

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at FRANKFORT

THOMAS CLYDE BOWLING,
and RALPH BAZE,

Plaintiffs,

v.

SCOTT HAAS, et al.,

Defendants.

Civil Action No. 3: 07-032-KKC

**MEMORANDUM OPINION
AND ORDER**

**** * * * * *

Plaintiffs Thomas Clyde Bowling and Ralph Baze, two Kentucky death row inmates, have filed a complaint under the Controlled Substances Act, 21 U.S.C. § 801-971 (“CSA”), and the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301-399a (“FDCA”), against defendants Scott Haas, Medical Director for the Kentucky Department of Corrections (“KDOC”); John D. Rees, Commissioner of the KDOC; Thomas Simpson, Warden of the Kentucky State Penitentiary; and Unknown Executioners. [R. 5] Having reviewed the submissions of the parties, the Court will dismiss the complaint with prejudice, as the statutes do not expressly or impliedly provide plaintiffs with a private right of action to enforce their requirements, and because the plaintiffs would be barred from pursuing any such claims under principles of claim preclusion.

I. Background

In their complaint, plaintiffs contend that the defendants’ intended use of sodium thiopental, pancurium bromide; and/or potassium chloride to carry out a sentence of death (1) is not a use approved by the Food and Drug Administration (“FDA”) and (2) would not comply with the requirement that these chemicals be obtained and prescribed or administered by a licensed physician. Plaintiffs sought a declaration to this effect, as well as an injunction barring the defendants from carrying out their

execution by lethal injection in any manner which violates the CSA or FDCA. [R. 5 at ¶¶ 10, 12, 15, 16]

Plaintiffs assert that in carrying out a sentence of death by lethal injection, the KDOC uses a combination of three drugs: sodium thiopental; pancurium bromide; and potassium chloride. The first of these, sodium thiopental, is a “controlled substance” under Schedule III of the CSA. 21 U.S.C. § 812; [R. 5 at ¶40]. Plaintiffs allege that the defendants violate the CSA by purchasing the sodium thiopental in a manner not permitted by the statute, and by either “dispensing” or “administering” the drug by someone who is not a licensed practitioner of medicine. 21 U.S.C. § 829. Plaintiffs further allege that pancurium bromide is a substance regulated by the FDCA, but that the FDA has not approved any of the three chemicals for use in carrying out a sentence of death. [R. 5 at ¶47, 50]

Shortly after the filing of the Complaint, the Court entered a show cause order directing the plaintiffs to establish that the Court possessed subject matter jurisdiction over their claims and that their complaint stated a viable claim for relief. In its order, the Court noted a substantial body of case law which held that neither the CSA nor the FDCA expressly provide for a cause of action for a private litigant, and that courts should not imply one in light of congressional intent. [R. 9]

Prior to service of summons, plaintiffs filed an amended complaint. [R. 12] The plaintiffs have indicated that the amended complaint is identical in all respects to their original complaint except for the deletion of their request for injunctive relief. [R. 16 at 2]

After the plaintiffs filed their response to the Court’s show cause order [R. 16] and following service of summons, the Court directed the defendants to file a responsive pleading and a memorandum of law. [R. 21] In their answer to the complaint, defendants acknowledge and assert that no physician, including defendant Dr. Haas, participates in an execution by lethal injection, as Kentucky law prohibits

such participation except to certify the cause of death. Ky. Rev. Stat. 431.220(3).¹ Defendants further assert that the warden purchases the chemicals used in lethal injections pursuant to a certificate of registration issued by the Drug Enforcement Administration, and that federal regulations implementing the FDCA permit an “institutional practitioner” to handle controlled substances. 21 C.F.R. § 1300.01(11). [R. 25]

Following additional submissions by the parties, the Court entered an order noting that in *Moore v. Rees*, No. 06-CV-0002-KKC (E.D. Ky. 2006), it had denied plaintiffs Bowling and Baze permission to intervene in that proceeding because their participation in prior state court litigation asserting similar claims challenging the constitutionality of Kentucky’s lethal injection protocol precluded the assertion of related claims in *Moore* under principles of claim preclusion under Kentucky law. The Court therefore directed the parties to submit written legal memoranda as to whether the plaintiffs claims under the CSA and FDCA were likewise barred by claim preclusion. [R. 42]

In response, the plaintiffs argue that (1) federal courts have exclusive jurisdiction over claims under the CSA and FDCA, thus they could not have asserted their claims in the prior state court proceedings, and (2) Kentucky preclusion law does bar the subsequent assertion of a claim unless it was affirmatively required to be asserted in the prior litigation. [R. 44, 46] For their part, the defendants assert that plaintiffs misapprehend Kentucky’s preclusion law, and their claims could and should have been pursued in the prior state court litigation. [R. 45]

¹ In light of the Court’s resolution of this case, it need not resolve the independent question whether the present action might implicate the rule that a civil action, which as a practical matter challenges the validity of the death sentence itself, constitutes a second or successive habeas petition notwithstanding its label. *Nelson v. Campbell*, 541 U.S. 637, 643-44 (2004). The rule may apply because the plaintiffs contend that death sentences carried out by lethal injection must comply with a federal law which effectively requires the participation of a licensed physician. However, Kentucky law expressly precludes such participation, both in its lethal injection statute, Ky. Rev. Stat. 431.220(3), and in its regulation of physicians, Ky. Rev. Stat. 311.595, which incorporates Article 2.06 of the American Medical Association’s Code of Ethics by reference. Thus, if plaintiffs’ claim were successful on the merits, there is apparently no way for the defendants to carry out such a sentence in compliance with existing state law.

II. Discussion

A. **The Controlled Substances Act and the Food, Drug, and Cosmetic Act do not permit a private right of action for declaratory relief.**

The Controlled Substances Act was enacted in 1970 as part of the Comprehensive Drug Abuse Prevention and Control Act, and regulates the manufacture, importation, distribution, possession and use of drugs covered by the Act. Under the CSA, the FDA and DEA share responsibility for adding or removing drugs from each of the five schedules of regulated drugs by federal regulation. 21 U.S.C. § 812. Because sodium thiopental is a Schedule III drug, 21 C.F.R. § 1308.13(c)(1)(iii), the CSA requires that a qualified medical practitioner write a prescription for the drug before it may be dispensed. 21 U.S.C. §§ 829(b), 841(a)(1).

The CSA provides for civil penalties of up to \$25,000 for violating the act, vesting federal courts with exclusive jurisdiction over such proceedings “in accordance with section 1355 of Title 28.”² 21 U.S.C. § 842(c)(1)(A). In addition, the CSA authorizes the Attorney General to initiate a civil action “for appropriate declaratory or injunctive relief” for violations of the CSA, and indicates that any such action “may be brought in the district court of the United States... in which the defendant is located or resides or is doing business.” 21 U.S.C. § 842(f)(1), (2).

The Food, Drug, and Cosmetic Act was enacted in 1938, and vests the FDA with regulatory authority to ensure the safety of products within the scope of the Act. To ensure the safety of drug products, the FDCA requires an extensive pre-approval process. 21 U.S.C. § 355(a). The marketing or sale of drugs in interstate commerce without such prior approval is prohibited. 21 U.S.C. § 331(d). The FDCA also requires certain potentially-dangerous drugs to be dispensed only upon a prescription written

² 28 U.S.C. § 1355(a) provides that “[t]he district courts shall have original jurisdiction, exclusive of the courts of the States, of any action or proceeding for the recovery or enforcement of any fine, penalty, or forfeiture, pecuniary or otherwise, incurred under any Act of Congress, ...”

by a licensed practitioner. 21 U.S.C. § 353(b)(1). Dispensing a drug in any manner noncompliant with Section 353(b)(1) “shall be deemed an act which results in the drug being misbranded while held for sale.” 21 U.S.C. § 353(b)(1)(iii). “Misbranding” a regulated drug, including by dispensing it without a prescription, is punishable under 21 U.S.C. § 331(a). *United States v. Nazir*, 211 F. Supp. 2d 1372, 1374 (S.D. Fla. 2002).

The FDCA provides that “all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.” 21 U.S.C. § 337(a). With certain exceptions not relevant here, actions to restrain violations of Section 331 may be prosecuted in the federal district courts. 21 U.S.C. § 332(a).

Interpreting these provisions, courts have uniformly held that the right to enforce the provisions of the CSA and FDCA is possessed exclusively by the Attorney General and the United States, respectively, and that no right of action, either expressed or implied, exists in favor of a private litigant. *McCallister v. Purdue Pharma L.P.*, 164 F. Supp. 2d 783, 793 (S.D. W. Va. 2001) (“The Court agrees with Plaintiffs’ representation that a careful review of the [CSA] establishes no Congressional intent to create a private, civil right of action nor to permit removal...”); *Jackson v. Purdue Pharma Co.*, No. 02-CV-14280, 2003 WL 21356783, at *6 (M.D. Fla. April 11, 2003) (no private right of action under CSA) (citing *Little v. Purdue Pharma. L.P.*, 227 F. Supp. 2d 838 (S.D. Ohio 2002)); *Buckman Co. v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) (“The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance ...”); *Bailey v. Johnson*, 48 F.3d 965 (6th Cir. 1995) (no private right of action under FDCA, citing *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 811-12 (1986)); *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 788 (3d Cir.1999) (same); *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir.1993) (same).

In an action involving identical claims challenging Missouri's lethal injection protocol as violative of the CSA and FDCA, the Western District of Missouri found that neither statute permitted a private right of action. *Ringo v. Lombardi*, No. 09-4095-NKL (W.D. Mo. 2009) (Order of August 19, 2010, slip opinion at 7) ("An action based purely on the CSA and FDCA that would require Defendants to come into compliance with the CSA and FDCA, amounts to a private enforcement action not allowed by the statutes.").

Notwithstanding the evident breadth and clarity of this body of decisional law, plaintiffs contend that their amended complaint – which omitted its claim for injunctive relief so as to pursue only a declaration that defendants' conduct would violate the CSA and FDCA – does not constitute an attempt to "enforce" either statute because it seeks neither monetary penalties nor injunctive relief, and hence falls outside the parameters of this established precedent. Plaintiffs assert that "[b]ecause Congress did not include declaratory judgment actions in this list of actions that must be taken in the name of the United States, private individuals are authorized to maintain solely declaratory judgment actions under this statute." [R. 16 at 10-11]

As a threshold matter, plaintiffs' argument is premised upon the absence of an explicit reference to declaratory judgment actions under the FDCA's enforcement provision, 21 U.S.C. § 337(a). In contrast, the CSA's enforcement provision does expressly authorize the Attorney General to initiate a civil action "for appropriate declaratory or injunctive relief" for violations of the CSA. 21 U.S.C. § 842(f)(1). Accepting Plaintiffs' argument on its own terms, therefore, does not permit the conclusion that a private individual may pursue even declaratory relief under the CSA, where the statute expressly vests that authority with the Attorney General.

Nor can the Court infer from Congress' failure to expressly refer to declaratory judgment actions in the FDCA's enforcement provisions any omen that it intended to leave such a remedial path open to

private citizens. Thus, the Court concludes that an action seeking a declaration that certain conduct will violate the terms of a federal statute constitutes an action to “enforce” that law. The Southern District of Ohio has recently rejected the same distinction proposed by plaintiffs here as specious. *See Durr v. Strickland*, No. 10-CV-288, 2010 WL 1610592, at *3 (S.D. Ohio April 15, 2010) (“In other words, Plaintiff is telling this Court that it can proceed to issue declaratory relief because the Court would not be enforcing federal law or restraining violation of that law by issuing declaratory relief that would stop conduct violating that law. Plaintiff’s semantic slight of hand proves unpersuasive.”)³, *aff’d*, 602 F.3d 788 (6th Cir. 2010) (“We therefore AFFIRM the order of Judge Frost, *for the reasons stated* in his April 15, 2010 opinion and order.”) (emphasis added), *cert. denied*, 130 S.Ct. 2147 (April 19, 2010).

Recent decisions by other courts have echoed this result. The Eastern District of Arkansas recently held that the Supreme Court’s decision in *Franklin v. Massachusetts*, 505 U.S. 788 (1992) could not reasonably be extended so far as to authorize a complaint solely for declaratory relief challenging the state’s lethal injection protocol as violative of the CSA and FDCA, where Congress had declined to create any private right of action at all. As the court aptly explained,

The availability of relief under the Declaratory Judgment Act “presupposes the existence of a judicially remediable right.” *Schilling v. Rogers*, 363 U.S. 666, 677, 80 S.Ct. 1288, 1296, 4 L.Ed.2d 1478 (1960). In *Schilling*, the Supreme Court held that “federal courts may not declare a plaintiff’s rights under a federal statute that Congress intended to be enforced exclusively through a judicially unreviewable administrative hearing. *C & E Servs., Inc. v. D.C. Water and Sewer Auth.*, 310 F.3d 197, 201 (D.C. Cir. 2002).

Congress created two elaborate statutory schemes, the FDCA and the CSA, that are at issue here. In both statutory schemes, Congress defined the scope of jurisdiction granted to the district courts, and in neither instance did Congress include within the jurisdiction of district courts the authority to entertain causes of action brought by private individuals to enforce the statutes. Congress, instead, provided for enforcement of both the FDCA

³ In *Durr*, the court also found that the plaintiff, a death-sentenced inmate, lacked standing to pursue claims directly under the CSA and FDCA where, if his claims were found to have merit, only the defendant prison officials would be at risk of civil penalties or criminal prosecution for violations of federal law, and thus he failed to allege injury to himself sufficient to confer standing. *Id.* at *3-4.

and the CSA by the executive branch.

Jones v. Hobbs, 2010 WL 2985502, at *4-5 (E.D. Ark. July 26, 2010). In light of that comprehensive statutory framework, the court concluded that:

To entertain, under the auspices of the Declaratory Judgment Act, a cause of action brought by private parties seeking a declaration that the FDCA or the CSA has been violated would, in effect, evade the intent of Congress not to create private rights of action under those statutes and would circumvent the discretion entrusted to the executive branch in deciding how and when to enforce those statutes

Id. at *6. The Court concurs with the reasoning in *Jones*, and concludes that any action which seeks a determination that certain conduct would be contrary to the terms of the CSA or the FDCA constitutes an effort to enforce those statutes, regardless of whether that determination is a predicate to only a declaration to that effect, or to further relief by way of civil penalty, disgorgement, destruction of offending articles, further injunctive relief, or criminal prosecution.

Finally, plaintiffs contend that the Supremacy Clause *requires* this Court to find that it possesses jurisdiction over their claims. The nature of their argument is not entirely clear, but plaintiffs assert:

If federal statutes are the supreme law of the land, then it is the federal courts that have the responsibility of interpreting that federal law. ... The judicial branch not only has the authority, it has the duty to declare whether state actors are violating the law.

[R. 16 at 13-14]

Plaintiffs' argument misconprehends the nature of the Supremacy Clause's constitutional command. The Supremacy Clause makes federal law the law of each of the several States, which must be obeyed by state and federal courts alike, even at the expense of subservient state laws. *Swift & Co. v. Wickham*, 382 U.S. 111, 120 (1965). To the extent plaintiffs imply that federal courts have exclusive jurisdiction to decide questions of federal law, the suggestion runs directly contrary to the rule that state and federal courts possess concurrent jurisdiction to decide such matters: "[s]tate courts have inherent authority, and are presumptively competent, to adjudicate claims arising under the law of the United

States.” *Tafflin v. Levitt*, 493 U.S. 455, 458 (1990). Accordingly, “[t]he Supremacy Clause does not address whether a state court must entertain a federal cause of action; it provides only a rule of decision that the state court must follow if it adjudicates the claim.” *Haywood v. Drown*, 129 S.Ct. 2108, 2123 (2009). The Supremacy Clause thus simply creates a hierarchy between state and federal laws, not between state and federal courts which must interpret them.

The Court’s conclusion that there exists no private right of action does not undermine the authority or the duty of a court to decide whether a state actor has complied with federal law; rather, it establishes only that federal law enforcement officials rather than private citizens must be the ones to ask the question in the first instance.

B. Plaintiffs’ claims are barred by principles of claim preclusion.

In prior federal proceedings, this Court denied Bowling and Baze’s motions to intervene in a case challenging Kentucky’s lethal injection protocol on Eighth Amendment grounds, holding that their commencement of a civil suit in the Kentucky courts asserting factually and legally similar claims barred their subsequent assertion of such a challenge in federal court under principles of claim preclusion. *Moore v. Rees*, No. 06-CV-22-KKC (E.D. Ky. 2006) [R. 188, 189 therein]

As noted in that case, federal law requires a federal court to afford full faith and credit to a prior state court judgment to the same extent a state court located in the state where the judgment was rendered would do so. 28 U.S.C. § 1738; *Migra v. Warren City School Dist. Bd. of Educ.*, 465 U.S. 75, 81-85 (1984). Kentucky courts apply claim preclusion to bar “not only ... the issues disposed of in the first action, but to every point which properly belonged to the subject of the litigation in the first action and which in the exercise of reasonable diligence might have been brought forward at the time.” *May v. Webb*, Ky. App., 2004 WL 1699910 (2004); *Whittaker v. Cecil*, Ky., 69 S.W.3d 69, 72 (2002) (final judgment precludes subsequent litigation of claims that were or could have been presented in the prior

action).

In *Ralph Baze and Thomas C. Bowling v. Jonathan D. Rees, et al*, Civil Action No. 04-CI-1094, Franklin Circuit Court, Baze and Bowling contended that numerous aspects of Kentucky's lethal injection protocol would, if implemented, violate the Eighth Amendment. In particular, plaintiffs challenged the use of pancurium bromide and the combination and sequence of the drugs involved, "the methods for obtaining, storing, mixing, and appropriately, labeling the drugs," as well as the lack of involvement of physicians in carrying out the executions. [R. 45 at 3-4]

Plaintiffs contend that although those proceedings challenged the legality of Kentucky's procedures in carrying out a death sentence by lethal injection, (1) they could not have asserted their claims in the prior state court proceedings because federal courts possess exclusive jurisdiction over claims under the CSA and FDCA, and (2) Kentucky preclusion law does not bar their claims because Kentucky law did not affirmatively require them to assert those claims in the prior litigation. [R. 44 at 7-8, 4-5] Neither argument is persuasive.

As to the first, under the federal Constitution, state and federal courts presumptively possess concurrent jurisdiction to decide claims arising under federal law. Congress may choose to vest that authority exclusively with the federal courts; however, to do so, Congress must withdraw state court jurisdiction "by explicit statutory directive." See *Holmes Finan. Assoc., Inc. v. Resolution Trust Corp.*, 33 F.3d 561, 564-66 (6th Cir. 1994); *Yellow Freight System, Inc. v. Donnelly*, 494 U.S. 820, 823 (1990) ("Title VII contains no language that expressly confines jurisdiction to federal courts or ousts state courts of their presumptive jurisdiction. The omission of such a provision is strong, and arguably sufficient, evidence that Congress had no such intent.")

There is no language in either the CSA or the FDCA which expressly retracts the jurisdiction of the state courts to hear and decide enforcement actions brought by the Attorney General under either

statute. Rather, the CSA provides that Attorney General may bring an enforcement action “in the district court of the United States... in which the defendant is located or resides or is doing business.” 21 U.S.C. § 842(f)(2). The FDCA similarly provides that enforcement actions may be brought in federal district court. 21 U.S.C. § 332(a). Plaintiffs argue that “[b]y expressly authorizing one type of litigation under the FDCA to be brought outside of a federal court and not mentioning any others in state court, Congress intended to limit the type of actions under the FDCA that can be brought in state court and to exclude actions not expressly mentioned by the statute.” [R. 44 at 7-8] This argument is refuted by the well-established rule that “the mere grant of jurisdiction to a federal court does not operate to oust a state court from concurrent jurisdiction over the cause of action.” *Gulf Offshore Co. v. Mobil Oil Corp.*, 453 U.S. 473, 479 (1981). It is also undermined by Congress’ express direction in 21 U.S.C. § 842(c)(1)(A) that actions seeking civil penalties for violations of the CSA may only be pursued in federal court pursuant to 28 U.S.C. § 1355, which vests federal courts with both original and exclusive jurisdiction over such matters, a powerful indication that when Congress wished to confer exclusive jurisdiction over enforcement matters under the CSA with the federal courts, it knew how to do so and did so expressly. The courts of the Commonwealth of Kentucky therefore were possessed at all times with concurrent subject matter jurisdiction over actions to enforce the CSA and FDCA where Congress did not expressly provide otherwise. Therefore, plaintiffs’ current claims under the CSA and FDCA were not unavailable to them in the prior state court litigation on the ground that Kentucky courts lacked subject matter jurisdiction to entertain them.

The plaintiffs also argue that Kentucky preclusion law does not foreclose the subsequent assertion of a claim arising from the same set of operative facts unless the applicable substantive and procedural law affirmatively requires the claim to have been asserted in the prior action. Plaintiffs cite *Buis v. Elliot*, Ky., 142 S.W.3d 137 (2004) for this proposition. In *Buis*, the Kentucky Supreme Court

reached the unspectacular conclusion that under Kentucky law, a co-defendant is not required to assert a cross-claim for indemnification against another co-defendant in the original proceeding, as “cross-claims in Kentucky are merely permissive and not compulsory. Cr 13.07.” *Id.* at 141.

Nothing in *Buis* or the subsequent cases construing it supports the conclusion that its holding effected any sea change in longstanding Kentucky jurisprudence that requires a plaintiff to assert all claims arising out of a cause of action in a single initial proceeding. *Cf. Whitton v. Weis*, 2009 WL 4882840 (Ky. App. December 18, 2009) (citing *Buis*, finding plaintiff’s claim of fraudulent inducement in signing corporate minutes barred as claim that should have been brought in prior action by plaintiff alleging forgery of resulting contract). As the Kentucky Court of Appeals has explained, under Kentucky law “[a] cause of action is ‘a group of operative facts giving rise to one or more bases for suing; a factual situation that entitles one person to obtain a remedy in court from another person.’” *Conner v. Patton*, 2008 WL 162875, at * 2-3 (Ky. App. January 8, 2008) (noting continued vitality of rule against splitting causes of action after *Buis*).

The operative facts giving rise to any claimed violation of the CSA and FDCA in the implementation of Kentucky’s lethal injection protocol are the very same ones at issue in the 2004 litigation challenging various aspects of the protocol on constitutional grounds. The fact that plaintiffs failed to realize that the underlying facts at issue could give rise to claims under legal theories other than those already asserted does not negative the application of claim preclusion where they failed to do so. *Cf. Saud v. Bank of New York*, 929 F.2d 916, 919 (2d Cir. 1991) (“it is the facts surrounding the transaction or occurrence which operate to constitute the cause of action, not the legal theory upon which a litigant relies.”); *see also Smith v. Lambert*, No. 2002-CA-136, Ky. App., 2004 WL 1125039, at *2 (Ky. App. May 21, 2004); *Harnett v. Billman*, 800 F.2d 1308, 1313-14 (4th Cir. 1986) (“It is the existence of the present claim, not party awareness of it, that controls.”); plaintiff’s claimed discovery

of new evidence does not prevent application of *res judicata* unless fraud, concealment or misrepresentation caused the plaintiff to fail to include these claims in the prior action). Because such claims could and should have been pursued in the prior state court litigation, the rule against splitting causes of actions applies, and plaintiffs are barred from pursuing them now.

III. Conclusion

Accordingly, **IT IS ORDERED** that:

1. Plaintiffs' "Motion to expedite ..." [R. 48] is **GRANTED**.
2. Plaintiffs' Complaint [R. 5] is **DISMISSED WITH PREJUDICE**.
3. The Court will enter an appropriate judgment.

This the 23rd day of September, 2010.



Signed By:

Karen K. Caldwell *KKC*

United States District Judge