No. 07-5439

IN THE Supreme Court of the United States

RALPH BAZE, et al,

Petitioners,

v.

JOHN D. REES, et al., Respondents.

ON WRIT OF CERTIORARI TO THE SUPREME COURT OF KENTUCKY

REPLY BRIEF FOR PETITIONERS

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REPLY BRIEF FOR PETITIONERS

By choosing to use pancuronium and potassium chloride to conduct lethal injections, Kentucky has built into its execution procedures an inherent danger of inflicting excruciating pain condemned prisoners. Unable to contest this proposition, respondents stake their constitutional case on the factual proposition that the danger is insignificant because their procedures ensure that prisoners will be adequately anesthetized before the paralyzing pancuronium and burning potassium chloride take effect. But the purported safeguards on which respondents rely to ensure effective delivery of adequate anesthesia consist of little more than using an EMT and phlebotomist to insert the IV at the outset of the procedure, and do not address the many deficiencies in the procedure that could lead to an agonizing death. Likewise, respondents do next to nothing to monitor whether a condemned inmate is adequately anesthetized. Their "monitoring" consists of visual observation by the warden and his deputy to determine (from several feet away) whether the inmate appears to have "gone to sleep." JA 281.

The danger of a torturous execution using these procedures is real, not hypothetical – as the history of botched executions and the experience of States using the three-drug formula confirms. *See infra* pages 15-17; Pet'r Br. 20-24. And this experience almost certainly understates the magnitude of the danger because pancuronium will mask the visible evidence that the inmate is suffering.

Rather than acknowledge the very real dangers posed by Kentucky's procedures, respondents seek to change the subject, contending that petitioners have advanced a "least risk" standard that would invalidate any execution procedure so long as a slightly less risky alternative can be posited. That is a caricature. Under petitioners' test, a condemned prisoner challenging an execution procedure must show that the procedure presents a danger of severe pain that amounts to cruelty, that the danger is unnecessary in that it can be avoided by adopting reasonably available alternatives, and that it is significant in that the danger will materialize into cruel executions for some Speculative or hypothetical risks, or risks of less than severe pain, do not suffice - and even significant risks of severe pain do not suffice if the risks are not reasonably avoidable. It is this standard. and respondents' not seemingly unattainable "substantial risk" standard, that best comports with fundamental Eighth Amendment principles.

Kentucky's procedures fail this test. The record establishes that a massive dose of a barbiturate would bring about death swiftly without the dangers inherent in using pancuronium or potassium. And even if Kentucky were to choose to continue with the three-drug approach despite this alternative, it could readily reduce the dangers of the three-drug approach by monitoring effectively to assure that a condemned inmate is anesthetized. The risk posed by those chemicals – a risk of excruciating pain that qualifies as cruel and unusual under any definition –

is thus plainly an unnecessary one. It is equally plain that the risk is a significant one. Botched lethal injections have occurred in the past and can be expected to occur in the future if Kentucky's haphazard procedures receive the Court's imprimatur. It cannot be any less a violation of the Eighth Amendment that these procedures will inflict excruciating pain on some rather than all inmates subjected to them.

ARGUMENT

- I. Kentucky's Procedures Subject Inmates To A Significant and Unnecessary Risk Of Excruciating Pain.
 - A. Kentucky's Deficient and Dangerous Procedures.

The trial record establishes beyond peradventure that pancuronium and potassium will cause a torturous death if they are injected into an inadequately anesthetized inmate. Respondents' brief does not contest this fact, and instead asks this Court to uphold Kentucky's procedures on the sole ground that those procedures ensure that inmates will be adequately anesthetized before these chemicals are injected into their veins.

But respondents have failed to rebut petitioners' showing that each step in Kentucky's unwieldy process creates the danger that inadequate anesthesia will be delivered to the inmate. As petitioners established at trial, the executioners can get the dose wrong by preparing a solution with the wrong concentration of thiopental; they can err in placing catheters; they can push the drugs too hard

and "blow out" the catheter by perforating the vein; and they can inject the syringes in the wrong order. These dangers are sufficiently serious that even personnel who, unlike Kentucky's personnel, possess expertise and appropriate training would have difficulty reliably carrying out the procedure.

Respondents have likewise failed to show that they effectively verify that a condemned prisoner is sufficiently anesthetized before receiving pancuronium and potassium. To the contrary, Kentucky's procedures virtually guarantee that a failure to administer adequate anesthesia will go undetected.

Doubtless because of the dangers posed by pancuronium and potassium, Kentucky law forbids using a comparable three-drug protocol to euthanize animals and allows the use of potassium only when trained personnel can assure that anesthesia has been effectively administered. See Ky. Rev. Stat. § 258.095(12); AVMA Guidelines on Euthanasia, at 12 (2007). Respondents do not even attempt to justify using procedures to execute humans that are so dangerous that they would be unlawful if used to euthanize animals, and they fail to convincingly answer the record evidence establishing the proliferation of dangers created by their procedures.

1. Foreseeable Administration Problems.

Petitioners have shown that Kentucky's procedures are rife with problems that can prevent effective anesthesia. Nothing in respondents' brief

(or in the two specific trial court findings related to these dangers) refutes that showing.

Dosing Problems. To deliver a three-gram dose of thiopental into an inmate's veins effectively, the IV team must prepare a solution that will deliver the dose in the proper concentration. Doing so entails knowing how many vials of thiopental powder to combine with what quantity of diluent; how to combine multiple vials into one or two larger syringes; and how to ensure that the entire amount of powder is drawn into the syringes. If this process is not performed accurately, it will result in a concentration of thiopental that is either too low or too high – either of which would prevent delivery of a reliable dose of anesthetic. JA 433-34, 473; Taylor v. Crawford, No. 05-4173-CV-FJG, 2006 WL 1779035, at *4-*5 (W.D. Mo. June 26, 2006), rev'd, 487 F.3d 1072 (8th Cir. 2007), cert. pending.

Yet Kentucky's protocol says nothing about how to perform these tasks. It states only that personnel "shall prepare two (2) sets of execution chemicals in 60 cc syringes," JA 987, and it nowhere explains how many thiopental vials will be used, how they should be combined, or what concentration should be used. Id. 472-73, 986-89. Execution personnel apparently are expected to figure out how to create the threegram dose for the first time on the night of an execution. Respondents' own brief vividly Id. confirms how easy it is to err in preparing a solution with the proper concentration. Respondents assert that "three grams of thiopental are dissolved into 20 milliliters of sterile solution." Resp. Br. 42. If that is indeed what Kentucky's executioners do, they will

be creating a far higher concentration of thiopental than can safely be used. See JA 677-78. At this concentration, the solution will be over-saturated and the full dose of the thiopental will not dissolve. See generally id. 673; Taylor, 2006 WL 1779035, at *4-*5. The resulting solution will then be of a dose that is substantially lower than intended. See id.

Improperly Placed Catheters. IV catheters can be improperly placed: they can perforate the vein, or be inserted so that they are partially or fully outside the vein. When this happens, a portion of each drug will be injected into the tissue surrounding the vein (a problem known as infiltration). JA 358, 463. Although infiltration might prevent delivery of the full dose of all three drugs, a small portion of the intended doses of pancuronium and potassium will cause paralysis, pain and death, whereas the same proportion of the intended thiopental dose may be insufficient to induce anesthesia for the duration of the execution. See Pet'r Br. 14 n.8, 20-21.

These problems are not hypothetical. IV problems occur regularly in clinical settings, JA 463, and are more likely in the execution context. As the trial court found, there are numerous difficulties attendant to IV insertion in an execution that increase the likelihood of an improperly placed catheter, including "failure to find a suitable I.V. site, 'blowouts,' problems with scar tissue, and problems caused by nervousness." *Id.* 762; *id.* 217.

Four aspects of Kentucky's procedures increase this danger. First, executions will proceed even when the prospect of achieving reliable catheter placement is poor. By providing a 60-minute window for IV insertion (rather than the 20 minutes that is standard medical practice, *id.* 475), the protocol contemplates attempting IV access even though the chances of setting a reliable IV have become "exponentially lower," because the personnel have already "blow[n]" the "good veins." *Id.* 476.

Second, unqualified personnel determine which of Kentucky's two IVs to use as the primary line based on the "presence of blood" in the needle – a criterion with no medical validity that could lead to an erroneous assumption that the catheter was properly set. *Id.* 315, 466-67; Pet'r Br. 15.

Third, the use of inexperienced prison personnel (who lack even the basic qualifications of the EMT and phlebotomist) to push the drugs increases the danger that an initially reliable catheter will be "blown out" – *i.e.*, the catheter will perforate the vein, causing infiltration – by pushing too hard on the syringes. JA 217, 219-20. Because these personnel practice this task by pushing solution through tubing unconnected to a catheter, they have never confronted the problems that foreseeably arise when injecting solution into human veins.

Fourth, Kentucky's choice to deliver the chemicals remotely via five feet of IV tubing that snakes from a separate room through a wall and to the gurney in the execution chamber – a choice made solely to protect the sensibilities of the executioners – renders blowouts more likely. With longer tubing, there is greater resistance to the syringe push, so the executioner must apply more force, which, coupled

with the volume of the fluid used, increases the danger of "IV disruption." See Harbison v. Little, 511 F. Supp. 2d 872, 889 (M.D. Tenn. 2007) (quoting expert testimony).

Syringe Problems. Because Kentucky's procedures require an inexperienced prison employee to administer a series of syringes in quick succession stressful conditions, administering chemicals in the wrong order is a foreseeable danger - one that Dr. Dershwitz has acknowledged. Harbison, 511 F. Supp. 2d at 888; see also Tr. 784 (syringe problems in clinical practice). Missouri's executioner, describing procedures Kentucky's, similarly testified that he was concerned about syringe problems because "the people who do the injections ... [have to] quickly identify the syringes, make the appropriate connections and injections, disconnect, clamp the tube." Taylor, 2006 WL 1779035, at *5. An execution in which the inmate receives the pancuronium out of order, while potentially agonizing, would appear unremarkable to execution personnel. Moreover, by failing to provide adequate monitoring and contingency procedures, respondents have made it likely that a syringe problem will go undetected and uncorrected. infra.

2. Untrained Personnel Increase The Likelihood of Administration Problems.

Exacerbating these problems is the fact that the bulk of the execution tasks are performed by personnel with no relevant expertise. Aside from setting IVs, EMTs and phlebotomists have no clinical training or experience in the other tasks the execution team must perform: mixing doses ofintravenous calculating anesthetics; administering anesthesia or drugs like pancuronium; deciding how to correct an administration failure.¹ JA 528-29, 625; see 202 Ky. Admin. Reg. § 7:701(2) (describing scope of practice). Moreover, the prison employee who pushes the drugs has no experience in calibrating the force of the push or detecting resistance within IV lines. See JA 285, 287; Pet'r Br. 17-18. In these respects, Kentucky ignores the warning provided by the manufacturer of sodium thiopental that the drug should be administered only by individuals trained and experienced in doing so. JA 528-29, 675.

Kentucky's execution personnel therefore do not have the minimal experience that respondents' expert, Dr. Dershwitz, has asserted is necessary to ensure that executions are performed properly: personnel "should be people who do this [each task] as part of their daily job and ... they should be able to troubleshoot and that only comes with experience." *Harbison*, 511 F. Supp. 2d at 879 (quoting Dershwitz). As a result, courts have found that employing personnel with only paramedic or IV-therapy qualifications as the purportedly expert

¹ Amicus United States suggests that Kentucky, "like the federal government," employs qualified personnel. U.S. Amicus Br. 27. The recent disclosure in discovery that the United States entrusts its execution procedure to a doctor whose incompetence led to his being banned from participating in Missouri executions casts doubt on this assertion. See Morales Amicus Br. 15-16.

personnel is a "severe problem." *Harbison*, 511 F. Supp. 2d at 888; *Morales v. Tilton*, 465 F. Supp. 2d 972, 979 (N.D. Cal. 2006) (personnel with qualifications similar to Kentucky's personnel were "unprepared" for execution tasks).

In sum, petitioners demonstrated at trial that Kentucky's complex procedures are rife with problems at each stage of the execution process — unsurprisingly, in light of Kentucky's failure to conduct any independent inquiry into the adequacy of the approach it copied from other States which had also adopted it without careful study.

Kentucky seeks to defend the ruling below by claiming that the trial court's factual findings are entitled to deference. But the court made only two specific findings pertinent to the effectiveness of Kentucky's procedures for delivering the anesthetic (regarding the mixing of individual packets of thiopental and the risk of precipitate forming in IV lines, JA 761-63). Those findings do not address the many other deficiencies in Kentucky's procedures that can lead to agonizing death. Thus, the court did not analyze the overall danger that Kentucky's procedures will result in inadequate anesthesia and severe pain.

3. Kentucky's Purported Safeguards Are Illusory.

Respondents essentially acknowledge that the injection of pancuronium and potassium into a conscious individual would produce extreme pain and that Kentucky's procedure can avoid this result

only if it assures that a condemned inmate has received a sufficient dose of thiopental to cause a surgical level of anesthesia before the pancuronium and potassium are administered. The State's entire defense of the procedure as "humane," *e.g.*, Resp. Br. 10, is based on the assertion that it assures inmates will receive an anesthetizing amount of thiopental. *E.g.*, *id.* 9, 10, 24, 43, 49-50, 55, 57. This assertion, in turn, rests solely on the claim that a series of "safeguards" assures that thiopental delivery failures cannot occur. But these "safeguards" do not come close to alleviating the dangers created by Kentucky's ill-designed protocol.

First, respondents' reliance on the participation of EMTs and phlebotomists (whose only role is to set the IV), id. 39, does not ensure that Kentucky's unwieldy procedure will reliably deliver anesthetic. Whatever their expertise in setting an IV line, EMTs and phlebotomists have no training or expertise in any of the remaining steps in the execution process. Thus, the warden's confidence that he could rely on them to respond to problems that arise during the procedure, id. 279, is entirely misplaced.

Second, the rudimentary "training" to which respondents point (Resp. Br. 39) falls woefully short. The reality is that execution personnel do not practice most of what they must do to carry out a lethal injection. They do not practice constituting a three-gram dose of thiopental at an appropriate concentration level. JA 298. Nor do they practice injecting saline solution into a human vein or use any other technique that would allow them to learn to assess IV problems that can be expected to arise

during the lethal injection process. Instead, they simply push solution through a tube unconnected to a catheter. *Id.* 318-19, 285. They do not consider or practice taking remedial steps if infiltration or any other foreseeable problem occurs during administration of thiopental. JA 191. *See Harbison*, 511 F. Supp. 2d at 891 (monthly training regimen that, in addition to the tasks practiced in Kentucky, included actual injections, was inadequate because personnel did not receive "instruction [in] the actions they are actually charged with performing"). As a result, the execution team will be performing some of the most crucial execution tasks *for the first time* on the night of the execution.

Third, respondents do virtually nothing to detect inadequate anesthesia. As the trial court found, respondents do not use available technology – such as an EKG, blood pressure cuff or BIS monitor – to gather the information necessary to assess whether the anesthesia is working. JA 764. Instead, respondents rely on the warden's visual "check" of whether the inmate appears to have "gone to sleep" within seconds after being injected 60 thiopental. Resp. Br. 41; JA 283. But lav distinguish observation cannot among full consciousness (with eyes closed), light anesthesia caused by a partial dose of thiopental, or the surgical level of anesthesia that is necessary to safeguard against the pain of potassium. JA 349-51, 406-07, 418, 439; Morales v. Hickman, 415 F. Supp. 2d 1037, 1047 (N.D. Cal. 2006). The visual consciousness "check" is virtually useless. That is particularly so if, as in the Harper execution, the warden is only able to see the inmate "from the waist down" – precluding even a rudimentary observation of consciousness. JA 213-14; 418-19, 421. In any event, these purported measures would be effective, if at all, only until pancuronium is injected. After that, no indications of consciousness will be discernible to observers. *Id.* 441.

Fourth, to detect infiltration and other IV problems, respondents rely entirely on untrained and inexperienced prison officials who stand in the execution chamber, attempting to observe subtle indicia of infiltration from obstructed positions up to ten feet away. *Id.* 183, 213, 276-77. Contrary respondents' misstatement, the record does not demonstrate that IV problems would be "obvious" to untrained observers. Drs. Haas and Hiland – both trained medical professionals - testified that they personally would be able to detect infiltration, not that an untrained person could do so. *Id.* 353, 386. In contrast, Dr. Heath testified that the ability to palpate and closely observe – which require experience and knowledge – are necessary to detect infiltration and other problems. *Id.* 463. generally Harbison, 511 F. Supp. 2d at 889 (quoting expert: "visual observation [of catheter site] by a minimally trained person is not adequate"). although Dr. Dershwitz speculated that a thiopental infiltration might cause an inmate to complain of pain, JA 600-01, thiopental infiltration frequently does not cause pain. See D. Denison Davies, Local Complications of Thiopentone Injection, 38 Brit. J. Anaesth. 530 (1966); cf. Lightbourne v. McCollum, No. SC06-2391, __ So. 2d __, 2007 WL 3196533, at

*15 (Fla. Nov. 1, 2007). Therefore this is not a reliable indicator of problems. And infiltration is only one of the problems that can result in inadequate anesthetization.

For these reasons, Dr. Dershwitz has opined that "it is logical to assume that there's an increased risk" if the only personnel observing the inmate during the execution are untrained in monitoring IV lines. Harbison, 511 F. Supp. 2d at 888. He has also asserted that "all the steps involved in putting in and maintaining and checking an IV are best done by somebody who regularly does ... all of these steps as part of" his or her normal employment duties. *Id.* Asthe evidence demonstrates, Kentucky's procedures fall far below this standard. JA 268, 276, 287, 300, 340, 433-34, 441-42, 463, 525, 528-29.

Fifth, respondents state that personnel can ameliorate any IV problems, if they detect them, by using the backup IV line. Resp. Br. 41. That is not so. Even if personnel detected any problems – itself a large assumption – they will not know how to react effectively to problems they have never before encountered, and for which they have not trained. JA 279, 283; Morales Amicus Br. 30-35. Any backup procedure is only as effective as the people administering it. See, e.g., Summary of the Findings of the Dep't of Corrections Task Force Regarding the Dec. 13, 2006 Execution of Angel Diaz, at 5-7 (Dec. 20, 2006) (personnel insufficiently trained to implement contingency procedures).

In sum, respondents' proffered safeguards are illusory, and will not ameliorate the grave risks created by their procedures.

4. Deficiencies Similar to Kentucky's Have Led To Problematic Executions.

Although respondents dismiss the dangers described above as "speculative," Resp. Br. 6-7, petitioners' expert testimony regarding problems leading to inadequate anesthesia has been borne out repeatedly.

For instance, execution personnel in California and Missouri, who, like those in Kentucky, had EMT-level training but no expertise in mixing drugs, have had difficulty constituting the proper dose of thiopental, to the point where it is impossible to know whether they prepared adequate doses. See, e.g., Morales, 465 F. Supp. 2d at 980 (describing dosing problems and impossibility of determining whether adequate anesthesia was given); Taylor, 2006 WL 1779035, at *4-*5 (surgeon had "difficulty in dissolving [thiopental] powder"). IV problems have frequently occurred and have led to botched executions. See JA 778; Morales Amicus Br. at 31-33; Lightbourne, 2007 WL 3196533, at *15-*16. In several jurisdictions, execution team members lacked the training and expertise to carry out written execution protocols accurately. See Taylor, 2006 WL 1779035. at *7; The Governor's Comm'n on Administration of Lethal Injection, Final Report With Findings and Recommendations, at 8-9 (2007). And when problems have arisen, execution personnel have often been inadequately trained to react effectively. *Morales*, 465 F. Supp. 2d at 979; Morales *Amicus* Br. at 29-35.²

In California, for instance, where personnel had expertise and training comparable to that in Kentucky, six of eleven inmates executed by lethal injection apparently received insufficient thiopental to induce surgical levels of anesthesia. Morales, 465 F. Supp. 2d at 980. The execution team failed to recognize the problem before injecting pancuronium and potassium. At least one inmate displayed vital signs consistent with consciousness during the injection of the second two drugs. *Id.* at 979-81 (state's expert testified that "Massie well may have been awake when he was injected with potassium").3 The California evidence demonstrates that because pancuronium is used, executions can be botched in a manner that is not readily evident unless execution records are examined.⁴ See id. at 980; see also JA 441. In numerous other jurisdictions, inmates have

² Petitioners' arguments below regarding the existence and foreseeability of these problems make the trial court's denial of the opportunity to depose Kentucky's execution personnel inexplicable. *See* Tr. 128:20-26, 134:10-135:16, 195:14-17.

³ Amici States acknowledge that this evidence indicates "insufficient anesthesia," but assert it "does not establish that [inmates were] awake and experienced any pain." States Amicus Br. 30; see also U.S. Amicus Br. 26. Because the inmates were given pancuronium, there is no way to definitively determine whether they felt pain. But an insufficiently anesthetized prisoner given potassium is virtually certain to experience excruciating pain.

⁴ It is precisely this danger that has led veterinarians to conclude that neuromuscular blockers should never be used in euthanasia. Concannon *Amicus* Br. 16-18; *Beardslee v. Woodford*, 395 F.3d 1064, 1073 (9th Cir. 2005).

exhibited more obvious signs of potentially inadequate anesthesia, see, e.g., Brown v. Beck, No. 5:06 CT 3018, 2006 WL 3914717, at *5 (E.D.N.C. Apr. 7, 2006), yet in many cases execution personnel have not noticed or reacted to these problems. See Morales Amicus Br. 29-35.

These examples give the lie to respondents' assertion that the "safeguards" in Kentucky's execution procedure are sufficient to assure that condemned inmates will be anesthetized before pancuronium and potassium are injected, and that the execution team will detect and react to any problems that arise. Yet respondents continue to insist that these problems could never occur in Kentucky, because, they contend, no execution has yet been botched in Kentucky. Resp. Br. 6. But this is no reason to disregard the evidence marshaled in this case and the problems revealed in other iurisdictions. The absence of definitive proof of suffering in this single execution is hardly sufficient to validate Kentucky's procedure. In addition, as a result of respondents' use of pancuronium and failure to collect meaningful data, there is no evidence from which any conclusions as to the humaneness of Harper's execution can be drawn.⁵ JA 441, 502-03.

B. Less Dangerous Alternative Procedures Are Reasonably Available.

Respondents do not seriously dispute that alternative procedures – execution by barbiturate, or

⁵ The lay witnesses admitted that they could make no meaningful observations of consciousness. JA 192, 213-14, 283.

the addition of effective anesthetic monitoring to the three-drug protocol (with or without eliminating pancuronium) — would be less dangerous than Kentucky's current procedures. Resp. Br. 53-54, 63-65. Instead they contend that these alternatives are not reasonably available. That objection is meritless.

Executing By Barbiturates Would Not Compromise Legitimate Penological Interests.

Performing lethal injection by means of a single massive dose of thiopental or another barbiturate such as pentobarbital (which is longer acting, and used by veterinarians for animal euthanasia), would obviate all of the dangers of an agonizing and excruciatingly painful death that are created by Kentucky's three-drug protocol.⁶ It was undisputed below that pancuronium and potassium are not needed to cause death, JA 492, 547, because thiopental alone will cause death promptly. Tr. 656:16-18, 553:21-24.

Respondents' primary argument against the barbiturate-only formula is that it is "untested." Resp. Br. 53. Yet, the three-drug protocol was similarly "untested" when it was first adopted. JA 105-06. In all events, respondents' objections to this

⁶ Contrary to respondents' contention, petitioners argued to the trial court that an alternative "chemical or combination of chemicals" should replace Kentucky's three-drug protocol. JA 684. Evidence regarding several potential methods, including the use of thiopental or other barbiturate, was entered into the record. See Tr. 294-95, 656:16-18, 553:21-24; JA 142, 457, 492, 547. The trial court, however, held that the existence of alternative procedures was irrelevant. JA 766.

Veterinarians routinely approach lack merit. perform euthanasia by barbiturate and have concluded that it is the method "preferred" over all others because it is reliably humane and causes "cardiac arrest within a matter of minutes." Concannon Amicus Br. at 19; 201 Ky. Admin. Regs. 16:090 § 5(1); Ky. Rev. Stat. § 321.207(5); AVMA Guidelines on Euthanasia, at 28 (2007) (barbiturate is required method for primates). Moreover, there is ample scientific and judicial recognition that the barbiturate-only formula, properly administered, is both lethal and far less dangerous than the threedrug formula. See Morales, 415 F. Supp. 2d at 1047; Morales, 465 F. Supp. 2d at 983-84; Harbison, 511 F. Supp. 2d at 876, 895-96 (quoting DOC testimony that the "recommended" barbiturate-only formula, and recognizing it as a safer alternative).

Ignoring the detailed findings in *Harbison*, and relying on the earlier decision in *Workman v. Bredesen*, 486 F.3d 896 (6th Cir. 2007), the United States erroneously contends that the Tennessee commission rejected the barbiturate-only approach. U.S. *Amicus* Br. 29. The *Harbison* court, after reviewing extensive evidence that was not available to the *Workman* court, concluded that the materials on which *Workman* relied gave an incomplete and "erroneous" picture of the deliberative process. 511 F. Supp. 2d at 899-900.

⁷ Respondents assert that the *Harbison* court's finding that Dr. Dershwitz recommended the barbiturate-only protocol is "erroneous." Resp. Br. 55. But that court credited multiple officials who testified that Dershwitz "recommended" it, 511 F. Supp. 2d at 876-77, 895, and rejected Dershwitz's contrary testimony. Moreover, after consulting with Dershwitz, the commission expressly recommended the barbiturate-only protocol to the corrections commissioner, who rejected it, in part because he did not want Tennessee to be the first State to adopt it. *See id.* at 876-79.

Respondents also assert that implementing the barbiturate only protocol would be "infeasible" because they could not continue to use an EKG to determine death. Resp. Br. 55. That is incorrect. An EKG flatline is a measure of death that can be used regardless of the drugs administered. See Harbison, 511 F. Supp. 2d at 876; Morales, 415 F. Supp. 2d at 1047 n.16. Moreover, death can be determined through physical examination without employing a physician: paramedics are trained to determine death in this manner. Ky. Rev. Stat. § 311A.185.

Nor have respondents advanced any good reason for using pancuronium. They make almost no effort to defend its use on the ground proffered below avoiding involuntary movements that might unsettle witnesses – because that interest is plainly insufficient to outweigh the dangers inherent in using pancuronium, JA 445, and because it can be addressed by explaining to witnesses that involuntary movements do not indicate pain. Br. 52-53 & n.15; Concannon *Amicus* Br. 17-18; Crit. Care Phys. Amicus Br. at 5-6, 12. Nor can the use of pancuronium be defended on the ground that involuntary movements might dislodge the catheters. That argument ignores the trial court's finding that pancuronium lacks any therapeutic purpose. JA 763. It is also insubstantial; inmates are restrained to prevent movement, id. 524, 975, and involuntary movements could be avoided by using cardiotoxins other than potassium, id. 628. Finally, the use of pancuronium cannot be justified on the ground that it has the legitimate purpose of stopping the inmate's breathing. *Compare* Resp. Br. 50, *with* JA 306. A three-gram dose of thiopental, if properly administered, should stop the inmate's breathing before pancuronium is injected. *See Morales*, 415 F. Supp. 2d at 1043-44.

2. Effective Assessment of Anesthetic Depth Will Not Compromise Legitimate Penological Interests.

Respondents are similarly unable to refute petitioners' showing that Kentucky could minimize the danger of continuing to use potassium in its lethal injection procedure by providing for effective assessment of anesthetic depth throughout the execution.⁸ Kentucky could substantially increase the likelihood of detecting inadequate anesthesia by eliminating pancuronium, the paralytic effect of which makes monitoring far more difficult. JA 418-19, 441, 446. And even if Kentucky were to persist in using pancuronium, petitioners demonstrated at trial that there are numerous steps respondents could take to reduce the danger of inadequate anesthesia. Pet'r Br. 57-59.

Rather than defend the palpable inadequacies of Kentucky's monitoring procedures, respondents

⁸ Contrary to respondents' claims, petitioners raised this argument in the Petition for Certiorari. It is plainly subsumed within the Questions Presented – in particular, whether the "means for carrying out an execution cause an unnecessary risk of pain and suffering ... upon a showing [of] readily available alternatives that pose less risk." Pet'r Br. i. Moreover, monitoring was the subject of extensive testimony and briefing below, as well as numerous findings by the trial court. See, e.g., JA 418-19, 421, 439, 597, 690-91, 764.

contend that effective monitoring requires the participation of physicians, and that such a requirement amounts to an "insurmountable problem" because physicians will not participate in Resp. Br. 63-64. Respondents are incorrect that physicians are the only personnel who are capable of monitoring anesthetic depth. See, e.g., Morales, 415 F. Supp. 2d at 1047-48 & n.18. In any event, if there is a problem, it is of the States' own making. Those courts that have ordered officials to institute anesthetic monitoring have done so only after finding significant risks in the procedures at issue, and as a means of minimizing those risks without forcing States to alter the three-drug formula or any other aspect of their procedures. See, e.g., id. at 1048 (giving State choice of remedies); Taylor v. Crawford, No. 05-4173-CV-C-FJG, at 1 Mo. Sept. 12, 2006) (unpub'd Order) (monitoring necessary if State chose to retain threedrug formula). To the extent that difficulties recruiting physicians have affected those States' conduct of executions, that is the result of the States' decision to retain their dangerous procedures, rather than explore other remedial options such as the barbiturate-only protocol which can administered without the participation of physicians, and which poses no danger of a torturous death when administration problems occur.

II. Petitioners' Test Is The Correct Test.

A. Significant Risk Is The Proper Measure Under The Eighth Amendment.

In their opening brief, Petitioners explained that the Eighth Amendment prohibits procedures that cause a significant and unnecessary risk of severe pain. This is a demanding standard. It requires a challenger to show a danger of pain amounting to cruelty, that the pain is readily avoidable without compromising legitimate penological objectives, and that the risk is significant in that the challenged approach poses a real and predictable danger that some condemned inmates will suffer severe pain.

Respondents do not dispute that execution procedures can constitute cruel and unusual punishment based on the risk that they will impose severe pain. They insist, however, that the risk must be "substantial." Like the courts below, respondents never define what they mean by a "substantial risk," but they imply that a challenger must show with mathematic precision a high probability that the execution will go wrong in every individual's case. Respondents' effort to justify this demand is unavailing. 9

⁹ The State *amici* assert that petitioners' standard and the substantial risk standard adopted by the Kentucky Supreme Court are the same. States Br. 4, 23. While petitioners are entitled to prevail under either standard, Petr. Br. 42, n.14, there are important differences between them. First, "significant" and "substantial" are not synonyms in this context. In contrast to petitioners' significant risk analysis, the lower courts' substantial risk test considered only the quantum of risk imposed by the procedures, and gave no weight to the severity

In particular, neither Gregg v. Georgia nor Farmer v. Brennan supports respondents' myopic approach. Respondents invoke *Gregg's* statement that courts "may not require the legislature to select the least severe penalty possible so long as the penalty selected is not cruelly inhumane," Resp. Br. 29 (quoting *Gregg v. Georgia*, 428 U.S. 153, 175 but (1976)), that statement isinapposite. Respondents do not that deny the pain that an inadequately anesthetized inmate will suffer if injected with pancuronium and potassium is "cruelly inhumane." There is thus no basis for "deference" to a State's choice to risk imposing that level of pain. Rather, the question is whether the danger that a condemned inmate should suffer that pain is sufficiently great to require the State to avoid it by adopting readily available alternatives. Gregg does

of the pain or the availability of alternatives. Pet'r Br. 42. Where, as here, the pain in question is severe, and other alternatives are readily available, petitioners should only need to show a significant risk. *Id.* "Significant" refers to a risk that is merely "important." XV *Oxford English Dictionary* 458 (2d ed. Oxford University Press 1989). "Substantial" connotes "considerable," and indicates a higher degree of risk. XVII *Oxford English Dictionary* 67.

Second, the fact that the Kentucky courts stated that the procedure could not cause "unnecessary pain" does not mean that they applied petitioners' unnecessary *risk* test. That conclusionary statement simply begged the question of what degree of risk is acceptable before the pain that it portends can be deemed unnecessary. The Kentucky courts erred in requiring a substantial, rather than a significant, risk.

not prescribe a standard for determining when that threshold has been met.¹⁰

Farmer is also inapposite. Farmer expressly did not decide "[a]t what point a risk ... becomes sufficiently substantial" to constitute a violation. Farmer v. Brennan, 511 U.S. 825, 834 n.3 (1994). Moreover, precisely because it was a prison conditions case in which the principal question was whether the challenged practice should be considered punishment at all, Farmer's "substantial risk" requirement was part and parcel of the Court's effort to define a standard that limited challenges to practices that were sufficiently severe in their effects that itwas legitimate to consider "punishment." Where - as here - there is no question that the state action is punishment carrying out an execution – no higher showing of risk is necessary to trigger the Constitution's protection.

Lacking support in precedent, respondents raise the specter of endless litigation challenging every refinement in lethal injection procedures. In doing so, however, they are forced to attack a straw man – claiming incorrectly that petitioners' test would result in Eighth Amendment violations predicated on "all" "insignificant" risks, "no matter how small and

¹⁰ Respondents also latch on to *Gregg*'s passing reference to "substantial risk" to claim the Eighth Amendment permits unnecessary risks. Resp. Br. 17. But the Eighth Amendment has been repeatedly read as prohibiting unnecessary pain in a line of cases – including *Gregg* – extending back to the 19th Century. Pet'r Br. 30-34. *Gregg* itself states directly that "punishment *must not involve the unnecessary* and wanton infliction of pain." *Gregg*, 428 U.S. at 173, 188.

remote." Resp. Br. 28-30. Petitioners' opening brief stated clearly that a challenger must demonstrate a risk that is both unnecessary in that it is readily avoidable, and *significant* in that it is sufficiently likely to occur such that it is worth undertaking to avoid. Pet'r Br. 39-40. Claims alleging insignificant risks - or even significant risks for which no reasonable means of correction exist - are not cognizable under petitioners' test. Far from requiring the States to respond to every risk, no matter how minor or irremediable, petitioners' test is tailored to the risks that matter most: the ones that are significant, avoidable, and of grave consequence. Once the constitutionality of a jurisdiction's procedures has been adjudicated, that determination will resolve in a straightforward manner claims brought by subsequent, similarly situated litigants; and, a State can immunize itself from future challenges if it chooses to "eliminate constitutional concerns" by adopting execution procedures that do not entail the potential for unconstitutional pain. Morales, 465 F. Supp. 2d at 983. To the extent that States adopt a barbiturateonly approach, for example, it is difficult to envision future Eighth Amendment challenges because administration problems would not result in the infliction of pain.

Finally, the significant risk test is highly deferential to penological prerogatives because it allows the States to choose any means of execution so long as it does not involve significant unnecessary risks. Pet'r Br. 40. One State might choose to carry out executions using only a large dose of barbiturate.

Another might use the three-drug formula in conjunction with effective anesthetic monitoring techniques that can discern consciousness in paralyzed individuals. Pet'r Br. 57-59; JA 439-40. Yet another might eliminate the use of pancuronium (as New Jersey did), which would both reduce the risk of undetected drug delivery failures, and permit effective anesthetic monitoring by a greater universe of personnel. JA 426-27, 441, 509-10, 594, 596-600.¹¹

B. Deliberative Indifference Has No Place In A Method Of Execution Challenge.

The United States asks this Court to hold that risk – no matter how serious – is not enough to show a violation unless there is also deliberate indifference on the part of the executioners. The argument fails.

First, deliberate indifference has always been limited to "conditions of confinement" cases. In a typical prison conditions case, a showing of intent is necessary to establish that the conduct in question is punishment. The "guard who accidentally stepped on a prisoner's toe and broke it" cannot be said to have carried out a "punishment." Wilson v. Seiter,

Moreover, the evidentiary burden even under the "unnecessary risk" standard urged by petitioners has served as a high bar to obtaining last minute stays because plaintiffs have been unable to carry their burden without discovery. *See, e.g., Cooper v. Rimmer,* 379 F.3d 1029, 1033 (9th Cir. 2004). And to the extent that inmates do attempt to use lethal injection claims to delay their executions, courts are amply equipped with equitable powers to "protect States from dilatory or speculative suits." *Hill v. McDonough*, 126 S. Ct. 2096, 2103 (2006).

501 U.S. 294, 300 (1991) (quotation marks omitted). But no showing of deliberate indifference is needed to establish that a lethal injection is punishment.

Second, a deliberate indifference requirement cannot be gleaned from the Court's statement in Gregg that the Eighth Amendment bars the "unnecessary and wanton infliction of pain." Gregg, 428 U.S. at 173. The wantonness requirement is satisfied here (as it was in Gregg) by the arbitrary administration of the punishment of death that risks subjecting some condemned inmates to an unconstitutional punishment. Id. at 188.

Third, the deliberate indifference doctrine would be a highly ineffective gatekeeper in the context of method-of-execution claims. Where a court finds there is an objective risk sufficient to violate the Eighth Amendment, it would be bizarre to hold that the execution could nonetheless go forward because the State was unaware of the risk at the time the suit was brought. The litigation itself would put the State on clear notice going forward. Farmer, 511 U.S. at 846-47 (officials' attitudes during litigation may be relevant to eligibility for relief).

Finally, even if this Court were to find that deliberate indifference must be shown, the record demonstrates that indifference. Putting aside the fact that respondents were aware of the dangers when Kentucky's protocol was adopted, Pet'r Br. 9 (citing Leg. Research Committee Report), they would unquestionably be deliberately indifferent if they continued to use the current protocol despite the

dangers documented at trial. See Farmer, 511 U.S. at 846.

C. The National Consensus Favors Petitioners' Standard.

The adoption of lethal injection by the States reflects a consensus that prisoners should undergo an anesthetized death. Pet'r Br. 39. To the extent deficiencies in Kentucky's procedures and personnel create a significant and unnecessary risk that petitioners will suffer severe pain, Kentucky's procedures are neither part of a national consensus, nor consonant with "evolving standards of decency."

The amici States respond that the relevant "consensus" for purposes of Eighth Amendment analysis is the administrative choice of the States to implement lethal injections by means of the threedrug formula, and that there is a consensus in favor of accepting the dangers this approach entails. This argument fails at every level. It is false to say that "State Houses across the country" have endorsed the three-drug formula. States Br. 15, 17. Most States (23 including Kentucky) have not legislated even the categories of chemicals to be used for lethal injections. No statute requires the use pancuronium and potassium, much less specifies the administration procedures that exacerbate the danger created by the three-drug formula. Resp. Br. 4 & n.4. Instead, the details of the execution procedures are typically delegated State corrections departments, which develop their protocols in secret and do not necessarily commit them to writing. See, e.g., ACLU Amicus Br. 14-18; Taylor v. Crawford, 487 F.3d 1072, 1077-78 (8th Cir. 2007), cert. pending.

Moreover, the dangers created by the three-drug formula can hardly be said to be ones that "society chooses to tolerate." U.S. Br. at 25. As the trial court found, Kentucky – like virtually every other State – adopted the three-drug formula without analyzing its dangers. JA 760.

three-drug formula and Kentucky's administration procedures thus do not reflect any consensus that is relevant under the Court's precedents. Rather, they contravene the legislative consensus because they undermine the very purpose of the States' adoption of lethal injection in the first See Atkins v. Virginia, 536 U.S. 304, 314 (2002) (assessing number of legislatures that had enacted laws prohibiting execution of the mentally retarded); Roper v. Simmons, 543 U.S. 543, 565-66 (2005)(conducting same analysis regarding "legislation" prohibiting execution of juveniles).

CONCLUSION

For the foregoing reasons, the judgment of the Kentucky Supreme Court should be reversed or, in the alternative, the case remanded for further proceedings.

Respectfully submitted,

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