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

EARL RINGO, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 2:09-cv-04095-NKL
	)	
GEORGE A. LOMBARDI, et al.,	)	
	)	
Defendants.	)	

ORDER

Missouri death row inmates ("Plaintiffs") seek a declaration from the Court that Defendants violate the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801, *et seq.*, and the Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, et seq., when they follow Missouri's protocol for execution by lethal injection. Plaintiffs also seek an injunction preventing Defendants from carrying out executions in a manner that violates these statutes. Before the Court are the parties' cross-motions for summary judgment. For the following reasons, Defendants' Motion for Summary Judgment [Doc. # 213] is GRANTED, and Plaintiffs' Motion for Summary Judgment [Doc. # 209] is DENIED.

I. Factual Background[1]

[1] The Court has considered the parties' statements of undisputed fact which are supported by evidence. In considering each party's motion, the Court has drawn all inferences in favor of the non-movant.

Plaintiffs, other than Richard Clay, are death-sentenced prisoners convicted of first-degree murder under Missouri law. Plaintiff Martin Link has now been executed. Defendant George A. Lombardi is Director of the Missouri Department of Corrections ("DOC") and has ultimate authority for overseeing and supervising Missouri executions, including the authority to change the types and dosages of drugs to be administered under the state's execution protocol.

The DOC's execution team consists of four members, including two medical personnel and two non-medical personnel; these members are anonymously designated M2, M3, NM1, and NM2. Previous medical personnel M1 is a physician who is no longer a member of the execution team. Defendant M2 is licensed as a Missouri Licensed Practical Nurse (LPN), is IV-certified under state law, and performs general nursing duties at a rural hospital, including caring for post-surgical patients. Defendant M2 has been a contracted member of Missouri's execution team for twelve years and has participated in approximately 57 executions in this state. Defendant M2 believes that he is not qualified, by virtue of his nursing licensure or otherwise, to administer the three drugs outlined in Defendants' execution protocol, including the Schedule III controlled substance sodium thiopental.

Defendant M3 is a board-certified anesthesiologist who is licensed to practice medicine in the state of Missouri, and he practices in a private group of anesthesia providers who serve a particular hospital. Defendant M3 has a controlled substances registration through the Missouri Bureau of Narcotics and Dangerous Drugs. M3 states that he has a similar registration through the federal Drug Enforcement Agency. M3 is under contract

with the Department of Corrections to assist with Missouri executions, and, in that capacity, he participated in the execution of Dennis J. Skillicorn on May 20, 2009. Defendants NM1 and NM2 are the non-medical personnel of the execution team, both of whom are employed by the Department of Corrections in non-medical capacities, and neither of whom has any verified medical training.

Plaintiffs claim that Defendants violate the CSA and FDCA by failing to obtain valid medical prescriptions for drugs that are administered to prisoners according to Missouri's execution protocol and by having non-medical personnel dispense controlled substances–the lethal injection drugs–through an "IV push." Plaintiffs term these failings as the "non-prescription problem" and the "IV-push problem."

A. The Execution Protocol

Defendants' execution protocol entails the administration of three drugs into the prisoner: sodium thiopental, pancuronium bromide, and potassium chloride. Sodium thiopental is administered in order to make the prisoner unconscious. The dosage of five grams of sodium thiopental, as called for in the execution protocol, may cause death. [Plaintiffs' Ex. 5 (M3 Depo.), at 57, 72-73]. Pancuronium bromide is a muscle relaxant and paralytic; it is administered in order to stop the prisoner's breathing, and also to prevent involuntary muscular twitching and seizure activity so that the prisoner may have a more peaceful and dignified death. [Doc. # 247, at 3 (citing Defendants' explanation in previous litigation for the use of pancuronium bromide)]. Potassium chloride is administered in order to stop the prisoner's heart.

The lethal injection drugs are prepared by the medical personnel. Anesthesiologist M3 dissolves a total of 5 grams of sodium thiopental powder in water, then draws this solution into four separate syringes, each containing a total of 50 cc of solution. M3 prepares four additional syringes containing an additional 5 grams of thiopental, in case additional thiopental is needed to render the prisoner unconscious or otherwise to complete the execution. Nurse M2 prepares a syringe containing 60 milliliters of solution with 60 milligrams of pancuronium bromide; because this drug arrives already in solution, M2 simply draws the solution into the syringe. In the same manner, M2 draws two syringes, each containing a 60 cc solution with 120 milliequivalents of potassium chloride.

Medical personnel are responsible for attaching IV lines into the prisoner, and this task is usually performed by the physician. M2 attaches the EKG leads to the prisoner, whose condition and level of consciousness are monitored by the medical personnel. Non-medical personnel, NM1 and NM2, directly administer the lethal injection drugs by attaching a syringe to a "port" along the IV line that flows into the prisoner, and then pushing the contents of the syringe into the IV line. NM1 and NM2 inject four syringes containing a total of 5 grams of thiopental, after which medical personnel assess whether the prisoner is unconscious. If the prisoner is not yet unconscious, then NM1 and NM2 would administer additional thiopental. NM1 and NM2 administer 30 cc of saline solution after the thiopental. If medical personnel conclude that the prisoner is unconscious, and so long as at least three minutes have elapsed since the beginning of the administration of thiopental, then NM1 and NM2 administer the syringe of pancuronium bromide, then a second syringe of saline

solution, then two syringes of potassium chloride, and finally a third syringe of saline solution. M3 pronounces the prisoner's death after all electrical activity of the heart has ended. After the execution, all members of the team–specifically, M2, M3, NM1, and NM2–complete required paperwork confirming that the three drugs were injected into the prisoner in the amounts specified by the protocol. These forms are reviewed, approved, and signed by DOC Director Lombardi, and Division of Adult Institutions Director Tom Clements.

If a prisoner were to be administered pancuronium bromide in the amount called for in Defendants' protocol, but without first being anesthetized, the prisoner would experience a painful suffocation while conscious. [Plaintiffs' Ex. 5 (M3 Depo.), at 58 ("Q: So the Sodium Thiopental anesthetizes them from these discomforts and this pain? A: Correct.")]. If a prisoner were to be administered potassium chloride in the amount called for in Defendants' protocol, but without first being anesthetized, the prisoner would experience a painful burning sensation, and would also likely experience chest pain associated with coronary arrest.

Defendants administer thiopental to the prisoner in order to make him unconscious so that he does not experience pain and physical suffering from the other two lethal injection drugs. Defendant M3 stated that such use of sodium thiopental has a medical purpose. [Plaintiffs' Ex. 5 (M3 Depo.), at 54-55]. Anesthesiologist M3 participates in executions in order to, among other reasons, ensure that the prisoner does not suffer pain. M3 considers himself the condemned prisoner's doctor. [Plaintiffs' Ex. 5 (M3 Depo.), at 112-13].

According to Nurse M2, his role during an execution is to "help comfort the patient," in accordance with his professional nursing duties. As part of his role, M2 offers the condemned prisoner comfort and reassurance: "I'm the nurse, and I'm here to help you try to get through this." He offers the prisoner an oral sedative, places a pillow behind his head, asks whether the prisoner needs a drink of water or another pillow, explains that the EKG leads will feel cold but do not hurt, and warns that the IV insertion will cause a mild "stick" or pinching sensation. By offering reassurance, helping to manage the prisoner's anxiety, dispensing oral sedatives, and placing EKG patches, M2 performs services that are comparable to those he otherwise performs as an LPN nurse. M2 believes that a nurse is required in order to perform these services, and "the person who benefits from my services is my patient." [Plaintiffs' Ex. 3 (M2 Depo.), at 172-73].

Defendants' Answer refers to the condemned prisoner as a "patient." [Doc. # 178, ¶ 124 ("Defendants admit in the sense that a non-medical member of the execution team actually pushes the plunger that pushes the chemical into the tubing, although the chemicals are prepared by a board certified anesthesiologist who is present and monitoring the patient during the execution.")].

Medical personnel M2 and M3 evaluate the prisoner's medical history by reviewing a pre-execution questionnaire. The medical questionnaire alerts the medical personnel to aspects of the prisoner's medical history that might complicate an execution, such as damaged veins due to chronic abuse of intravenous drugs. One purpose of assessing the prisoner's medical history is to address conditions that may lead to pain or discomfort during

the execution; among other potential problems, a chronic drug abuser may be "tolerant" of sedatives like thiopental.

Approximately four and one-half hours before the execution, Nurse M2 offers the condemned prisoner an oral sedative, specifically, Valium (also known as Diazepam), for therapeutic or medical purposes. The purpose of the oral sedative is to help the prisoner relax, and to reduce his level of anxiety. Although most executed prisoners have declined the offer of a sedative, M2 may offer the prisoner up to two 5 milligram doses of Valium. In the event that a prisoner suffers an unusually severe degree of anxiety, M3 may administer intravenous or injected sedatives, including Versed (also known as Midazolam), Ketamine, Haldol, and Flumazenil (also known as Romazicon). M2 cannot intravenously administer these sedatives because such a "controlled substance IV push" is beyond the scope of his LPN licensure and medical training.

B. Lack of Prescriptions

Sodium thiopental is a Schedule III controlled substance. Pancuronium bromide and potassium chloride are federally regulated drugs that are available only by prescription. No medical prescriptions–either a traditional prescription or a doctor's oral prescription later reduced to writing–have ever been issued for any of the lethal injection drugs involved in Missouri executions, and Defendants do not currently use or employ such prescriptions when carrying out executions. Defendants do not intend to require or incorporate the issuance of medical prescriptions into Missouri's execution process even though federal law requires a prescription from a doctor for these drugs.

C. Administration of Intravenous Drugs

Non-medical personnel, NM1 and NM2, inject the sodium thiopental, pancuronium bromide, and potassium chloride into the inmate by pushing the contents of seven different syringes into a "port" connected to the prisoner's IV line, approximately 30 inches away from where the IV enters the prisoner. NM1's and NM2's administration of the lethal injection chemicals amounts to an "IV push," which occurs when medicine is drawn into a syringe and is then administered directly into a port along the IV line. Medical personnel observe NM1 and NM2 as they inject the three lethal injection chemicals into the prisoner's IV line. NM1 and NM2 have no verified medical credentials or licenses, and they are employed by the Department of Corrections in non-medical positions. NM1 and NM2 are not federally registered to dispense controlled substances, including sodium thiopental. NM1 and NM2 were not taught how to perform their drug-injecting responsibilities by a physician; rather, DOC personnel train all medical and non-medical members of the execution team, and M3 observes NM1 and NM2 when they empty the syringes during practice executions.

The four syringes containing thiopental, which are administered by NM1 and NM2, each contain a total of 50 cc of solution; the two syringes of potassium chloride and the one syringe of pancuronium bromide each contain 60 cc of solution. NM1 and NM2 are supposed to inject the syringes containing the lethal injection drugs at a rate of approximately 1 cc per second. If the IV push were to be performed too rapidly during an execution, it could cause the prisoner's vein to rupture, which, in the case of thiopental, could prevent the drug from reaching its intended destination in order to anesthesize the prisoner. In addition,

sodium thiopental causes a painful burning sensation when injected into muscle tissue as opposed to a vein.

In the course of Anesthesiologist M3's medical practice, non-medical persons never carry out IV pushes. In the course of his nursing practice, M2 never performs IV pushes of medication. M2's nursing licensure does not allow him to conduct an IV push unless he is in an emergency situation and is being directly supervised by a physician. M2 does not ever administer intravenous sedating drugs, including thiopental, in the course of his nursing practice, because to do so is beyond the realm of his expertise and professional licensing. When treating patients, M2 is not professionally qualified to carry out a "controlled substance IV push" because he does not have any license or certification to dispense or administer controlled substances. Specifically, M2 is not professionally qualified or authorized to administer to any medical patient any of the three lethal injection drugs involved in Missouri executions. In M2's opinion, if the task of administering the three lethal injection chemicals were transferred to him, he would have to withdraw from the execution team, due to the limitations of his nursing license.

The execution team conducts rehearsals or practices of executions on a roughly quarterly basis, and it uses actual execution drugs in the process. The purposes of the simulated executions include giving NM1 and NM2 the opportunity to practice the proper rate of pushing the lethal injection chemicals, and M3 watches NM1 and NM2 practice this task. At the time of the filing of the motions, Defendants had a stock of 50 grams of thiopental, or enough to carry out five executions. This stock expired on March 1, 2011.

Because of the DOC's dwindling supply of thiopental, the execution team's training session of October 12, 2010, did not involve the practiced mixing or administration of actual thiopental.

D. No FDA Approval

The Federal Drug Administration has not approved, either singly or in combination, the use of sodium thiopental, pancuronium bromide, or potassium chloride for the execution of prisoners, including for the medical purpose of preventing or suppressing pain. The FDA has expressed the position that it does not regulate or approve chemicals for use in executions by lethal injections. Defendants have not sought the FDA's approval to use these or any other drugs during executions. Anesthesiologist M3, in the course of his medical practice, does not write a prescription for an anesthesia drug because it is administered by himself or another anesthesia specialist. M3 does not specifically know whether the FDA has approved sodium thiopental, pancuronium bromide, or potassium chloride for executions, but he does not issue medical prescriptions for these or any other drugs in the course of an execution.

Hospira, Inc., is the sole domestic manufacturer of sodium thiopental. Hospira has publicly stated that its pharmaceuticals should not be used for lethal injection. Defendants' supply of sodium thiopental has been manufactured by Hospira, which also manufactures some or all of the pancuronium bromide and potassium chloride that Defendants have obtained for the purpose of carrying out executions. Defendants are aware of Hospira's statements that its drugs, including sodium thiopental, should not be used during executions.

Defendants do not inform their supplier of the purpose for which they intend to use sodium thiopental, pancuronium bromide, and potassium chloride.

E. Valium

Diazepam, or Valium, is a Schedule IV controlled substance. M2, a licensed practical nurse (LPN), is the first medical member of the team to arrive at an execution, and he offers the prisoner an oral Valium tablet. No prescription or standing doctor's order is issued for Valium/Diazepam. M2 does not have a license or other professional certificate allowing him to dispense or administer controlled substances. Valium is a federally regulated drug that is available only by prescription.

F. Risk of Harm

Plaintiffs have obtained an affidavit from board-certified anesthesiologist Mark J.S. Heath, M.D., who is on the medical faculty at Columbia University in New York City, and who has described the relevant medical risks from the "IV-push problem" and "non-prescription problem" in detail. [Plaintiffs' Opposition Ex. D]. According to Dr. Heath, Missouri's execution procedures, as described in the protocol and Defendants' depositions, create "an unacceptable likelihood that a prisoner will have some level of consciousness during his execution," and thereby give rise to "substantial and medically unacceptable risks of inflicting excruciating pain and suffering on inmates while the lethal injection is administered." [*Id*. at 2-3].

According to Dr. Heath, the fact that Defendants delegate to non-medical personnel the task of administering the sodium thiopental through an IV push "represents a gratuitous

source of risk that the execution will be botched and agonizing" and creates a "gratuitous and substantial risk that anesthetic depth will be inadequate and that the execution will be agonizing." [*Id*. at 5-6]. Dr. Heath opines that a lay person lacks the experience and qualifications needed to gauge and act upon the varying degree of "back-pressure" sensed by an anesthesia specialist while injecting a syringe. That skill is necessary in order to determine when an anesthetic such as thiopental is being pushed into the patient's circulatory system through the vein, as opposed to infiltrating the surrounding tissue. Dr. Heath states that proper administration requires a grasp of medical subtlety that is simply unavailable to non-medical personnel. According to Dr. Heath, it is not clinically acceptable for Defendants to rely on a pre-arranged injection rate of 1 cc per second, as NM1 and NM2 are instructed and trained, because there is no "one size fits all" rate of injection of drugs. "Instead, the correct rate of injection depends on factors such as the size of the IV catheter and the geometry of its situation in the vein and the attributes of the veins that are receiving the drug, and since these factors vary tremendously it is necessary to tailor the injection rate." [*Id*. at 5]. According to Dr. Heath, Defendants' failure to customize the rate of injection represents a "gratuitous and substantial departure from acceptable practice and is a direct result of the delegation of the injection process to lay individuals." [*Id.*].

Dr. Heath also opines, to a reasonable degree of medical certainty, that anesthesiologist M3's inability to exercise his independent medical judgment, such as by prescribing the choice of anesthetic and its manner of administration, presents "a gratuitous and substantial risk of a cruel execution." [*Id*. at 6].

II. Discussion

Article III of the United States Constitution grants federal courts limited jurisdiction to decide "cases and controversies." To satisfy this jurisdictional requirement, a plaintiff must establish (1) an injury in fact which is (2) fairly traceable to the defendant's conduct and which (3) will likely be redressed by a favorable decision. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-181 (2000). The party invoking federal jurisdiction must "show that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant," and that the injury "fairly can be traced to the challenged action" and "is likely to be redressed by a favorable decision." *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982) (quotations omitted).

At this stage of litigation, injury in fact requires a "factual showing of perceptible harm." *Committee to Save the Rio Hondo v. Lucero*, 102 F.3d 445, 449 (10th Cir. 1996). Here, Plaintiffs state that due to what they term the "IV-push problem" and the "non-prescription problem" caused by Defendants' alleged violations of the CSA and FDCA, they are at risk of vein rupture and ineffective sedation, which can result in severe pain or cruel execution. Plaintiffs argue that they "need not show that they will certainly, or even probably, suffer pain as a result" of Defendants' alleged violations. [Doc. # 247, at 18]. They assert that it is "well-settled that a risk of injury or suffering may create a cognizable injury in fact." [Doc. # 226, at 11 (emphasis omitted)]. However, for the reasons explained

below, the Court finds that Plaintiffs are incorrect in their assertion that the risk they describe is sufficient to demonstrate a cognizable injury in fact.

Plaintiffs suggest that medical licensing laws and common medical practice corroborate their assertion that the degree of the risk of harm to Plaintiffs, which is caused by Defendants' violations, is unreasonable. Additionally, Plaintiffs point to the statements of Dr. Mark Heath that Missouri's protocol of delegating the IV-push to non-medical personnel gives rise to "substantial and medically unacceptable risks of inflicting excruciating pain and suffering on inmates while the lethal injection is administered." [Plaintiffs' Opposition Ex. D at 2-3]. He similarly opines that Anesthesiologist M3's inability to exercise his independent medical judgment, which stems from the non-prescription problem, presents "a gratuitous and substantial risk of a cruel execution." [*Id.* at 6]. Plaintiffs, however, do not indicate that such harm has ever occurred to any of the Plaintiffs, or to any individual who had been subject to Missouri's protocol or to any other person executed elsewhere under similar circumstances.

Plaintiffs state that such "threatened injuries" present an injury in fact. However, even an unreasonable risk of harm remains just that–a risk or a possibility of future harm. Recognizing mere risk of injury as injury in fact is counter to well established jurisprudence that an injury in fact must be a "concrete and particularized injury that is either actual and imminent," *Massachusetts v. E.P.A.*, 549 U.S. 497, 518 (2007) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)), and not a "mere possibility in the remote future." *Pierce v. Soc'y of the Sisters of the Holy Names of Jesus & Mary*, 268 U.S. 510, 536 (1925).

Here, Plaintiffs point to no evidence that the harm has ever occurred. As it stands, Plaintiffs fail to show any perceptible, present harm. The case law presented to the Court by Plaintiffs in support of their argument that mere risk of harm is sufficient to demonstrate injury in fact does not convince the Court otherwise.

Plaintiffs rely on *Dimarzo v. Cahill*, 575 F.2d 15 (1st Cir. 1978), as the "clearest illustration" of Plaintiffs' standing. [Doc. # 247, at 18]. The plaintiffs in that case were prisoners who charged the Commissioner of Correction and other officials under Section 1983 for numerous unconstitutional conditions and practices. According to the district court, one of the more serious allegations was the condition of the jail as a fire hazard. *Id.* at 16. The Court of Appeals specifically noted evidence submitted to the district court concerning the hazardous fire conditions of the jail: evidence of a serious fire at the jail in February 1975; affidavit testimony that inmates set small fires in their cells; and the personal inspection of the jail by the district judge and his conclusion that it presented a serious fire hazard. *Id.* at 18 n.4. Indeed, there were few exits from the cells, the floors were made of wood and covered in several layers of old paint or flammable covering, the cells could only be unlocked individually, and mattresses were made of material that was flammable or emitted toxic gas when ignited. *Id.* at 16.

The defendants in *Dimarzo* argued that the plaintiffs lacked standing because they failed to demonstrate an injury in fact. According to defendants, plaintiffs needed to show that they would "inevitably . . . suffer physical injury or death from fire" before acquiring standing to challenge the hazardous fire conditions at the jail. *Id.* at 18. The court rejected

this argument: "We find this proposition to fall far below contemporary expectations of constitutionally-mandated humane treatment. One need not wait for the conflagration before concluding that a real and present threat exists." *Id.* at 18. Thus, the injury in fact suffered by the plaintiffs in *Dimarzo* was not the mere risk of future physical harm or death by fire. Rather, the injury in fact was the plaintiffs' ongoing imprisonment in hazardous, inhumane conditions. Such a reading of *Dimarzo* comports with established jurisprudence. Causes of action under the Eighth Amendment for conditions-of-confinement claims can be to remedy potential, serious, future harms, but inmates must demonstrate that it is the current, ongoing prison conditions that pose a substantial risk for those harms. *See Farmer v. Brennan*, 511 U.S. 825, 823 (1994); *Helling v. McKinney*, 509 U.S. 25, 35 (1993); *see also Jacob v. Clarke*, 129 Fed. Appx. 326, 330 (8th Cir. 2005).

Thus, Plaintiffs' reliance on *Dimarzo* is misplaced because the case does not support their contention that hypothetical risk of injury is a cognizable injury in fact. Rather, the jail was found to be hazardous because a fire had taken place in the jail in February 1975 and there was a pattern of small fires set by inmates in their cells while surrounded by highly flammable material; the evidence also suggested that if a fire occurred the prison was maintained in a way that would make it difficult to rescue prisoners. Here, Plaintiffs assert that the selection and administration of sodium thiopental by non-medical personnel creates a risk of injury, but, unlike in *Dimarzo* they have not shown that such harm previously occurred. Further, there is a doctor who is present during the process and the participants rehearse the process. While the actual participants have not been able recently to use the

drugs during rehearsals, there is no evidence that the absence of drugs in the IV solution, alters the process. It remains a hypothetical risk without the likely if not inevitable consequences that were present in *Dimarzo.*

Similarly unavailing is Plaintiffs' dependence on *Massachusetts v. E.P.A.*, 549 U.S. 497 (2007), and *Missouri Coalition for Environment v. Federal Energy Regulatory Commission*, 544 F.3d 955 (8th Cir. 2008). In *Massachusetts v. E.P.A.*, the Supreme Court considered whether Massachusetts had standing to sue the EPA for its decision to decline regulating the emission of various greenhouse gases. The Court found that the "serious and well recognized" harms associated with climate change comprised the injury suffered by Massachusetts. *Id.* at 521. Many of these harms have already been inflicted, such as the "earlier spring melting of ice on rivers and lakes, and the accelerated rate of rise of sea levels during the 20th century relative to the past few thousand years." *Id.* at 521 (citation omitted). Specifically, the rise in sea levels had already "begun to swallow Massachusetts' coastal land." *Id.* at 522. Thus, while the Court recognized that Massachusetts' interests included Massachusetts' coastal property, whether owned by the State, it specifically found that "[b]ecause the Commonwealth owns a substantial portion of the state's coastal property, it has alleged a particularized injury in its capacity as a landowner." *Id.* at 522.

Massachusetts v. E.P.A. is distinguishable from this case on two grounds. First, Massachusetts' injury included harm already suffered–the loss of coastal land due to rising sea levels–not merely projected future harms. Second, any injury that would occur in the future was "serious," "well recognized," and certain to come based on a "strong consensus"

in the relevant scientific community. *Id.* at 521. Here, Plaintiffs present neither an injury already suffered nor demonstrate any certainty that Plaintiffs will ever be subject to severe pain due to the "IV-push problem" or the "non-prescription problem." Thus, Plaintiffs present merely an abstract injury that fails to meet the threshold showing for an injury in fact.

In *Missouri Coalition for Environment v. Federal Energy Regulatory Commission*, 544 F.3d 955 (8th Cir. 2008), the plaintiffs alleged that the defendant, a federal agency, failed to obtain an environmental impact statement prior to authorizing the construction of a hydroelectric generating plant. Key to the court's injury in fact analysis was that the environmental harm at issue stemmed from defendant's non-compliance with the procedural requirements of the National Environmental Policy Act. *Id.* at 957 ("Injury under NEPA occurs when an agency fails to comply with the statute. The injury-in-fact is increased risk of environmental harm stemming from the agency's allegedly uninformed decision-making."). Thus, the increased risk of environmental harm alone was not the injury in fact; rather, the injury in fact was the coupling of the agency's non-compliance under the National Environmental Policy Act and the increased risk of environmental harm which was the very harm intended to be avoided. The Court of Appeals clearly stated that the context of its injury in fact finding was "injury under NEPA." *Id.*; *see also Comm. to Save the Rio Hondo v. Lucero*, 102 F.3d 445, 448-49 (10th Cir. 1996) ("The injury of an increased risk of harm

due to an agency's uninformed decision is precisely the type of injury the National Environmental Policy Act was designed to prevent.").[2]

Plaintiffs call the risk "unreasonable" because the method of administering sedation to Plaintiffs does not conform with medical licensing laws or common medical practice. While the Court acknowledges that medical licensing laws are intended to ensure proper care of patients and to minimize potential harm, Plaintiffs have not shown that the failure to comply with such rules under these particular circumstances necessitates the conclusion that there exists a substantial risk of harm.

Finally, even if the Plaintiffs have sufficiently established a concrete, particularized injury, the Court on further reflection, is not convinced that Plaintiff's preemption claim is viable. However, it need not reach that question because it finds as a preliminary matter that Plaintiffs have not established injury in fact.

III. Conclusion

Accordingly, it is hereby ORDERED that Defendants' Motion for Summary Judgment [Doc. # 213] is GRANTED. Plaintiffs' motion [Doc. # 209] is DENIED.

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[2]While it appears that Missouri is violating federal law by failing to obtain its execution drugs with a doctor's prescription and by failing to use a doctor to administer the drugs, the Court does not believe that *Missouri Coalition for Environment v. Federal Energy Regulatory Commission* means that injury in fact is established when a state is violating federal law and there is some theoretical risk of injury as a result. To so find would require the Court to resolve the merits of the case before deciding whether there was an injury and would mean that any violation of federal law would establish injury in fact, if the Plaintiff might be harmed by it.

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

Dated: August 15, 2011
Jefferson City, Missouri