

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

EARL RINGO, JR., JOHN CHARLES)	
MIDDLETON, RUSSELL E. (RUSTY))	
BUCKLEW, JOHN WINFIELD, DENNIS)	
J. SKILLICORN,)	
)	Case No. 09-4095-CV-C-NKL
Plaintiffs,)	
)	
v.)	
)	
GEORGE A. LOMBARDI, STEVE)	
LARKINS, JOHN DOES 2-40,)	
)	
Defendants.		

ORDER

Plaintiffs Earl Ringo, Jr., John Charles Middleton, Russell Bucklew, John Winfield, and Dennis Skillicorn filed this action seeking a declaratory judgment that Missouri’s lethal injection protocol violates the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 801, *et seq.* (“FDCA”), as well as the Controlled Substances Act, 21 U.S.C. §§ 301, *et seq.* (“CSA”). Plaintiff Dennis Skillicorn is deceased, having been executed by lethal injection in 2009; the surviving Plaintiffs are prisoners of the State of Missouri sentenced to death. They name the following Defendants: Director of Missouri’s Department of Corrections, George Lombardi; Warden, Eastern Reception Diagnostic & Correctional Center, Steve Larkins; and Anonymous Executioner, John Does 2-40. In essence, Plaintiffs assert that Defendants' use of lethal injection drugs (sodium thiopental, pancuronium bromide, and potassium chloride): (1) violates the CSA in that Defendants do not obtain the drugs lawfully; and (2) violates the

FDCA in that the drugs are not prescribed by a licensed practitioner and have not been approved by the FDA for use in lethal injections. Pending before the Court is Defendants' Amended Motion to Dismiss [Doc. # 29]. For the reasons stated below, the Court denies the motion.

I. Background¹

A. The Parties

Plaintiffs are death row inmates in Missouri state penitentiaries. Defendant Lombardi is the Director of the Department of Corrections for Missouri; as such, he is authorized to determine how the Department of Corrections of the State of Missouri carries out lethal injections. *See* Mo. Rev. Stat. § 546.720. Defendant Steve Larkins serves as Warden of the Eastern Reception Diagnostic and Correctional Center (ERDCC) in Bonne Terre, Missouri, where Missouri conducts its executions. Plaintiffs state that they are unable to provide names for the John Doe Defendants because Missouri statute forbids the release of names and identities of those on the execution team. *See* Mo. Rev. Stat. § 546.270.2.

B. The CSA and FDCA

The CSA classifies controlled substances into “schedules” and specifies how substances in each schedule may be distributed and regulated. 21 U.S.C. § 812. The CSA requires a medical practitioner to write a prescription for substances classified under “Schedule III” before that substance may be dispensed. 21 U.S.C. §§ 829(b), 842; *see also*

¹ For purposes of this motion to dismiss, the Court assumes true the factual allegations of Plaintiffs' Complaint.

21 C.F.R. § 1308.13(c)(1)(iii). The CSA classifies sodium thiopental as a Schedule III drug. 21 U.S.C. § 829; *see also* 21 C.F.R. § 1308.13(c)(1)(iii).

The FDCA requires that “drugs” be dispensed only by a medical practitioner where they are not safe to use except under the supervision of a licensed practitioner. 21 U.S.C. § 353. The FDCA also requires that drugs be approved by the Food and Drug Administration (“FDA”) before they are administered, and proven effective for their intended purpose. 21 U.S.C. § 355. The FDCA provides that all proceedings to enforce or restrain violations shall be brought in the name of the United States or states. 21 U.S.C. § 337. Other than in prohibiting declaratory judgment suits regarding generic drugs, 21 U.S.C. §§ 355(c)(3)(D)(i)(I), (j)(5)(C)(i)(I), the statute does not expressly prohibit declaratory judgment actions. The parties do not appear to dispute that the FDCA prohibits obtaining pancuronium bromide and potassium chloride without a prescription; they also do not appear to dispute that the lethal injection chemicals have not been authorized by the FDCA for use in lethal injection.

The statutes have certain exemptions for certain types and uses of drugs by certain people. For example, the CSA allows agents of registered persons to dispense drugs, 21 C.F.R. §§ 1301.22(a), (b); it allows state officers enforcing controlled substance laws to possess such substances in the course of their duties, 21 C.F.R. §§ 1301.24(a)(1), (a)(2). The parties appear to agree that the CSA, FDCA, and their corresponding regulations do not provide exceptions to their requirements for purposes of lethal injection executions.

C. Missouri’s Lethal Injection Statute and Protocol

Missouri's lethal injection statute prescribes "lethal injection" or "lethal gas" as acceptable methods of execution. Mo. Rev. Stat. § 546.720. The statute does not dictate particularities like types of personnel or chemicals to be used in carrying out different aspects of the executions.

According to the Complaint – and as Defendants appear to concede – Missouri's protocol for lethal injection executions does set forth particularities, but does not set forth procedures which require compliance with the CSA and FDCA. Missouri's lethal injection protocol is not statutory – it is issued by the Department of Corrections and sets out technical procedures for carrying out lethal injections, and it is exempt from Missouri's typical notice and comment rulemaking requirements. *Middleton v. Missouri Dep't of Corr.*, 278 S.W.3d 193, 195-96 (Mo.), *cert. denied*, 129 S. Ct. 2430 (2009). The protocol does not require the lethal injection chemicals to be prescribed or dispensed by a medical practitioner; and those chemicals have not been approved for use in lethal injections. Defendants intend to execute Plaintiffs using the lethal injection chemicals under the protocol; a doctor will not be obtaining, prescribing or administering those chemicals.

The parties appear to agree that the intended use of thiopental in the lethal injection protocol is to render a prisoner unconscious so that the prisoner does not suffer pain in the administration of pancuronium bromide and potassium chloride.

D. Exhaustion of Administrative Remedies

According to the Complaint, to the extent they were required to do so, Plaintiffs have exhausted their administrative remedies with regard to their claims. They filed grievances with the Missouri Department of Corrections alleging their claims concerning the CSA and FDCA, requesting that the department comply with the statutes before proceeding with executions by lethal injections. The department issued an “Appeal Response” asserting that it is not subject to the statutes because its use of the chemicals is not a threat to public health and safety. *See generally Bowling v. Haas*, No. 07-CV-07-KKC, 2007 WL 403875, at *3 (E.D. Ky. Jan. 31, 2007) (dismissing declaratory judgment claims that Kentucky’s lethal injection protocol violated the CSA and FDCA for failure to exhaust administrative remedies).

E. The Complaint

Plaintiffs assert that this Court has jurisdiction under: 21 U.S.C. § 322, granting district courts jurisdiction to restrain violations of the FDCA; 28 U.S.C. § 1331, in that it arises under the laws of the United States; 28 U.S.C., § 1651, the All Writs Act; and 28 U.S.C. § 2201(a), in that the purpose of this action is to secure declaratory relief. Plaintiffs appear to concede that the CSA and FDCA provide no private right of action for enforcement. *See Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804, 817 (1986) (stating that there is no private cause of action for violation of the FDCA). Plaintiffs clarify that they do not seek to force the FDA nor do they seek to have a United States governmental

agency or official enforce the CSA or FDCA. Instead, Plaintiffs seek merely a declaration that Defendants' intended actions as applied to Plaintiffs would violate the CSA and FDCA.

I. Discussion

A. Standing

Defendants move under Rule 12(b)(1) of the Federal Rules of Civil Procedure to dismiss Plaintiffs' claims for lack of standing. Where a plaintiff lacks standing, a district court has no subject matter jurisdiction. *Faibisch v. University of Minn.*, 304 F.3d 797, 801 (8th Cir. 2002). To have standing to bring a declaratory judgment action, Plaintiffs must show a personal injury which would likely be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Defendants argue that Plaintiffs cannot meet this test.

Defendants focus their standing argument on redressability: they state that a favorable declaration would not benefit Plaintiffs. The Declaratory Judgment Act allows courts to "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). *Franklin v. Massachusetts* demonstrates that suits for declaratory relief against government officials are appropriate even where other relief is not available, because it can be presumed that those officials will behave in compliance with a court's interpretation of a statute – even where injunctive relief is not available. *See* 505 U.S. 788, 803 (1992). In *Franklin*, a divided Court considered the challenge of Massachusetts and two of its voters to Congress's reapportionment of seats in the House of Representatives as unconstitutional and inconsistent

with the Administrative Procedures Act. *See id.* at 796. The plurality found that plaintiffs had standing to seek a declaratory judgment, even if injunctive relief was not available, because it could be assumed that it was “substantially likely” that executive and Congressional officials “would abide by an authoritative interpretation of the ... statute and constitutional provision by the District Court, even though they would not be directly bound by such a determination.” *Id.* at 803.

The plurality opinion was adopted by six Justices in another apportionment case, *Utah v. Evans*. *See* 536 U.S. 452, 462-64 (2002). In that case, the Court emphasized that steps could be taken to bring the apportionment process in compliance with a favorable declaratory judgment. *See id.* at 462.

Franklin and its progeny indicate that a complete remedy need not be absolutely certain. In *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC)*, a group of fishermen and boaters brought a citizens’ suit for violations of the Clean Water Act by a holder of a pollution discharge certificate. 528 U.S. 167, 185 (2000). The Court found the plaintiffs’ alleged injuries – river pollution – redressable through the remedy of civil financial penalties paid to the government; although the penalties would not necessarily stop the pollution, the Court found it likely to deter future violations. *Id.* at 184-85. The *Friends of the Earth* Court acknowledged that there may be a “vanishing point,” at which claimed relief becomes so insubstantial or remote that it cannot support standing. *Id.* at 186 (“Judgment on the deterrent effect of the various weapons in the armory of the law can lay little claim to scientific basis.” (quoting *Tigner v. Texas*, 310 U.S. 141, 148 (1940))). *See also Made in the*

U.S.A. Found. v. United States, 242 F.3d 1300 (11th Cir. 2001) (finding standing in a challenge to the constitutionality of the North American Free Trade Agreement, finding that the plaintiffs' alleged labor-market-related injuries were sufficiently redressable via an injunction or declaration against subordinate officials in the executive branch, even if other countries might not comply so as to give the plaintiffs full relief). Defendants do not offer a basis upon which to distinguish *Franklin*.

Here, Plaintiffs' standing is not undermined to the vanishing point by the possibility that Defendants would ignore a declaration that the CSA and FDCA apply to Missouri's lethal injection protocol. Under *Franklin*, the Court may presume that Defendants would seek to comply with those statutes should they be declared applicable to lethal injections. A suggestion that compliance is likely appears in *Brown v. Vail*, a suit for declaratory and injunctive relief challenging the state of Washington's lethal injection protocol as violating federal controlled substance regulations, among other laws; there, Washington's assistant secretary of health services for the state's department of corrections had resigned over – among other issues – concerns about obtaining lethal injection chemicals for executions in violation of federal law. 623 F. Supp. 2d 1241, 1247 (W.D. Wash. 2009) (abstaining based on the presence of a parallel state lawsuit). A declaratory judgment that Defendants are violating the CSA and FDCA would make it likely that Defendants would stop any such violations. *See also Banks v. Secretary of Indiana Fam. & Soc. Servs. Admin.*, 997 F.2d 231, 241 (7th Cir. 1993) (presuming that a state Medicaid agency would abide by the court's authoritative construction of federal Medicaid regulations).

In addition to challenging redressability, Defendants seem to argue that Plaintiffs lack standing because they are not claiming to suffer a personal injury. Defendants say that Plaintiffs want a declaration of the legal relationship between the Missouri Department of Corrections, its employees and the federal government. According to Defendants, “the only persons that are at possible risk” of noncompliance with the CSA and FDCA are Defendants – by way of federal criminal penalties. [Doc. # 56 at 3.]

The Court touched on the harm that would be suffered by violations of the CSA and FDCA in ruling on Plaintiff Skillicorn’s emergency motion for a stay of execution, filed within days of his execution date. *See Ringo v. Lombardi*, No. 09-4095-CV-C-NKL, 2008 WL 1406980 (W.D. Mo. May 19, 2009). In that motion, Plaintiffs argued that they would suffer if not assured the protections of the statutes. *See id.* at *3. In balancing this alleged harm with Missouri’s significant interest in prompt execution and other factors relevant to examination of a late-filed motion for a stay of execution, the Court found that the alleged harm did not – for purposes of that motion – warrant a stay. *See id.*

On Defendants’ motion to dismiss, the Court must assume true Plaintiffs’ allegations concerning their threatened injury. *See Lujan*, 503 U.S. at 561. A fair reading of the Complaint indicates that Plaintiffs seek to redress the risk of inhumane lethal injection by clarifying that the precautions required by the CSA and FDCA apply. If the CSA and FDCA apply, they provide safeguards against improper use of lethal injection chemicals by assuring that medical practitioners are adequately involved in the use of those chemicals. If the statutes apply to lethal injection, ignoring those safeguards, as Plaintiffs allege Defendants

intend to do, places Plaintiffs at risk. Thus, to the extent Plaintiffs seek a declaration that the statutes' safeguards apply to lethal injection, they seek a declaration of their own rights. Plaintiffs have standing to bring this declaratory action.²

B. Substantive Claims

Defendants also move under Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss for failure to state a claim upon which relief can be granted. To survive such a motion, the Complaint must state a claim that is plausible on its face. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). According to the Complaint, Missouri's lethal injection protocol does not comply with the CSA and FDCA. Defendants do not appear to dispute this. The parties appear to agree that the plain language of the statutes contains no exception for lethal injection protocols. What the parties dispute is whether the requirements of the CSA and FDCA extend to lethal injections.

1. Congressional and Executive Inaction

Both parties argue that Congressional inaction in this field weighs in their favor with regard to whether the statutes apply. They say that Congress has not issued exceptions to the CSA and FDCA for lethal injection purposes, despite the attention lethal injection litigation has received. Plaintiffs say this means that there is no exception to the statutes for use of the

² Defendants do not appear to argue that Plaintiffs cannot show that their claimed injury is traceable to Defendants' alleged misconduct. *Cf. Nova Health Sys. v. Gandy*, 416 F.3d 1149, 1156-57 (10th Cir. 2005) (finding that an abortion provider did not have standing to challenge a state statute making providers responsible for certain costs associated with performing abortions without parental consent; the alleged harm – losing some minor patients – could not be shown to be traceable to enforcement officials' conduct, as opposed to the providers' independent decision to demand parental consent from all minor patients).

chemicals in lethal injections. Defendants say this means the statutes do not apply to them; Defendants further argue that the lack of FDA enforcement action or criminal prosecution for use of the chemicals in lethal injections indicates that the statutes do not apply to them.

“[W]e walk on quicksand when we try to find in the absence of corrective legislation a controlling legal principle.” *Helvering v. Hallock*, 309 U.S. 106, 121 (1940) (quoted in *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 186-87 (1994)). Of course, there are likely many reasons for Congressional and executive inaction with regard to lethal injection protocols, including a desire to avoid the politics of execution. Congressional and executive inaction do not warrant granting Defendants’ motion to dismiss. *See generally United States v. Marshall*, 998 F.2d 634, 636, n. 4 (8th Cir. 1993) (“[W]e do not discount the force of inertia in governmental affairs.”).

2. Accepting Jurisdiction in the Absence of Action

The decision of whether to accept jurisdiction is within the Court’s discretion. *Wilton v. Seven Falls Co.*, 515 U.S. 277, 282 (1995). The key questions in deciding whether to exercise jurisdiction are whether a judgment would serve to clarify and settle the legal relations at issue, and whether a judgment would afford relief from uncertainty and controversy giving rise to the proceedings. *See Alsager v. District Ct. of Polk County*, 518 F. 2d 1160, 1163-64 (8th Cir. 1975).

Defendants argue that *Heckler v. Chaney* dictates that the Court should not exercise its jurisdiction over Plaintiffs’ declaratory judgment claims. *Heckler* held that an express FDA decision, in response to citizen requests, not to take enforcement action regarding lethal

injection chemicals was not reviewable under the Administrative Procedures Act. *See* 470 U.S. 821, 838 (1985) (affirming a district court's refusal to compel the FDA to investigate and enforce the allegedly illegal use of lethal injection drugs after the FDA had expressly refused to do so; stating that the FDA's refusal was discretionary and not subject to judicial review).

Courts have distinguished *Heckler* in cases challenging general enforcement policies, as opposed to express administrative decisions. In *Roane v. Holder*, the plaintiffs sought relief from federal officials' alleged general policy of failing to enforce the CSA against those who participated in federal executions. 607 F. Supp. 2d 216, 219 (D.D.C. 2009). The *Roane* court found that *Heckler* does not mandate dismissal of an Administrative Procedures Act challenge to the Drug Enforcement Administration's alleged general policy – divorced from any particular factual scenario – of not enforcing the CSA as to lethal injection. *Id.* at 226-27 (citing *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994), as suggesting that *Heckler* indicates that general policy statements, as opposed to individual enforcement decisions such as those addressed in *Heckler*, "may be reviewable for legal sufficiency where the agency has expressed the policy as a formal regulation after the full rulemaking process ... or has otherwise articulated it in some form of universal policy statement[.]"). The *Roane* court allowed the case to continue to the extent the plaintiffs were claiming that the DEA had made a general statement of enforcement of the CSA concerning federal lethal injections, and to the extent they were claiming that the protocol was illegal in that it failed to require registration. *Id.* at 227.

Here, as in *Roane*, Plaintiffs do not challenge a particular express decision not to enforce the CSA and FDCA against Defendants. Instead, they seek a declaration that applying the Missouri protocol to them would be illegal because the protocol fails to meet the requirements of those statutes. Plaintiffs seek only a general declaratory judgment – a declaration that would apparently not run against a stated federal agency’s policy much less its application of such a policy to a fact-specific scenario. *Heckler* does not preclude the exercise of jurisdiction in such cases.

As to whether the Court should accept jurisdiction over this declaratory judgment action, *Franklin* indicates that it should. A declaratory judgment in this case would serve to clarify and settle Defendants’ legal obligations with regard to the CSA and FDCA. It would also be likely to afford relief for both parties from the uncertainty and controversy giving rise to the proceedings. As in *Evans*, at this stage of the litigation, it appears that there may be steps Defendants could take to bring the protocol in compliance with the relevant statutes. Thus, the exercise of jurisdiction under 28 U.S.C. § 2201(a) is appropriate.

C. Preemption

Defendants argue that the CSA and FDCA do not preempt Missouri's lethal injection statutes or regulations. They argue that the FDCA and CSA were not intended to address lethal injection protocols and thus cannot "preempt" those protocols. Defendants note that Congress -- as well as other federal agencies -- did not intend to bar states from regulating controlled substances and has not prohibited states from carrying out lethal injections with

the drugs used by Missouri and the federal government. Thus, they seem to conclude that Missouri is allowed to use a lethal injection protocol which violates the FDCA and CSA.

Where, as here, there is no express preemption, state law is only preempted by federal law to the extent that it actually conflicts with federal law, such that compliance with both state and federal law is impossible or state law is an obstacle to the accomplishment of Congressional objectives. *Lankford v. Sherman*, 451 F.3d 496, 510 (8th Cir. 2006). Defendants do not cite to a state statute or regulation that prescribes a particular manner of lethal injection. Missouri's lethal injection protocol is not statutory – it is issued by the Department of Corrections; it is exempt from Missouri's typical notice and comment rulemaking requirements. *Middleton v. Missouri Dep't of Corr.*, 278 S.W.3d 193, 195-96 (Mo.), *cert. denied*, 129 S. Ct. 2430 (2009). Missouri's lethal injection statute prescribes only "lethal injection" or "lethal gas" as acceptable methods of execution. Mo. Rev. Stat. § 546.720.

Construing Plaintiffs' Complaint favorably, there is presumably a way to use these methods that does not violate the FDCA and CSA. At this stage of the litigation, there is no indication that either the protocol or statute precludes compliance with the CSA and FDCA such that all cannot coexist. Here, the question is whether Defendants are violating federal law, not whether that federal law preempts a contrary Missouri law. It is plausible that Defendants could bring Missouri's lethal injection protocol in line with the FDCA and CSA without contradicting Missouri law. To the extent that could not be accomplished, preemption analysis would be appropriate. Thus, the Missouri lethal injection statute is

unlike the statute at issue in *State v. Deputy*, which considered whether the FDCA and CSA preempted a state statute expressly providing that lethal injection was not a medical procedure and expressly allowing any pharmacist to dispense the chemicals without a prescription; the *Deputy* court found no preemption. 644 A. 2d 411, 417-19 (Del. Super. 1994). Without details on Missouri's lethal injection protocol, it is too soon to know the extent to which the relevant statutes and protocol can coexist, and the extent to which any preemption has occurred. On Defendants' motion to dismiss, a showing by Plaintiffs that there is a preemption is unnecessary at this stage of the litigation.

The Court also addressed preemption in its Order on Plaintiff Skillicorn's motion for a stay execution. *See Ringo*, 2008 WL 1406980 at *3. The arguments raised by the parties in that emergency motion, fully briefed within three-days of filing the Complaint, demonstrated that Plaintiff Skillicorn could not meet the standards for success on the merits for several reasons, including that he could not show a likelihood of success on the merits which included a showing of preemption. *See id.* (citing *Delaware v. Deputy*, 644 A.2d 411 (Del. Super. Ct. 1994)). To clarify, to succeed on the merits, Plaintiffs need to either show preemption or that Defendants can carry out executions in compliance with the CSA, FDCA, and Missouri law at the same time. Plaintiff Skillicorn showed neither under the standards applicable to a motion for stay of execution. But under the standards applicable to a motion to dismiss, Plaintiffs need not show a likelihood of success on the merits; rather, they need only state a claim plausible on its face.

1. Statutory Purposes

Apparently to facilitate their preemption analysis, Defendants argue that the CSA and FDCA do not apply here because they were not intended to address lethal injection situations. Contrary to Defendants' assertions, applying the FDCA and CSA in this case appears to be consistent with their purposes.

The two statutes generally insure careful handling of drugs. One of the FDCA's core objectives is to ensure that drugs are both "safe" and "effective" for their intended use. *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000). Defendants concede that the purpose of the FDCA is to protect the public by limiting the use of dangerous drugs to medically supervised situations.

The general purpose of the CSA is to deal with drug abuse in a comprehensive fashion, H.R. Rep. No. 91-144, 1970 U.S.C.C.A.N. 4566, 4567. The purpose of the particular provision on which Plaintiffs rely, 21 U.S.C. § 829(b), is to ensure that patients use controlled substances under doctors' supervision to prevent abuse and bar doctors from peddling to patients who abuse the substances. *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006).

According to Defendants, these concerns are irrelevant in the case of prisoners sentenced to death. "Safety, measured as the lack of adverse effects on a person, is not at issue in an execution." [Doc. # 29 at 18-19.] Defendants say that thiopental cannot be abused because it results in death. [Doc. # 29 at 18, Doc. # 38 at 6.]

Defendants' position poses an interesting contrast to the Supreme Court's recent statement in *Baze v. Rees*, 128 S. Ct. 1520, 1533 (2008). Considering death row inmates'

declaratory judgment challenge to Kentucky's lethal injection protocol under the Eighth Amendment, the *Baze* Court stated: "It is uncontested that, failing a proper dose of sodium thiopental that would render the prisoner unconscious, there is a substantial, constitutionally unacceptable risk of suffocation from the administration of pancuronium bromide and pain from the injection of potassium chloride." This statement was echoed by the Eighth Circuit in *Taylor v. Crawford* when considering whether Missouri's lethal injection protocol violated the Eighth Amendment:

The evidence reveals that the only inherent risk in Missouri's written procedure arises from the specific chemicals chosen by the State to carry out the sentence of death by lethal injection. Lethal injection itself is commonly thought to be the most humane form of execution. . . . There is no dispute, however, that the third and last chemical chosen for use in this protocol will cause excruciating pain if the inmate is not adequately anesthetized and that use of the second chemical in the sequence will simultaneously mask any visible sign of that pain.

487 F.3d 1072, 1082 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 2047 (2008). In *Taylor*, the Eighth Circuit found persuasive the involvement of medical personnel and rules for administering the chemicals in the lethal injection protocol in holding that the protocol did not give rise to an Eighth Amendment violation as cruel and unusual punishment. *Id.* at 1083-84. Plaintiffs point out that the Department of Corrections argued before the Eighth Circuit in its appellate brief in *Taylor*, 2006 WL 3857886, that thiopental was used for the medical purpose of rendering the prisoner unconscious "so that the execution is humane." Where the Eighth Amendment requires protocols that include adequate safeguards against unnecessary pain, *see Taylor*, 487 F.3d at 1084, and superior courts have indicated that the involvement of medical professionals and rules for administration enhances such safeguards,

the safeguards provided by the CSA and FDCA are not irrelevant. At least at this stage of litigation, Plaintiffs' claims do not appear to run contrary to the purposes of the CSA and FDCA.

D. Res Judicata

Citing to matters outside the Complaint, Defendants also assert in their Rule 12(b)(6) motion that Plaintiffs' claims are barred by the doctrine of res judicata. Res judicata applies where a prior judgment involves the same cause of action and the same parties or their privies. *Wedow v. City of Kansas City, Mo.*, 442 F.3d 661, 669 (8th Cir. 2006). Specifically, Defendants argue that a recent judgment on the pleadings in *Clemons v. Crawford* precludes Plaintiffs' claims. *See* No. 07-4129-CV-C-FJG, 2008 WL 2783233 (W.D. Mo. July 15, 2008), *affirmed*, 585 F.3d 1119 (8th Cir. 2009). Plaintiffs here were denied leave to intervene in *Clemons*, *see id.* at *2; Defendants – apparently not named in *Clemons* – make no argument that they are in privity with the *Clemons* defendants. In *Clemons*, the plaintiffs challenged the constitutionality of Missouri's lethal injection protocol, alleging that Missouri's past failure to select and train qualified lethal injection personnel put the plaintiffs at risk of unconstitutional pain and suffering in the course of their executions; the *Clemons* court found that the plaintiffs' claim was not viable under *Baze* and *Taylor*. *See id.* at *1-2. Here, Plaintiffs seek a declaration that Missouri's execution protocol is in violation of the FDCA and the CSA, raising questions not reached by *Baze*, *Taylor*, or *Clemons*. Res judicata is an affirmative defense on which Defendants bear the burden. *See Taylor v. Sturgell*, 128 S. Ct. 2161, 2179-80 (2008). Even if the Court were to consider the matters

outside the Complaint concerning res judicata on Defendants' motion to dismiss, it would find that Defendants have not carried their burden.

II. Conclusion

Accordingly, it is hereby ORDERED that Defendants' Motion to Dismiss [Doc. # 29] is DENIED.

s/ Nanette K. Laughrey
NANETTE K. LAUGHREY
United States District Judge

Dated: March 2, 2010
Jefferson City, Missouri