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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

RICHARD WADE COOEY II, et al.,
Plaintiffs,

KENNETH BIROS (Intervenor),
Plaintiff-Appellant,

v.

TED STRICKLAND, Governor, et al.,
Defendants-Appellees.

No. 09-4474

Appeal from the United States District Court
for the Southern District of Ohio at Columbus.
No. 04-01156—Gregory L. Frost, District Judge.

Submitted: December 7, 2009

Decided and Filed: December 7, 2009

Before: SILER, GIBBONS, and SUTTON, Circuit Judges.

OPINION

JULIA SMITH GIBBONS, Circuit Judge. This appeal presents the question of whether to stay the execution of Kenneth Biros, scheduled for December 8, 2009, at 10:00 a.m., based on his challenge to the lethal injection procedure by which Ohio intends to carry out his death sentence. The district court denied Biros's request for a stay, and, because we agree that Biros in particular is unable to demonstrate a likelihood of success on the merits of his Eighth Amendment claim, we affirm.

When a state permissibly chooses to impose the death penalty on a properly convicted criminal, the state, not the federal courts, is in charge of carrying out the sentence, but it may not impose "cruel and unusual" punishment in imposing that sentence. U.S. Const. amend VIII. This means that the courts will not allow a state to use an execution procedure that creates an "objectively intolerable risk of harm" or a "demonstrated risk of

severe pain" that is "substantial when compared to the known and available alternatives." *Baze v. Rees*, 553 U.S. 35, 128 S. Ct. 1520, 1531, 1537 (2008) (plurality opinion).

Kenneth Biros previously challenged Ohio's old execution protocol, one that mirrored the Kentucky execution protocol in all material aspects and was upheld by the United States Supreme Court. *See Baze v. Rees*, *supra*. He now challenges Ohio's new execution protocol, which made two relevant changes. Both are designed to render capital punishment in Ohio more humane.

One change eliminates Ohio's use of a three-drug protocol, which allegedly created a risk that the individual would not be properly anesthetized before the third, painful injection induced cardiac arrest. Even though the Supreme Court permitted this precise three-drug protocol in *Baze*, Ohio sought to address this concern by adopting a one-drug protocol—the same protocol advanced by the losing plaintiffs in *Baze*. *Id.* at 1534. While Biros understandably does not wish to be the first individual executed with this new drug, his medical expert, Dr. Mark Heath, acknowledges that Ohio's change is a positive one and that the one-drug protocol is a more humane execution procedure.[1] Indeed, his fellow litigants in the *Cooey* method-of-execution litigation, ongoing since 2004, have demanded that Ohio change to this precise procedure.

The second change in Ohio's protocol responds to another criticism—that the Ohio execution team has had difficulty accessing the veins of some individuals, most recently in the attempted execution of Romell Broom on September 15, 2009. Both in the *Baze* litigation and in the *Cooey* litigation, the claimants have registered complaints about the training of the EMTs responsible for inserting the intravenous ("IV") lines used to deliver the fatal drugs and about their inability to start an IV line promptly on some individuals. In response to these concerns, Ohio has established a two-drug, intramuscular injection as a back-up procedure if the execution team cannot obtain IV access.

[1] Dr. Heath began his testimony by stating: "[I]t was gratifying to see that Ohio had decided to renounce the use of pancuronium and potassium. That really is a big step forward, and it's taken many years, but I think they really are to be commended for doing that." Tr. at 35.

In denying Biros's stay of execution, the district court determined that Biros failed to produce evidence sufficient to demonstrate a likelihood that his challenge to Ohio's new protocol would succeed on the merits. After a thorough and considered review of the record before the district court, the testimony presented at the December 4, 2009, hearing, the Ohio protocol itself, and the district court's opinion, we agree that Biros has not met his burden. He has not demonstrated that, facially or as applied to him, Ohio's new protocol "demonstrate[s] risk of severe pain" that is "substantial when compared to the known and available alternatives." *Id.* at 1531, 1537. Although Ohio's new protocol may not be perfect, it conforms with the Constitution's prohibition on cruel and unusual punishment, and the record indicates that it is a decided improvement on the protocol that Ohio has utilized in the past.

I.

Biros's challenge to Ohio's lethal injection procedure under 42 U.S.C. § 1983, in which he argues that the new protocol violates his Eighth Amendment right to be free from cruel and unusual punishment, follows protracted proceedings in which Biros sought to overturn his 1991 conviction and death sentence. Biros was convicted of aggravated murder (with two capital punishment specifications), felonious sexual penetration, aggravated robbery, and attempted rape in connection with the death of Tami Engstrom and was sentenced to death. *Biros v. Bagley*, 422 F.3d 379, 382–85 (6th Cir. 2005). In the early morning of February 7, 1991, Biros and Engstrom left a bar in Hubbard, Ohio, together. Eventually, Biros told the police that Engstrom was dead, signed a waiver of his *Miranda* rights, and revealed the location of her body. Authorities recovered several of Engstrom's body parts in a desolate area of Butler County, Pennsylvania, and other portions of her body thirty miles north in Venango County. Engstrom's ring, two bloodstained knives, and clothing stained with Engstrom's blood were found in Biros's home and car.

Biros appealed his conviction and death sentence to the Ohio Court of Appeals and to the Ohio Supreme Court, *State v. Biros*, 678 N.E.2d 891 (Ohio 1997), and unsuccessfully sought post-conviction relief in state court, *State v. Biros*, No. 98-T-0051,

1999 WL 391090 (Ohio Ct. App. May 28, 1999). He later filed an application to reopen his appeal, which the Ohio Supreme Court denied on the merits. *State v. Biros*, 754 N.E.2d 805 (Ohio 2001). In September 2001, Biros filed a petition for a writ of *habeas corpus* in federal district court, which issued the writ as to his death sentence and withheld it as to his remaining claims. On appeal, we addressed each claim in turn and rejected them. After careful consideration, we concluded that the jury had imposed the death penalty after Biros had received the benefit of a fundamentally fair trial as required by the United States Constitution. *See Biros*, 422 F.3d at 392.

In November 2006, Biros intervened in an action initiated in the United States District Court for the Southern District of Ohio in 2004 challenging Ohio's three-drug lethal injection protocol under the Eighth and Fourteenth Amendments. Although the district court preliminarily enjoined Biros's execution in December 2006, it vacated its decision in a 159-page opinion issued in March 2009 after a five-day hearing. The district court determined that Biros had shown insufficient likelihood of success on the merits to warrant a stay. Its opinion made clear that Biros was unlikely to demonstrate a risk of harm that rose to the level of a constitutional violation.

In September 2009, Governor Ted Strickland postponed the execution of Romell Broom after an attempt to execute him was halted when the execution team was unable to access a vein. The Governor temporarily stayed other executions scheduled for October and November 2009 but left Biros's December 8 execution in place. On October 19, 2009, the district court stayed Biros's execution and scheduled the trial date of his and his co-plaintiffs' lawsuit for July 12, 2010. The district court made no findings with respect to Biros's likelihood of success on the merits of his challenges. On October 23, 2009, Ohio notified the district court that it was seeking alternatives to its execution protocol. Specifically, the State was considering a "single drug for intravenous administration . . . [or] the use of two drugs for intramuscular administration . . . either as primary and secondary alternatives, or as co-existing alternatives." R. 594 at 3.

On November 13, 2009, the State of Ohio filed a second motion for summary judgment in district court in which it announced that it had modified the Ohio Department of Rehabilitation and Correction ("ODRC") policy directive regarding executions by lethal injection. An attached affidavit of Terry Collins, director of the ODRC, explained the changes made to the Ohio protocol in response to the halted execution of Broom and subsequent inquiry. Collins outlined the two most significant alterations to the May 14, 2009, protocol that it replaced: the new protocol utilizes a one-drug, IV injection with a two-drug, intramuscular injection back-up procedure should the execution team fail to locate veins suitable for IV transmittal. The new protocol took effect on November 30, 2009, and is to be applied at Biros's scheduled December 8 execution.

Because this new protocol, and not its predecessor, which was at issue in Biros's original petition for relief, would govern his execution, the State asked the district court to vacate its October 19 stay of execution as moot. When the district court refused to vacate the stay, the State urged us to do so. On November 25, we vacated the stay, finding that the new protocol mooted Biros's challenge to the old protocol and that the district court had premised its stay primarily on "concerns related to the old procedure." *Cooey (Biros) v. Strickland*, No. 09-4300, Slip Op. at 3 (6th Cir. Nov. 25, 2009). The full court denied Biros's petition for rehearing *en banc* on December 4. *Cooey (Biros) v. Strickland*, No. 09-4300, Slip Op. at 1 (6th Cir. Dec. 4, 2009).

Meanwhile, on December 3, 2009, Biros filed a motion with the district court to amend his § 1983 complaint to challenge the new one-drug protocol, and the district court granted the motion on December 4. Supported by the affidavit of Mark J.S. Heath, M.D., Biros also asked the court to temporarily restrain the State from executing him. The State opposed the temporary restraining order, attaching the affidavit and declaration of Mark Derwshwitz, M.D., Ph.D. On December 4, the district court conducted an evidentiary hearing in which both Heath and Dershwitz testified by phone. Biros also introduced photos of Broom, a law review article, and depositions of Broom,

corrections officials involved in Broom's attempted execution, and Broom's medical expert.

The district court denied Biros's motion in a December 7, 2009, Opinion and Order. *Cooey (Biros) v. Strickland*, No. 2:04-cv-1156 (S.D. Ohio Dec. 7, 2009). The district court first described the testimony offered at its March 23–27, 2009, preliminary injunction hearing regarding the then-applicable three-drug protocol, the elements of the November 30, 2009, protocol, and the testimony offered at the December 4, 2009, hearing on Biros's motion for an emergency stay. After considering the facts before it, the district court concluded that Biros had not met his burden of demonstrating a strong likelihood of success on the merits of his claim of a constitutional violation under any standard set forth in *Baze*. *Id.* at 182. The court found unpersuasive Biros's contentions regarding the alleged problems with establishing IV access in light of Ohio's safeguards, which largely mirror those employed in Kentucky and approved in *Baze*. *Id.* at 155. Based upon its review of the evidence, the court further could not conclude that medical team members were "insufficiently trained, incompetent, or unable to perform competently under the circumstances of an Ohio execution," or that the new protocol's prescription of thiopental sodium through peripheral IV access was "a structural flaw of the protocol." *Id.* at 157. Moreover, the safeguards in place "acceptably mitigated" the risks of human error involved in the implementation of the protocol. *Id.* at 171. With respect to the particular drugs employed in both the IV and intramuscular procedures, the court determined that there was insufficient evidence that they created a sufficient risk of harm under *Baze*. *Id.* at 171–72, 178, 183.

The district court then considered Biros's claims under the Due Process Clause and the All Writs Act. On the former, the court concluded that Biros failed to present a strong likelihood of success given the dearth of authority as to the meaning of the Ohio statutory language regarding the execution of death sentences in Ohio and Biros's failure to fashion a complete argument based on the new execution protocol. *Id.* at 182–83. With respect to the latter, the court concluded that Biros had not demonstrated that he

is entitled to a stay of execution under the All Writs Act because such a stay was not necessary to preserve jurisdiction over this matter. *Id.* at 189.

Biros promptly appealed and moved for a stay of his execution.

II.

In reviewing the district court's order, we apply the following established standards: (1) whether Biros has demonstrated a strong likelihood of success on the merits; (2) whether he will suffer irreparable injury in the absence of equitable relief; (3) whether the stay will cause substantial harm to others; and (4) whether the public interest is best served by granting the stay. *Workman v. Bredesen*, 486 F.3d 896, 905 (6th Cir. 2007); *Ne. Ohio Coal. for Homeless & Serv. Employees Int'l Union, Local 1199 v. Blackwell*, 467 F.3d 999, 1009 (6th Cir. 2006). "These factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together." *Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991).[2]

III.

A.

On November 30, 2009, Ohio released the precise language of the new protocol—No. 01-COM-11—to the public and to Biros's counsel. The new protocol closely resembles the May 14, 2009, protocol in most material respects other than the two alterations mentioned in the Collins affidavit made public on November 13, 2009: the shift to a one-drug injection and the adoption of an intramuscular back-up procedure. Consistent with the prior protocol, there remains extensive provision for the training and qualifications of the medical team that administers the protocol. The execution team

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[2] In requesting a stay, Biros relies heavily on the stay order granted to another Ohio death-sentenced prisoner by a panel of this court following the halted Broom execution. *See Reynolds v. Strickland*, 583 F.3d 956 (6th Cir. 2009). He reasons that because the panel in *Reynolds* granted a stay, so should we. However, we find this argument unpersuasive. First, the lethal injection protocol challenged in *Reynolds* was that used during the attempted Broom execution—that is, the old protocol. Second, Biros has had the benefit of an evidentiary hearing before the district court, which included presentation of deposition testimony, testimony by Heath about the Broom incident, and photos of Broom. Thus, the situation that prompted the *Reynolds* stay order is not present here.

conducts training exercises no less than weekly for one month prior to an execution, and each member receives medical training prior to joining the team and annually thereafter. The execution team must include individuals "who are currently qualified under Ohio Law to administer and prepare drugs for intravenous and intramuscular injections, and . . . have at least one year experience as a certified medical assistant, phlebotomist, EMT, paramedic or military corpsman." R. 617-1 at 4, 8.

Ohio also continues to employ several safeguards and checks on each team member during the dispensing of the drugs, preparation of the syringes and IVs, administration of the IV, and monitoring of IV flow and pharmacological effects of any injections. Each step of the protocol is also closely supervised by both the Warden or ODRC Director and medically trained team members. During use of the IV method, the medical team member administering the injection and the Warden will observe the inmate as the drugs are administered to "look for signs of swelling or infiltration at the IV site, blood in the catheter, and leakage from the lines and other usual signs or symptoms." R. 617-1 at 9. Another team member will enter the execution chamber and inspect the IV sites for problems after each injection.

One major difference in the new protocol, however, is the combination of drugs to be used in the execution process. Until November 30, Ohio employed the same three-drug IV injection that twenty-seven other states and the federal government use: 2 grams of thiopental sodium (a barbiturate), followed by 100 milligrams of pancuronium bromide (a muscle paralytic), and then 100 milliequivalents of potassium chloride (a salt that causes cardiac arrest and rapid death). *See Baze*, 128 S. Ct. at 1527 (discussing Kentucky's three-drug protocol); *Workman*, 486 F.3d at 902 (describing Tennessee's three-drug protocol). The use of pancuronium bromide and potassium chloride formed the basis of most of the challenges to lethal injection protocols in federal and state courts, including Biros's original complaint in the instant case. In fact, in the challenges to both Kentucky and Tennessee's three-drug protocol, the prisoners advocated the one-drug injection adopted by Ohio here as a more humane alternative to the risk of pain

arising from the use of the three drugs. *See Baze*, 128 S. Ct. at 1531–32; *Harbison v. Little*, 571 F.3d 531, 538–39 (6th Cir. 2009).

After reconsidering its protocol in light of the halted execution of Broom, Ohio decided to switch to what it considers a more humane injection procedure using only thiopental sodium. In implementing the new procedure, "a person qualified to administer and prepare drugs for intravenous and intramuscular injections" will prepare five labeled syringes containing in total 5 grams of thiopental sodium. An additional five labeled syringes and 5 grams of thiopental sodium are to be on hand in case the initial dosage does not produce death.

When administering the lethal injection via IV, medically trained team members "evaluate and consider the establishment of one or two viable IV sites." R. 617-1 at 8. Then, those team members "shall make such number of attempts to establish IV sites as may be reasonable under the circumstances and shall take the amount of time necessary when pursuing this objective" and then test any chosen sites. *Id.* The protocol notes that the preferred site for IV injection is the "joint between the upper and lower arm" but that "a qualified medical person authorized to administer intravenous and intramuscular drugs may use an alternative site to deliver the drugs as they may be authorized by law." *Id.* Should the team members "question the feasibility of establishing two or even one site" due to difficulty, passage of time, or any other reason, the team members must consult with the Warden. *Id.* At that time, the Warden must consult with the Director of ODRC and "others as necessary" to determine whether to continue to search for an IV site, pursue the alternative procedure, or halt the execution. *Id.* at 9.

The other significant alteration in the new Ohio protocol, and one that Biros challenges as untested, is the implementation of a back-up procedure for use if the prisoner's veins—like Broom's—prove difficult to access. "If the Director and Warden decide IV injections should not be used, or if an IV injection is commenced and abandoned," a two-drug injection of 10 milligrams of midazolam and 40 milligrams of hydromorphone shall be administered in a single syringe intramuscularly. *Id.* at 8. A second syringe of the same mixture will be available if necessary as will a third syringe

of 60 milligrams of hydromorphone. *Id.* A medical team member will administer the first injection and, after five minutes, examine the prisoner for signs of breathing. If necessary, the medical team member will then administer the second injection and reexamine the prisoner after five minutes. *Id.* Should the prisoner still exhibit signs of breathing, the medical examiner will administer the 60 milligrams of hydromorphone. *Id.*

B.

The plurality opinion in *Baze* sets the ground rules for gauging Biros's likelihood of success in challenging Ohio's procedure. *See Marks v. United States*, 430 U.S. 188, 193 (1977) ("When a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of [the majority], 'the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds.'" (citing *Gregg v. Georgia*, 428 U.S. 153, 169 n.15 (1976) (plurality opinion))). To demonstrate that Ohio seeks to impose "cruel and unusual" punishment, U.S. Const. amend. VIII, Biros must show that its protocol ignores a "*sure or very likely*" risk of serious pain "and needless suffering," *Baze*, 128 S. Ct. at 1531, which "creates a demonstrated risk of severe pain" that is "substantial when compared to the known and available alternatives," *id.* at 1537.

In thinking about what *Baze* requires, it is helpful to remember what it does not. The opinion contains several controlling premises within which Biros must formulate his challenge: Capital punishment is constitutional, *see id.* at 1529; death-row inmates cannot use method-of-execution challenges to prohibit what the Constitution allows, *id.*; "the Constitution does not demand" a pain-free execution, *id.* at 1529, 1537; and an inmate cannot question a state's execution protocol without providing "feasible, readily implemented" alternatives that "*significantly* reduce a substantial risk of severe pain," *see id.* at 1532 (emphasis added); *id.* at 1531 ("[A] condemned prisoner cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative."). Significantly, the Constitution does not allow the federal courts to act as a best-practices board empowered to demand that states adopt the least

risky execution protocol possible. *See id.* at 1529, 1531. Within this framework, the Supreme Court has never held that an inmate met the "heavy burden" of demonstrating that a state's execution protocol is "cruelly inhumane" in violation of the Constitution. *See id.* at 1533 (citing *Gregg*, 428 U.S. at 175); *see also id.* at 1529, 1531; *Harbison*, 571 F.3d at 535 (rejecting a challenge to Tennessee's lethal injection protocol after *Baze*).

Since *Baze*, this court and other circuits have addressed challenges to various states' lethal injection protocols according to this standard—in all cases finding that *Baze* prevented the challengers from demonstrating either a violation of the Eighth Amendment, a genuine issue of material fact regarding the existence of a violation, or a likelihood of success on the merits for the alleged violation. *See Clemons v. Crawford*, 585 F.3d 1119, 1128 (8th Cir. 2009) (Missouri); *Harbison*, 571 F.3d at 535 (Tennessee); *Wellons v. Hall*, 554 F.3d 923, 942 (11th Cir. 2009), *overruled on other grounds*, *Cone v. Bell*, 129 S. Ct. 1769 (2009), *as recognized in*, *Owen v. Sec'y for Dep't of Corrs.*, 568 F.3d 894, 915 n.23 (11th Cir. 2009) (Georgia); *Emmett v. Johnson*, 532 F.3d 291, 295 (4th Cir. 2008) (Virginia); *Hankins v. Quarterman*, 288 F. App'x 952, 961 (5th Cir. 2008) (Texas). Two other circuits addressed similar challenges before *Baze* and came to identical conclusions. *See Hamilton v. Jones*, 472 F.3d 814, 816–17 (10th Cir. 2007) (Oklahoma); *Beardslee v. Woodford*, 395 F.3d 1064, 1075 (9th Cir. 2005) (*per curiam*) (California).

In the face of these requirements and this guidance, Biros has little prospect of being the first inmate to show that an execution protocol is unconstitutional—either with respect to the primary method of execution (the one-drug IV protocol) or with respect to the back-up method of execution (the two-drug intramuscular protocol). A thorough review of the evidence presented regarding Ohio's new one-drug IV procedure reveals that the similarities with *Baze* are considerable and the risk of severe pain no greater—and likely less—than the risk of pain inherent in any lethal injection procedure found constitutional by a federal court. Furthermore, although the two-drug intramuscular back-up injection differs from the protocol discussed in *Baze*, it is not likely "cruelly inhumane" and does not "create[] a demonstrated risk of severe pain."

Baze, 128 S. Ct. at 1533, 1537. Finally, Biros "has not shown a sufficient likelihood that the administration [of the protocol] will be improper in his case, or that there are specific risks unique to him that require modification of the protocol." *See Beardslee*, 395 F.3d at 1076.

C.

Before embarking on a detailed analysis of Ohio's new protocol, it is appropriate to briefly outline the historical role of the Eighth Amendment in the context of capital punishment in the United States. Although the notion of execution is uncomfortable for many—and abhorrent to some—the Supreme Court has found it to be constitutional. *See Gregg*, 428 U.S. at 169 (finding that capital punishment "does not invariably violate the Constitution"). It is an extreme punishment reserved for "the most extreme of crimes." *See id.* at 187 ("There is no question that death as a punishment is unique in its severity and irrevocability . . . ."). The Court has struggled for more than a century to articulate "with exactness the extent" of the Eighth Amendment's protections. *Wilkerson v. Utah*, 99 U.S. 130, 135–36 (1878). The Court has said that "[p]unishments are cruel when they involve torture or a lingering death . . . . [or imply] something inhuman and barbarous—something more than the mere extinguishment of life," *In re Kemmler*, 136 U.S. 436, 447 (1890), when they cause "unnecessary pain" or "wanton infliction of pain," *Louisiana ex rel. Francis v. Resweber*, 329 U.S. 459, 463 (1947) (plurality opinion), or when they do not "accord with 'the dignity of man, which is the basic concept underlying the Eighth Amendment,'" *Gregg*, 428 U.S. at 173.

The role of the Eighth Amendment has thus become a check on states' imposition of this constitutional punishment and an encouragement to develop more humane methods of execution. *See Baze*, 128 S. Ct. at 1537 ("State efforts to implement capital punishment must certainly comply with the Eighth Amendment, but what that Amendment prohibits is wanton exposure to 'objectively intolerable risk,' not simply the possibility of pain." (citation omitted)). The May 14 and November 30 changes to Ohio's lethal injection protocol have been in furtherance of this aim. *See* Governor Ted Strickland, Warrants of Reprieve, Oct. 6, 2009; *cf. Baze*, 128 S. Ct. at 1527 n.1 ("[I]t is

. . . undisputed that, in moving to lethal injection, the States were motivated by a desire to find a more humane alternative to then-existing methods."); *Workman*, 486 F.3d at 907 ("The whole point of the Tennessee lethal-injection protocol is to avoid the needless infliction of pain, not to cause it."). By adopting a one-drug injection, Ohio purposely ceased using the pancuronium bromide and potassium chloride that had been the focus of previous Eighth Amendment challenges to lethal injection protocols, including in Biros's original complaint. *See, e.g.*, *Baze*, 128 S. Ct. at 1534–35; *Emmett*, 532 F.3d at 295, 300; Compl. at 2. Additionally, Ohio's decision to employ a back-up intramuscular injection option was a direct response to the difficulties encountered during Broom's halted execution. That is, the purpose of the intramuscular injection seeks to avoid an unduly prolonged search for difficult-to-access veins and to provide a safe, non-IV lethal injection method.

In addressing challenges to execution methods, the Supreme Court has determined that the Eighth Amendment does not require a state to employ a painless execution method, but rather one free from "needless suffering" and a "demonstrated risk of severe pain." *Baze*, 128 S. Ct. at 1531, 1537; *see, e.g.*, *Resweber*, 329 U.S. at 464 ("The cruelty against which the Constitution protects a convicted man is cruelty inherent in the method of punishment, not the necessary suffering involved in any method employed to extinguish life humanely."); *see also Hamilton*, 472 F.3d at 816 ("[T]he Constitution does not require the use of execution procedures that may be medically optimal in other contexts. Rather, . . . such procedures [must] 'not involve the unnecessary and wanton infliction of pain.'"). The lethal injection protocols are designed to minimize pain and the likelihood of improper administration of the procedure. Because "capital punishment is constitutional[, i]t necessarily follows that there must be a means of carrying it out. Some risk of pain is inherent in any method of execution—no matter how humane—if only from the prospect of error in following the required procedure." *Baze*, 128 S. Ct. at 1529. "It is clear, then, that the Constitution does not demand the avoidance of all risk of pain in carrying out executions." *Id.*; *see also Emmett*, 532 F.3d at 303 ("[I]t is enough to observe that Virginia is not

constitutionally required to eliminate every possibility that pain might occur or every unnecessary risk that may exist.").

In considering Ohio's new lethal injection protocol, therefore, we do not consider whether it is the best possible procedure, but rather whether the protocol itself presents a "demonstrated risk of severe pain." *Baze*, 128 S. Ct. at 1537; *see also Beardslee*, 395 F.3d at 1073 ("In the context of this particular challenge [of reviewing the district court's denial of a preliminary injunction], the more important consideration may be the examination of the objective evidence as to the pain caused by the particular method employed . . . ."); *Campbell v. Wood*, 18 F.3d 662, 683 (9th Cir. 1994) (*en banc*) (holding that judicial review of a method of execution "focuses more heavily on objective evidence of the pain involved in the challenged method" (internal quotation marks and citation omitted)).

D.

Biros raises questions regarding the appropriateness of Ohio's protocol and indicates specific elements of that protocol that he alleges present a demonstrated risk of severe pain sufficient to rise to the level of cruel and unusual punishment. Biros does not challenge the use of the one-drug IV injection if properly administered, and indeed his medical expert praises Ohio's decision to abandon the three-drug injection. His allegations regarding the unconstitutionality of Ohio's primary procedure—IV injection of thiopental sodium—therefore solely address the risk of improper administration of the drug. These challenged elements of the protocol can be fairly summarized as: (a) the undue risk of improper implementation of Ohio's protocol, leading to severe pain; (b) the employment of untrained and insufficiently competent medical personnel; (c) the lack of supervision of the execution process by a licensed physician; (d) the lack of a prescribed limit to the time allowed the execution team to search for accessible veins for IV administration; and (e) the lack of an explicit ban on the use of cut-down procedures for accessing veins as an alternative method to the preferred peripheral IV access. His challenge to Ohio's new back-up procedure is more substantive but less detailed: (a) the untested nature of the intramuscular procedure; (b) the slow-acting and unpredictable

effect of that procedure; and (c) the existence of a more humane alternative to intramuscular injection. We will consider first those challenges related to the IV injection and implementation of the protocol. We will then turn to Biros's allegations regarding the back-up procedure.

1. Challenges to IV Injection and Ohio's Implementation of the New Protocol

The majority of the claims regarding the one-drug IV injection are foreclosed by *Baze* and its progeny.

a. Undue Risk of Improper Implementation of Ohio's Protocol. In *Baze*, the Court held that Eighth Amendment challenges to lethal injection protocols on the grounds that the protocol could be improperly administered are insufficient to demonstrate a violation. The Court stated:

> Petitioners agree that, if administered as intended, that procedure will result in a painless death. The risks of maladministration they have suggested—such as improper mixing of chemicals and improper setting of IVs by trained and experienced personnel—cannot remotely be characterized as "objectively intolerable." Kentucky's decision to adhere to its protocol despite these asserted risks, while adopting safeguards to protect against them, cannot be viewed as probative of the wanton infliction of pain under the Eighth Amendment.

Baze, 128 S. Ct. at 1537–38; *see also Beardslee*, 395 F.3d at 1071–72 (rejecting a prisoner's claim that "the lack of specificity" in the protocol leading to many "variables that can complicate the proper administration of the drugs, such as the use of Valium as a pre-execution sedative, and the problems in finding acceptable veins for the insertion of an intravenous tube"). Consequently, Biros's general claim that the possibility of maladministration of the IV could lead to severe pain is without merit. To demonstrate a likelihood of success on this ground, therefore, Biros must distinguish his maladministration claims from those rejected in *Baze*. He has failed to do this.

Biros relies heavily on Ohio's halted execution of Broom to distinguish his case from that of *Baze*.[3] The Supreme Court has found, however, that evidence of prior accidents in the administration of an execution protocol does not render the protocol itself *per se* unconstitutional. In *Resweber*, Louisiana attempted to execute a prisoner by electrocution, but when the executioner flipped the switch, nothing happened. The Court first noted that "we must and do assume that the state officials carried out their duties under the death warrant in a careful and humane manner. Accidents happen for which no man is to blame." *Resweber*, 329 U.S. at 462. It then found that a subsequent execution of the same prisoner by electrocution would not be unconstitutional. *See id.* at 464 ("The fact that an unforeseeable accident prevented the prompt consummation of the sentence cannot, it seems to us, add an element of cruelty to a subsequent execution. There is no purpose to inflict unnecessary pain nor any unnecessary pain involved in the proposed execution."). The Court in *Baze* affirmed that "an isolated mishap alone does not give rise to an Eighth Amendment violation, precisely because such an event, while regrettable, does not suggest cruelty, or that the procedure at issue gives rise to a 'substantial risk of serious harm.'" *Baze*, 128 S. Ct. at 1531 (citation omitted).

Furthermore, in a case similar to the one before us today, the Eighth Circuit addressed a challenge to Missouri's lethal injection protocol after a series of mistakes in administration of the protocol came to light. *See Clemons*, 585 F.3d at 1119. The Eighth Circuit rejected the prisoner's claim that there was a substantial risk of pain due to incompetent personnel despite the fact that the court had previously found that medical personnel administering the protocol—since removed—had been incompetent. *Id.* at 1127 ("We reject the prisoners' attempt to distinguish their case from *Baze* on the basis of alleged past incompetence on the part of Missouri's medical personnel."). For

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[3]Broom's attempted execution took place on September 15, 2009. The execution team was unable to find a vein on Broom's arm after repeated attempts over two hours. They attempted to insert the IV catheter into the crook of Broom's elbow, his wrists, over the knuckle of his first finger, and near his ankles. Twice, the team managed to insert a catheter that was not secured properly and caused bleeding. Biros contends that the new one-drug protocol is identical to the old protocol in terms of the training and supervision of the execution team and thus, he could be subjected to a failed execution like Broom's. Biros uses little more than speculation and the argument that if failure happened once, it could happen again. Biros cannot rely upon Broom's experience without more specific evidence that would show a *likelihood* that his own execution would be unsuccessful. Without such evidence, we must, as the Supreme Court has instructed, assume that the execution team will implement the protocol as specified.

the same reasons, we cannot assume that the same misfortunes that befell Broom will befall Biros, nor can we assume that Ohio's execution team—if faced with difficulty administering the lethal injection intravenously—will not cease searching for veins and turn to the back-up intramuscular protocol. Speculations, or even proof, of medical negligence in the past or in the future are not sufficient to render a facially constitutionally sound protocol unconstitutional.

Permitting constitutional challenges to lethal injection protocols based on speculative injuries and the possibility of negligent administration is not only unsupported by Supreme Court precedent but is also beyond the scope of our judicial authority. *See, e.g.*, *Gregg*, 428 U.S. at 174–75 ("[W]hile we have an obligation to insure that constitutional bounds are not overreached, we may not act as judges as we might as legislators."). While the Eighth Amendment does provide a necessary and not insubstantial check on states' authority to devise execution protocols, its purpose is not to substitute the court's judgment of best practices for each detailed step in the procedure for that of corrections officials. *See Baze*, 128 S. Ct. at 1537 ("[A]n inmate cannot succeed on an Eighth Amendment claim simply by showing one more step the State could take as a failsafe for other, independently adequate measures. This approach would serve no meaningful purpose and would frustrate the State's legitimate interest in carrying out a sentence of death in a timely manner."); *Gregg*, 428 U.S. at 175–76 ("We may not require the legislature to select the least severe penalty possible so long as the penalty selected is not cruelly inhumane or disproportionate to the crime involved. . . . Caution is necessary lest this court become, 'under the aegis of the Cruel and Unusual Punishment Clause, the ultimate arbiter of the standards of criminal responsibility . . . throughout the country.'" (quoting *Powell v. Texas*, 392 U.S. 514, 533 (1968) (alteration in original))); *Emmett*, 532 F.3d at 303 ("While Dr. Henthorn is of the view that such delay [of administering each subsequent injection] would be a better practice, we are not at liberty to dictate what is in our judgment or the judgment of any expert a 'better' or 'less risky' procedure."). Indeed the Court has all but foreclosed this form of Eighth Amendment challenge:

> Given what our cases have said about the nature of the risk of harm that is actionable under the Eighth Amendment, a condemned prisoner cannot successfully challenge a State's method of execution merely by showing a slightly or marginally safer alternative.
>
> Permitting an Eighth Amendment violation to be established on such a showing would threaten to transform courts into boards of inquiry charged with determining "best practices" for executions, with each ruling supplanted by another round of litigation touting a new and improved methodology. Such an approach finds no support in our cases, would embroil the courts in ongoing scientific controversies beyond their expertise, and would substantially intrude on the role of state legislatures in implementing their execution procedures—a role that by all accounts the States have fulfilled with an earnest desire to provide for a progressively more humane manner of death.

Baze, 128 S. Ct. at 1531. Thus, Biros's advocacy for modest improvements to the administration of Ohio's lethal injection protocol is not sufficient to demonstrate that a protocol without those improvements is unconstitutional.

b. Employment of Untrained and Insufficiently Competent Medical Personnel. Biros's more specific criticisms of the Ohio protocol with respect to proper training of personnel, supervision, and lack of guidance on when and how to determine that the back-up procedure should be used also fail to demonstrate a likelihood of success. Biros argues that Ohio's requirement of one year of medical training and the use of medical assistants, phlebotomists, and EMTs is insufficient to ensure competent execution personnel.[4] In considering Kentucky's protocol, however, the *Baze* Court noted the existence of "important safeguards to ensure that an adequate dose of sodium thiopental[,] . . . [t]he most significant of [which] is the written protocol's requirement that members of the IV team must have at least one year of professional experience as a certified medical assistant, phlebotomist, EMT, paramedic, or military corpsman . . .

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[4]The presence of a supervising or attending physician at an execution by lethal injection undoubtedly could help to ensure that executions proceed as smoothly and painlessly as possible. *See* Atul Gawande, *When Law and Ethics Collide—Why Physicians Participate in Executions*, 354 New Eng. J. Med. 1221, 1223 (2006). However, the majority of doctors refuse to participate in executions in any meaningful way, *see* Neil J. Farber *et al.*, *Physicians' Willingness to Participate in the Process of Lethal Injection for Capital Punishment*, 135 Ann. Intern. Med. 884, 886 (2001), and the relevant medical ethics guidelines prohibit such participation, *see Baze*, 128 S. Ct. at 1539–40 (Alito, J., concurring). For this reason, Ohio must rely on non-physicians to implement its lethal injection protocol, and its requirements of training and qualifications provide adequate supervision in the absence of physicians.

[and] participate in at least 10 practice sessions per year." *Baze*, 128 S. Ct. at 1533–34; *see also id.* at 1528 (explaining the qualifications and training of Kentucky's execution team); *cf.* R. 617-1 at 4, 8. *Baze* found that the same training and qualification requirements also "substantially reduce the risk of IV infiltration." 128 S. Ct. at 1534.

This court and other circuits that have addressed challenges to the competency and training of execution personnel have upheld requirements similar to those listed in Ohio's protocol. *See Harbison*, 571 F.3d at 538 (finding that the use of two paramedic technicians to administer the IV and monthly training sessions of the execution team provided sufficient safeguards to assume proper administration of Tennessee's protocol); *Emmett*, 532 F.3d at 295 (finding sufficient Virginia's requirements that the execution team undergo eight hours of training per month and that at least two team members "have received training as military corpsmen, cardiac emergency technicians, or should receive on-the-job training from a physician in receiving and dispensing medications, to include starting and administering IV fluids" (citation omitted)); *Hamilton*, 472 F.3d at 816 (rejecting a similar challenge to Oklahoma's protocol, which requires that "an EMT-P or person with similar qualifications and expertise in IV insertion" establish the IV drips (citation omitted)). Biros's claim that Ohio's protocol is constitutionally deficient on the basis of poorly trained personnel or the ceding of too much discretion to those personnel is therefore meritless.

Biros's medical expert, Dr. Heath, further suggests that Ohio should employ physicians to implement the new protocol.[5] This alternative is not required by *Baze* and state law itself would subject any participating physician to severe discipline by the state medical board. It is undisputed that the American Medical Association guidelines prohibit physician participation in execution. American Medical Association, *Opinion 2.06—Capital Punishment* (2000), http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/ opinion206.shtml. Ohio permits the state medical board to "limit, revoke or

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[5] Dr. Heath also references Ty Alper, *The Truth About Physician Participation in Lethal Injection Executions*, 88 N.C. L. Rev. ___ (forthcoming 2009).

suspend an individual's certificate to practice [medicine in the state for a] . . . violation of any provision of a code of ethics of the American Medical Association." Ohio Rev. Code. Ann. § 4731.22(B)(13). Indeed, so long as the medical board has "reliable, probative, and substantial" evidence of a violation of the AMA guidelines, a doctor is subject to its penalty without resort even to the courts. *Schechter v. Ohio State Med. Bd.*, No. 04-AP-1115, 2005 WL 1869733, at *19 (Ohio Ct. App. Aug. 9, 2005) ("When the board's order is supported by reliable, probative, and substantial evidence and is in accordance with law, a reviewing court may not modify a sanction authorized by statute."). Dr. Heath's proposed alternative is therefore not feasible.

c. Lack of Supervision of the Execution Process by a Licensed Physician. For similar reasons, we find that Biros's claim that a lack of proper supervision of the IV injection by a physician constitutes an Eighth Amendment violation also must fail. Like the Kentucky protocol upheld in *Baze*, Ohio's protocol calls for the medical team members to administer the drug remotely by IV while the Warden and Director of ODRC remain in the execution room to visually inspect the prisoner to determine if he is unconscious, needs further injections, or exhibits any problems with the IV catheters and tubing such as infiltration of the tissue. *Compare Baze*, 128 S. Ct. at 1528, 1534, *with* R. 617-1. This court and other circuits have rejected allegations of the unconstitutionality of similar supervisory procedures. *See Harbison*, 571 F.3d at 536–38 ("Medical experts in *Baze* testified that identifying signs of possible infiltration occurring at the IV site would be very obvious to the average person because of the swelling that would result." (citing *Baze*, 128 S. Ct. at 1534)); *Emmett*, 532 F.3d at 295–96; *Hamilton*, 472 F.3d at 816 ("[W]hile monitoring of anesthetization level is the optimal practice appropriate for a surgical operating room . . . , the risk inherent in the lethal-injection procedure under review is already so attenuated that we cannot say there is a significant likelihood that a challenge to the protocol under the minimal requirements imposed by the Eighth Amendment on executions could succeed on our record."). Thus Biros cannot demonstrate that Ohio's supervision procedures are unconstitutional.

d. Lack of a Prescribed Limit to the Time Allowed the Execution Team to Search for Accessible Veins for IV Administration. Invoking the experiences of Broom and of Joseph Clark before him, Biros says that there are no limits on how long the execution team may "poke and stick" him before moving to the alternative intramuscular injection, raising the risk that the protocol will cause "unconstitutional pain and suffering" in the interim. Am. Compl. at 12. As established in *Baze*, the training and qualifications of the medical personnel required by the protocol ensure that they can make this determination competently. *See* 128 S. Ct. at 1533–34.

Biros argues that an easy and feasible alternative to the challenged discretion exists. Biros advocates that Ohio, like Kentucky, adopt a sixty-minute limit on how long the execution team be allowed to search for an accessible vein. *Baze* held that "proffered alternatives must effectively address a 'substantial risk of serious harm.' To qualify, the alternative procedure must be feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain." *Id.* at 1532 (citation omitted). Therefore, it is now settled law that "[a] prisoner cannot successfully challenge a method of execution merely by showing that the method may result in pain, either by accident or as an inescapable consequence of death, or that a slightly safer alternative is available." *Harbison*, 571 F.3d at 535 (citing *Baze*, 128 S. Ct. at 1531, 1537); *see also Walker v. Epps*, 287 F. App'x 371, 376 (5th Cir. 2008) (finding that the prisoner "ha[d] not demonstrated irreparable harm 'through the mere possibility that some unforeseen complication will result in a lingering death causing [him] to suffer unnecessary pain[; therefore,] [h]e cannot rely on this possibility as the grounds for substantial risk of harm'" (citing *Lambert v. Buss*, 498 F.3d 446, 452 (7th Cir. 2007), and *Beardslee*, 395 F.3d at 1075) (alterations in original)). In light of the constitutionally adequate medical supervision, the requirement that Ohio impose a sixty-minute limit on the amount of time allowed to search for veins for IV injection does not alleviate a "substantial risk of serious harm." Furthermore, this proposed amendment to Ohio's protocol is eminently the kind of cost–benefit judgment that courts are ill-suited to perform and that *Baze* discouraged. *See Baze*, 128 S. Ct. at 1531.

The unfortunate incident of Ohio's unsuccessful execution of Broom does not distinguish Ohio's protocol from that at issue in *Baze*. When administered properly, both protocols are humane and constitutional. Ohio's protocol, like Kentucky's, is regrettably open to the possibility of mistaken application. The complete eradication of all risk of accident, however, is not yet possible, and the assertion that the mere possibility of future improper administration of the lethal injection despite the training and safeguards is too "attenuated" and "speculative"—and certainly not intended—to constitute cruel and unusual punishment. *See id.* at 1536–37; *United States v. Emerson*, 270 F.3d 203, 262 (5th Cir. 2001).

e. Lack of an Explicit Ban on the Use of Cut-Down Procedures. Biros also asserts that Ohio's protocol does not prohibit the use of a cut-down procedure when a prisoner's veins prove difficult to locate. A cut-down procedure entails making an incision into an arm or leg to gain IV access. *See Nelson v. Campbell*, 541 U.S. 637, 641 (2004). First, generally physicians or nurses are needed to perform this procedure, and the Ohio protocol does not envision physicians or nurses as members of the execution team nor has Ohio generally been able to acquire the assistance of either at executions in the past. Second, Biros presents no evidence that Ohio has previously employed the cut-down procedure. It was not employed during the attempted execution of Broom, and there is no evidence that it would be used in the execution of Biros. Furthermore, the Director of ODRC has stated that the procedure will not be used—an assurance that Dr. Heath acknowledged and accepted in testimony. Furthermore, Ohio's protocol indicates that the alternative intramuscular injection is to be utilized if the execution team finds the prisoner's veins difficult to access, and the implication is that it is this intramuscular procedure—and not cut-down—that will be employed should the execution team find peripheral IV injection impossible. Finally, because we upheld Tennessee's lethal injection protocol, which included cut-down as the approved back-up procedure, we need not address it in further detail here. *See Harbison*, 571 F.3d at 539.

2. Challenges to the Back-Up Intramuscular Procedure

Biros raises a series of distinct challenges to Ohio's contingency intramuscular injection of hydromorphone and midazolam. While *Baze* forecloses Biros's claims that Ohio's use of the one-drug IV injection are unconstitutional, the protocol at issue in *Baze* is less factually similar to Ohio's back-up intramuscular injection procedure. Biros first asserts that the intramuscular injection is unconstitutional because it has never before been used in an execution, thereby rendering him "a human guinea pig." Dr. Heath, Biros's medical expert, expresses concern that there is insufficient analysis of what happens when this combination of drugs is administered to humans. Second, Biros alleges that the intramuscular injection is cruel and unusual because it is slower—a matter of minutes rather than seconds—than the IV procedure. The delayed effect of the drug, Dr. Heath argues, increases the likelihood that the prisoner will experience the common but unpleasant side effects of the two drugs.

Before addressing those challenges, however, it bears noting that Biros faces a threshold problem. The record gives us little reason to think that the execution team will have to resort to this contingency. Biros has never argued, much less shown, that he has difficult-to-access veins, and the intramuscular injection comes into play only when an IV injection is not possible. Furthermore, Biros's own medical expert concedes that it is very unlikely that the intramuscular injection protocol will be necessary because thiopental sodium is likely to work. Indeed, Dr. Heath has explicitly endorsed the thiopental-sodium protocol. That reality alone diminishes the alleged risks.

It is also important to note that Ohio's adoption of a back-up procedure to the IV injection arose out of concerns regarding the pain that may ensue from attempting to find veins in prisoners—like Broom—whose veins are difficult to access. That is, the back-up procedure is patently an attempt by the State of Ohio to render its execution process *more* humane, rather than less. The procedure is an improvement on the prior protocol in two ways. First, it provides an approved alternative method of execution by lethal injection that medical personnel can turn to quickly should they encounter difficulty in accessing a prisoner's veins. The availability of an alternative should curtail the

searching and poking that Biros fears. Second, the alternative is less invasive than the cut-down procedure employed by Tennessee.[6] *See Harbison*, 571 F.3d at 539 (upholding Tennessee's procedure, including the cut-down alternative); *Workman*, 486 F.3d at 903 (outlining Tennessee's alternative cut-down procedure); *see also Nelson*, 541 U.S. at 641 (describing the cut-down procedure in detail).

a. Untested Nature of the Intramuscular Procedure. That the procedure has never before been used does not itself establish that the procedure is cruel and unusual. The Supreme Court has previously considered various modes of execution and has yet to find one violative of the Eighth Amendment. *See Baze*, 128 S. Ct. at 1530 ("This Court has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment."). Indeed, the development of increasingly humane methods of execution is to be encouraged:

> The broad framework of the Eighth Amendment has accommodated this progress toward more humane methods of execution, and our approval of a particular method in the past has not precluded legislatures from taking the steps they deem appropriate, in light of new developments, to ensure humane capital punishment. There is no reason to suppose that today's decision will be any different.

Id. at 1538. In determining whether a new execution method is constitutional, we must analyze it under the same framework as any other alleged Eighth Amendment violation. *See In re Kemmler*, 136 U.S. at 447 (considering the constitutionality of New York's novel adoption of execution by electrocution and noting that "[t]he courts of New York [had found] that the mode adopted in this instance might be said to be unusual because it was new, but that it could not be assumed to be cruel in the light of that common knowledge which has stamped certain punishments as such").

[6] Dr. Heath also alludes to standards promulgated by the American Veterinary Medical Association for intramuscular euthanasia. The record is not well-developed on this point and the overwhelming weight of the testimony indicates that the intramuscular injection protocol drugs are not likely to cause pain and suffering. Furthermore, the Supreme Court addressed a similar claim with respect to laws prohibiting the use of pancuronium bromide by veterinarians in euthanasia, noting that "veterinary practice for animals is not an appropriate guide to humane practice for humans." *See Baze*, 128 S. Ct. at 1535–36.

We now turn to whether Biros has presented sufficient evidence to demonstrate that the intramuscular injection of hydromorphone and midazolam presents a risk of severe pain. We conclude that he has not.

b. Slow-Acting and Unpredictable Effect of the Intramuscular Procedure. According to Dr. Mark Dershwitz, a board-certified anesthesiologist and professor at the University of Massachusetts and the State's medical expert, a large dose of hydromorphone, an opioid most commonly used for pain relief, causes cessation of breathing.[7] Midazolam, the second drug used in the intramusculatory injection procedure, is commonly used to sedate and relieve the anxiety of patients undergoing uncomfortable procedures or anesthetization before surgery. Both drugs cause ventilatory depression, and the effect is increased and hastened when the two drugs are administered together. According to Dr. Dershwitz, an inmate injected with the dosage required by the Ohio protocol will become sleepy and slow breathing after several minutes and lose consciousness within two to four minutes. Approximately five minutes after breathing stops, the heart and brain "will become damaged irreversibly, and death will occur a few minutes later." R. 611-1 at 3. Although the "peak pharmacological effect will occur in about 20–30 minutes," the State has shown that the loss of consciousness sets in shortly—and Dr. Dershwitz avers that "perceptible effects" will "occur within a minute or two"—the inmate will not experience the side effects Biros fears. Even if death does not occur until several minutes later, the inmate will not be aware of the delay. Biros has presented no evidence that the pharmacological effect of the two-drugs would be otherwise. The Federal Drug Administration has approved both drugs for intramuscular injection, and although this mode of administration acts more slowly than IV administration, it is used on patients around the country daily.

[7] At the outset, we note Dr. Dershwitz's extensive professional experience with pharmacokinetics and pharmacology. *See United States v. Diaz*, 25 F.3d 392, 394 (6th Cir. 1994) ("When an expert has been qualified, other evidence, including the testimony of other experts, that contradicts or undermines the testimony of the expert affects that expert's credibility . . . ."). Dr. Dershwitz has a Ph.D. in pharmacology, has taught the subject for more than thirty years, and has published extensively in the field. He based his expert opinions of the intramuscular injection protocol on an extensive literature review as well as his own professional experience.

Biros has presented evidence that hydromorphone and midazolam—like all pharmaceuticals—can lead to uncomfortable side effects. Specifically, he has identified side effects such as nausea, vomiting, aspiration, biliary spasm, anxiety, and combativeness. Dr. Heath testified that the intramuscular injection protocol drugs could induce nausea and vomiting that could cause pain and violent coughing that could wake up a prisoner if he is unconscious. Even if a prisoner did not wake up, Dr. Heath believes it possible that the vomit could enter his airways and lead him to aspirate. He further testified that it is possible that the drugs could render a prisoner disoriented, anxious, and intoxicated such that it could provoke a combative fight-or-flight response.

At the recent hearing, Dr. Heath was unable to quantify the likelihood of any of these side effects occurring if the State turned to the intramuscular injection method. At most, he was able to say that "some" prisoners could have an individualized adverse reaction to the drugs. Tr. at 63. He also pointed out that, because patients in the clinical context are administered much lower doses of the drugs, the likelihood and intensity of the side effects is uncertain. Dr. Dershwitz, on the other hand, gave a definite expert opinion, explaining, "[I]t is my belief beyond a reasonable degree of medical certainty, if [intramuscular injection] is implemented . . . it is very unlikely that the inmate will suffer any pain." Tr. at 219–20. The expert opinion to a reasonable degree of medical certainty offered by Dr. Dershwitz contrasts sharply with the speculation by Dr. Heath: "[S]ome prisoners who are exposed [to this intramuscular injection]" may have adverse reactions that result in a "distasteful" procedure. Tr. at 35. As we have emphasized repeatedly, the Constitution does not require perfection; it does require Biros to show more to convince us that he faces a substantial likelihood of pain and suffering.

Furthermore, according to Dr. Dershwitz, the likelihood of seizure-type activity is low and midazolam is both an anti-emetic (a drug effective against vomiting and nausea) and anti-seizure medication that counteracts many of the side effects Dr. Heath identified as resulting from hydromorphone. The opioids would more likely than not dull any possible pain and not exacerbate it. Dr. Dershwitz offered testimony that an individual would lose consciousness within two to four minutes of the first

administration of midazolam and would thus be unlikely to aspirate. Even if a person did vomit, they would not suffer pain because they would be unconscious. Any inter-individual variation in the absorption rates, and thus the efficacy of the drugs, would be overwhelmed by the dosage amounts.

Biros points to an additional uncertainty. If the execution team uses the intramuscular procedure after injecting thiopental sodium into his bloodstream during an attempted IV injection, the unintended combination of drugs may exacerbate the side effects of the intramuscular drugs or reduce their absorption rate. However, even Biros's own expert could not give a definitive opinion on whether those were legitimate possibilities. Uncertainties built on so many other uncertainties cannot show a substantial risk of severe pain and needless suffering.

At best, Biros has pointed to a four minute window within which he could possibly suffer some discomfort. However, he has neither established any likelihood that he would experience the side effects of hydromorphone or midazolam nor has he demonstrated any likelihood that these side effects would cause him pain.[8] Dr. Heath has presented speculative evidence that certain patients in certain circumstances with certain combinations of risk factors may experience unpleasant side effects. None of his testimony outweighs the evidence presented by Dr. Dershwitz that midazolam and hydromorphone will almost certainly have an anti-emetic, anti-seizure, and analgesic effect on an individual and that the overwhelming doses of these drugs would counteract any discomfort. In sum, Biros has failed to provide any objective evidence that in the few minutes during which the prisoner would lapse into unconsciousness after the first injection, these side effects would pose a substantial risk of severe pain or needless suffering.

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[8] Dr. Heath's request for a pharmacokinetic analysis of hydromorphone by Dr. Dershwitz similarly has no bearing on the likelihood of severe pain during the process. Indeed, it is Dr. Dershwitz's uncontradicted testimony that additional studies would not change the fact that a high dose of hydromorphone would induce death after a prisoner loses consciousness, and thus the ability to sense pain. Even moderate variability in the effectiveness of the drugs from person to person is irrelevant due to the overwhelming dosages involved.

c. More Humane Alternative to Intramuscular Injection. Dr. Heath faults the new protocol for using an intramuscular injection backup instead of instructing the execution team to insert a "central line," or long IV catheter, through a vein in the prisoner's neck, under the collar bone, or along the femur, so that the catheter rests a few inches from the heart. He contends that this is the accepted back-up procedure in a number of other jurisdictions. Yet Heath concedes that "a central line has a far *greater capability* of causing *severe* injury and pain and morbidity and mobility." Tr. at 110 (emphasis added). The insertion of a central line may be one alternative to peripheral venous access, but even Biros's expert's testimony confirms that the State's chosen procedure is *less* dangerous than the alternative and *less* likely to cause severe injury and pain. Dr. Heath also agreed that "in order to avoid substantial risk that the central line will not be performed effectively," it would "be necessary to use a physician." Tr. at 112. Yet Ohio has consistently proven unable to obtain assistance from medical doctors in the administration of the death penalty.

Therefore, the use of a central line as an alternative does not satisfy *Baze*'s requirements that an alternative "be feasible, readily implemented, and in fact significantly reduce a substantial risk of severe pain." *Baze*, 128 S. Ct. 1532. Furthermore, because Biros fails to demonstrate a risk of severe pain in the intramuscular procedure, and thus no "substantial risk of serious harm" posed by it, *see id.*, we need not address the relative merits of the two procedures because the mere existence of an alternative is insufficient to render Ohio's chosen protocol unconstitutional.

* * *

Biros argues that Ohio is unduly "rush[ing]" to carry out his death sentence and unreasonably holding itself to an "arbitrary" execution schedule. R. 610 at 3. However, many years have elapsed between Biros's 1991 conviction and the first challenge to Ohio's lethal injection protocol in 2004. Still more years have passed between that first challenge to the protocol and the present. In the meantime, no federal appellate court has concluded that a state's lethal injection procedure is unconstitutionally cruel and

unusual. Throughout this entire period, states have sought to improve their lethal injection protocols and to attempt to make executions more comfortable for citizens sentenced to death. A state's efforts to reduce the likelihood of discomfort for those whom it must lawfully execute cannot be seen as unconstitutionally undue haste unless the condemned prisoner can demonstrate that those procedures present a "sure or very likely" risk of serious pain "and needless suffering" that "creates a demonstrated risk of severe pain" that is "substantial when compared to the known and available alternatives." *Baze*, 128 S. Ct. at 1531, 1537. Certainly, states should not be discouraged from attempting to improve their protocols—to obtain a "more humane manner of death"—"a role . . . [that] the States have fulfilled with an earnest desire" for more than two hundred years. *Id.* at 1531. If, however, a state changes its protocol in pursuit of a more humane punishment and the alteration becomes the subject of protracted, stay-inducing federal litigation, the change impedes the state's interest in swiftly executing those sentenced to death. When that occurs, we risk stifling the necessary impetus to seek more humane execution methods and insert the courts into a policy and scientific debate not suited to judicial authority. The standards and inquiries set out by the Supreme Court in *Baze* strike a balance between turning the federal courts into tribunals of best practices and maintaining their rightful function as a constitutional check on the "wanton infliction of pain" by the state. *See Resweber*, 329 U.S. at 463.

Biros further maintains that a stay is necessary to maintain the *status quo* and permit him additional time—even a matter of days—to further develop the record. The evidence presented by the parties and the testimony of both medical experts persuade us, however, that additional time will not enhance Biros's likelihood of success on the merits. Biros's burden in demonstrating an Eighth Amendment violation is a "heavy" one, and there is nothing in the record before us to indicate that additional testing and discovery will reveal a "substantial risk of severe pain" or contradict Dr. Dershwitz's testimony regarding the remoteness of a possibility of adverse side effects to the intramuscular procedure. Dr. Heath's concerns are without objective, concrete evidentiary support, as evidenced by his concession that adverse side effects are extremely unlikely to occur and, if they do at all, will do so for individualized,

unforeseeable reasons. Furthermore, Biros's assertions that time is needed to conduct further discovery regarding the halted Broom execution are unavailing. The extensive depositions of Broom, members of his execution team, and other corrections personnel were part of the record before the district court and before us. We have reviewed those depositions and conclude that further discovery regarding the Broom incident—including deposing Governor Strickland, who has declined questioning—would not bring to light evidence sufficient to enable Biros to demonstrate a likelihood of success on the merits of his Eighth Amendment claim based on the new protocol.

Biros also argues that the State has no legitimate interest in executing him hastily under a new protocol without discovery or thorough federal court review, so the public interest factor cuts in his favor. We disagree because this overlooks the state's "strong interest in enforcing its criminal judgments without undue interference from the federal courts." *Hill v. McDonough*, 547 U.S. 573, 584 (2006).

For these reasons, we find that Biros has failed to demonstrate that Ohio's decision to adopt an alternative, non-IV method of lethal injection poses any risk of severe pain. He is therefore unable to demonstrate a likelihood of success on his claim that it or the one-drug IV administration violate the Eighth Amendment's prohibition on cruel and unusual punishments.

IV.

Biros also claims that the planned execution will violate his right to a "quick and painless death." R. 610 at 9. He cites Ohio Revised Code § 2949.22(A), the statute that provides for a death caused by "a lethal injection of a drug . . . of sufficient dosage to quickly and painlessly cause death." But § 2949.22 creates no cause of action to enforce any right to a quick and painless death. *See State v. Rivera*, Nos. 08CA009426, 08CA009427, 2009 WL 806819, at *7 (Ohio Ct. App. Mar. 30, 2009) ("There is no 'action' for a quick and painless death" under Ohio Reg. Code Ann. § 2949.22(A).). We are not persuaded by Biros's assertion that § 2949.22 creates a federal right because the statute creates "liberty and property interests in a 'quick and painless execution'"

protected by the substantive component of the Due Process Clause of the Fourteenth Amendment. R. 610 at 9. Biros is unlikely to show that the reach of any such right extends beyond the incorporation of the Eighth Amendment. *Cf. Furman v. Georgia*, 408 U.S. 238, 359 n.141 (Marshall, J., concurring).

V.

Finally, Biros asks us to stay his execution under the All Writs Act. That Act authorizes us to "issue all writs necessary or appropriate in aid of [our] jurisdiction[] and agreeable to the usages and principles of law." 28 U.S.C. § 1651(a). Biros argues that we can stay his execution without a showing of a likelihood of success on the merits because the Act looks to our exercise of jurisdiction over this case, which we lose once Ohio executes him on December 8, rather than to the affect of the litigation on the parties. Biros's assertion is unpersuasive and unsupported by precedent. "There is no reason why the All Writs Act can or should be used to thwart the proper application of the [TRO] factors," *Lambert*, 498 F.3d at 454, and every reason to assume that the use of the Act in this way would erode the customary grounds for obtaining stays of execution.

The All Writs Act provides "a residual source of authority" when no other provision "addresses the particular issue at hand," not an alternative to available but unavailing procedures concerning the matter at hand. *See Pa. Bureau of Corr. v. U.S. Marshals Serv.*, 474 U.S. 34, 43 (1985). Biros's interpretation of the Act amounts to circumvention of the requirements of Federal Rule of Civil Procedure 65, and would do exactly what *U.S. Marshals Service* prevents: substitute the Act for the requirements that Congress provided for obtaining emergency stays.

VI.

For the foregoing reasons, we affirm.