by the Food and Drug Administration ("FDA"). Since its launch in 1994, Defendants have advertised, sold, marketed, and distributed Risperdal to Kentucky's health care providers, pharmacies, and consumers. (Compl. [DN 1-2] ¶¶ 1-5.) On May 14, 2013, the Commonwealth of Kentucky, through its Attorney General, filed a one-count complaint against Defendants in the Jefferson Circuit Court, Division Three. (*See id.*) In that complaint, the Commonwealth alleges that Defendants violated the Kentucky Consumer Protection Act ("KCPA") by labeling and promoting Risperdal in an unfair, false, misleading, or deceptive manner. (*See id.* ¶¶ 41-44.)

The Commonwealth's complaint contains lengthy, detailed factual allegations regarding Defendants' conduct in testing and marketing Risperdal, as well as in concealing its risks. (*Id.* ¶¶ 15-40.) Specifically, the Commonwealth alleges that Defendants knew that taking Risperdal would increase the risks of diabetes, hyperglycemia, clinically significant weight gain, cerebrovascular adverse events (including stroke in elderly patients with dementia), hyperprolactinemia, and other

serious health conditions. However, Defendants “never warned doctors and patients about the serious risk of cerebrovascular adverse events in the elderly with dementia until mid-2003,” “never warned . . . of the increased risk of diabetes and hyperglycemia until late 2003,” “never warned . . . of the serious risk of increased weight gain,” and “only warned . . . about the hyperprolactinemia risk associated with Risperdal beginning in mid-2007.” (Id. ¶ 18.) The Commonwealth also alleges that Defendants “obfuscated, downplayed, misrepresented, hid, and lied about vital safety information” concerning Risperdal use. (Id.)

As an example of this behavior, the Commonwealth alleges that Defendants concealed clinical trial results. (Id. ¶¶ 19-24.) It also alleges that instead of warning about Risperdal’s risks, Defendants merely listed weight gain and hyperglycemia as two of the drug’s sixty infrequent adverse reactions, “incorrectly convey[ing] that weight gain and diabetes are infrequent adverse effects, i.e., occur in less than one patient out of a hundred, when Defendants knew that weight gain and diabetes occur at a much higher incidence rate in patients taking Risperdal.” (Id. ¶ 30.) Further, the Commonwealth alleges that Defendants’ sale aids and promotional materials falsely represented safety information regarding Risperdal’s risks, (id. ¶ 33), and that Defendants sent Kentucky doctors a “Dear Doctor” letter which falsely stated that Risperdal “is not associated with an increased risk of diabetes.” (Id. ¶ 40.)

On June 14, 2013, Defendants removed the Commonwealth’s action to federal court. According to them, the FDA’s control over prescription drug labeling vis-à-vis the federal Food, Drug & Cosmetic Act (“FDCA”) gives rise to substantial federal questions in this case. (See Not. of Removal [DN 1].) The Commonwealth responds that removal was inappropriate, as Defendants have failed to show that there is a substantial federal question. According to the Commonwealth, the Court must remand the case to the Jefferson Circuit Court, Division Three. (See Pl.’s Mot. to

Remand [DN 10].) On September 18, 2013, the Court heard oral arguments on this issue. It now finds that the Commonwealth's motion to remand is **GRANTED**.

## II. DISCUSSION

As the removing party, Defendants bear the burden of establishing federal jurisdiction. See Alexander v. Elec. Data Sys. Corp., 13 F.3d 940, 948–49 (6th Cir. 1994). “All doubts as to the propriety of removal are resolved in favor of remand.” Coyne v. Am. Tobacco Co., 183 F.3d 488, 493 (6th Cir. 1999). In the present case, Defendants argue that they have established federal jurisdiction under 28 U.S.C. § 1331. (See Not. of Removal [DN 1] 1.) Section 1331 states that “district courts shall have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. The Supreme Court has explained that a plaintiff's claim may arise under federal law if the plaintiff pleads: (1) a cause of action created by federal law or (2) “state-law claims that implicate significant federal issues.” Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 312 (2005). Here, Defendants argue that the Commonwealth's state-law KCPA claim will require the application of the Food, Drug, & Cosmetic Act (“FDCA”), thus implicating significant federal issues. The Commonwealth counters that federal jurisdiction is lacking and that remand is appropriate.

The Sixth Circuit has held that for a state-law claim to implicate a significant federal issue: “(1) the state-law claim must necessarily raise a disputed federal issue; (2) the federal interest in the issue must be substantial; and (3) the exercise of jurisdiction must not disturb any congressionally approved balance of federal and state judicial responsibilities.” Mikulski v. Centerior Energy Corp., 501 F.3d 555, 568 (6th Cir. 2007) (citing Grable & Sons Metal Prods., Inc., 545 U.S. at 319). The parties' arguments track this framework.

## 1. Disputed Federal Issue

Defendants argue that the Commonwealth's KCPA claim is based on a disputed federal issue because it is premised on the alleged misplacement of risk information on Risperdal's label. (See Defs.' Mem. in Opp. to Pl.'s Mot. to Remand [DN 13] 4-9.) As discussed above, in its complaint, the Commonwealth alleges that Defendants violated the KCPA by listing certain risks as infrequent adverse reactions instead of as warnings, "incorrectly convey[ing] that weight gain and diabetes are infrequent adverse effects, i.e., occur in less than one patient out of a hundred, when Defendants knew that weight gain and diabetes occur at a much higher incidence rate in patients taking Risperdal." (Compl. [DN 1-2] ¶ 30.) Defendants argue that the Commonwealth's right to relief turns on construing and applying the FDCA, which specifies the information that must be put in each section of a package insert of an FDA-approved medicine. See 21 C.F.R. § 201.57 (outlining the requirements on the content and format of labeling for prescription drugs).

According to Defendants, the existence of a disputed federal issue is most apparent with respect to the placement of risk information regarding hyperprolactinemia. In its complaint, the Commonwealth alleges that Defendants' Risperdal labeling did not "disclose any warning that Risperdal has the potential to cause hyperprolactinemia until mid-2007 . . . ." (Compl. [DN 1-2] ¶ 31.) This allegation seems to relate to the fact that risk information on hyperprolactinemia was not placed in the "Warnings and Precautions" section of Risperdal's label until mid-2007. (See Aug. 2007 Package Insert, Ex. from Oral Arg.). However, Defendants highlight that ever since Risperdal was first approved in the early 1990s, its label included the same risk information on hyperprolactinemia—only in the "Precautions" section. (See Dec. 1993 Package Insert, Ex. from Oral Arg.) Thus, Defendants argue that the Commonwealth's "label claims" are based on the alleged misplacement of risk information in Risperdal's label. In other words, Defendants propose that the Commonwealth's theory is that Defendants were violating the KCPA when the risk information

was in the “Precautions” section; however, when that information was moved to the “Warnings and Precautions” section in 2007, Defendants were no longer violating the KCPA. Defendants argue that since the FDCA specifies the information that must be put in each section of a package insert of an FDA-approved medicine, a disputed issue of federal law exists. (See Def.’s Mem. [DN 13] 6-7.)

The Commonwealth responds that Defendants have mischaracterized their allegations by wrongly limiting the scope of the dispute to the proper location of risk information on the FDA-approved drug label. According to the Commonwealth, federal law is implicated here only, if at all, through Defendants’ federal-based defenses—i.e. their efforts to shield themselves from liability by virtue of the fact that Risperdal’s labels were FDA-approved. (See Pl.’s Mem. in Supp. of its Mot. to Remand [DN 10-1] 5-7.) The Commonwealth maintains that this cannot support removal jurisdiction. See Mikulski, 501 F.3d at 560 (holding that to “determine whether the claim arises under federal law,” the Court must examine “the ‘well pleaded’ allegations of the complaint and ignore potential defenses”). In support of this argument, the Commonwealth highlights that it makes no allegations regarding the FDA’s labeling decisions; the complaint never even mentions the FDA. According to the Commonwealth, it simply alleges that Defendants took actions to omit and downplay serious risk information, despite their awareness of risks. (See Compl. [DN 1-2] ¶ 44.) The Commonwealth thus suggests that its claims are not based on disputed federal issues.

The Court finds Defendants’ argument more persuasive. In this case, it is undisputed that to succeed on its KCPA claim, the Commonwealth must show that Defendants engaged in unfair, false, misleading, or deceptive practices. See K.R.S. § 367.170. While the Commonwealth never mentions the FDA in its complaint, it seems clear to the Court that part of its proof will involve interpreting the FDCA’s provisions to determine whether Defendants actually misplaced certain risk information on Risperdal’s labels. (See Compl. [DN 1-2] ¶ 44.) In this respect, it will be necessary

for the parties to interpret various FDCA provisions—and it seems almost certain that their interpretations will differ. Therefore, the Court finds that there is a disputed federal issue.

However, the nature of the disputed federal issue in this case is limited. Specifically, the only issue is whether Defendants complied with the FDCA’s labeling provisions in light of their knowledge concerning Risperdal’s various risks. The Court notes at the outset that this issue will be decided in the context of state law and whether Defendants’ compliance, or non-compliance, with the FDCA indicates that Defendants acted in an unfair, false, deceptive, or misleading manner.

## **2. Substantial Federal Interest**

The Court must next determine whether the federal interest in the disputed issue is substantial. The Sixth Circuit has held that courts must consider four factors in this analysis:

(1) whether the case includes a federal agency, and particularly, whether that agency’s compliance with the federal statute is in dispute; (2) whether the federal question is important (i.e., not trivial); (3) whether a decision on the federal question will resolve the case (i.e., the federal question is not merely incidental to the outcome); and (4) whether a decision as to the federal question will control numerous other cases (i.e., the issue is not anomalous or isolated).

Mikulski, 501 F.3d at 570. Importantly, “no single factor is dispositive and these factors must be considered collectively, along with any other factors that may be applicable in a given case.” Id. Here, the Court finds that the factors weigh against characterizing the federal interest as substantial.

*Federal Agency.* Defendants argue that the first factor supports a finding that a substantial federal interest is at stake because the case includes a federal agency, the FDA, which is responsible for both the format and the content of prescription drug labels. While Defendants concede that the Commonwealth seeks no relief from the FDA, they maintain that the FDA is still included in this case because it approved the Risperdal labels that are challenged by the Commonwealth. (See Defs.’ Mem. [DN 13] 11.) Defendants cite Grable for the proposition that an agency can be

included in a case even if it is not a party to the action. 545 U.S. at 315-16 (discussing the IRS' involvement and inclusion in a quiet title action even though it was not a party).

The Commonwealth counters that this first factor weighs against a finding that the federal interest is substantial. Essentially, it argues that the FDA is not included in this case in the Grable sense because its actions are not actually in dispute. In Grable, the parties' dispute centered around the actions of the IRS and their compatibility with a federal statute. 545 U.S. at 315; see Empire Healthchoice Assurance, Inc. v. McVeigh, 547 U.S. 677, 700 (2006) (explaining Grable). Here, however, the Commonwealth contends that it is not challenging any FDA action or whether the FDA complied with federal regulations. According to the Commonwealth, the issue in this case is simply whether Defendants disclosed their knowledge of various health risks at all: either to the FDA or to health care providers, pharmacies, and consumers. The issue is not whether the FDA properly applied the FDCA's regulations to Risperdal's labels. Thus, the Commonwealth contends that the FDA is not involved in this case. It may continue to interpret and apply federal regulations as it wishes. (See Pl.'s Mem. [DN 10-1] 9.)

The Court agrees with the Commonwealth that this factor weighs against characterizing the federal interest as substantial. Defendants seem to overlook the fact that the FDA's actions—namely, its decisions to approve the placement of the subject risk information in certain sections of Risperdal's labels—are not being challenged here. Instead, the critical question is whether **Defendants'** actions relative to Risperdal's labeling were unfair, deceptive, misleading, or false so as to violate **Kentucky** law. As the Commonwealth correctly notes, the FDA is not included here in the Grable sense. Its actions are not actually disputed. While Defendants will certainly raise the defense that they did not violate the KCPA because the FDA deemed their conduct to comply with federal law, the question is not whether the FDA should have applied its regulations

differently when approving Defendants' proposed Risperdal labels. Therefore, the Court finds that the FDA is not included in this action. The first factor supports the Commonwealth.

*Importance of Federal Question.* Defendants next argue that the second factor supports a finding that a substantial federal interest is at stake. According to Defendants, the federal question is important because a resolution of the Commonwealth's "label claims" will require an interpretation of the FDCA. (See Defs.' Mem. [DN 13] 11-12.) In this regard, Defendants highlight that there is a federal interest in the uniform application of the FDCA. Defendants also highlight that the FDA has a significant interest in the uniform format of prescription labels. (See *id.*)

Defendants cite *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 398378 (E.D.N.Y. Feb. 12, 2008), to support their position that the federal question here is important. In that case, a federal court chose to exercise jurisdiction in a lawsuit filed by the Montana Attorney General against a pharmaceutical manufacturer. *Id.* at \*7. In so doing, the court found that the Attorney General's state-law Montana Consumer Protection Act claim raised a substantial issue of federal law. The court reasoned, in part, that Montana's claims of off-label marketing would "necessarily raise substantial federal questions by requiring the court to interpret the meaning of the FDCA and its implementing regulations." *Id.* at \*5. Defendants argue that here, the Commonwealth's label claims would similarly raise a substantial federal question; the federal question here is important.

The Commonwealth responds that this second factor weighs against a finding that the federal interest is substantial. The Commonwealth first distinguishes the *In re Zyprexa* decision. In so doing, the Commonwealth notes that in *In re Zyprexa*, Montana was seeking to recover costs allegedly incurred by the state's Medicaid program as a result of the drug manufacturer's wrongful promotion of Zyprexa. *Id.* at \*3. In deciding to exercise federal jurisdiction, the court reasoned that the "question of the state's obligation to reimburse its insured for prescription drugs, using funds largely provided by the federal government, is essential to the state's theory



of damages and presents an unavoidable central and disputed federal issue.” Id. at \*3-4. In addition, the court noted that there is “no state-law equivalent of ‘off-label.’” Id. at \*5. But in this case, Kentucky seeks civil penalties under the KCPA. It does not seek federally-funded Medicaid reimbursement payments. Also, there are no issues regarding any off-label promotion of Risperdal. (See Pl.’s Reply [DN 15] 7.)

Further, the Commonwealth argues that at most, the mere interpretation of certain FDCA provisions will be at issue. The Commonwealth cites In re Vioxx Prods. Liab. Litig., 843 F. Supp. 2d 654 (E.D. La. 2012), for support. In that case, the Kentucky Attorney General filed a state Kentucky Consumer Protection Act suit against the drug manufacturer of Vioxx to recover civil penalties and injunctive relief under the KCPA, alleging that the manufacturer failed to disclose certain study results to the FDA or to the public. Id. at 668. After the action was removed, the federal court remanded it, finding that the action did not raise a substantial federal question. Id. at 668-70. It held that while the complaint “alleges facts regarding Merck’s conduct vis a vis the FDA . . . those facts are only some allegations among many.” Id. at 669.

Notably, the In re Vioxx court distinguished the In re Zyprexa decision, holding that the specific federal dimensions present in Montana’s case were lacking in Kentucky’s case. It noted that in In re Vioxx, Kentucky sought “civil penalties pursuant to the KCPA and not federally-funded Medicaid reimbursement payments.” Id. It also noted that there were “no issues of off-label promotion of Vioxx.” Id. The Commonwealth argues that the facts here are similar to In re Vioxx.

The Court agrees with the Commonwealth that In re Zyprexa is distinguishable from this case—and that In re Vioxx is persuasive authority. Thus, the Court holds that this second factor weighs in favor of remand. The federal question here is not important. At most, the interpretation of certain FDCA provisions will be at play—and any interpretation will be done in the context of state law when analyzing Defendants’ knowledge and disclosure of certain risks on Risperdal’s

labeling. While Defendants argue that *In re Vioxx* does not control the outcome of this case since the federal issue is not a mere element of the Commonwealth’s “label claims” (but is the crux of those claims), the Court finds that this argument ignores the true character of the Commonwealth’s complaint. Like the complaint in *In re Vioxx*, the complaint here seeks civil consumer protection penalties and injunctive relief for Defendants’ alleged concealment of risk information from Kentucky health care providers, pharmacies, and consumers. Any allegation as to the proper labeling of Risperdal is only part of the Commonwealth’s larger state-law claim. Contrary to Defendants’ position, the Commonwealth does not separately assert “label claims.” Instead, a review of the complaint reveals that it asserts a KCPA claim—and labeling considerations are only raised as proof of Defendants’ alleged KCPA violations. As in *In re Vioxx*, any federal question in this case will be resolved in the context of whether Defendants’ labeling constitutes a violation of **Kentucky** law. The second factor supports the Commonwealth.

*Case’s Resolution.* Defendants next argue that the third factor supports a finding that a substantial federal interest is at stake because the Commonwealth’s “label claims” will fail if it cannot establish that certain risk information should have been placed in the “Warnings” section of Risperdal’s label. Defendants maintain that the answer to the federal question in this case will be dispositive of the Commonwealth’s “label claims.” (See Defs.’ Mem. [DN 13] 15-16.)

The Commonwealth counters that this third factor weighs against a finding that the federal interest is substantial because the so-called “label claims” are only some of its allegations among many. As an example, the Commonwealth highlights that it has alleged that Defendants failed to disclose certain known health risks altogether and that they sent a “Dear Doctor” letter to Kentucky doctors which contained false information. (See Compl. [DN 1-2] ¶¶ 26-29, 40.) The Commonwealth argues that these allegations are also part of its KCPA claim. (See Pl.’s Mem. [DN 10-1] 11.) The Commonwealth maintains that its case is similar to *In re Vioxx* because even

if Kentucky did attempt to prove that Defendants failed to comply with the FDCA by misplacing certain information in their labels, that question would be resolved in the context of whether that conduct constituted a violation of **Kentucky** law. See *In re Vioxx*, 843 F. Supp. 2d at 669.

The Court agrees with the Commonwealth that this factor weighs against finding that the federal interest is substantial. As in the *In re Vioxx* decision, the question of whether Defendants complied with the FDCA with respect to placing certain risk information in the proper sections of Risperdal’s label will be resolved in the context of whether that conduct violated Kentucky law. The question will be whether Defendants had the requisite knowledge such that they should have placed the risk information in a different section of Risperdal’s label under the FDCA—and whether their alleged failure to place such information in a different section violated the KCPA.

Further, the Court believes that the facts of this case are similar to those in *Mikulski*. In that case, the Sixth Circuit found that certain federal issues would not be dispositive of the case, noting that if those issues were resolved in favor of the defendant, the plaintiffs could still prevail. 501 F.3d at 571. The same can be said here. If the federal issues are resolved in favor of Defendants (i.e. the Commonwealth fails to establish that Defendants had knowledge of certain risks such that they should have placed risk information in the “Warnings” section of Risperdal’s label under the FDCA), the Commonwealth could still prevail in its KCPA case. To do so, it would only need to demonstrate that some other conduct of Defendants was misleading, deceptive, unfair, or false—and the Commonwealth has alleged that such conduct was present (i.e. in Defendants’ alleged failure to disclose their knowledge of certain health risks altogether and in Defendants’ sending of a “Dear Doctor” letter to Kentucky doctors). Thus, the Court finds that resolving the federal issue will not necessarily conclude this action.<sup>1</sup> The third factor supports the Commonwealth.

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<sup>1</sup> In this respect, the Court notes that Defendants seem to misconstrue the nature of the third factor, arguing that the resolution of the federal question will resolve the Commonwealth’s “label claims.” (See Defs.’ Mem. [DN

*Impact on Other Cases.* Defendants argue that the fourth factor supports a finding that a substantial federal interest is at stake because a decision on any federal question will impact the FDA, as well as other state-Plaintiff enforcement actions involving the labeling of prescription drugs. According to Defendants, the Commonwealth’s “label claims” raise questions of statutory and regulatory construction—and questions about applying federal labeling law to Risperdal’s label. Defendants argue that similar questions will necessarily recur in other enforcement actions, whether they involve Risperdal or the prescription medicines of other pharmaceutical companies.

The Commonwealth responds that Defendants have failed to show that any federal issues resolved in this forum will necessarily “control” other cases, as required by Mikulski. Further, the Commonwealth maintains that Defendants have failed to show that any federal issues resolved in this forum will necessarily “control” the FDA. The Commonwealth proposes that while it, and other states, will certainly continue to enforce their respective consumer protection laws, the FDA will be able to persist in its mission, as directed by Congress. According to the Commonwealth, it will be of no consequence to the FDA whether this case is resolved in federal court rather than state court. (See Pl.’s Mem. [DN 10-1] 11-12.)

The Court agrees with the Commonwealth and holds that this fourth factor weighs against finding that the federal interest is substantial. In this respect, the Court again turns to Mikulski. There, the Court found that it was “of no consequence to the IRS whether this case, or any like it, is resolved in federal court rather than the state court.” 501 F.3d at 572. In so finding, the Court noted that the “IRS’s ability to collect taxes in accordance with the law is unaffected by the judicial forum.” Id. The same can be said here for the FDA. Regardless of whether Defendants

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13] 15-16.) However, in analyzing the third factor, a court’s focus must be on whether a resolution of the federal question will impact “the case.” See Mikulski, 501 F.3d at 570. Here, the case involves the KCPA and whether it has been violated. A resolution of the federal question will not be dispositive of whether the Commonwealth prevails on its KCPA claim. The Court reiterates that the Commonwealth does not actually allege any separate “label claims.” Instead, it simply asserts a KCPA violation. Labeling considerations only come into play within the KCPA context.

are found to have misplaced certain risk information on Risperdal’s label, the FDA will continue to enforce its labeling standards and specifications; its ability to do so will be the same regardless of whether this action is resolved here or in state court. The fourth factor supports the Commonwealth.

*Summary of Factors.* In sum, the Court finds that the four substantiality factors identified in Mikulski point toward a holding that the “federal interest in this case is not so substantial that it compels a finding that these traditional state law claims actually ‘arise under’ federal law . . . .” 501 F.3d at 572. After all, the “mere presence of a federal issue in a state law cause of action does not automatically confer federal question jurisdiction, either originally or on removal.” Id. at 565.

The Court notes that other courts have reached similar conclusions when considering federal issues under the FDCA and whether they should exercise federal jurisdiction. See, e.g., Oregon ex rel. Kroger v. Johnson & Johnson, 832 F. Supp. 2d 1250, 1257 (D. Or. 2011) (“[T]he application of the FDCA regulatory regime is not a federal interest that requires the experience, solicitude, or uniformity provided by federal courts. To the contrary, the Supreme Court has recognized that state courts have traditionally handled state claims with embedded FDCA standards. . . . [E]ven a *novel* FDCA issue raised as part of a state cause of action would not typically justify the exercise of federal jurisdiction.”) (internal citations omitted) (emphasis in original); Durack v. MTC Fin., Inc., 2012 WL 2047731, at \*2 (D. Nev. June 5, 2012) (noting that while Plaintiff asserted that Defendants were in violation of the FDCA, that was “not the principal claim[] on the face of Plaintiff’s pleading; the stated federal claim[] [is] not substantial and [is] not clearly raised for dispute in this action. Plaintiff’s complaint is limited to . . . Nevada’s Deceptive Trade Practices Act. While Plaintiff may have alleged that Defendants violated federal law, the alleged violation is not pivotal.”) (internal citations omitted).

### 3. Balance of Federal and State Judicial Responsibilities

Under the final step of the substantial federal question inquiry, the Court must “inquire into the risk of upsetting the intended balance by opening the federal courts to an undesirable quantity of litigation.” Mikulski, 501 F.3d at 573. In this case, Defendants argue that the risk of opening the federal courts to an undesirable quantity of litigation is small. Defendants seem to concede that the FDCA does not provide a federal cause of action. (See Defs.’ Mem. [DN 13] 17-18.) However, they propose that the absence of a private federal cause of action may, or may not, be indicative of congressional intent as to the division between federal and state courts. Compare Merrell Dow Pharm. Inc. v. Thompson, 478 U.S. 804 (1986) (relying on Congress’s failure to provide a private federal cause of action to deny federal jurisdiction), with Grable & Sons Metal Prods., Inc., 545 U.S. at 317-18 (finding that federal question jurisdiction existed despite Congress’s failure to provide a federal cause of action under I.R.C. § 6335, the federal tax provision on sales of seized property). Defendants argue that the inquiry is thus contextual. According to Defendants, the context here indicates that the Court should exercise jurisdiction because doing so would not disturb the balance of judicial responsibilities. They argue that in cases where a violation of federal labeling law is the **entire** basis of a state’s claims, as it is here, a district court’s exercise of jurisdiction would not open flood gates of litigation to federal courts.

The Commonwealth counters that the Supreme Court’s decision in Merrell Dow Pharm. Inc. shows that Congress intended for there to be no federal private right of action under the FDCA. See 478 U.S. at 811-12 (holding that there is no such action under the FDCA and noting that “[t]he significance of the necessary assumption that there is no federal private cause of action . . . cannot be overstated” because “the ultimate import of such a conclusion . . . is that it would flout congressional intent to provide a private federal remedy for the violation of the

federal statute”). As such, the proper jurisdictional question is whether Congress intended for the Court to expand federal question jurisdiction to include claims involving federal prescription drug labeling law. See id. at 813-17. The Commonwealth argues there is no support for such a contention.

The Court agrees with the Commonwealth that this final factor weighs against exercising federal jurisdiction. Several courts have emphasized that the Supreme Court has not recognized a federal remedy for FDCA violations—and have noted that allowing such actions would upset the balance of judicial responsibilities. See, e.g., Marcus v. Med. Initiatives, Inc., 2013 WL 718630, at \*5 (M.D. Fla. Feb. 27, 2013) (“Regarding the FDCA regime in particular, the Supreme Court has put great weight on Congress’s decisions (1) not to create a federal remedy for violations of the FDCA, while (2) selectively declining to pre-empt most state causes of action based on FDCA standards. That is, Congress has affirmatively decided to keep such actions out of federal courts while tolerating overlapping regulation and litigation in state forums. All of this strongly suggests there is no need in drug-related consumer protection cases for the ‘experience, solicitude, and hope of uniformity that a federal forum offers.’ Within the context of the FDCA regime in particular, the Supreme Court [in *Merrell Dow*] has therefore concluded ‘that the presence of a claimed violation of the [FDCA] statute as an element of a state cause of action is insufficiently ‘substantial’ to confer federal-question jurisdiction.”); Grable & Sons Metal Prods., Inc., 545 U.S. at 318 (“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.”) This Court similarly concludes that exercising federal jurisdiction over the Commonwealth’s action here would upset the balance of judicial responsibilities.

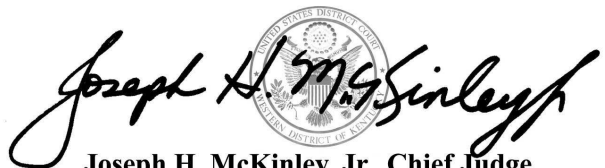
The Court rejects Defendants’ argument that its exercise of jurisdiction would not open flood gates since the Court would only be permitting claims premised entirely on federal labeling law. As discussed above, any allegation about the placement of certain risk information on

Risperdal's label is only **part** of the Commonwealth's KCPA claim. Further, while Defendants claimed in their oral argument that exercising federal jurisdiction would not open flood gates because **only** cases brought by the state involving violations of federal labeling law would give rise to federal jurisdiction—not cases brought by individual consumers involving such violations—the Court finds that this argument is also without merit. The Court sees no difference in the two scenarios. If the Court were to find that the Commonwealth's claims gave rise to federal jurisdiction here, it would similarly find that an individual plaintiff's claims based on the same facts would give rise to jurisdiction. Defendants arguments are accordingly rejected.

Therefore, the Court concludes that it must remand the Commonwealth's case to state court. The FDCA does not provide a cause of action against entities like Defendants. See Merrell Dow Pharm. Inc., 478 U.S. at 811-12. This absence of liability “suggests that Congress did not intend for federal courts to exercise jurisdiction.” PremierTox, Inc. v. Ky. Spirit Health Plan, Inc., 2012 WL 1950424, at \*7 (W.D. Ky. May 30, 2012). In this case, when all the factors are considered, it seems clear to the Court that Defendants have failed to prove that there is a disputed, substantial federal question—or that the resolution of the question in federal court will not upset Congress's balancing of judicial responsibilities. The Commonwealth's motion to remand is thus **GRANTED**.

### III. CONCLUSION

For the reasons set forth above, **IT IS HEREBY ORDERED** that Commonwealth's Motion to Remand [DN 10] is **GRANTED**.

  
Joseph H. McKinley, Jr., Chief Judge  
United States District Court

October 15, 2013

cc: counsel of record  
Jefferson Circuit Court, Division Three