IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: OHIO EXECUTION PROTOCOL LITIGATION	:	Case No. 2:11-cv-1016
	:	Chief Judge Edmund A. Sargus, Jr. Magistrate Judge Michael R. Merz
This document relates to: Plaintiff Warren Henness	:	

DECISION AND ORDER ON MOTION FOR STAY OF EXECUTION AND PRELIMINARY INJUNCTION

This method-of-execution case, brought pursuant to 42 U.S.C. § 1983, is before the Court for decision of Plaintiff Warren Keith Henness's Motion for a Stay of Execution and a Preliminary Injunction (ECF No. 1929[1]). Defendants oppose the Motions (ECF No. 1934) and Plaintiff has filed a Reply in support (ECF No. 1942). The Court heard testimony on the Motions December 11-14, 2018, and received written closing arguments (ECF Nos. 2105, 2106). Transcripts of the hearing are at ECF Nos. 2112, 2113, 2117, and 2120.

The findings of fact and conclusions of law required by Fed.R.Civ.P.52 are embodied in this Decision and Order. They are not binding at trial on the merits or at future preliminary injunction proceedings in this consolidated case. *United States v. Edward Rose & Sons*, 384 F.3d 258, 261 (6th Cir. 2014), citing *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981).

[1] Part of the same document is Henness's Motion for an Evidentiary Hearing, which was granted by separate order (ECF No. 1960).

Table of Contents

Jurisdiction

The Court has subject matter jurisdiction of this case under 28 U.S.C. §§ 1331 and 1343. Henness and the Defendants have consented to plenary magistrate judge jurisdiction under 28 U.S.C. § 636(c) for purposes of the preliminary injunction motion and ancillary practice, and Chief Judge Sargus has referred the Motion on that basis (ECF No. 1912).

The relevant pleadings are Plaintiffs' Fourth Amended Omnibus Complaint (ECF No. 1252) and Henness's Second Amended Individual Supplemental Complaint (ECF No. 1494). Without denominating which of the numbered claims in those pleadings he is pursuing, Henness argues for injunctive relief on Eighth Amendment claims recognized in *Glossip v. Gross*, 135 S.Ct. 2726 (2015). *Glossip* was authoritatively interpreted in this consolidated case by the Sixth Circuit in *Fears v. Morgan (In re: Ohio Execution Protocol)*, 860 F.3d 881 (6th Cir. 2017) (*en banc*), reversing 853 F.3d 822 (6th Cir. Apr. 6, 2017) and vacating preliminary injunction granted at *In re Ohio Execution Protocol Litig. (Otte, Phillips, Tibbetts)*, 235 F. Supp. 3d 892 (S.D. Ohio 2017) (Merz, Mag. J.). Henness also argues a separate Eighth Amendment claim purportedly recognized in *Baze v. Rees*, 553 U.S. 35 (2008), requiring Ohio to adopt one of his alternative methods (ECF No. 1929, PageID 74975.)

Litigation History

This case and its predecessors,[2] brought by most of Ohio's death row inmates, have been pending in this Court since very shortly after the Supreme Court allowed method-of-execution

[2] *Cooey v. Kasich*, Case No. 2:04-cv-1156;, *Hartman v. Kasich*, Case No. 2:09-cv-242; *Broom v. Kasich*, Case No. 2:09-cv-823; and *Reynolds v. Kasich*, Case No. 2:10-cv-027.

claims to be brought under § 1983. *Nelson v. Campbell*, 541 U.S. 637 (2004). District Judge Gregory Frost managed this litigation from its inception until his retirement in May 2016.

On December 5, 2011, with the agreement of counsel, Judge Frost consolidated all lethal injection method-of-execution § 1983[3] cases in this District, ordering:

> **Nature of agreement**. In light of the then-anticipated filing of new complaints by numerous additional Ohio death row inmates who were not currently involved in the existing litigation, counsel for many of the plaintiffs proposed adopting procedures culled from multidistrict litigation, class action litigation, and mass tort litigation. Given the sheer number of plaintiffs that were either going to attempt intervention or file a new case, the parties and the Court therefore agreed to the filing of a new case and bifurcated pleading in which the majority of the new plaintiffs would file one omnibus complaint that sets forth all common factual allegations and claims and individualized supplemental complaints that set forth individualized factual allegations and individualized claims. It was agreed that the Court would then consolidate all the execution protocol cases under that new case number and close the four original cases on the docket so that the parties would be able to proceed under only one case. This led to the November 2011 filing that created Case No. 2:11-cv-1016.

Cooey v. Kasich, Case No. 2:04-cv-1156, ECF No. 1067, PageID 31061.

In the same Order, Judge Frost set a bench trial date of August 13, 2012, but no trial has ever been held in this case or its predecessors. *Id*. at PageID 31064. Over time since 2004, Judge Frost granted injunctive relief to some Plaintiffs and denied it to others, with varying results on appeal.[4] The pattern has been of hurried litigation of preliminary injunction motions, with

[3] Many death row inmates have also pleaded method-of-execution claims in habeas corpus under *Adams v. Bradshaw*, 644 F.3d 481 (6th Cir. 2011) and *Adams v. Bradshaw*, 817 F.3d 284 (6th Cir. 2016), *amended by and superseded at Adams v. Bradshaw*, 826 F.3d 306 (6th Cir. 2016). The viability of these claims in habeas is gravely in doubt in light of *In re Campbell*, 874 F.3d 454 (6th Cir. 2017).

[4] In his last preliminary injunction decision, *In re Ohio Execution Protocol Litigation (McGuire)*, 994 F. Supp. 2d 906, 908, n.2 (S.D. Ohio 2014), Judge Frost referred the reader to the following cases for history: *In re Ohio Execution Protocol Litigation (Phillips)*, No. 2:11-cv-1016, 2013 U.S. Dist. LEXIS 159680, 2013 WL 5963150 (S.D. Ohio Nov. 7, 2013); *In re Ohio Execution Protocol Litigation (Hartman)*, 906 F. Supp. 2d 759 (S.D. Ohio 2012); *In re Ohio Execution Protocol Litigation (Wiles)*, 868 F. Supp. 2d 625 (S.D. Ohio 2012); *In re Ohio Execution*

executions when relief was denied either in this Court or on appeal, rendering moot the claims of those executed. (*See, e.g.*, ECF Nos. 675, 1130, and 1251.) There has never been a final judgment in the case[5]; appeals have all been on the grant or denial of preliminary injunctive relief, except for the interlocutory protective order appeal mentioned below.

There was a hiatus in Ohio executions after that of Dennis McGuire on January 16, 2014. Concerned about obtaining drugs for use in executions, the Ohio General Assembly, at the urging of then-Attorney General (now Governor) R. Michael DeWine, adopted H.B. 663 (codified at Ohio Revised Code §§ 2949.221 and 2949.222) to provide confidentiality to suppliers of execution drugs and sought a protective order in this case for that information. Judge Frost upheld the constitutionality of the new statutes, *Phillips v. DeWine*, 92 F. Supp. 3d 702 (S.D. Ohio 2015), granted the protective order (ECF No. 629, PageID 19409), certified that order for interlocutory appeal, and stayed this litigation pending appeal. *Id.* at PageID 19411-12.

Without awaiting the results of either of those appeals, Ohio announced a new execution protocol October 7, 2016, and scheduled executions at approximately one-month intervals to begin in January 2017 with former Plaintiff Ronald Phillips.[6] (ECF No. 667.) The Court[7] then vacated the litigation stay as to Plaintiffs Phillips, Tibbetts, and Otte and set an aggressive schedule to prepare for a preliminary injunction hearing on those three Plaintiffs' motions in early January

---

Protocol Litigation (Lorraine), 840 F. Supp. 2d 1044 (S.D. Ohio 2012); *Cooey (Brooks) v. Kasich*, Nos. 2:04-cv-1156, 2:09-cv-242, 2:09-cv-823, 2:10-cv-27, 2011 U.S. Dist. LEXIS 128192, 2011 WL 5326141 (S.D. Ohio Nov. 4, 2011); and *Cooey (Smith) v. Kasich*, 801 F. Supp. 2d 623 (S.D. Ohio 2011).

[5] Except that the Court issued a Fed.R.Civ P. 54 (b) judgment on claims of Plaintiffs Campbell, Tibbetts, and Otte under the Ohio Corrupt Practices Act. *In re Ohio Execution Protocol Litig.*, 2017 U.S. Dist. LEXIS 107468, 115583 & 121545 (S.D. Ohio Jul 12, July 25, and Aug. 2, 2017), *aff'd. sub. nom. Otte v. Kasich*, 709 F. App'x 779 (6th Cir. Sept. 7, 2017).

[6] Phillips was then scheduled for January 12, 2017; Tibbetts for February 15, 2017; and Otte for March 15, 2017.

[7] After Judge Frost's retirement, the case was randomly reassigned to Chief Judge Sargus; the Magistrate Judge reference had earlier been transferred to the undersigned.

2017.

On November 2, 2016, the Sixth Circuit held death row inmates lacked standing to attack H.B. 663, affirming Judge Frost's dismissal of the attack on that legislation. *Phillips v. DeWine*, 841 F.3d 405 (6th Cir. 2016),*cert den. sub nom. Tibbetts v. DeWine*, 138 S.Ct.301 (2017). The circuit court upheld Judge Frost's protective order. *Fears v. Kasich*, 845 F.3d 231 (6th Cir. 2016), *cert. den.* 138 S.Ct. 191 (2017).

After hearing five days of testimony in January 2017, this Court preliminarily enjoined the executions of Phillips, Tibbetts, and Otte. *In re Ohio Execution Protocol Litig*., 235 F. Supp. 3d 892. Although affirmed by the hearing panel, that decision was reversed by the *en banc* Sixth Circuit, *Fears v. Morgan*, 860 F.3d 881. Phillips was executed the day after certiorari was denied. This Court denied Otte's renewed preliminary injunction motion. (ECF No. 1168, denied at ECF No. 1226.) He took no appeal and was executed September 13, 2017. (ECF No. 1251.)

Plaintiffs Alva Campbell, Jr. and Raymond Tibbetts then moved for preliminary injunctive relief (ECF Nos. 1261 and 1262).[8] The Court denied those motions November 3, 2017 (ECF No. 1362; reported at *In re Ohio Execution Protocol Litig*, 2017 U.S. Dist. LEXIS 182406 (Merz, Mag. J.), *aff'd Campbell v. Kasich*, 881 F.3d 447 (6th Cir. 2018), *cert den. sub nom. Tibbetts v. Kasich*, 139 S.Ct. 216 (2018).

Plaintiff Warren Henness being the next plaintiff set for execution, the Court adopted in August 2018 a schedule for preliminary injunctive proceedings. (ECF No. 1914.)

The Court forebears any discussion of Henness's underlying crime. The appropriateness

[8] Although Tibbetts had been scheduled for execution in October 2017, Governor Kasich reprieved him on September 1, 2017, to February 13, 2018 (ECF No. 1193), and again on February 8, 2018, to October 17, 2018 (ECF No. 1421-1). The Governor later commuted his sentence to life imprisonment and he was dismissed as a plaintiff (ECF No. 1894). The State tried unsuccessfully to execute Campbell in November 2017 and he died of natural causes March 3, 2018, and was then dismissed as a plaintiff (ECF No. 1443).

of punishing that crime capitally is committed to a jury and the Ohio courts, which have all found a death sentence appropriate. *State v. Henness*, 79 Ohio St. 3d 53 (1997). The constitutionality of that conclusion has been finally litigated in habeas corpus in the federal courts. *Henness v. Bagley*, No. 2:01-cv-43, 2007 U.S. Dist. LEXIS 80647 (S.D. Ohio Oct. 31, 2007) (Merz, Mag. J.), *aff'd* 644 F.3d 308 (6th Cir. 2011). What is pertinent to the instant case is the method of execution. The Constitution prohibits a cruel and unusual method of execution without regard to the heinousness of the crime.

General Standard for Preliminary Injunctive Relief and Stay of Execution

In determining whether preliminary injunctive relief is merited in a capital § 1983 case, a trial or appellate court must apply the following established standards:

> (1) whether [plaintiff] 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); *[N.E.]. 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).

Cooey (Biros) v. Strickland, 589 F.3d 210, 218 (6th Cir. 2009) ("*Cooey I*"); *see also Miller v. Parker*, No. 18-6222, ___ F.3d ___, 2018 U.S. App. LEXIS 33858, *3 (6th Cir. Dec. 3, 2018), *citing Jolivette v. Husted*, 694 F.3d 760, 765 (6th Cir. 2012), and *Cooey v. Strickland*, 604 F.3d 939, 943 (6th Cir. 2010) (*"Cooey II"*). Judge Frost applied these criteria in *In re Ohio Execution Protocol Litig. (Lorraine)*, 840 F. Supp. 2d at 1048 . The Sixth Circuit consistently applies these

criteria to preliminary injunctive relief requests across subject matter areas. *Overstreet v. Lexington-Fayette Urban Co. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002); *Nightclubs, Inc. v. City of Paducah*, 202 F.3d 884, 888 (6th Cir. 2000), *overruled on other grounds at 729, Inc. v. Kenton Cnty. Fiscal Ct.*, 515 F.3d 485 (6th Cir. 2008); *Washington v. Reno*, 35 F.3d 1093, 1099 (6th Cir. 1994); *NAACP v. City of Mansfield*, 866 F.2d 162, 166 (6th Cir. 1989); *Frisch's Restaurant, Inc. v. Shoney's, Inc.*, 759 F.2d 1261, 1263 (6th Cir. 1985); *In re DeLorean Motor Co.*, 755 F.2d 1223, 1228 (6th Cir. 1985).

Supreme Court case law is consistent:

> A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of the equities tips in his favor, and that an injunction is in the public interest.

Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008), *citing Munaf v. Geren*, 553 U.S. 674, 689-90 (2008); *Amoco Prod. Co. v. Gambell*, 480 U.S. 531, 542 (1987); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311-12 (1982).

The purpose of a preliminary injunction is to "preserve the court's power to render a meaningful decision after a trial on the merits[.]" *Alabama v. United States Army Corps of Engineers*, 424 F.3d 1117, 1128 (11th Cir. 2005), *quoting* 11A CHARLES ALAN WRIGHT, ARTHUR R. MILLER, & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE: CIVIL, § 7 (2d ed.).

> Although the fundamental fairness of preventing irremediable harm to a party is an important factor on a preliminary-injunction application, the most compelling reason in favor of entering a Rule 65(a) order is the need to prevent the judicial process from being rendered futile by defendant's action or refusal to act. . . . [T]he preliminary injunction is appropriate whenever the policy of preserving the court's power to decide the case effectively outweighs the risk of imposing an interim restraint before it has done so.

Id.

Failure to enjoin an imminently pending execution will obviously render the case moot as to that inmate long before any trial can be held. As noted above, there has never been a trial in this consolidated case; Plaintiffs who failed to obtain preliminary injunctive relief have had their cases rendered moot by their executions.[9] Nevertheless, stays of execution are not to be granted routinely. A court must weigh the interest of a State in carrying out a lawful death sentence and its parallel interest in finality of criminal judgments. *Workman v. Bredesen*, 486 F.3d 896, 912-13 (6th Cir. 2007).

In reversing this Court's prior grant of preliminary injunctive relief to Phillips, Tibbetts, and Otte, the Sixth Circuit held the Plaintiffs failed to demonstrate likelihood of success on the merits, the first branch of the preliminary injunction test. *Fears v. Morgan*, 860 F.3d at 892. This Court found for the Plaintiffs on the irreparable harm, balance of equities, and public interest branches. *In re Ohio Execution Protocol Litig.*, 235 F. Supp. 3d at 959-60. The Sixth Circuit did not disturb those conclusions on appeal. As Defendants' counsel agreed on the record the first day of the hearing, Henness is in exactly the same position as those three Plaintiffs were on the other three branches: his execution will be an irreparable harm to him; he filed his motion for preliminary injunction in accordance with a court-ordered schedule to allow time for adjudication; and the public interest is on balance served by allowing this case to be decided on the merits (Hrg. Tr., ECF No. 2112, at PageID 103658-59). The Sixth Circuit has recently confirmed that although "the obvious harm weighs in [the movant's] favor, it is not dispositive when there is no likelihood of success on the merits, and in execution protocol challenges, the likelihood of success is often

[9] Preliminary injunctive relief was granted to Plaintiffs Kenneth Smith, Charles Lorraine, and Michael Webb. Because those injunctions were grounded in execution protocols that have been superseded, the preliminary injunctions were dissolved in 2018. (ECF No. 1453.)

the determinative factor." *Zagorski v. Haslam*, 741 F. App'x 320, 321 (6th Cir. 2018). Because Henness is similarly situated to Phillips, Tibbetts, and Otte on these three factors, this Decision addresses only the likelihood of success on the merits branch of the test.

General Standard for 42 U.S.C. § 1983 Relief

42 U.S.C. § 1983, R.S. § 1979, creates a cause of action sounding essentially in tort on behalf of any person deprived of a constitutional right by someone acting under color of state law. *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 709 (1999); *Memphis Community School District v. Stachura*, 477 U.S. 299 (1986); *Carey v. Piphus*, 435 U.S. 247 (1978). "The purpose of § 1983 is to deter state actors from using the badge of their authority to deprive individuals of their federally guaranteed rights and to provide relief to victims if such deterrence fails." *Wyatt v. Cole*, 504 U.S. 158, 161 (1992) (*citing Carey*, 435 U.S. at 254-57). In order to be granted relief, a plaintiff must establish that the defendant deprived him of a right secured by the Constitution and the laws of the United States and that the deprivation occurred under color of state law. *See West v. Atkins*, 487 U.S. 42, 48 (1988); *Flagg Brothers Inc. v. Brooks*, 436 U.S. 149, 155 (1978).

Named and served as Defendants in this case are Ohio Governor John R. Kasich, Jr.,[10] Ohio Department of Rehabilitation and Corrections ("ODRC") Interim Director Stuart Hudson,[11]

[10] The Court takes judicial notice that Mike DeWine became Governor of Ohio earlier today. He is hereby substituted as a Defendant for former Governor Kasich by operation of law. Fed. R. Civ. P. 25(d).

[11] Interim Director Hudson was substituted for former Director Gary Mohr as of Director Mohr's retirement on August 31, 2018 (ECF No. 1915). On January 3, 2019, Governor-elect DeWine nominated Annette Chambers-Smith to be the Director of the Ohio Department of Rehabilitation and Corrections.

and Director Hudson's subordinates in the ODRC Ronald Erdos, Donald Morgan, Stephen Gray, Edwin Voorhies, Richard Theodore, Charlotte Jenkins, John Coleman, and anonymous members of the Execution Team. These Defendants are referred to herein collectively as the Defendants.[12] Each of them is sued in his or her official capacity and for acts to be done under color of state law. (*See,* Fourth Amended Omnibus Complaint, ECF No. 1252, PageID 45464; Second Amended Individual Supplemental Complaint, ECF No. 1494.)

Actions against state officials in their official capacities are deemed actions against the State itself. *Kentucky v. Graham*, 473 U.S. 159, 165 (1985). An action against a state official in his official capacity for injunctive relief to prevent a constitutional violation is not barred by the Eleventh Amendment. *Ex parte Young*, 209 U.S. 123 (1908); *Cory v. White*, 457 U.S. 85 (1982); *Thomson v. Harmony*, 65 F.3d 1314, 1320 (6th Cir. 1995).

There is no dispute that the actions Defendants intend to take in the execution of Warren Henness are pursuant to formal State policy embodied in the execution protocol, 01-COM-11 (effective October 7, 2016) (JX 1,[13] ECF No. 2026-1, PageID 96818-38).

Prior Decisions in this Consolidated Case

In prior proceedings in these consolidated cases since October 2016, the parties have often argued how the law of the case doctrine might apply to constrain this Court's judgment on one issue or another. (*See, e.g.*, Report and Recommendations on Defendants' Motion to Dismiss,

[12] Plaintiffs have also named pseudonymously one hundred pharmacies, one hundred pharmacists, twenty-five drug suppliers, and twenty-five John Does who are "employed by or associated with the defendant pharmacies or drug suppliers. Although Plaintiffs allege these other Defendants are state actors within the meaning of § 1983 jurisprudence, none of them have ever been identified or served with process. A recommendation that they be dismissed for want of prosecution is pending before Chief Judge Sargus (ECF Nos. 1798, 1907.)

[13] All exhibits for this preliminary injunction hearing have been separately numbered for Henness's case alone.

ECF No. 1429, PageID 55217-21.) The Magistrate Judge focused the parties' attention on this issue shortly after assuming management of the case because there had been many prior rulings by Judge Frost and the Sixth Circuit during the twelve years the case had then been pending. (Notice, ECF No. 728, PageID 23044-46, relying largely on *Westside Mothers v. Olszewski*, 454 F.3d 532, 538 (6th Cir. 2006).

In general, under the law of the case doctrine, findings made at one point in litigation become the law of the case for subsequent stages of that same litigation. *United States v. Moored*, 38 F.3d 1419, 1421 (6th Cir. 1994), *citing United States v. Bell*, 988 F.2d 247, 250 (1st Cir. 1993). "As most commonly defined, the doctrine posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case." *Arizona v. California*, 460 U.S. 605, 618 (1983), *citing* 1B J. Moore & T. Currier, MOORE'S FEDERAL PRACTICE ¶0.404 (2ed. 1980); *Patterson v. Haskins*, 470 F.3d 645, 660-61 (6th Cir. 2006); *United States v. City of Detroit*, 401 F.3d 448, 452 (6th Cir. 2005). Judge Sutton recently gave the rationale for the doctrine: "If it is important for courts to treat like matters alike in different cases, it is indispensable that they 'treat the same litigants in the same case the same way throughout the same dispute.'" *United States v. Charles*, 843 F.3d 1142, 1145 (6th Cir. 2016) *quoting* BRYAN A. GARNER, ET AL., THE LAW OF JUDICIAL PRECEDENT 441 (2016).

Writing six months before *Charles*, the Sixth Circuit voiced that rationale, but noted how consolidated cases differ:

> The law-of-the-case doctrine "provides that the courts should not reconsider a matter once resolved in a continuing proceeding." *Howe v. City of Akron*, 801 F.3d 718, 739 (6th Cir. 2015) (internal quotation marks omitted). Describing the doctrine, the Supreme Court has stated:
>
> > A court has the power to revisit prior decisions of its own or of a coordinate court in any circumstance, although as a

> rule courts should be loathe [sic] to do so in the absence of extraordinary circumstances such as where the initial decision was "clearly erroneous and would work a manifest injustice."

Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 817 (1988). Thus, like the doctrines of claim and issue preclusion, law-of-the-case is designed to "prevent[] the relitigation of an issue once there has been a judgment on the merits." *Bowles v. Russell*, 432 F.3d 668, 676 (6th Cir. 2005) (citing 18 [M. Bender, MOORE'S FEDERAL PRACTICE § 134.20] (3d ed.)); *see also Howe*, 801 F.3d at 740 (observing that law-of-the-case doctrine "is a prudential practice" intended "to encourage efficient litigation and deter indefatigable diehards" (internal quotation marks omitted)).

Unlike claim or issue preclusion, however, the law-of-the-case doctrine is not used to prevent relitigation of the same issues across different cases; rather, "'"[t]he purpose of the law-of-the-case doctrine is to ensure that the *same* issue presented a second time in the *same case* in the *same court* should lead to the *same result*."."' *Howe*, 801 F.3d at 739 (emphases in original) (internal quotation marks omitted); see also *Arizona v. California*, 460 U.S. 605, 618 (1983) ("the [law-of-the-case] doctrine posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case"); 18B CHARLES ALAN WRIGHT ET AL., FEDERAL PRACTICE & PROCEDURE: JURISDICTION & RELATED MATTERS § 4478 (4th ed. 2015) ("Law-of-the-case rules have developed to maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit. They do not apply between separate actions." (footnotes omitted)); Joan Steinman, *Law of the Case: A Judicial Puzzle in Consolidated and Transferred Cases and in Multidistrict Litigation* ("*Law of the Case*"), 135 U. PA. L. REV. 595, 597-98 (1987) (describing law-of-the-case doctrine as "a concept that precludes the relitigation of issues within the context of a single case once they have been decided").

This raises the question of whether consolidated cases, like those at issue here, can be considered the "same case" for law-of-the-case purposes. In answering this question, we begin with the well-established principle "that consolidated cases remain separate actions." *Beil v. Lakewood Eng'g & Mfg. Co.*, 15 F.3d 546, 551 (6th Cir. 1994). "[A]lthough consolidation is permitted as a matter of convenience and economy in administration, it does not merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." *Lewis v. ACB*

> *Bus. Servs., Inc.*, 135 F.3d 389, 412 (6th Cir. 1998) (internal brackets and quotation marks omitted) (quoting *Johnson v. Manhattan Ry.*, 289 U.S. 479, 496-97, 53 S.Ct. 721, 77 L.Ed. 1331 (1933)). Using the law-of-the-case doctrine to bar relitigation of similar issues across consolidated cases would therefore seem to implicate the bedrock principle of due process that "one is not bound by a judgment *in personam* in a litigation in which he is not designated as a party or to which he has not been made a party by service of process." *Hansberry v. Lee*, 311 U.S. 32, 40, 61 S.Ct. 115 (1940).

GMAC Mortg., LLC v. McKeever, 651 F. App'x 332, 338-39 (6th Cir. 2016) (Clay, J.) (parallel citations omitted).

Based on these discussions in the circuit court, this Court concludes it is not *bound* by the law of the case doctrine to decide issues in Warren Henness's § 1983 case as it decided the same issues in the Phillips, Otte, Tibbetts, and Campbell cases. On the other hand, applying general principles of precedent, Henness's § 1983 case is very similar to those prior cases, about as similar as any five such cases could be: all are being decided by the same Court, all are parties to the same or very similar omnibus complaints, all attack the same method of execution and seek to enjoin the same state officials, all have been litigated by the same institutional litigators within two years of one another, subject to review by the same appellate court. Very few distinguishing facts among the Plaintiffs are relevant to their § 1983 cases.[14]

Although the Court is not bound by law of the case doctrine to decide issues the same way, it would destroy the economy of consolidation as well as raise serious equal justice considerations to decide the issues differently. Like cases should be decided alike, and Henness's case is very like those of former Plaintiffs Phillips, Otte, Tibbetts, and Campbell. Therefore, prior rulings in

[14] Each of these Plaintiffs litigated to finality a habeas corpus case challenging, on very different factual bases, their underlying aggravated murder convictions. In a series of capital habeas corpus cases, this Court decided method of execution claims were required to be brought under § 1983 and could not be brought simultaneously in habeas, a position the Sixth Circuit has endorsed. *In re Campbell*, 874 F.3d 454 (6th Cir. 2017).

this consolidated case, including those made by Judge Frost, will be treated as very persuasive precedent, but not binding under the law of the case doctrine. Prior rulings in the case, just like precedent from other courts, will be analyzed and applied based on the context in which they were made and therefore applied with appropriate nuance, and not like proof-texts.[15]

Part of that context is the speed with which decisions in capital cases seeking stays of execution have been made. Many of such cases have required more speed and less deliberation than far less weighty decisions facing federal judges. For example, *In re Ohio Execution Protocol Litig. (Lorraine)*, 671 F.3d 601, *Workman*, 486 F.3d at 905, and *Miller*, 2018 U.S. App. LEXIS 33858, were all decided on appeal mere days before a scheduled execution. The speed with which decisions must be made and opinions written inevitably affects their utility in deciding future cases. *See* DANIEL KAHNEMAN, THINKING, FAST AND SLOW (2011), for which Kahneman was awarded the Nobel Prize in economics. The required speed may inhibit the careful consideration of all the possible consequences which should inform decisions expected to be precedential. Jeremy Waldron, *Stare Decisis and the Rule of Law: A Layered Approach*, 111 MICH.L.REV. 1 (2012). This again requires caution in application of the precedents.

Applying these principles, the Court gives much more weight to the *en banc* decision in *Fears v. Morgan* than to the cursory, albeit published, decision in *Lorraine.*

[15] Proof-texting is the practice of using isolated out-of-context quotations to establish a proposition in eisegesis, "[t]he act of reading into a text one's own desired meaning." BLACK'S LAW DICTIONARY (10th ed.) BLACK'S LAW DICTIONARY (10th ed. 2014).

***Daubert* Concerns**

As a preliminary matter, the Court required identification of proposed expert witnesses and their furnishing of reports (Scheduling Order, ECF No. 1914). One of Defendants' proposed expert witnesses, Daniel E. Buffington, Pharm. D., was stricken for failure to comply with Fed.R.Civ.P. 26(a)(2)(B)(v) (Decision and Order, ECF No. 2068, following *Roberts ex rel. Johnson v. Galen of Va.*, 325 F.3d 776, 782 (6th Cir. 2003)). Therein the Court noted that Dr. Buffington had been a defense expert in the *Fears* and *Campbell* cases and had also failed, despite Plaintiffs' objections, to comply with the rule in those cases. Finding that prior warnings had been insufficient, the Court declined to allow Dr. Buffington to testify.

During the course of the hearing, Plaintiff made an oral motion to exclude the testimony of defense expert Joseph F. Antognini, M.D., under both *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and Fed.R.Evid. 702. Counsel argued that

> Under Rule 702 and *Daubert*, scientific evidence, to be admissible must be based on reliable methodology and accepted paradigm within the scientific community.
>
> The paradigm that Dr. Antognini relies on for anesthesia has only three domains. As he stated in prior testimony before this Court and is evident from the preface of his book,[16] those three domains involve unconsciousness, amnesia and akinesia. They do not include analgesia.
>
> Because of that his view is at odds with the anesthesia community in this nation. . . .[T]he very premise of his expertise in anesthesiology has been rejected by the American Board of Anesthesiology, the American Society of Anesthesiologists, and academics, as Dr. Lubarsky has established, all those groups which have established for years that anesthesiology involves four domains, unconsciousness, amnesia, akinesia, and analgesia.

[16] The book in question was identified as NEURAL MECHANISMS OF ANESTHESIA, edited by Antognini, Carsten, and Raines (Humana Press 2002).

(Hrg. Tr., ECF No. 2120, PageID 104826.)

Henness objected further that Dr. Antognini's expert report purported to offer opinions of the meaning of the "sure or very likely" test from *Glossip*, a legal question. Moreover, he was offered as an expert on the autopsy reports reviewed by Dr. Edgar, without being a pathologist, and the acidic nature of midazolam, without being a pharmacologist. *Id.* at PageID 104828-29. Defendants responded by questioning the expertise of Plaintiff's expert witness, Dr. Stevens, and by noting that Dr. Antognini had been accepted as an expert on the issues in suit by the Sixth Circuit, and lower federal and state courts. The Court ruled that, in the absence of a jury, it would take Dr. Antognini's testimony subject to the objection. *Id.* at PageID 104841.

While it is true, as counsel argued, that Plaintiff Henness has not previously had a hearing in this consolidated case, it is also true that the Sixth Circuit treated Dr. Antognini's testimony as at least admissible in *Fears v. Morgan*. 860 F.3d at 888. Dr. Antognini certainly presented at least the basic qualifications to be heard as an expert in anesthesiology and the Court is competent to weigh his testimony against that of other experts presented in the case. Having considered the matter since the hearing, the Court OVERRULES Plaintiff's objection to Dr. Antognini's testifying at all.

The weight to be given to Dr. Antognini's opinions is another matter entirely and is discussed below in the section labeled "Court Findings on the First Prong of *Glossip*."

Does Ohio's Method of Execution Cause "Serious Pain and Needless Suffering"? (The First Prong of *Glossip*)

To prevail on an Eighth Amendment challenge to a method of execution, Henness must first prove that the challenged method "presents a risk that is *sure or very likely* to cause serious pain and needless suffering." *Fears v. Morgan*, 860 F.3d at 886 (emphasis in original) (internal quotation marks omitted), quoting *Glossip*, 135 S.Ct. at 2737; citing *Baze*, 553 U.S. at 50; *Cooey II*, 604 F.3d at 944; and *Cooey I*, 589 F.3d at 220. Cir. This is the first prong of the Eighth Amendment test enunciated in *Glossip*.

In *Fears*, the Sixth Circuit was considering the same three-drug protocol[17] which is at issue here: an initiatory 500 mg intravenous injection of midazolam, followed after a consciousness check by a paralytic drug, followed by milliequivalents of potassium chloride. The Sixth Circuit framed the relevant question as whether an inmate who receives such a dose of midazolam is ""'sure or very likely' to be conscious enough to experience serious pain from the second and third drugs in the protocol." *Fears* 860 F.3d at 886, *citing Glossip*, 135 S.Ct. at 2737. In former Plaintiff Alva Campbell's appeal from denial of preliminary injunctive relief as to the same protocol, the Sixth Circuit said the relevant inquiry "concerns the likelihood that the inmate is conscious enough to experience that serious pain, whether physical or psychological." *Campbell*, 881 F.3d at 450 .

Plaintiff's Position on the First *Glossip* Prong

Henness claims the Sixth Circuit "mistakenly framed the relevant question" in *Fears*.

[17] A much smaller 10 mg dose of midazolam was used as the initiatory drug in the January 2014 execution of Dennis McGuire.

(Motion for Preliminary Injunction, ECF No. 1929, PageID 74875.) He continues

> But that framing of the purported "relevant question" is a direct manifestation of the scientific inaccuracies in this case that cry out for re-evaluation and correction. As stated, the inquiry misstates the actual relevant scientific question; it conflates three unique and distinct concepts—consciousness, awareness, and sensation—into just "consciousness." This Court consequently misinterpreted evidence demonstrating sensation; the significance of that evidence; the critical distinction between consciousness and sensation of pain; and the scientific truth that being unconscious does not prevent a person from experiencing pain in the absence of a true analgesic agent.
>
> . . .* * *. . .
>
> The relevant inquiry on *Glossip*'s first prong, framed from a scientifically accurate perspective, is whether an inmate who receives a 500-milligram dose of midazolam is sure or very likely to experience the serious pain associated with the drugs in the protocol, including the pain we now understand such a large dose of IV-injected midazolam itself causes. And that, in turn, can be distilled even further as follows: "Does midazolam at any dose act as a pain-blocking drug?" And the scientific consensus answer to that is "No."

Id. at PageID 74876-77.

The mistake made by this Court and the Sixth Circuit, according to Henness, is "erroneously conflat[ing] 'insensation' and 'unconsciousness.'" (Motion for Preliminary Injunction, ECF No. 1929, PageID 74890.) Whereas this Court and the Sixth Circuit held that "unconsciousness" of pain from the second and third drugs was constitutionally sufficient, Henness asserts in his Motion that "insensation *must* be constitutionally necessary." *Id.* at PageID 74891 (emphasis in original.) Having faulted both this Court and the Sixth Circuit, he goes further to criticize the Supreme Court for using "unconscious" in *Baze* "for the more accurate consideration: sensation." *Id.* at PageID 74892. Then, he claims, the Supreme Court got it mostly right in *Glossip* by "expressly focusing on sensation as the key consideration," although "the

majority opinion conflated "unconsciousness" and "insensation" on occasion." *Id.* at PageID 74893.

Henness argues this Court further erred when it found insensation was not constitutionally required by relying on the Supreme Court's conclusion that "some pain is incidental to any lethal injection procedure." *In re Execution Protocol Litig. (Campbell & Tibbetts)*, 2017 U.S. Dist. LEXIS 182406, *36-37, *citing Glossip*, 135 S.Ct. at 2739-40; *Baze*, 553 U.S. at 47-48. He claims the Supreme Court must have meant only the pain incidental to "competent placement of the peripheral IVs." (Motion, ECF No. 1929 at PageID 74892.)

Henness contends that "the key term for consideration, from a scientific standpoint, is 'sensation.' . . . . [C]consciousness is, at bottom, the ability to tell someone what one is experiencing, to articulate or convey what is happening to him or her. . . . . [S]ensation is the ability to feel and experience external stimuli, including severe pain." (Motion, ECF No. 1929, PageID 74901, citing no sources.)

Having taken these positions when he filed his Motion for Preliminary Injunction in late September, Henness presented his evidence for several days in mid-December. He and the Defendants then filed written closing arguments at the end of the hearing (ECF Nos. 2105, 2106). Therein, Henness argued there that he had proven the following propositions:

1. Midazolam is not an analgesic and therefore cannot block or attenuate pain. 2106.)

2. Midazolam itself causes pain because it is acidic and injected in a sufficiently large volume as to require time for the normal blood volume to lower its pH.

3. Midazolam also causes pain because it causes pulmonary edema, a condition that makes it increasingly hard to breathe and induces the panic associated with drowning.

(*See* ECF No. 2106, PageID 103529.)

Henness backed off his claim that insensation is constitutionally required by admitting that "there is no freestanding constitutional requirement that a condemned inmate be brought to a state of 'general anesthesia,' or be wholly prevented from feeling any and all pain." *Id.* at PageID 103530. Instead, he claims midazolam itself causes "severely painful pulmonary edema" and does not block the severe pain from the paralytic and potassium chloride. *Id.*

Defendants' Position on the First *Glossip* Prong

In opposing Henness's Motion for Preliminary Injunction, Defendants referred to the prior evidentiary hearings related to the current Execution Protocol since it was adopted October 7, 2016. (Memo in Opp., ECF No. 1934, PageID 75018-20.) They argued that Henness would not be able to produce the new evidence he promised, based on testimony his proposed expert witnesses, Drs. Mark Edgar and Charles Greenblatt, gave in *Abdur'Rahman v. Parker*, Case No. 18-183-II (III) (Tenn. Chanc. Ct., 20th Jud. Dist., Davidson Cty.) in the summer of 2018.[18] Defendants complained that, because no evidentiary support was actually given with the Motion, Plaintiff was playing the "hide the ball" tactic called out by Judge Frost in *In re Ohio Execution Protocol Litig. (Hartman)*. 906 F. Supp. 2d 759, 772-73 (S.D. Ohio 2012).

In their written closing argument, Defendants assert that, even taken together with evidence presented at prior preliminary injunction hearings, Henness has not proven Ohio's protocol is sure or very likely to cause severe pain and needless suffering. They argue that the evidence actually offered in the instant hearing is by Defendants to be "the same type of evidence that this Court, and the Sixth Circuit, rejected when it was presented by former plaintiffs Tibbetts and Campbell."

[18] In *Abdur'Rahman* the plaintiffs unsuccessfully challenged Tennessee's lethal injection protocol, which uses midazolam as the initiatory drug.

(ECF No. 2105, PageID 103512.) Indeed, the present evidence does not "differ in quality from the evidence presented before." *Id.* at PageID 103513. Defendants dismiss the "finding of pulmonary edema in a small, incomplete sample set of autopsies" as "not scientific proof that any of the [executed] inmates actually felt or experienced serious or severe pain." *Id.* They note that Dr. Edgar did not review an autopsy report from former plaintiff Gary Otte. *Id.* at PageID 103514.

Defendants assert the lay eyewitness observations from executions are not scientific evidence and may suffer from the confirmation bias the Court found in the Campbell and Tibbetts decision. (ECF No. 2105, PageID 103515, *citing* Decision and Order, ECF No. 1362, PageID 51345, n.19.) Besides, say Defendants, the lay witness observations are "cumulative to the earlier testimony" offered by former Plaintiffs. *Id.* at PageID 103516. Defendants rely on conclusions about consciousness reached by the Sixth Circuit in *Fears* and this Court in *Campbell and Tibbetts*. *Id.* at PageID 103517, *citing* Decision and Order, ECF No. 1362, PageID 51338. They assert Henness's "proof" about the acidity of midazolam is, in actuality, mere speculation. *Id.* at PageID 103518.

Summary of Testimony Received

Testimony at the hearing consisted largely of lay observations and expert opinions on this first *Glossip* prong.

Lay Observation Testimony

Plaintiff began the hearing by presenting testimony from lay witnesses who had observed

executions in Ohio and elsewhere in which an initial dose massive IV-injected dose intravenously administered midazolam had been used. Their testimony was consistent with that received in prior preliminary injunction hearings in this consolidated case: they observed condemned inmates appear to struggle to breathe in various ways after the midazolam injection. *See, e.g.*, the testimony of Elizabeth Peiffer about the execution of Ricky Gray in Virginia on January 18, 2017 (Hrg. Tr., ECF No. 2112, PageID 103689-94.) Ms. Peiffer had been Mr. Gray's counsel for approximately seven years, but testified her relationship with him did not affect her testimony. *Id.* at PageID 103692. Eric Motylinski, an assistant federal public defender in Philadelphia, had been appointed as counsel to Arkansas death row inmate Kenneth Williams sixteen days before his execution on April 27, 2017. *Id.* at PageID 103702; his description of Williams's breathing after the midazolam injection is at ECF No. 2112, PageID 103709-11. He also denied his representation of Williams affected his objectivity. *Id*. at PageID 103712.

Cameron Knight, a reporter with the *Cincinnati Enquirer*,[19] witnessed the July 18, 2018, execution of Robert Van Hook, a prior Plaintiff in this case. He described how Van Hook's breathing became labored after the midazolam injection (Hrg. Tr., ECF No. 2112, PageID 103729-34.) Spencer Hahn is an assistant federal defender with the Capital Habeas United for the Middle District of Alabama. *Id*. at PageID 103741-42. at PageID 103741-42. He had testified in a prior preliminary injunction hearing about his observations at the Alabama execution of Ron Smith. Since then he had observed the Alabama execution of Walter Moody on April 19, 2018. Alabama uses the same initiatory dose of midazolam as Ohio. *Id*. at PageID 103744. After the midazolam was administered, Moody began to "breathe very heavily and dramatically . . ." for three to four minutes. *Id*. at PageID 103754-55. Although Hahn had represented Moody, he testified that fact

[19] Mr. Knight and his employer initially sought to quash the subpoena for his appearance on First Amendment grounds, but withdrew the objection before the Court ruled. (ECF Nos. 2047, 2056, 2058, 2060, 2077, 2079.)

did not affect his testimony. *Id*. at PageID 103758.

Martin Schladen is a reporter with the *Columbus Dispatch* who witnessed the Van Hook execution. (Hrg. Tr., ECF No. 2112, PageID 103766.) After Van Hook was injected with midazolam, Schladen observed

> His breathing became more labored. His face became flushed.· He at a certain point, as he exhaled, his lips puffed out, and the breathing became shallower with time, it appeared to be, as you watched his chest. . . . You could hear it. The – the microphone was placed in the back of the chamber,· and even so, you could hear it, even -- it – it sounded kind of like wheezing, I suppose.

Id. at PageID 103773-74. This wheezing continued about a minute and was after the consciousness check. *Id*. at PageID 103774-75. He testified his reading about prior executions did not affect his testimony. *Id*. at PageID 103776.

Steven Hale, a reporter with the *Nashville Scene*, testified by video. He witnessed the August 9, 2018, Tennessee execution of Billy Ray Irick. (Hrg. Tr., ECF No. 2112, PageID 103783.) Hale had not witnessed an execution before, but had read about them and written on the death penalty. *Id.* at PageID 103784-85.[20] He had learned about midazolam from covering the *Abdur'Rahman* trial in Tennessee Chancery Court in the summer of 2018 before the Irick execution. *Id.* at PageID 103792-94. After the midazolam was injected, he observed:

> And then Mr. Irick pretty quickly began snoring pretty loudly and, you know, we -- from our vantage point, we could just see him breathing and snoring, kind of his -- his – he had quite a large belly that was protruding from the -- the restraints, and we could see him breathing, and he was snoring quite loudly for quite a bit of time.

Id. at PageID 103795. This continued for seven minutes until the consciousness check. *Id.* at PageID 103796. After the consciousness check, Irick made a choke or cough sound. strained

[20] After the Irick execution but before his testimony here, Hale witnessed the execution by electrocution of David Miller, but did not testify about it.

against the restraints, and moved his head a bit and briefly – movements Hale characterized as "sudden." *Id.* at PageID 103798. Hale opposes the death penalty generally but believed his newfound familiarity with the process did not impact how he reported the facts. *Id.* at PageID 103802-04. The testimony during the *Abdur'Rahman* trial led him to expect the possibility of "prisoners moving their heads and choking – and choking." *Id.* at PageID 103814.

The Magistrate Judge had given less weight to eyewitness testimony in the *Campbell* case on the basis of confirmation bias, the tendency of persons to see what they have been led to expect to see. (Decision and Order, ECF No. 1362, PageID 51345, n.19.) On appeal, Campbell's counsel criticized this weighing by saying the Court had not explained why it was applicable. To obviate that criticism, the Magistrate Judge asked lay witnesses in the hearing what they had seen or read about midazolam-initiated executions.

On balance, the accounts given are sufficiently consistent with one another and with prior lay descriptions of midazolam-initiated executions to be accepted as factual, yet different enough to belie any sense of repetition from one to the other.[21] And they are likely the best accounts the courts can expect, since witnesses are not allowed to make a video record or even audio record their observations as they occur.[22] While there may be some confirmation bias, it did not obviously affect the observation testimony.

In *Fears*, the Sixth Circuit wrote this Court had found that eyewitnesses who were capital-defense attorneys or even the condemned person's own lawyer were likely to be "highly biased." That verbiage is quoted not from the Court's decision, but from the Court's cross-examination of

[21] Indeed, the lay witnesses were not permitted to be in the courtroom until their respective testimonies were completed (Hrg. Tr., ECF No. 2112, PageID 103656-57).

[22] Although policies differ in details, no State allows video or audio recording by witnesses. Some do not allow witnesses, even the press, to bring their own writing materials into the witness rooms.

Plaintiffs' expert Sergio Bergese, M.D. as to whether he considered the possible bias of these witnesses in making and reporting observations, which he said he did. (Hrg. Tr., ECF No. 923, PageID 30869). Given an attorney's duty of loyalty to her or his clients and the adversarial nature of our litigation process, it is only natural to question whether an attorney witness's potential bias has been taken into account by an expert witness who relies on the account.

All things considered, however, this Court has not found attorney eyewitness testimony to be biased. Both in the December 2018 hearing and in prior hearings, witnessing counsel have delivered their testimony in completely descriptive tones without characterizations or emotional appeals. And because Ohio and other States narrowly limit who may witness an execution, these attorney witnesses are in some cases the only eyewitnesses available.

Plaintiff's Expert Opinion Testimony on the First Prong of *Glossip*

Report and Testimony of Mark Edgar, M.D.

Plaintiff first called Mark Edgar, M.D., an Associate Professor of Pathology at Emory University School of Medicine in Atlanta, Georgia, and a practicing, Board-certified anatomic pathologist and neuropathologist. Dr. Edgar was offered as an expert in anatomic pathology, neuropathology, and scientific research. (Hrg. Tr., ECF No. 2112, PageID 103864, 80.)

Dr. Edgar described his profession as "involv[ing] primarily the diagnosis of biopsies and surgical specimens removed from patients at surgery." (Hrg. Tr., ECF No. 2112, PageID 103822-23.) He estimated that in the course of his current employment, he conducts autopsies once or twice per month. *Id.* at PageID 103833. Dr. Edgar also noted that specimens removed during

surgery that he observes and documents on a daily basis are very similar to specimens removed during an autopsy. *Id*. He is also assistant director of the "soft tissue expert pathology consultation service[.]" *Id*. at PageID 103827.) He provides consultation to other pathologists "in which very difficult and diagnostically challenging cases are sent . . . by pathologists who do not know what they're looking at. . . ." *Id*.

Asked to explain the process of scientific research, Dr. Edgar noted that science begins with an observation, which leads to the formation of a hypothesis, which is then challenged by the collection and comparison of data. A series of observations (or experiments in other branches of science) showing the same appearance and/or behavior, such as for a particular type of tumor, strengthen the hypothesis. Dr. Edgar also explained that his field involves frequent comparison between what is observed under a microscope and what is observed macroscopically in patients. (Hrg. Tr., ECF No. 2112, PageID 103841.)

Dr. Edgar then explained the importance in scientific methodology of replicability, expounding that if a finding by one of more scientists/observers has been replicated by another group of scientists/observers, that makes it much more likely that the observation at issue is valid. (Hrg. Tr., ECF No. 2112, PageID 103849.)

Dr. Edgar proceeded in his report to define and describe the condition of pulmonary edema – "the movement of fluid from small blood vessels in the lung (alveolar capillaries) into the air spaces." (ECF No. 1950, PageID 76794.) He continued:

> It can be caused by increased hydrostatic pressure and congestion in capillaries as the result of fluid back-up in the lungs resulting from a failing heart (cardiogenic pulmonary edema). It can also be the result of a variety of chemical, infectious, or physical insults to the lung, such as inhaled toxic gas or reaction to intravenous contrast media used by radiologists.

Id.

Dr. Edgar next explained in his report that "[p]ulmonary edema has a variety of effects on the body." *Id*. According to Dr. Edgar:

> First, the presence of fluid in airspaces (alveolar sacs) interferes with normal gas exchange, which reduces the amount of oxygen in the blood. It also increases the work of breathing; in mild cases, this causes shortness of breath, sometimes coughing or wheezing, and increase in the rate of breathing, but with increasing severity it greatly increases the work of breathing such that the chest muscles and diaphragm strain as they expend greater effort to move air into the lungs. This also produces sensations similar to drowning or asphyxiation as fluid occupies a greater volume of the air space. Severe pulmonary is an intolerable state that produces panic and terror.

Id.

Dr. Edgar noted in particular that "[w]hen pulmonary edema is fulminant—that is, when it is both sudden (*i.e.*, acute) *and* severe in onset—it may result in the presence of foam or froth in the small/lower or large/upper airways (bronchi and trachea) resulting from the mixture of air, edema fluid, and pulmonary surfactant (a detergent-like secretion normally present in the airspaces)." *Id*.

Dr. Edgar's report addressed Ohio's execution of Robert Van Hook in July 2018.[23] He was informed that Ohio used the same protocol for that execution as is intended for Henness. (ECF No. 1950, PageID 76795-96.) Dr. Edgar conducted an autopsy of Mr. Van Hook's body, which "revealed significant abnormalities in Mr. Van Hook's lungs." *Id*. at PageID 76796. Dr. Edgar expounded:

> The lungs were heavy (left and right lungs weighing 665 and 709 grams, respectively)[24] and showed grossly evident pulmonary edema with cut sections exuding serosanguineous, frothy fluid.

[23] Van Hook was a Plaintiff in this case but did not seek preliminary injunctive relief to stay his execution.

[24] Dr. Edgar had noted earlier in his Report that normal adult lungs weigh approximately 350 to 400 grams, that these weights are seen in people who die very suddenly, and that deaths that are not instantaneous usually involves multiple organ failure and heavy, congested lungs. (ECF No. 1950, PageID 76795.)

> There was bloody froth seen in both main bronchi. No other abnormalities were seen in the lungs. . . .

(ECF No. 1950, PageID 76796-97.) He testified consistently with that observation. (Hrg. Tr., ECF No. 2112, PageID 103876.) His report included several picture-figures/histologic slides of lung tissue from Van Hook's body demonstrating the presence of fluid. (ECF No. 1950, PageID 76798-99.) "After he was administered 500 mg of midazolam," Dr. Edgar recounted in his report, "it was reported that Van Hook stopped singing and that his chest was rapidly rising and falling for a few minutes and he fell silent." Dr. Edgar continued, "A minute later, his breathing remained labored. A few minutes later, he began puffing out his lips as he exhaled and then he was gasping and wheezing loudly enough that it was audible into the witness room." *Id*. at PageID 76800.

Dr. Edgar testified on direct examination that he was originally retained in this case to conduct the autopsy of Robert Van Hook. (Hrg. Tr., ECF No. 2112, PageID 103856.) But he first came to review autopsy reports or pathology samples from inmates executed with midazolam protocols two years earlier, when a colleague at Emory was reviewing a series of autopsy reports looking at the chemistry and drug levels, and asked Dr. Edgar to look at the anatomical component. *Id*. at PageID 103853-55. Dr. Edgar explained that he agreed to conduct Van Hook's autopsy because having two years earlier read autopsy reports of other executed inmates, Dr. Edgar wanted to see with his own eyes whether those reports were reproducible, whether he could find the same things, and whether he could find an explanation. *Id*. at PageID 103857. During cross-examination, Dr. Edgar confirmed that he saw the Van Hook autopsy as an opportunity to see for himself what was going on, and to see if he could find an explanation or any other findings in the lungs that may have been missed by others. (Hrg. Tr., ECF No. 2113, PageID 104121.) He testified that he had not at that time anticipated participating in litigation. *Id*. He also agreed that the Van Hook autopsy was another data point, and one that turned out to be consistent with many

of the previous data points. *Id*. at PageID 104121-23.

According to Dr. Edgar's report, the autopsy data confirmed his opinion that Mr. Van Hook developed acute pulmonary edema during his execution. (ECF No. 1950, PageID76800.) The eyewitness accounts of rapid or labored breathing, gasping, and wheezing further support that conclusion. *Id*. at PageID 76800-01. It is also Dr. Edgar's opinion that "the findings in the brain indicate that Mr. Van Hook was alive for at least 3 to 5 minutes following which time his brain suffered insufficient oxygen delivery or blood flow." *Id*. at PageID 76801.

Dr. Edgar's further opinion, set forth in his report, is that neither rocuronium bromide nor potassium chloride would cause pulmonary edema. (ECF No. 1950, PageID 76801.) Once fully effective, rocuronium bromide "would prevent the development of frothy fluid in the lungs and airways because as a neuromuscular blocking agent it paralyzes the muscles of respiration which would stop the flow of air necessary for production of froth." *Id*. (*citing Journal of Clinical Investigation* 1965; 44(3): 458-64).) Dr. Edgar further explained that "paralytics paralyze" and "stop skeletal muscle," thus taking away the ability for air and water to mix to produce that froth once the movement of air has stopped. (Hrg. Tr., ECF No. 2112, PageID 103909.)

Dr. Edgar stated in his report that the third drug, potassium chloride, "would not cause pulmonary edema because it rapidly causes cessation of electrical activity in the heart, cardiac arrest, and cessation of the blood flow necessary for development of pulmonary edema." (ECF No. 1950, PageID 76801.)

Dr. Edgar's report noted that "there was no evidence in the autopsy reports or eyewitness observations to suggest that Mr. Van Hook or any of the other executed inmates in whom pulmonary edema was identified post-mortem suffered from pulmonary edema before their respective executions." (ECF No. 1950, PageID 76801; *see also* Hrg. Tr., ECF No. 2112, PageID

103911.) Dr. Edgar testified that he had reviewed Van Hook's medical records[25] from the three or four years preceding his execution and had found no other medical condition that might have caused the pulmonary edema. (Hrg. Tr., ECF No. 2112, PageID 103927-28 (identifying JX 36, ECF No. 2026-36).) Dr. Edgar reached the same conclusion as to the other executed inmates in whom he had found pulmonary edema because it would be "extraordinary" if all of those inmates coincidentally had a medical condition that might have produced the pulmonary edema. *Id*. at PageID 103928-29.)

Dr. Edgar thus opined in his report "that the 500 mg dose of IV-injected midazolam was responsible for the development of pulmonary edema in Mr. Van Hook's case. The same applies as to the other cases in which the autopsy reports confirm the presence of pulmonary edema." (ECF No. 1950, PageID 76801-02; *see also* Hrg. Tr., ECF No. 2112, PageID 103911-12.) Dr. Edgar agreed, based on what he concluded in twenty-four of the 28 twenty-eight cases he reviewed, that it was his opinion to a reasonable degree of medical certainty that an inmate given 500 mg of IV-injected midazolam would be sure or very likely to develop pulmonary edema during execution. (Hrg. Tr., ECF No. 2112, PageID 103905-06.) When asked on direct examination what a person developing pulmonary edema would experience if he or she were sensate, Dr. Edgar answered that a person who received a 500 mg dose of midazolam would be extremely likely to experience extremely labored breathing, severe dyspnea (shortness of breath), and symptoms of asphyxiation, drowning, terror, and panic. *Id*. at PageID 103922-24.

Dr. Edgar further noted his opinion "is also supported by Dr. Greenblatt's explanation of why and how large doses of IV-injected midazolam, as a highly acidic solution, will rapidly cause damage to the lungs after injection." (ECF No. 1950, PageID 76802.) Dr. Edgar explained that

[25] Medical records of the Plaintiffs are regularly produced by Defendants to Plaintiffs' counsel in continuing discovery.

he had initially come up with the hypothesis on his own that it was the high acidity of IV-injected midazolam that was damaging the tissue, causing pulmonary edema. (Hrg. Tr., ECF No. 2112, PageID 103912-16.) Dr. Edgar continued that, during the *Abdur'Rahman* trial in Tennessee, listening to the testimonies of Drs. Greenblatt, Lubarsky, and Stevens – whom Dr. Edgar had never met and did not know -- gave Dr. Edgar "a high level of certainty that that's the mechanism." *Id*. at PageID 103916.

On cross-examination, Dr. Edgar agreed "that the primary cause of the pulmonary edema identified in these executed inmates is the relatively rapid IV injection of a large dose of midazolam in a highly acidic form which enters the lungs almost immediately after injection and promptly begins to destroy the delicate blood vessels in the lungs, thereby causing the lungs to immediately begin to fill with fluid and blood." (Hrg. Tr., ECF No. 2113, PageID 104123.) Dr. Edgar confirmed that he had not reached that firm conclusion when deposed in *Abdur'Rahman*, but had since heard Dr. Greenblatt's testimony and examined additional literature on the effects of injected acid on the lungs. *Id*. at PageID 104127.

Dr. Edgar agreed that without understanding the mechanism by which pulmonary edema was being caused in drug overdoses, including with drugs other than midazolam, it would be difficult to offer an opinion as to how quickly the pulmonary edema developed. (Hrg. Tr., ECF No. 2113, PageID 104130.) He clarified that we know from the autopsies the course of time over which the pulmonary edema occurred because it had to have occurred prior to the cessation of respiration which would occur with the paralytic drug. *Id.* at PageID 104132.

Dr. Edgar next addressed autopsy reports he had reviewed in every IV-injected midazolam execution for which an autopsy report existed, vis-à-vis the presence or absence of pulmonary edema. (ECF No. 1950, PageID 76802-826.) There were twenty-eight such reports reviewed and

his expert report sets forth in detail his findings as to each autopsy or his conclusions from reading eyewitness accounts. For the full detail on each execution examined, the reader can consult Dr. Edgar's expert report (ECF No. 1950).

Dr. Edgar confirmed that in twenty-four of the twenty-eight cases for which he had read autopsy reports, pulmonary edema was evident either with the naked eye or with the use of a microscope. He was surprised, "because I would have expected with the execution protocol involving first a benzodiazepine, then a paralytic, and then an electrolyte that stops the beating of the heart, to find the organs in a state that very closely approximated the state when the inmate went into the execution chamber." (Hrg. Tr., ECF No. 2112, PageID 103860-61.) Dr. Edgar further explained that when a person dies instantaneously, for example from a sudden heart attack, his organs generally present in the same state as when he was alive, in contrast to when a person dies after a prolonged illness or incapacitation, when his organs would tend to become heavy. *Id*. at PageID 103861. Dr. Edgar continued that he would have expected to find lungs filled with air and have normal weight, but instead found that they were heavy, and in many cases, contained water in the air spaces in the form of pulmonary edema. *Id*.

Dr. Edgar explained that any doctor and good medical student will know the symptoms of pulmonary edema, "so I feel comfortable in saying that I know what witness observations of pulmonary edema might look like, what – what the signs might be." (Hrg. Tr., ECF No. 2112, PageID 103866.) At onset, people start to feel short of breath, they will start to breathe more quickly, and they may breathe more shallowly. As pulmonary edema becomes more severe, the sense of air hunger may develop and the work to get air into and out of the lungs increases, as the airways progressively fill with water; the work of breathing is extreme and you may have things like heaving-type respiration, the abdomen protruding in and out because the diaphragm is pushing

in a desperate effort to inflate lungs that are still and filled with fluid; and you may have gasping, wheezing, and coughing. *Id.* at PageID 103866-67. He testified pulmonary edema will cause a person to experience anything from shortness of breath to sensations of drowning, asphyxiation, terror, and panic. *Id.* at PageID 103889. In reviewing eyewitness accounts of executions, he was sensitive to any kind of change in respiration reported because that would tend to support the finding of pulmonary edema, and it is "very powerful corroboration to have an entirely different kind of evidence . . . ." *Id.* at PageID 103867-68. Even as to the autopsy reports from which he could not definitively diagnose pulmonary edema (four cases), some of those inmates exhibited signs of pulmonary edema such that he could not rule out the possibility that pulmonary edema was developing. *Id.* at PageID 103869-70.

Dr. Edgar's report stated that "what forensic pathologists from multiple states independently and repeatedly saw and reported was scientific autopsy evidence of acute, often fulminant, pulmonary edema *that could only be attributable to the large doses of IV-injected midazolam*." (ECF No. 1950, PageID 76827 (emphasis added).) Midazolam as prepared for injection is highly acidic and an intravenous injection of large amounts of acid solutions is known to produce acute lung injury with pulmonary edema in animal models. *Id.* Dr. Edgar extrapolated from those conclusions that large doses of IV-injected midazolam, such as the 500-mg dose that Ohio uses, "are unquestionably and surely causing acute lung injury in the form of pulmonary edema in the condemned inmates from the very start of the execution protocol's administration." *Id*. at PageID 76827-28. To the extent this Court had previously characterized new evidence from recent executions consistent with evidence from older executions as cumulative, Dr. Edgar noted that, "in science and medicine each new supportive observation adds strength to a hypothesis…." *Id*.

With respect to Defendants' assertion that autopsy reports of inmates executed using pentobarbital showed evidence of pulmonary edema, Dr. Edgar responded that, since pentobarbital, like midazolam, has a very high alkaline pH, evidence that IV-injected pentobarbital executions often resulted in pulmonary edema only "adds support to my conclusion that the IV injection of a large volume of fluid with a highly abnormal acidic or alkaline pH exerts a caustic effect on lung tissue. (ECF No. 1950, PageID 76829.)

Finally, Dr. Edgar took issue in his report with the understanding of this Court, the Sixth Circuit, and the Supreme Court "that there were 12 executions using midazolam that were apparently without problems, including 11 in Florida and the Warner execution in Oklahoma." (ECF No. 1950, PageID 76831.) According to Dr. Edgar, "my review of the autopsy evidence from those executions, along with reconsideration of the timing and thus the significance of Warner's statement that 'my body is on fire,' conclusively demonstrates that is not true." *Id*.

In his rebuttal expert report, Dr. Edgar provided detailed, point-by-point responses to various critiques of his conclusions presented in the expert reports of Dr. Robert Davis (ECF No. 2035-3 PageID 100381-403) and Dr. Joseph Antognini. *Id*. at PageID 100403-05. With respect to Dr. Davis's statement that overdose deaths related to opioids and barbiturates, as well as to midazolam, are known to be associated with pulmonary edema, Dr. Edgar countered that Dr. Davis's argument does not undermine his conclusions about the near certainty that 500 mg of IV-injected midazolam will cause acute pulmonary edema, due to the highly acidic nature of injectable midazolam. (ECF No. 2035-3, PageID 100374; *see also id*. at PageID 100385-87.)

With respect to Dr. Davis's critique of Dr. Edgar's findings from the autopsy of Robert Van Hook that the heart was abnormal, showing cardiomegaly, and showed evidence of right ventricular failure, Dr. Edgar asserted that "[n]either claim is true based on published, current, and

generally accepted data." (ECF No. 2035-3, PageID 100374-75; *see also id*. at PageID 100388-89.)

With respect to Dr. Davis's suggestion that the unavailability of medical history in the autopsied inmates undermined the data, Dr. Edgar questioned how medications or chronic illnesses that might have been documented in such records would be relevant to Dr. Edgar's findings. (ECF No. 2035-3, PageID 100375; *see also id*, at PageID 100390-91.) Dr. Edgar explained that "[w]hile pre-existing heart disease may have contributed to pulmonary edema in some cases, these disparate statistics would give us no reason to suppose that pre-existing heart disease could account for the presence of pulmonary edema in the vast majority of autopsies reviewed." (ECF No. 2035-3, PageID 100390-91.) As noted earlier, during direct examination, Dr. Edgar emphasized that he found pulmonary edema in twenty-four of the twenty-eight autopsy reports he reviewed, and that it would be extraordinary if they all coincidentally had a medical condition that could have contributed to that pulmonary edema. (Hrg. Tr., ECF No. 2112, PageID 103928-29.)

Dr. Edgar also stated in his rebuttal that "Dr. Davis wrongly equates 'agonal movements' with those observed following administration of midazolam; there is no reason to believe that patients given a high dose of a drug which only exceptionally causes death in overdoses, and who are still breathing, are in the process of dying (prior to the administration of the second and third drugs in the protocol)." (ECF No. 2035-3, PageID 100375; *see also id*. at PageID 100402-03.) On direct examination, he further stated that observations of movements, particularly agonal respirations, have to be seen in a new context now that we know how frequent pulmonary edema is in the executed inmates. (Hrg. Tr., ECF No. 2112, 103945-46.)

Dr. Edgar further noted in the point-by-point responses in his rebuttal report that Dr. Davis does not appear to dispute Dr. Edgar's "expert opinion that that an inmate who is subjected to

Ohio's three-drug midazolam execution protocol, including Plaintiff Henness, is certain or very likely to experience acute pulmonary edema after peripheral IV injection of 500 mg or more of midazolam." (ECF No. 2035-3, PageID 100381 (internal quotation marks omitted).) Nor did Dr. Davis appear to dispute Dr. Edgar's "expert opinion that unless rendered insensate by a drug that either deeply depresses brain function or otherwise prevents perception of pain, inmates subjected to a 500 mg intravenous injection of midazolam would experience severe respiratory distress with associated sensations of drowning, asphyxiation, panic, and terror." *Id.* at PageID 100381-82. Dr. Edgar expressed both these opinions on direct examination. (Hrg. Tr., ECF No. 2112, PageID 103889; 103922-24; 103905-06; 103925-26.)

Dr. Edgar also pointed to the explanations he set forth in his report as to why neither the paralytic drug nor the potassium chloride could have caused the pulmonary edema. (ECF No. 2035-3, PageID 100382-83.) He also faulted Dr. Davis for failing to offer any other plausible explanation for why such a very high percentage of inmates executed with a massive dose of IV-injected midazolam developed pulmonary edema. *Id*. at PageID 100384.

With respect to Dr. Davis's assertion that thousands of doses of midazolam are injected every day, including in children, without a significant number of complaints of burning on injection, Dr. Edgar noted that those clinical doses were far lower than 500 mg. (ECF No. 2035-3, PageID 100399-400.)

In his rebuttal report, Dr. Edgar also responded to certain critiques raised by Dr. Antognini. First, he noted that Dr. Antognini did not include Dr. Edgar's report among the materials Dr. Antognini considered in forming his opinions, but offered a single paragraph opining that midazolam is not likely to produce pulmonary edema via an acid effect. (ECF No. 2035-3, PageID 100375-76; *see also Id*. at PageID 100404.) Dr. Edgar disagreed with Dr. Antognini's conclusion,

and noted that Dr. Antognini did not dispute that Dr. Edgar found pulmonary edema in eighty-five percent of the executions involving IV-injected midazolam for which there were written autopsy reports. *Id*. at PageID 100376; *see also Id*. at PageID 100404.

Finally, Dr. Edgar disputed Dr. Antognini's contention that midazolam, despite being in an acidic solution, is not painful on injection. (ECF No. 2035-3, PageID 100404.) Dr. Edgar asserted that Dr. Antognini failed to account for the crucial distinction between a clinical dose of IV-injected midazolam and a 500 mg dose. *Id*. at PageID 100405. On cross-examination, Dr. Edgar explained that whereas Dr. Antognini focused on the ability of the entire blood volume in the body to buffer the amount of acid given in that intravenous injection of midazolam, Dr. Edgar is of the view that the high dose of acid goes into the vein and then to the heart, without mixing with all of the buffering capacity of the body's whole blood volume, before affecting the lungs. (Hrg. Tr., ECF No. 2113, PageID 104134-39.)

Report and Testimony of Matthew Exline, M.D.

On the second day of the hearing, Plaintiff Henness presented the testimony of Matthew Exline, M.D., M.P.H., F.C.C.P – an Associate Professor of Internal Medicine and Director of the Medical Intensive Care Unit ("ICU") at The Ohio State University Wexner Medical Center (Hrg. Tr., ECF No. 2113, PageID 01, *et seq*.) Dr. Exline is a board-certified internist, pulmonologist, critical care, and sleep physician with advanced certifications such as Advanced Cardiac Life Support and Difficult Airway Management, and that he has extensive experience in the use of midazolam for procedural sedation and management of respiratory distress in critically ill patients. He is a practicing physician, as well as a teacher and researcher. Dr. Exline was accepted by the

Court as an expert witness in critical care medicine, pulmonary medicine, sleep, and internal medicine without objection by Defendants. (Hrg. Tr., ECF No. 2113, PageID 104063.)

In his report and on direct examination, Dr. Exline first recounted in detail the materials that he reviewed in preparing his report and reaching his expert opinions, (ECF No. 1948, PageID 76171-72), and described his background and professional qualifications, *Id*. at PageID 76172; (Hrg. Tr., ECF No. 2113, PageID 104004-12.) He stated he holds the opinions expressed in his report and on direct to a reasonable degree of medical certainty. *Id*. at PageID 104010-11.

Dr. Exline testified that, as director of the medical intensive care unit at The Ohio State University, he spends about ten percent of his time in an ambulatory clinic seeing patients with COPD, asthma, or other breathing complaints and the remainder in the intensive care unit. (Hrg. Tr., ECF No. 2113, PageID 104011.) In the ICU, approximately fifty percent of his patients are on mechanical ventilation, with a breathing tube down their trachea, and that about half of those patients are on some degree of conscious sedation "where we are trying to mitigate the discomfort of . . . ICU care." *Id*. at PageID 104011-12. He summarized his clinical experience as involving the adjudication and treatment of patients' pain and distress, as well as treatment of the pulmonary edema or acute respiratory distress syndrome they are experiencing. *Id*. at PageID 104012. As ICU director he has a role in developing and teaching protocols in the ICU for nurses, respiratory therapists, and junior physicians to follow. *Id*.

With respect to any of his references to the best practice of clinical care, Dr. Exline was asked during cross-examination whether that clinical standard of care would apply to executions. (Hrg. Tr., ECF No. 2113, PageID 104064-65.) Dr. Exline explained:

> So to your point, obviously we have not developed, or I at least have never been part of a development of a protocol for an execution, so all I can do when asked to render an opinion is extrapolate the principles we've learned from our clinical use of these agents and

> clinical causes of pain into a setting that I agree is outside of what I would see in clinical practice.

(Hrg. Tr., ECF No. 2113, PageID 104065.) Dr. Exline did agree that a critical issue in this case is whether a particular procedure during an execution presents a risk of pain. *Id*. He was asked on cross-examination, "Would you say that a particular procedure used in executions may not necessarily comply with the clinical standard, but that may not necessarily mean that it presents a risk of pain?" Dr. Exline answered:

> If I understood you correctly, what you were saying is an execution procedure would not meet a clinical standard but might not cause pain, and I would agree that any protocol whose goal is execution would not be a clinically used standard, but we would still try to mitigate pain as best we could.

(Hrg. Tr., ECF No. 2113, PageID 104068.)

It is Dr. Exline's opinion, based on review of autopsy reports of inmates subjected to an execution method using IV-injected midazolam, that "a great number of cases reviewed included a notation identifying pulmonary edema (23 out of 28 for which there was an autopsy report available)." (ECF No. 1948, PageID 76173.)

It is also the opinion of Dr. Exline that "[p]otassium chloride is a sclerotic agent, especially in high doses, that would cause severe pain during injection in individuals that are sensate." (ECF No. 1948, PageID 76173) "Furthermore," Dr. Exline continued, "the development of a cardiac arrhythmia would lead to severe chest pain and dyspnea in a patient that is sensate." *Id*.

His opinion is that paralytic agents such as rocuronium bromide possess neither analgesic nor amnestic properties, and that administration of a paralytic agent to a sensate patient would cause "severe pain and discomfort." (ECF No. 1948, PageID 76173.) "Furthermore," Dr. Exline added, "paralytic agents mask the ability for individuals to manifest their pain[,]" and thus are strictly prohibited in medical practice for patients who have not received adequate analgesic

medications. *Id*.

Dr. Exline testified on direct examination about the use of paralytic agents in his practice. (Hrg. Tr., ECF No. 2113, PageID 104015.) He explained that for patients experiencing acute respiratory distress syndrome ("ARDS"), "we will give paralytic agents to alleviate extra oxygen consumption by the peripheral muscles and also to take away the patient's respiratory drive so they are not fighting our ventilator." *Id*.

Dr. Exline noted that midazolam is a central nervous system ("CNS") depressant that binds to gamma-Aminobutyric acid (GABA) receptors, whose properties include sedation, anxiolysis, and amnestic. (ECF No. 1948, PageID 76173) "In high doses," Dr. Exline continued, "midazolam is a respiratory depressant and may also cause relaxation of muscles of upper airway leading to upper airway obstruction." *Id*. at PageID 76173-74. Dr. Exline also opined that midazolam does not have analgesic effects and may potentially increase pain perception. *Id*. at PageID 76174. Midazolam alone cannot produce analgesia to make a person insensate to pain and must be combined with opioid or other analgesic agents for any painful procedure. *Id*.

Dr. Exline uses midazolam to achieve sedation, usually for procedures that are relatively brief, such as a bronchoscopy – where a camera is placed down the trachea to see what is happening in the lungs. (Hrg. Tr., ECF No. 2113, PageID 104013.) Because that procedure can make patients cough and feel anxious, Dr. Exline testified that he would use a combination of a low dose of midazolam and fentanyl, an opioid painkiller, to provide comfort during the procedure. *Id*. He would also use midazolam, often in continuous doses, for a patient who is in respiratory distress and on a ventilator. *Id*. at PageID 104014. Dr. Exline explained that they would also be using opioid painkillers. *Id*. at PageID 104015. Dr. Exline agreed on cross examination that he, as a clinician, does not administer large doses of midazolam such as Ohio uses in executions. *Id*. at

PageID 104078. He also agreed that he had not personally researched, and is not aware of anyone who would know, what 500 milligrams of midazolam would do to anyone. *Id*. at PageID 104084.

Dr. Exline testified about the use in the ICU of analgesics, or opioid painkillers such as Dilaudid, and answered "No" when asked whether midazolam would ever be used in the ICU as an analgesic. (Hrg. Tr., ECF No. 2113, PageID 104015-16.) Dr. Exline explained:

> Midazolam is an anxiolytic, and at higher doses, and that level varies patient-to-patient, but at higher doses, it is a sedative, but all of the critical care literature I'm familiar with does not label midazolam as an analgesic and, in fact, we actively discourage our nurses to the point of they're not allowed to give midazolam for pain, and vice-versa, we don't give fentanyl for agitation. We try to really teach the nurses to understand what they're using each drug for appropriately.

(Hrg. Tr., ECF No. 2113, PageID 104016.)

When asked on direct examination about the literature he consulted in forming his expert opinions for this hearing, Dr. Exline remarked "when reviewing this matter, one of the challenges was finding the evidence for something that is just accepted practice in the ICU for as long as I've been there, the last twelve years, which is midazolam is not a painkiller." (Hrg. Tr., ECF No. 2113, PageID 104016-17.) He did point to a study by Frölich from the University of Alabama at Birmingham, in which subjects were exposed to a variety of painful stimuli following both sedation with midazolam or propofol or dexmedetomidine and a painkiller, "and what they found is for three of the four painful stimuli they used, midazolam actually increased the patients' perception of pain." *Id*. at PageID 104017. He clarified on cross-examination that he was offering no opinion on whether the administration of midazolam causes pain. *Id*. at PageID 104093-94. When asked whether he has ever seen midazolam work as an analgesic, Dr. Exline answered:

> No. I believe often when physicians use midazolam and say the patient appears more comfortable, what they've achieved is they've taken away the patient's ability to voice or display their pain so that

> they look comatose, but they haven't actually taken away their pain, and I base this on the fact that if you ask patients when they leave the ICU how was your ICU stay, what do you remember from it, a lot of patients have memories of painful procedures.

(Hrg. Tr., ECF No. 2113, PageID 104017-18.)

Dr. Exline next described pulmonary edema as "the development of increased interstitial fluid (the fluid found in the spaces around cells, which comes from substances that leak out of blood capillaries) in the lung tissue, airways, and alveoli." (ECF No. 1948, PageID 76174.) According to Dr. Exline, "[p]atients with pulmonary edema will complain of dyspnea (difficult or labored breathing), intense feelings of chest tightness and of suffocation, and severe chest pain." *Id*. Based on Dr. Exline's training, education, and experience, signs of pulmonary edema include coughing, sputtering, wheezing, and making increased respiratory efforts or heavier breathing. *Id*. Another outward sign of pulmonary edema is noticeable movement of the abdomen. Dr. Exline acknowledged that a great number of eyewitness accounts of executions involving midazolam, particularly in Ohio, noted these signs. *Id*. at PageID 76174-75.

Dr. Exline's report next explained that consciousness, or the ability to be aroused to stimuli, "is distinctly different from" the ability to perceive pain (sensation). (ECF No. 1948, 76175.) He cited intensive care literature that calls for an assessment for level of consciousness or coma scale, and a separate assessment for pain. He testified that consciousness is an awareness and ability to respond to external stimuli, while sensation, with regard to pain, is an unpleasant sensation due to stimulation of your pain fibers and/or tissue damage. (Hrg. Tr., ECF No. 2113, PageID 104018-19.) He stated that one who appears to be unconscious could "absolutely" still be sensate. *Id*. at PageID 104019. He testified his opinion was based on his experience as an ICU doctor "and also the kind of received wisdom of my mentors, and if I went into my ICU tomorrow and said, this patient appears unconscious, I'm not going to worry about their pain, the nurses would run me out

on a rail, and rightfully so." *Id*. at PageID 104019-20.

Dr. Exline opined in his report that the best scale for assessment of level of consciousness is the Richmond Agitation-Sedation Scale ("RASS"), which he expounded upon in his Report with a chart. (ECF No. 1948, PageID 76175-76.) After explaining on direct examination different types and severity of painful stimuli, as well as the difficulties in using common terms such as "mild, moderate, severe" in accurately assessing pain, he testified about the RASS, explaining that it is relatively quick for nurses to perform and has a high degree of reproducibility in that most people using it come up with the same number. (Hrg. Tr., ECF No. 2113, PageID 104020-23; *Id*. at PageID 104023.) With the assistance of a projected image of the scale, Dr. Exline testified that the scale "puts normal at zero and then anything that's positive we know means you're more agitated, and anything that's negative means you're more sedate." *Id*. at PageID 100423-24. Dr. Exline continued that while a plus one might represent slight anxiousness and a negative one might represent slight drowsiness, a minus four would represent the deepest sedation, "meaning you're not responsive other than if we come in and really do a sternal rub or some other noxious stimuli to see if you could respond. . . ." *Id*. at PageID 104024-25. Minus five, Dr. Exline testified, "means no matter what we do, you don't seem to respond." *Id*. at PageID 104025. The two most common stimuli he applies are the sternal rub and squeezing fingertips. *Id*. He confirmed that RASS scores are based on the user's sensory observations of the patient. *Id.* at PageID 104026.

Moving on from consciousness to sensation, Dr. Exline opined that the inability to respond to either vocal or physical stimulation does not preclude an ability to sense pain. He explained that pain assessment begins with asking an alert person to describe his or her pain on a scale of one to ten, or, for a child, on a scale from happy face to frowny face. (Hrg. Tr., ECF No. 2113, PageID 104026.) A frequently used scale for assessing pain in unconscious patients is the Critical-

Care Pain Observation Tool ("CPOT"), which he illustrated in his Report with a chart. (ECF No. 1948, PageID 76176; Hrg. Tr., ECF No. 2113, PageID 104027.)

After a brief explanation of how the CPOT scale is used to measure pain in conscious and unconscious individuals, Dr. Exline noted, "[t]he notion that individuals who appear unconscious may still experience pain is a well-established scientific principle, described frequently in the critical-care literature." (ECF No. 1948, PageID 76178.) According to Dr. Exline, ICU personnel used to use vital signs alone, such as heart rate and blood pressure, to assess when an unconscious patient was experiencing pain, but that was problematic because oftentimes in a clinical setting, there are a lot of reasons a heart rate might go up, only one of which is from experiencing pain. (Hrg. Tr., ECF No. 2113, PageID 104029.) So the CPOT involves adding a variety of other markers of pain, such as facial expression, body movement, and respiratory rate or respiratory pattern for patients on a ventilator. *Id*. at PageID 104029-30. Dr. Exline testified, consistent with the Gelinas Study's validation of the tool, that CPOT is probably the best tool for assessing whether an unconscious patient is having pain. *Id*. at PageID 104028.

With respect to consciousness and sensation, Dr. Exline agreed on direct examination "[a]bsolutely" that a person who is sedated to a level of negative four or five on the RASS can score a two or higher on the CPOT. (Hrg. Tr., ECF No. 2113, PageID 104035.) Dr. Exline stated again, "your level of consciousness and your ability to sense pain are two distinctly different phenomena." *Id*. When asked on direct examination whether he agreed with Dr. Antognini's statements that an individual must be awake to experience pain, Dr. Exline answered, "I don't believe that statement conveys the understanding of pain that we use in the ICU, and I certainly think there are many settings where we would say an unconscious patient should be treated as if they can feel pain." *Id*. at PageID 104036-37.

According to Dr. Exline, "Insensation can only be established through an analgesic agent such as an opioid or through a drug that can depress the consciousness to the depth at which it is scientifically accepted that insensation may occur, such as a barbiturate or a general anesthetic drug like propofol. Midazolam is not such a drug." (ECF No. 1948, PageID 76179.) "Unconscious patients, including patients sedated to the point of deep coma (RASS -5), still have a respiratory drive and an ability to feel air hunger." *Id*. "In my opinion," Dr. Exline continued, "an inmate sedated [with] midazolam would be similarly situated—appearing to be unconscious, but still being sure or very likely to remain sensate to the severe pain from the drugs involved." *Id*. at PageID 76180.

Dr. Exline was asked about the various "consciousness checks" set forth in Ohio's lethal injection execution protocol. (Hrg. Tr., ECF No. 2113, PageID 104037-38.) When asked whether approaching an individual and asking him to respond to his name indicates that the individual is insensate, Dr. Exline answered, "It does not." *Id*. at PageID 104039. Dr. Exline repeated that answer as to brushing an eyelid and pressing something into the fingernail bed. *Id*. According to Dr. Exline, all of these, including a sternal rub, only demonstrate that the person cannot externally respond to noxious stimuli, but do not demonstrate that they are truly insensate. *Id*. He reminded the Court that movement is only one of the markers on the CPOT scale. *Id*.

On cross-examination, Dr. Exline appeared to largely agree that some of the consciousness checks prescribed in Ohio's execution protocol – such as speaking the inmate's name and performing a sternum rub – are similar to initial steps a clinician or nurse would perform vis-à-vis the RASS process to measure the level of sedation. (Hrg. Tr., ECF No. 2113, PageID 104072-73.) When asked what it means when a RASS determination is made that a patient is "basically unresponsive," Dr. Exline answered:

> [M]y testimony would be not that that these patients are not achieving deep sedation, which is the minus four and the minus five, which is consistent with the RAS scale and also with a consciousness check as you described, but rather, that the assessment of consciousness is not where you end in terms of assessing whether someone can experience pain.

(Hrg. Tr., ECF No. 2113, PageID 104072-73.)

Dr. Exline was next asked on direct examination whether certain actions and behaviors by individuals, testified about the previous day, would be signs of pain under the CPOT or any other tool. (Hrg. Tr., ECF No. 2113, PageID 104039.) Dr. Exline agreed that, after exposure to noxious stimuli, clenching of fists, straining of muscles, movement of the upper arm, puffing of lips as an indicator of change in respiratory pattern, straining upward, or moving one's head would all be consistent with pain. *Id*. at PageID 104039-40. On cross he agreed with testimony he had provided on direct examination that there can be reasons other than pain that a person might exhibit certain signs – such as an elevated blood pressure and heavy breathing. (Hrg. Tr., ECF No. 2113, PageID 104074-75.)

Dr. Exline was also asked on direct examination about an autopsy report and media reports he had reviewed as to the execution of Ohio inmate Robert Van Hook. (Hrg. Tr., ECF No. 2113, PageID 104041 (discussing Plaintiff's Exhibit 32, at PageID 100454-60).) He pointed to descriptions of the inmate's lips puffing with breath at 10:30 am as a possible indication of air hunger, and gasping and wheezing at 10:33 am as indicating an increase in respiratory drive and fighting to try to get air through the upper airway. *Id.* at PageID 104042-43.

Dr. Exline testified, consistent with his report, that patients who are experiencing pulmonary edema variously describe having chest pain, having chest tightness, feeling like they cannot get a breath in, or feeling like they are drowning. (Hrg. Tr., ECF No. 2113, PageID 104046.) Referencing an article about the execution of Billy Ray Irick (Plaintiff's Exhibit 32, ECF

No. 2113, PageID 100461, 100465), Dr. Exline was asked whether he could identify any manifestations of pain. He noted that snoring may or may not indicate pain but would indicate that the upper airway tissues are beginning to collapse in on the airway, so the person would be struggling to breathe. (Hrg. Tr., ECF No. 2113, PageID 104047.) Dr. Exline pointed out that after a consciousness check on Irick was completed, he was jolting, coughing, making a choking noise, and straining against his arm restraints – all as signs, Dr. Exline believed shortly after the injection of the second drug, that the individual was experiencing pain from noxious stimuli. *Id*. at 104047-48.

Dr. Exline was asked what components of Ohio's execution protocol that he reviewed are certain or very likely to be painful and named four. (Hrg. Tr., ECF No. 2113, PageID 104054.) The first is the use of a very large sedative dose of midazolam, which lessens muscle tone and has a tendency to cause collapse the upper airway, such as in someone who has had too many drinks and begins to snore. *Id*. at PageID 104055. Dr. Exline continued that in his clinical practice, "patients who have snoring will wake up and say, I felt like I was choking, I felt like I couldn't breathe, I felt like I was dying." *Id*. at PageID 104065. He explained that some patients, but not all, would complain of pain from this.

The second source of pain that Dr. Exline identified was pulmonary edema. (Hrg. Tr., ECF No. 2113, PageID 104055.) Dr. Exline testified that pulmonary edema is described as painful or unpleasant, as patients variously report chest tightness, chest pain, and sensations of drowning, suffocating, and dying. *Id.* at PageID 104057. He agreed on cross-examination that there are different degrees of pulmonary edema, but that exhibition, within two to four minutes after injection of a drug, of heaving and gasping that is audible through a thick pane of glass would be consistent with severe pulmonary edema. (Hrg. Tr., ECF No. 2113, PageID 104097-098.)

Another source of pain that Dr. Exline identified was the injection of potassium chloride – which "is very uncomfortable when injected peripherally," and many patients complain of a burning sensation. (Hrg. Tr., ECF No. 2113, PageID 104058.)

Dr. Exline explained that in his clinical practice, a paralytic would only be used in a patient verified as both unconscious and free of pain, "to the point of if we had a comatose patient. . . ." (Hrg. Tr., ECF No. 2113, PageID 104058.)

Dr. Exline concluded his report as follows:

> In summary, the three-drug cocktail used by the state of Ohio for lethal injection contains two agents (potassium chloride and a paralytic agent) that are known to result in significant and severe pain when administered. The scientific literature and my professional experience also establishes that acute pulmonary edema is a severely painful condition. Scientific evidence from autopsies demonstrates that inmates subjected to a lethal injection protocol that involves large doses of IV-injected midazolam will be sure or very likely to develop acute pulmonary edema. It is a generally accepted consensus among practitioners such as myself that midazolam is a sedative that, by its pharmacology, is incapable of treating pain, at any dose. There is a wealth of literature from the ICU population of unconscious patients experiencing significant, sometimes severe, pain. Indeed, ICU practitioners are admonished, as a scientific principle, to assume that all unconscious patients are capable of feeling pain when exposed to noxious or painful stimuli such as the injection of potassium chloride or the development of pulmonary edema. That literature and the scientific application of it in the medical context is helpful to establishing the same principle will apply to the inmate in a lethal-injection execution context; the science beneath it all remains consistent regardless of the context. Thus, as a matter of applying scientific principles to the execution context, the condemned inmates will be sure or very likely to suffer severe pain and suffering during their executions unless they are made insensate. Midazolam, however, is incapable of producing insensation.
>
> Thus, it is my professional opinion to a reasonable degree of medical and scientific certainty that individuals exposed to the triple drug lethal injection cocktail of IV-injected, large doses of midazolam, potassium chloride, and a paralytic agent like Ohio uses will be sure or very likely to remain sensate throughout the procedure, and

> therefore sure or very likely to experience significant pain and suffering prior to cardiac arrest and death.

(ECF No. 1948, PageID 76180-81.) His direct testimony was consistent.

Dr. Exline also filed a rebuttal expert report in response to the expert reports filed by Defendants' expert witnesses, to wit: Dr. Buffington, Dr. Antognini, and Dr. Davis.[26] (ECF No. 2001.) In that rebuttal report, Dr. Exline reiterated that "[a]utopsy cases of inmates subjected to execution using IV midazolam have a high prevalence of pulmonary edema." (ECF No. 2001, PageID 94330.) Noting that the reports of both Dr. Davis and Dr. Antognini conceded the association between midazolam overdoses and pulmonary edema, Dr. Exline opined that "[t]he fact that other medications may also result in pulmonary edema does not exculpate the role of midazolam in the autopsies referenced." *Id*. He reiterated that patients with pulmonary edema will experience pain, and that midazolam is not an analgesic agent. Dr. Exline thus stated that the opinion of Dr. Antognini that midazolam makes patients insensate to pain are "not consistent with the science and the medical consensus concerning midazolam." (ECF No. 2001, PageID 94330.)

Dr. Exline noted that Dr. Antognini conceded that, according to *Miller's Anesthesia*, benzodiazepines lack analgesic properties. Miller's is a text acknowledged to be the authoritative text in anesthesiology by every expert witness who was asked. (ECF No. 2001, PageID 94330.) With respect to Dr. Antognini's references to the use of midazolam for endotracheal intubation as evidence of midazolam's analgesic effects, Dr. Exline opined that endotracheal intubations can be potentially uncomfortable but may not be painful for most. In support of that opinion, Dr. Exline pointed to a YouTube video by Dr. Michael Bailin of Dr. Bailin intubating himself that Dr. Exline shows to his students every year. Dr. Exline concluded that "[t]he fact that midazolam facilitates

[26] Because this Court struck the Report and barred proposed testimony of Dr. Buffington, the Court will not address any of the rebuttal opinions that Dr. Exline expressed as to Dr. Buffington. *See* ECF No. 2112, PageID 103931-32.

endotracheal intubation is not proof that it has analgesic effects." *Id*. With respect to Dr. Antognini's opinion that midazolam can be used to treat the discomfort of pulmonary edema, Dr. Exline testified that the studies – Bosomworth and Dominguez, et al. – that Dr. Antognini referenced do not advocate the use of benzodiazepines to protect an individual against experiencing pulmonary edema. *Id*. at PageID 94331-32.

Dr. Exline next turned to the assertion by Defendants' experts that patients who are "unconscious" are unable to feel pain. (ECF No. 2001, PageID 94332.) He took issue with the "loose" use of the term "unconscious" and failure to define that term, stating this opinion "is inconsistent with current scientific understanding as shown in medical practice for comatose or unresponsive patients, which advocates for assessment for pain even if in deep coma." *Id*. "It is also inconsistent," Dr. Exline continued "with the neuroscience literature which demonstrates that even outwardly unresponsive patients can manifest changes in their brain wave activity, via electroencephalogram (EEG) when exposed to painful stimuli, demonstrating continued sensation." *Id*. In the execution context, according to Dr. Exline, "an inmate given only midazolam may be outwardly 'unconscious' by visible appearance (he looks to be 'asleep'), or may not respond to the consciousness checks that Defendants conduct, but since midazolam cannot produce insensation, the inmate will be sure or very likely to remain sensate nevertheless." *Id*. at PageID 94333.

Dr. Exline next took issue with Dr. Antognini's suggestions that a patient would need to be awake in order to experience air hunger. He stated that that opinion is not consistent with any of his extensive experience as a critical care provider. (ECF No. 2001, PageID 94333.) Dr. Exline pointed to evidence of unresponsive patients, and some inmates during IV midazolam executions, showing rapid breathing, labored breathing, and use of accessory muscles (those not normally

needed for breathing). *Id*. at PageID 94333-34. He concluded that Dr. Antognini's speculative theory does not stand up to the actual science involved. *Id*. at PageID 94334.

Report and Testimony of David L. Greenblatt, M.D.

David J. Greenblatt, M.D., is a professor of anesthesiology at Tufts University School of Medicine and a Board-certified clinical pharmacologist. (ECF No. 1956, PageID 84173-74.) In addition to his training and work experience, Dr. Greenblatt is arguably the preeminent scholar on the pharmacological effects of benzodiazepines, including midazolam. He co-authored C.A. Naranjo *et al.*, *A method for estimating the probability of adverse drug reactions*, CLINICAL PHARMACOLOGY AND THERAPEUTICS 30: 239-245 (1981), which has been cited in more than 8000 subsequent scholarly works.[27] Dr. Greenblatt has also authored hundreds of articles about benzodiazepenes generally, and more than thirty scholarly articles about midazolam specifically (Hrg. Tr., ECF No. 2113, PageID 104168-69), including J.G. Reves., *et al.*, *Midazolam: Pharmacology and Uses*[,] ANESTHESIOLGY 62(3): 239-245 (1985), which has been cited more than 1100 times.[28] *Id.* Much of his research on the pharmacokinetics and pharmacodynamics of midazolam occurred during the early 1980s as part of a New Drug Application ("NDA") for midazolam that was submitted to the United States Food and Drug Administration ("FDA") during that time period (ECF No. 1956, PageID 84180-81.)

In his testimony, which was consistent with his Reports, Dr. Greenblatt stated that, as part of the NDA, he had devised a method for analyzing midazolam in the blood, which he then applied

[27] Google Scholar, David J. Greenblatt, https://scholar.google.com/citations?user=IBsLHTcAAAAJ&hl=en&oi=sra (last accessed December 17, 2018).

[28] *Id*.

to numerous clinical studies with the drug. (Hrg. Tr., ECF No. 2113, PageID 104172-73.) Among the drug's original and intended uses was to provide "the starting point so you can transition to actual anesthesia." However, "it's not midazolam producing anesthesia, it's the initial stage of induction." *Id*. at PageID 104174-75. On cross-examination, he reiterated that "midazolam and benzodiazepines can be used at the initial stage of the anesthesia process in which people are made calm and sedate, and to reduce the patient's anxiety, so that they will accept the next step[.]" *Id.* at PageID 104252. Consequently, the FDA did not approve, and has never approved, midazolam for use as an anesthetic. *Id*. at PageID 104175.

Dr. Greenblatt stated his agreement with the reports of other experts on the painful effects of the paralytic and potassium chloride, the second and third drugs, respectively, in Ohio's lethal injection protocol. (ECF No. 1956, PageID 84182-84.) Moreover, he opined that midazolam "shares the same pharmacologic properties as the other benzodiazepines, including that it has no analgesic (pain-blocking) characteristics, and that it cannot suppress consciousness to the point at which the person becomes unconscious and insensate together." *Id*. at PageID 84185. If a patient were sensate at the time the paralytic was injected, it would be "pain and suffering clustered together[,] . . . a very, bad horrifying experience," as the paralysis would be "essentially the same as suffocation. In order to get oxygen into their lungs, they would try to breathe, but the muscles wouldn't work." (Hrg. Tr., ECF No. 2113, PageID 104180-81.) Dr. Greenblatt continued that, if an inmate was sensate for the injection of potassium chloride, "an extremely noxious, caustic agent which causes great pain on injection[,]" it would feel as though fire was being poured into his veins. *Id*. at PageID 104181. This pain is not comparable to that felt during an endotracheal intubation (a procedure in which midazolam has been used without the assistance of another drug), and an inmate was "sure or very likely" to suffer severe pain from the administrations of the second

and third drugs in the protocol. *Id*. at PageID 104183. Moreover, suppression of consciousness to the level of sedation possible with midazolam alone would not be sufficient to shield an inmate from surely or very likely experiencing that pain. *Id*. at PageID 104183-84.

Dr. Greenblatt continued that the only way to ensure that an individual was made insensate or sufficiently unconscious from the pain would be to induce "[a] depth of sedation consistent with general anesthesia," or "to administer specific analgesics, antipain medication such as opiates." (Hrg. Tr., ECF No. 2113, PageID 104185-86.) He emphasized that, due to the chemical nature of the drug, midazolam "does not have analgesic properties at any dose." *Id*. at PageID 104187. Rather, midazolam is a "facilitator" that allows Aminobutyric, an inhibitory neurotransmitter, to attach to GABA receptors in a cell. This attachment, in turn, opens a cell's "chloride channel" and allows a greater number of chloride ions to enter a cell, which induces sedation in a person (ECF No. 1956, PageID 84185-86.) Midazolam increases the *frequency* with which the chloride channels open. However, unlike a barbiturate or general anesthetic drug, it does not affect the *duration* for which those channels are open. *Id*. at PageID 84186. "That means there is a limit on how much chloride can enter the cell. That means there is a limit on how much sedation a benzodiazepine can cause. This is termed the maximum effect. Once the maximum is reach [*sic*], additional doses—even when very large—will not produce additional sedation." *Id*.

Indeed, Dr. Greenblatt wrote, "studies demonstrate there is a point in the range of 15-40 mg at which there is no further sedative effect created by additional doses of midazolam." (ECF No. 1956, PageID 84191). These studies showed both that the "maximum sedative effect occurs somewhere in that 25-40 mg dosage range[,]" and that "there was an average delay in onset of up to 20 minutes, or possibly more, to reach whatever midazolam's maximum effect was." *Id*. *citing* David J. Greenblatt *et al., Kinetics and EEG effects of midazolam during and after 1-Minute, 1-*

Hour, and 3-Hour intravenous infusions, J. CLINICAL PHARMACOLOGY 44: 605-11 (2004); M. Bührer *et al.*, *Electroencephalographic effects of benzodiazepines*, CLINICAL PHARMACOLOGY & THERAPEUTICS 48: 544-54 (1990); David J. Greenblatt *et al.*, *Pharmacokinetic and Electroencephalographic study of intravenous diazepam, midazolam, and placebo*, CLINICAL PHARMACOLOGY & THERAPEUTICS 45: 356-65 (1989). Dr. Greenblatt authored an article based on cases of almost one hundred patients who had presented at Massachusetts General Hospital between 1962 and 1975 for benzodiazepine overdoses (Hrg. Tr., ECF No. 2113, PageID 104188-89, *citing* David J. Greenblatt *et al.*, *Acute overdosage with benzodiazepine derivatives*, CLINICAL PHARMACOLOGY & THERAPEUTICS 21(4): 497-514 (Apr. 1977)). He also discussed three other articles on which he was a co-author regarding benzodiazepine overdoses. *Id*. at PageID 104190-104192 (citations omitted). Based upon that research and expertise, he strongly disputed the notion that we could not know what the effect of injecting 500 mg of midazolam into an individual would be, "[b]ecause we actually have extensive experience with overdosage of other benzodiazepines, and since all the drugs in this class act on the brain in the same way[.]" *Id*. atPageID 104192. The findings from these studies, Dr. Greenblatt testified, are uniform: when an individual "take[s] a benzodiazepine alone, *no matter how big the dose is*, they get sleepy for a while, they're somnolent, you can still rouse them, and then they wake up and they're fine, uniform experience." *Id*. at PageID 104193 (emphasis added). Given that experience with other, nearly identical drugs, Dr. Greenblatt opined that "it's totally reasonable to extrapolate that to midazolam even though obviously midazolam . . . at doses of five hundred milligrams [h]as never been the subject of a research study." *Id*. On cross-examination, he reiterated that there were no studies connecting overdoses midazolam and pulmonary edema, because "you couldn't possibly do such a study." *Id*. at PageID 104243.

Dr. Greenblatt derived his opinion from "hav[ing] been personally involved in conducting studies involving patients who were hospitalized because of benzodiazepine overdosage." (ECF No. 1956, PageID 84191-92, *citing* M. Divoll, *Benzodiazepine Overdosage: Plasma Concentrations and Clinical Outcome*, PSYCHOPHARMACOLOGY 73: 381-383 (1981); M. Divoll, *Pharmacokinetic Study of Lorazepam Overdosage*, AM. J. PSYCHIATRY 137: 11 (Nov. 1980); David J. Greenblatt *et al.*, *Rapid Recovery From Massive Diazepam Overdose*, J. OF AM. MED. ASS'N 240(17) (Oct. 20, 1978); Greenblatt, D.J., et al., *Acute Overdosage with Benzodiazepine Derivatives*, CLINICAL PHARMACOLOGY AND THERAPEUTICS 21(4): 497-514 (Apr. 1977).) The studies evaluated patients using "the Lawson Mitchell sedation scale, which grades sedation and Central Nervous System (CNS) depression on a scale of 1 to 4. Levels 1 and 2 involved patients that remained more alert, with only slight levels of sedation, while the more serious levels of sedation were Levels 3 and 4." *Id*. at PageID 84192. "The findings from those studies are all consistent. . . . [O]verdoses of benzodiazepines alone seldom if ever got to a sedation level of 3 or 4. Those that reached a Level 3 or 4 had taken other drugs in addition to the diazepam." *Id*.[29]

In addition to the existence of a maximum or "ceiling" effect of midazolam as to its ability to sedate an individual, Dr. Greenblatt noted that "[a]mong those properties that midazolam shares with other benzodiazepines is that it has no analgesic (pain-blocking) characteristics[.]" (ECF No. 1956, PageID 84185.) "It does not have the chemical properties such that it can act on pain receptors. It acts on the benzodiazepine receptors, not pain receptors like opioids do." *Id*. Midazolam, like other sedatives, "has an amnestic effect, which causes you to forget information acquired or experiences occurring after you have been given the drug." *Id*. at PageID 84187. "It

[29] While these studies did not examine midazolam specifically, as it was not yet commercially available, neither Dr. Greenblatt nor any expert offered by Defendants has suggested that midazolam has properties distinct from those of diazepam or other benzodiazepines, such that the findings from those earlier studies would not be applicable to midazolam.

also has an anxiolytic effect, which is helpful as a pre-medication to calm people down, such as before a surgery when they might have very high anxiety." *Id.* It may be used to achieve light sedation, such that the medical professional may then begin "the process of general anesthesia to proceed through administration of other drugs or inhaled anesthetic gases." *Id.* Thus, while it may be classified as an anesthesia *induction agent*, *id.*, "it does not have the ability to so deeply sedate someone to the level of unconsciousness at which there is an associated occurrence of insensation such that a person will fail to be aroused by noxious stimuli such as those caused by the drugs in Ohio's execution protocol." *Id.* at PageID 84188. This is the case because of the nature of the drug; "*no matter what dose is given*," Dr. Greenblatt averred, midazolam lacks "the ability to so deeply sedatsomeone to the level of unconsciousness at which there is an associated occurrence of insensation such that a person will fail to be aroused by noxious stimuli such as those caused by the drugs in Ohio's execution protocol." *Id.* (emphasis added).

Dr. Greenblatt opined that midazolam's above-described characteristics and limitations mean that an inmate "will be sure or very likely to experience the severe pain and suffering caused by the three drugs in the three-drug midazolam protocol." (ECF No.1956, PageID 84189.) He claimed that to avoid such pain and suffering requires either induction of analgesia or suppression of "consciousness so deeply to the level at which unconsciousness and insensation occur together." Importantly, Dr. Greenblatt testified, midazolam can achieve neither of those. *Id.* at PageID 84214; *see also id.* at PageID 84216 ("I could not disagree more strongly with the conclusions reached by Dr. Antognini that midazolam, or any other benzodiazepine, has analgesic properties.").

Dr. Greenblatt further opined that it is "sure or very likely" that the "large volume of IV injected midazolam[,]" specifically, "the acidity of the solution," was causing pulmonary edema

in inmates who were injected with overdoses of midazolam. (Hrg. Tr., ECF No. 2113, PageID 104198-99.) He noted that midazolam must be "buffered into an acidic pH range of 3.0 to 3.5" to make the solution water soluble and, thus, suitable for injection. (ECF No. 1956, PageID 84187; Hrg. Tr., ECF No. 2113, PageID 104199.) However, making the midazolam water soluble causes the solution to become polar charged, which means "it cannot get across the blood/brain barrier . . . until the solution is buffered by the blood" (Hrg. Tr., ECF No. 2113, PageID 104201), at which point the drug will become lipid soluble, cross the blood-brain barrier, bind to receptors, and induce sedation. *Id*. When given in a therapeutic dose of between one and two milliliters of solution, which contains between five and ten grams of midazolam, the solution is quickly buffered back to a neutral pH without any discomfort to a patient or damage to his organs, tissue, or blood vessels. (ECF No. 1956, PageID 84199.) However, a dosage of approximately 100 milliliters (containing approximately 500 milligrams of midazolam), as required by Defendants' protocol, makes "all the difference in the world[.]" (Hrg. Tr., ECF No. 2113, PageID 104207.)

> [I]t will take at least a few circulations for that acid to mix and get buffered back to a 7.4 pH. As a result, the unbuffered acidic midazolam will immediately begin causing irritation and damage to the pulmonary capillaries and lung tissues, and that tissue damage is likely to persist even after the pH has been buffered back to 7.4.
>
> That also means that it will take at least a few circulations for the imidazole ring to close, at which point the drug can finally cross the blood-brain barrier and begin to act on the brain.

Id. at PageID 84199-200; Hrg. Tr., ECF No. 2113, PageID 104201.

As soon as "[t]he midazolam is injected, the acid goes to the lung, lung injury starts immediately, and [inmates] develop pulmonary edema." (Hrg. Tr., ECF No. 2113, PageID 104203.) Until the imidazole ring closes, the acidic solution is continuing to flow from the heart into the lungs, weakening the capillaries and tissues. This in turn, causes the lungs to fill with

fluid—*i.e.*, pulmonary edema. As the tissue damage is not immediately reparable, an individual's lungs continue to fill with fluid even after the midazolam solution neutralizes and crosses the blood-brain barrier. *Id*. at PageID 104204-05. Moreover, the damage produced by the pulmonary edema—and the consequent pain and suffering—cannot be repaired prior to the inmate dying from the second and third drugs, even if the "dose of midazolam is ultimately buffered back to neutral pH within two minutes[.]" *Id*. at PageID 104208. The damage to the lungs from pulmonary edema is "sure or very likely" to cause severe pain and suffering, to which the inmate will remain sensate, including but not limited to "pain in the chest . . . gasping for breath. There's a feeling of you need to breathe[,] but you can't, the feeling of drowning or suffocation." *Id*. at PageID 104209.

Compounding matters, "[t]he sedative effect of midazolam will be delayed during that buffering process as well." (ECF No. 1956, PageID 84200.) While there are no studies on how long it would take 500 milligrams of midazolam to buffer sufficiently for peak sedative effect, a 1989 study conducted by Dr. Greenblatt concluded, "a 9 mg dose did not reach peak sedative effect for 15 minutes. The 500 mg dose of midazolam is approximately fifty times larger[.]" *Id*. at PageID 84196, *citing* David J. Greenblatt *et al.*, *Pharmacokinetic and Electroencephalographic study of intravenous diazepam, midazolam, and placebo*, CLINICAL PHARMACOLOGY & THERAPEUTICS 45: 356-65 (1989). Dr. Greenblatt continued that, even if one were to make the dubious assumption that an overdose of that magnitude would not delay peak sedative effect beyond fifteen minutes, *see id*. ("It is my expert opinion . . . that it is sure or very likely that such a large volume of midazolam will cause a delay in the onset of peak sedative effect"), the speed with which Ohio administered the protocol with respect to Otte, Phillips, and Van Hook meant that the inmates always felt the pain from the paralytic prior to peak sedative effect:

> [I]t appears that the State is injecting the 100 m[L] (500 mg) of midazolam rather quickly; 1:49 from the start of the first injection

> to the completion of the midazolam injections for Phillips, 2:24 for Otte, and 2:29 for Van Hook. It also appears that the State is finishing (let alone starting) its potassium chloride injections rather quickly after it finishes the injection of midazolam; 7:14 for Phillips, 8:26 for Otte, and 8:19 for Van Hook.

Id. Thus, even if the overdose of midazolam worked as intended, without any side effects such as pulmonary edema, the drug would not—indeed, could not—provide peak sedation against "the suffocating effects of the paralytic drug; or from the severe burning upon rapid injection of a large dose of potassium chloride." *Id*.

Dr. Greenblatt concluded that, far from fulfilling its intended purpose of blocking the "severe pain" that would be felt by "a person who is fully conscious" upon injection of the paralytic and potassium chloride, *Fears v. Morgan*, 860 F.3d at 886, an inmate injected with the midazolam solution "is sure or very likely to suffer the pain and suffering of acute pulmonary edema. Having experienced that severe pain and suffering, the inmate will further experience the severe pain and suffering associated with the second and third drugs of the protocol." (ECF No. 1956, PageID 84201; Hrg. Tr., ECF No. 2113, PageID 104213-14.) Further, he opines that "that volume of acid being injected into the veins can be experienced as burning pain, causing sensations like being on fire." *Id*. Dr. Greenblatt then discussed the autopsy and eyewitness reports of other executions using midazolam that he had reviewed, and concluded that:

> Either the autopsy results confirmed the inmate suffered pulmonary edema during the execution, or eyewitness accounts offer compelling evidence that the inmates were not insensate, or both. At worst, the other executions neither support nor undermine my opinions. Any assessment that these executions were problem-free is incorrect as a matter of indisputable scientific fact.

Id. at PageID 84210.

Finally, Dr. Greenblatt sought to clarify this Court's previous finding that 500 mg of midazolam "appears to be sufficient to suppress consciousness to the extent that an inmate will not

respond to the consciousness checks used by emergency medical technicians and used by [Defendants]." *In re Ohio Execution Protocol Litig. (Campbell & Tibbetts)*, 2017 U.S. Dist. LEXIS 182406, *56. "While that may be true, . . . that does not mean he is unable to feel the stimulus being applied. It simply means his consciousness is depressed to the point where he cannot convey what he is feeling." (ECF No. 1956, PageID 84212-13.) In other words, an inmate's unresponsiveness to consciousness checks indicates nothing about whether he is experiencing pain after receiving midazolam, and, he opined, inmates "will still feel pain associated with the noxious stimuli[.]" (Hrg. Tr., ECF No. 2113, PageID 104218.)

On November 19, 2018, Dr. Greenblatt filed a rebuttal report, "reaffirm[ing] the statements and opinions expressed in my previously submitted expert report." (ECF No. 2003, PageID 94517.) He argued that Dr. Antognini's assertion that midazolam can be used by itself in a "painful clinical procedure," *i.e.*, endotracheal intubation, "incorrectly equates th[at] discomfort . . . with the severe pain and suffering associated with Ohio's execution drugs[,]" which "is on a different level than that associated with endotracheal intubation." *Id*. at PageID 94519, *quoting* Antognini Report, ECF No. 1983, PageID 88446. He also claimed that Dr. Antognini's statement that "the fact midazolam by itself might not be the first choice for an otherwise painful clinical procedure does not lessen in anyway [sic] its proven ability to be used for such procedures" (Antognini Report, ECF No. 1983, PageID 88446) (emphasis removed), distorts the underlying science and medical consensus "that midazolam by itself does not have clinically meaningful analgesic properties, and does not by itself produce an insensate condition. (ECF No. 2003, PageID 94520.)

Dr. Greenblatt also "disagree[d] adamantly with Dr. Antognini's conclusions" that midazolam could induce a state of unconsciousness sufficient to produce insensation. (ECF No. 2003, PageID 94521, *citing* Antognini Report, ECF No. 1983, PageID 88446.) He did not dispute

that "midazolam can . . . cause sedation on a range of levels, and to the extent that Dr. Antognini is using the term 'unconsciousness' to mean a state within the range of sedation levels, then he is correct that midazolam can create that state." *Id*. However, "there is no scientific evidence that validly supports Dr. Antognini's novel theory that midazolam at a 500 mg dose suddenly acquires scientifically relevant analgesic properties so as to be able to shield the condemned inmate from the horrific, severe pain" associated with the execution protocol. *Id*. at PageID 94521-22. On cross-examination, Dr. Greenblatt conceded that "you can perhaps apply [midazolam] to an isolated spinal cord and find antinociception." (Hrg. Tr., ECF No. 2113, PageID 104234.) However, he clarified that the only studies finding antinociception had occurred in the laboratory, rather than clinical, context, on animals. More importantly, antinociception occurred only when midazolam was injected directly into the brain of the animal subjects. *Id*. at PageID 104234, 104258-59.

The Court, in evaluating and assessing Dr. Greenblatt's reports and testimony, takes particular note of his *curriculum vitae*, ECF No. 1956-1, which denotes nearly one thousand peer-reviewed articles that he has authored or co-authored on benzodiazepines, and of the fact that he has studied midazolam for almost as long as it has existed. The Court accepts that the findings from studies of benzodiazepine overdoses conducted by Dr. Greenblatt and others are readily applicable to midazolam, and that those findings permit him to testify with a reasonable degree of medical and scientific certainty as to what an injection of 500 milligrams of midazolam is likely to do or not do, even though no study has been—or could be—done to test such hypotheses by injecting test human subjects with 500 milligrams of midazolam. The Court also agrees that the studies showing midazolam producing antinociception in some animals are inapposite, as those involve intrathecal injections of midazolam, which are not possible (nor ethically acceptable) with

respect to Henness.

Report and Testimony of David A. Lubarsky, M.D.

Plaintiff then presented the testimony of David Lubarsky, M.D., M.B.A., who is a board-certified anesthesiologist and also certified in pain management by the American Academy of Pain Management. (ECF No. 1952, PageID 80845.) Dr. Lubarsky earned his B.A. and M.D. at Washington University. He completed his internship at the Westchester County Medical Center in 1985, and his residency in the anesthesiology department at the New York University Medical Center in 1987. Thereafter, he served as vice-chair of the Department of Anesthesiology at Duke University Medical Center from July 1988 to November 2001. From 2001 to 2018, he was a professor of anesthesiology and chair of the Department of Anesthesiology at the University of Miami Miller School of Medicine in Florida. (Hrg. Tr., ECF No. 2113, PageID 104266.) He is Currently the Vice Chancellor for Human Health Sciences and the CEO of University of California at Davis Health in Sacramento, California. *Id*. at PageID 104264.

Dr. Lubarsky's Report summarizes his opinions, held to a reasonable degree of medical certainty, that:

1. Ohio's execution protocol is sure to cause severe pain and needless suffering from the intravenous administration of 500 mg of midazolam which will trigger pulmonary edema, a terrifying and painful condition during which the inmate will remain sensate. Furthermore, the midazolam will fail to protect the inmate from the horrifying paralysis and excruciating pain associated with the second and third drugs;

2. Administration of an analgesic agent or a drug that will make the prisoner so deeply sedated that he is fully unconscious and insensate is required to protect the inmate from the severe pain and needless suffering associated with the three drugs in Ohio's

protocol. Midazolam is not suitable or appropriate to do so as it will not cause the inmate to become insensate and unconscious in the face of noxious stimuli;

3. Intravenous administration of 500 mg of midazolam is sure or very likely to leave the inmate sensate and not fully unconscious;

4. As a matter of scientific consensus, midazolam has no analgesic properties and there are no well-regarded published scientific reports finding any analgesic effect of midazolam in the medical literature;

5. As a matter of scientific consensus, midazolam cannot render the inmate insensate by suppressing his level of consciousness to a depth at which he is both unconscious and insensate; it simply is not that powerful;

6. Midazolam has a ceiling effect beyond which any more of the drug will not create any greater sedative effect on the body. It also has a peak effect level beyond which the drug has reached the maximum effect the drug can achieve, but which will not render the inmate sufficiently insensate and unconscious to noxious stimuli;

7. Intravenous administration of 500 mg of midazolam initially produces a level of unconsciousness such that he does not appear to respond to the so-called consciousness checks in Ohio's protocol, but which is insufficient to protect the inmate from the severe pain and needless suffering associated with the drugs specified in the protocol;

8. It is sure or very likely that the pulmonary edema caused by midazolam will overcome the drug's peak sedative effect, causing the inmate, who is sure or very likely to remain sensate, to feel and experience the severe pain and needless suffering caused by the midazolam;

9. The other noxious stimuli associated with Ohio's protocol drugs, from suffocation and oxygen deprivation caused by the paralytic and the scorching pain of the potassium chloride, will overcome midazolam's peak sedative effect, leaving the inmate sensate to the full brunt of the severe pain and suffering from the second and third drugs in the protocol.

> 10. The reports of inmates' movements, actions, and other occurrences in previous executions must be assessed with the understanding that they were sure or very likely beginning to experience pulmonary edema almost immediately after the first injection of midazolam, as demonstrated by the overwhelming majority of autopsy reports from those executions;
>
> 11. His opinions reflect the general scientific consensus about midazolam's limitations, as well as application of valid scientific principles to determine that scientific consensus applied in the context of an execution;
>
> 12. Intravenous administration of 500 mg of midazolam will not protect the inmate from experiencing the full brunt of the severe pain and suffering associated with each of the three drugs in Ohio's lethal injection protocol because the inmate will be sure or very likely to experience the severe pain and horrible suffering associated with the execution drugs.

(*See* ECF No. 1952, PageID 80846-50.)

To support his stated expert opinions, Dr. Lubarsky explained that midazolam is a short-acting benzodiazepine primarily used to treat anxiety and in the clinical setting prior to the induction of anesthesia to sedate and relax the patient, and to block the formation of traumatic memories during surgery. (ECF No. 1952, PageID 80852.) It has no analgesic properties as it does not act on analgesic receptors. *Id*. at PageID 80852, 80859, 80862. Nor can midazolam suppress consciousness to the point at which a person would be fully unconscious and insensate to pain. *Id*. at PageID 80853. Thus, it is not a suitable drug with which to induce and maintain an unconscious, insensate state. *Id*. Furthermore, since midazolam has no analgesic effect, it is not approved by the FDA for use "to produce and maintain insensation in minor surgical procedures and is never used as the sole agent to produce insensation in a procedure that involves any noxious stimuli." *Id*., *citing* J.G. Reves, Robert J. Fragen, H. Ronald Vinik, David J. Greenblatt, *Midazolam; Pharmacology and Uses*, 62 ANESTHESIOLOGY, 310-24 (1985). Although midazolam can render most people "unconscious to the external environment, . . . that is only true so long as

there are no competing ambient stimuli that cause pain or discomfort." (Hrg. Tr., ECF No. 2113, PageID 104304.) As Dr. Lubarsky pointed out, however, "when looking at the healthy volunteer studies, up to thirty percent of people administered large doses of midazolam up to . . . and exceeding the ceiling effect never went to sleep." *Id*. In any case, it is the consensus of the medical and scientific communities that 500 mg of midazolam will "absolutely not" render a person insensate or unconscious to the depth of anesthesia, and no studies show that midazolam can suppress consciousness to the point of insensation. *Id*. at PageID 104304-05, 104314.

Unlike barbiturates such as pentobarbital, midazolam has a ceiling effect which limits its ability to achieve the level of unconsciousness and insensation that can be achieved with a barbiturate. (ECF No. 1952, PageID 80854, 80859.) Dr. Lubarsky explained that midazolam acts on the GABA receptors[30] whereas a barbiturate such as pentobarbital does not depend on the presence of GABA to produce sedation to such a depth that the person is fully unconscious and insensate to noxious stimuli. *Id*. Absent available GABA with which to bind, midazolam will have no direct effect. *Id*. The necessity of GABA for midazolam to have its effect also explains how, when the limited amount of GABA has been bound with midazolam, the drug has no increase in the depth of sedation; it has reached its ceiling. *Id*. at PageID 80854-55; Hrg. Tr., ECF No. 2113, PageID 104287. According to Dr. Lubarsky, the existing data suggests that midazolam's ceiling effect is probably apparent at 20-25 mg and reaches the asymptote at about 40-45mg. (Hrg. Tr., ECF No. 2113, PageID 104288.) He noted that the upper limit of the dosing range from the drug manufacturer for a 70 kg man would be 42 mg, using the drug manufacturer's upper limit of the dosing range, 0.6 mg/kg, as a guide. *Id*. There is no recommendation to give any higher dose

[30] In a previous hearing in this consolidated litigation, Dr. Stevens testified in great detail as to the interaction between midazolam and gamma-Aminobutyric acid, or GABA, and the difference between that and the interaction between pentobarbital and GABA. *In re: Ohio Execution Protocol Litigation*, 235 F.Supp.3d at 910-12.

than that since it is believed that midazolam reaches its ceiling at or near that dosage. *Id*. Dr. Lubarsky acknowledged that midazolam can cause sedation sufficient to depress the level of consciousness, but not to the depth of unconsciousness required to render a person insensate to noxious stimuli. *Id*. at PageID 80855, 80859. The maximum effect of midazolam is short of rendering a person unconscious, insensate, and immobile for a noxious procedure. *Id*.; Hrg. Tr., ECF No. 2113, PageID 104285.

Aside from the recognized and severe pain caused by the second and third drugs of Ohio's execution protocol, midazolam itself is highly acidic, and while that is not problematic when the drug is used in therapeutic doses, at the dosage used in the protocol, it may cause severe burning pain upon injection. (ECF No. 1952, PageID 80855-56.)

Dr. Lubarsky stated that because the dosage of midazolam is so large, the blood is unable to rapidly buffer its acidity. (ECF No 1952, PageID 80856.) Traveling from the injection site to the heart and then directly to the lungs, the drug's acidity will quickly cause damage to the tiny blood vessels in the lungs and in the lung membranes. *Id*. Once that happens, the lungs will begin to fill with fluids, causing the inmate to feel as if he were drowning. *Id*. The process just described is called acute pulmonary edema, and it is "extremely horrifying and painful." *Id*. at PageID 80856, 80862. Dr. Lubarsky likened it to waterboarding. *Id*. The suffering caused by pulmonary edema has been shown through inmates' struggling during their executions in spite of the high doses of midazolam. *Id*. at PageID 80862.

At the hearing on Henness' motion for a preliminary injunction, Dr. Lubarsky testified that he was unaware that an overdose of midazolam would cause pulmonary edema until fairly recently (Hrg. Tr., ECF No. 2113, PageID 104290.) He knew that midazolam is a calming drug, so the inmates should not have exhibited pulmonary symptoms such as barking coughs, snorting, heaving

chests, and discomfort during the executions, but many did. *Id*. When the autopsies revealed pulmonary edema in twenty-four out of twenty-eight inmates, however, "it made total sense." *Id*. Dr. Lubarsky opined that, to a reasonable degree of medical certainty, an inmate intravenously injected with 500 mg of midazolam has an "extremely high likelihood that ninety percent of them would [develop pulmonary edema], yes." *Id*. at PageID 104290-91.

Dr. Lubarsky's account of the effects of 500 mg of midazolam on the lungs can explain the many cases of pulmonary edema found during autopsies of inmates who have been executed using midazolam as the first drug. *Id*. at PageID 80857. The autopsy reports of those inmates indicated fluid and froth in a majority of the their lungs. *Id*. at PageID 80862. Dr. Lubarsky explained that it is certain that the pulmonary edema was caused by the administration of the high dose of midazolam because in order for the body to form froth in the fluid, the person must be breathing. *Id*. at 80862-63. But the inmates' breathing would have stopped when the paralytic was administered, meaning that the froth must have formed prior to administration of that drug. *Id*. The result is that the inmate drowns in his own fluids, which is "painful . . . incredibly uncomfortable . . . extremely uncomfortable." *Id*.; Hrg. Tr., ECF No. 2113, PageID 104291-92. In addition, "because the molecular structure of midazolam means it cannot cross the blood-brain barrier while still in acid solution, . . . the condemned prisoner will experience a delayed onset of sedation, even while he is experiencing the burning from [the midazolam] injection and the rapidly progressing pulmonary edema." *Id*. at PageID 80856. Dr. Lubarsky expressed his expert opinion, to a reasonable degree of medical certainty, that a prisoner who suffers from pulmonary edema caused by the intravenous injection of 500 mg of midazolam will experience severe pain and needless suffering. (Hrg. Tr., ECF No. 2113, PageID 104292.)

Dr. Lubarsky opined that although Henness may not respond to the consciousness checks used in the Ohio execution protocol, he will not be insensate when the paralytic is injected. *Id*. Administration of the second drug, the paralytic rocuronium bromide, will cause the inmate to experience "a sensation akin to being buried alive as the paralytic takes effect and his breathing musculature is paralyzed." (ECF No. 1952, PageID 80857.) Furthermore, the paralytic will render him unable to communicate the pain he is experiencing even as that pain causes his level of consciousness to be aroused. *Id*. Dr. Lubarsky testified at the hearing that after injection of the paralytic the inmate would still be alive, but "chemically buried alive." (Hrg. Tr., ECF No. 2113, PageID 104293.)

The third drug used in Ohio's protocol, potassium chloride, "is a caustic chemical that will cause excruciating pain upon injection to any condemned prisoner who has not been made or kept insensate." (ECF No. 1952, PageID 80858.) According to Dr. Lubarsky, "the only way to prevent the condemned prisoner from being subjected to severe pain and needless suffering associated with those drugs is to make sure he is insensate during that time." *Id*. at PageID 80858. And the only way to assure the inmate will be spared the severe pain and suffering inherent in Ohio's protocol is to administer an analgesic drug, in which case "the level of unconsciousness is not nearly as important." *Id*. at PageID 80861.

Dr. Lubarsky explained that potassium chloride is used when an animal which has been a research subject is euthanized, and that the American Veterinary Association's detailed instructions on protecting animals from unnecessary pain and suffering during euthanization requires that the animal be in a surgical plane of anesthesia. (Hrg. Tr., ECF No. 2113, PageID 104275.) In addition, that level of anesthesia must be verified and documented by someone trained in the delivery of surgical anesthesia. *Id*. Because midazolam has no analgesic properties and

"potassium chloride is among the most caustic of chemicals" to use, veterinarians cannot use midazolam to anesthetize an animal prior to administration of potassium chloride when euthanizing the animal. (Hrg. Tr., ECF No. 2113, PageID 104295.)

Dr. Lubarsky opined to a reasonable degree of medical certainty that an inmate injected with 500 mg of midazolam and to whom potassium chloride was then administered would suffer serious, severe pain and needless suffering. *Id*. at PageID 104302-03. He further testified that it is "fairly certain" that the pain caused by the rapid administration of potassium chloride would awaken the inmate and cause him to regain consciousness because midazolam has no analgesic properties and is incapable of tempering the experience of pain. *Id*. at PageID 10403-04.

In Dr. Lubarsky's opinion to a reasonable degree of medical certainty, midazolam cannot lessen the likelihood that the inmate will experience severe pain and needless suffering simply because it cannot produce the desired state of anesthesia that would accomplish that lessening. (Hrg. Tr., ECF No. 2113, PageID 104272.) At the hearing on Henness's motion for a preliminary injunction, he testified that there are various stages of anesthesia: first is excitation, then sedation, then the hypnotic state, which he explained is what midazolam will produce in reasonably high doses. (Hrg. Tr., ECF No. 2113, PageID 104274.) In the hypnotic state, the cortical neuronal activity is inhibited or dampened down, and, absent noxious stimuli, a patient will remain asleep. *Id*. at PageID 104274-75. Achieving that state completes the induction of anesthesia, which differs from the maintenance of anesthesia and the surgical plane of anesthesia. *Id*. at PageID 104275, 104325. "The induction of anesthesia has nothing to do with being insensate. It has to do with being unaware." *Id*. at PageID 104328. It is the state of general anesthesia that renders a patient insensate, immobile, unconscious, and amnestic, and it is the surgical plane of anesthesia at which a person will remain insensate, immobile, unconscious, and amnestic when a noxious stimulus is

applied to his or her body. *Id*. Dr. Lubarsky testified that to tolerate the pain from the second and third drugs in Ohio's execution protocol, an inmate would need to be in the surgical plane of anesthesia. *Id*.

In the surgical context, anesthesia requires a balance between dampening the brain activity and the "amping up" of brain activity caused by the surgery. *Id*. at PageID 104277. It requires constant monitoring to ensure that the patient remains unconscious. *Id*. Anesthesiologists use various monitors to constantly gauge a patient's physiologic responses during surgery. *Id*. at PageID 104305. Blood pressure and heart rate are monitored and brain waves are observed via an electroencephalogram. *Id*. General anesthetics, such as barbiturates and inhalable anesthetics are used to maintain that balance. *Id*. Midazolam is not used for that purpose, although Dr. Lubarsky testified that it along with opioids are only "partial anesthetics . . . and cannot deliver the full definition of anesthesia, which is insensate, immobile, unconscious, and amnestic. *Id*. at PageID 104277-78.) Absent any one of those four characteristics, the patient is not under general anesthesia. *Id*. at PageID 104278.

Dr. Lubarsky summarized the body's perception of pain as follows:

> [T]here's [sic] four different things that occur between an actual – something that causes pain and your perception of pain, right?
>
> So there's transduction, which is a thermomechanical conveyance of a noxious stimuli [sic] to an electrical impulse, there's transmission of that electrical impulse along the spinal peripheral nerves to the spinal cord and up through the spinal cord to the brain.
>
> As it travels up the spinal cord to the brain, there's a third process known as modulation, which is that electrical signal is modulated in strength at the level of the spinal cord, and spinal opioids and/or local anesthetics at the spinal level will modulate the ability to transmit that, and then when it hits the brain, there's perception, and our mental state of mind, including our anxiety level, will either amp up or amp down the perception of pain when it hits the cortex.

(Hrg. Tr., ECF No. 2113, PageID 104279-80.) The transmission of the electrical impulse can be interrupted at the spinal level with an intrathecal injection of an opioid, at the midbrain thalamus level with nitrous oxide, or at the cortex of the brain with opioids. *Id*. at PageID 104281-82. In the execution context, Dr. Lubarsky stated that absent opioids there would be no interruption of the electrical impulse from the point of injection to the cortex of the brain where the perception of pain is realized and the inmate will be jolted into awareness and awake. *Id*. at PageID 104284.

Ohio's protocol relies exclusively on midazolam to induce an insensate state, but while midazolam is capable of sedation deep enough so that the inmate may be unable to respond to minor levels of noxious stimuli and thus appear to be unconscious and insensate, Dr. Lubarsky stated "it is irrefutable by any published treatise and there exists a clear scientific consensus that IV midazolam at any dose cannot provide either analgesia or a comatose state that would cause a patient to be insensate." (ECF No. 1952, PageID 80858-59.) Dr. Lubarsky further maintained that midazolam will do nothing to diminish the likelihood that the inmate will experience severe pain during his execution. (Hrg. Tr., ECF No. 2113, PageID 104273.) He stated, "There's no authoritative text, publication, or scientist who would say anything differently. *Id*. at PageID 104274.

The pain caused by the second and third drugs in Ohio's protocol are, in Dr. Lubarsky's professional opinion, "sure or very likely to overcome the sedative effect of 500 mg (or more) of IV injected midazolam." (ECF No 1952, PageID 80859; Hrg. Tr., ECF No. 2113, PageID 104290.) He provided the following analogy: "[A] patient asleep might not awaken to calling their name, or the stroke of the eyelashes or a pinch to the finger, but would certainly awaken to a blowtorch applied to the skin." (ECF No. 1952, PageID 80860.) He stated that Ohio's consciousness checks are insufficient to determine whether the inmate is insensate and fully unconscious. *Id*. Making

such an assessment takes repetitive training and experience. *Id*. at PageID 80861. A common way of determining whether a patient is properly insensate and unresponsive in the clinical setting is to apply a surgical clamp on the area where the incision will be made. *Id*.; Hrg. Tr., ECF No. 2113, PageID 104298-99. The pain created from the surgical clamp cannot be equated with the consciousness checks performed during an execution in Ohio. *Id*. Dr. Lubarsky testified that Ohio's prescribed consciousness checks are not noxious stimuli. (Hrg. Tr., ECF No. 2113, PageID 104297.) A noxious stimulus must be painful enough so that the person experiences the adrenaline surge and neuronal activity that is capable of waking him or her up. *Id*.

Even with a perfectly noxious stimulus, signs of consciousness can be missed even by well-trained professionals. (Hrg. Tr., ECF No. 2113, PageID 104297-302.) Anesthesiologists train for four to five years and as recently as a few months prior to his testimony here, Dr. Lubarsky had a senior resident who missed the signs of consciousness a patient exhibited and was about to begin a procedure, which demonstrates that determining a person's consciousness is no easy task. *Id*. at PageID 104298-99. Signs of consciousness can be subtle. *Id*. at PageID 104298. Movements such as clenching of the hands, nodding, tearing, movement of the head, and trying to move away from pain are all signs that the patient is not sufficiently anesthetized. *Id*. at PageID 104305-06. An adequately anesthetized patient should exhibit no movement because the definition of anesthesia is that the person is immobile, insensate, unconscious, and amnestic. *Id*. at PageID 104306. Dr. Lubarsky testified that there have been incidents in which a patient appears to be fully asleep but sits bolt upright when the surgeon makes her incision, acknowledging that "[i]t's very bad as an anesthesiologist, right?" *Id*. at PageID 104299.

In the execution context, Dr. Lubarsky testified that movement during the process is actually seen more often than not. *Id*. at PageID 104306. In some executions in which movement

was not reported Dr. Lubarsky stated that steps had been taken to prevent any movements or to make it difficult to see them if they did occur. *Id*. He noted that some inmates were constrained on the gurney by x-shaped strapping across the entire torso, tenting of the sheets over the inmate, and wrapping of the wrists and hands so that subtle movements could not be seen. *Id*.

Examples of noxious stimuli sufficient to judge a patient's consciousness would be using a clamp at the incision site, as described above; a sternal rub, if enough compression is used and the area is rubbed hard enough; a trapezius squeeze, but that is a minor noxious stimulus and not sufficient in Dr. Lubarsky's opinion; and the nipple twist, which would "depend entirely on how richly innervated the patient's nipples were [and] there's a large variation in the human population." *Id*. at PageID 104300-01.

Dr. Lubarsky's Rebuttal to Dr. Antognini's Prior Declaration

Dr. Lubarsky reviewed Dr. Antognini's October 19, 2017, declaration and discussed it in his own declaration.[31] He believes "[s]everal of Dr. Antognini's assertions are misleading and/or patently false. (ECF No. 1952, PageID 80863.) Dr. Lubarsky disagreed with Dr. Antognini's statement that midazolam can be used as the sole medication for some painful medical procedures, specifically laryngoscopies followed by endotracheal intubation. *Id*. at 80864. Dr. Lubarsky explained that in emergency situations, the use of midazolam alone may be necessary, but when time is not of the essence, midazolam as the sole medication is not recommended as it cannot render or keep a patient insensate at any dose, no matter how it is administered. *Id*. at 80864, 80871; Hrg. Tr., ECF No. 2113, PageID 104314. Furthermore, Dr. Lubarsky pointed out that Dr.

[31] Dr. Lubarsky's report for the Henness hearing was due before Dr. Antognini's report for that hearing, but much of the prior evidence from prior hearings was designated to be considered in Henness's hearing.

Antognini cites no literature to show that laryngoscopy and endotracheal intubation are as or more painful than the various types of pain associated with the drugs used in the Ohio execution protocol. *Id*. at PageID 80871. At the hearing, Dr. Lubarsky testified that midazolam is not used alone for intubation of a healthy adult. (Hrg. Tr., ECF No. 2113, PageID 104285.) In intensive care for critically ill patients, it may be used because it would not be advisable to use "a whole bunch of other drugs" that might compromise their awareness. *Id*. Thus, for purposes of determining the propriety of using midazolam as the first drug in Ohio's protocol, it is important to consider only articles in which the subjects were healthy volunteers. *Id*. at PageID 104286. Studies involving intensive care patients or emergency situations are not the most appropriate comparators. *Id*.

Contrary to Dr. Antognini's opinion, Dr. Lubarsky repeatedly stated that midazolam, even in the dosage dictated by the execution protocol, cannot render a person fully unconscious and insensate to the pain of the second and third drugs. The pain from the administration of a large quantity of very acidic midazolam, pulmonary edema, the administration of the paralytic drug rocuronium bromide, the administration of potassium chloride will all be experienced by an inmate who is sedated but not insensate and fully unconscious. (ECF No. 1952, PageID 80865-66.)

Dr. Lubarsky called Dr. Antognini's assertion that the consciousness checks employed by the execution team are sufficient to determine whether the inmate is sufficiently unconscious as to be unaware of any pain caused by administration of the second and third drugs "patently false." *Id*. at PageID 80866-67. Dr. Lubarsky explained that the stimuli of the consciousness checks used are "minor" and demonstrate only that in the absence of noxious stimuli, the inmate will be asleep. *Id*. at PageID 80867. The checks cannot reveal whether the inmate will respond to truly noxious stimuli of the type inflicted by the drugs used in the execution protocol. *Id*.

Next, Dr. Lubarsky stated that Dr. Antognini characterizes a conclusion of an article as saying that although benzodiazepines have been used for the induction of anesthesia, the use of midazolam in particular is not typically used for that purpose.[32] (ECF No. 1952, PageID 80867-68.) Instead, Dr. Lubarsky asserted, "the authors state clearly that benzodiazepines are not sufficient to induce anesthesia on their own" and that other drugs must be administered at the same time to accomplish general anesthesia. *Id*. at PageID 80868. Only then is the patient sure to be unconscious, insensate, and immobile. *Id*. Dr. Lubarsky stressed his earlier point that midazolam is incapable of suppressing consciousness to a level deep enough to render a person unconscious and insensate to the pain of the execution drugs. *Id*. Dr. Antognini overlooks the significance of midazolam's amnestic effect, noting that an inability to remember pain does not prevent one from experiencing the pain. *Id*. at PageID 80869. Dr. Lubarsky faulted Dr. Antognini for asserting that because midazolam can cause some level of unconsciousness, it also prevents the experience of pain, and states unequivocally that Dr. Antognini's opinion is not generally accepted in the medical community and the only person holding it is Dr. Antognini himself. *Id*.; Hrg. Tr., ECF No. 2113, PageID 104313. Dr. Lubarsky stated that as a matter of scientific consensus, midazolam cannot achieve the first of those requirements, and that there is no guarantee that midazolam can maintain even the level of sedation it is capable of achieving. *Id*. at PageID 80869-70. He further states that one does not have to be awake to experience pain. (Hrg. Tr., ECF No. 2113, PageID 104312.) Rather, if one is not awake and experiences pain, the pain will likely jolt the person into consciousness. *Id*. Dr. Lubarsky gives the example of a person being deep in sleep and getting a leg cramp that causes the person to jolt awake, saying, "It's the same thing" as when one is sedated with midazolam and a noxious stimulus is applied. *Id*.; Hrg. Tr., ECF No. 2113, PageID 104312.

[32] Dr. Lubarsky stated that "using midazolam alone in advance of an intubation or laryngoscopy procedure is virtually unheard-of today." (ECF No. 1952, PageID 80871.)

Dr. Lubarsky strongly disagreed with Dr. Antognini's opinion that because midazolam can produce unconsciousness, it blocks pain. (ECF No. 1952, PageID 80869.) He opined that it is a matter of generally accepted scientific fact that midazolam cannot maintain a level of unconsciousness sufficient to protect a person from the pain of noxious stimuli, and that that is the reason the FDA has not approved the drug as an anesthetic. *Id*. at PageID 80870-71; Hrg. Tr., ECF No. 2113, PageID 104294-95. Midazolam can be used in conjunction with other drugs as part of a balanced anesthesia, however. (Hrg Tr., ECF No. 2113, PageID 104324.) Unconsciousness does not result in analgesia, and that belief as expressed by Dr. Antognini is not generally accepted by the medical community. (Hrg. Tr., ECF No. 2113, PageID 104313.) Dr. Lubarsky characterized Dr. Antognini's opinion that an inmate administered 500 mg of midazolam and then an intravenous infusion of potassium chloride would not experience pain "nonsensical, frankly" because midazolam has no analgesic properties, and even one one-hundredth of the dose of potassium chloride called for in Ohio's execution protocol would make a person cry out. (Hrg. Tr., ECF No. 2113, PageID 104316.)

Dr. Lubarsky disputed Dr. Antognini's estimate that 500 mg of midazolam is 100-200 times the normal therapeutic dose, stating that the foremost authoritative text on anesthesia, *Miller's Anesthesia*,[33] notes that up to 40 mg of midazolam, which is likely close to the clinical ceiling effect level, has been used to achieve the maximum depth of unconsciousness that midazolam can produce. (ECF No. 1952, PageID 80871-72.) Dr. Antognini's opinion that an inmate given 500 mg of midazolam would be rendered completely unconscious and insensate to pain and noxious stimuli is "absolutely contrary to the generally accepted scientific consensus and

[33] Dr. Lubarsky co-authored the chapter on intravenous induction agents for almost two decades, including the fourth, fifth, sixth, and seventh editions of *Miller's Anesthesia*. (Hrg. Tr., ECF No. 2113, PageID 104270.) That chapter included coverage of the academic literature on midazolam and its effects. *Id*.

disproven by the evidence from executions using midazolam." (ECF No. 1952, PageID 80872.) Dr. Antognini's denial that midazolam has a ceiling effect is inconsistent with all the science, all the receptor studies, all the animal studies, and the fact that some people never went to sleep with the administration of high doses of midazolam. (Hrg. Tr., ECF No. 2113, PageID 104310.) Dr. Lubarsky testified that his opinion on midazolam's ceiling effect is consistent with all known facts about the drug. *Id.* The American Society of Anesthesiology, the Joint Commission on Accreditation of Hospital Organizations, and the Centers for Medicare and Medicaid service all define anesthesia as including being insensate, and Dr. Lubarsky knows of no one in the anesthesia community who would agree with the contrary proposition, as Dr. Antognini does. *Id*. at PageID 104311-12.

Finally, Dr. Lubarsky stated that Dr. Antognini's extrapolations respecting large doses of midazolam are "far outside scientific consensus on the limitations of midazolam in terms of creating an anesthetic state." *Id*. at PageID 80873. In addition, Dr. Antognini's opinions are at odds with the definitive texts on anesthesia; the foremost authority on benzodiazepines and midazolam, Dr. Greenblatt; the FDA; and the maker of midazolam, Hospira.

In his rebuttal report (ECF No. 2005) to Dr. Antognini's current declaration (ECF No. 1983), Dr. Lubarsky repeated much of his criticism of Dr. Antognini's earlier-stated opinions. Thus, the Court will include below only those of Dr Lubarsky's comments that have not been stated above and any that might conflict with Dr. Lubarsky's declaration or testimony.

Dr. Lubarsky began his rebuttal report by noting that Dr. Antognini erroneously equates "unconsciousness" with "general anesthesia." *Id*. at PageID 95675. The two are not the same, Dr. Lubarsky stated, because for a person to be unaware of the pain produced by the injection of potassium chloride, he would have to be in a state of general anesthesia, not merely unconscious.

Id. And for the person to remain unconscious and unaware of that pain, he would have to be either anesthetized to a near-comatose state or be given an analgesic to suppress the excitatory effects of the pain projected from the thalamus and midbrain upon the cortex. *Id*.

Dr. Lubarsky went over the pathway from the situs of a noxious stimulus to the cortex again then described the interaction between hypnotics and analgesics as synergistic. *Id*. at PageID 94578. Though a hypnotic drug like midazolam can produce a state of deep conscious depression, it does not mean that level of depression will be maintained in the presence of noxious stimuli. *Id*.

Not all stimuli are truly noxious. Calling someone's name, a light touch, brushing of an eyelash, shouting, even shaking the person are not noxious, but benign. *Id*. at PageID 94578-79. Dr. Lubarsky stated that being sutured, rib retractions, and intubation are examples of noxious stimuli. *Id*. at PageID 94579. Without analgesics to interrupt the electrical signal caused by the painful stimuli, it arrives in the midbrain causing the person to become conscious. *Id*. In short, "hypnotics depress consciousness and analgesics suppress noxious stimuli. *Id*.

Dr. Lubarsky took issue with Dr. Antognini's failure to explain how he defines the terms "consciousness" and "unconsciousness" while seeming to use the latter term to refer to the state of being asleep. *Id*. at PageID 94580. Dr. Antognini equates "deep sedation" with "consciousness," too. *Id*. Dr. Lubarsky stated that Dr. Antognini's unique definition of anesthesia, which does not require analgesia, was "radical" and "hotly contested" at the time he adopted it in 2002. *Id*. at PageID 94581, *citing* B.W. Urban and M. Bleckwenn, *Concepts and correlations relevant to general anaesthesia*, BRITISH J. ANAESTHESIOLOGY 89: 3-16 (2002). In 2002, Dr. Antognini believed, and presumably still believes, that "the essential goals of general anaesthesia can depend on the perspective of the definer." *Id*. at PageID 94581, *citing* J.F. Antognini & E.

Carstens, *In vivo characterization of clinical anaesthesia and its components,* BRITISH J. ANAESTHESIOLOGY 89: 156-66 (2002).

Contrary to Dr. Antognini's iconoclastic definition of anesthesia, the American Board of Anesthesiology, the Guidelines for Patient Care in Anesthesiology, and the Centers for Medicare & Medicaid Services' Interpretive Guideline § 482.52 define anesthesia as including the prevention of pain during procedures, rendering the patient insensate to pain, or a blunting or loss of pain perception, respectively. *Id*. at PageID 94581. Dr. Lubarsky stated that the analgesic component of anesthesia is "not at all 'arbitrary," as Dr. Antognini suggests and instead "are consistently used by everyone in the relevant scientific community, from researchers to practicing anesthesiologists to regulatory agencies." *Id*.

Dr. Lubarsky allowed that Dr. Antognini's opinion that anesthesia encompasses only amnesia, unconsciousness, and immobility may have been true when Dr. Antognini was still actively practicing and studying inhaled anesthetics because it was thought then that a concentration of an inhaled anesthetic high enough to prevent movement also guaranteed that the patient was pain free. (ECF No. 2005, PageID 94582, *citing* B. Urban *et al.*, *Interactions of anesthetics with their targets: Non-specific, specific or both?*, PHARMACOLOGY & THERAPEUTICS, 111 (2006) 729-70, which he quoted as stating that "[w]ith today's combination anesthesia, this is no longer true.") Dr. Lubarsky further noted that Dr. Antognini has previously acknowledged that a chart he created to illustrate his belief that analgesia can be achieved via sedation to the point of unconsciousness (*see* ECF No. 852-1, PageID 25790) related only to inhaled anesthetics and not to intravenously injected anesthetics (ECF No. 2005, PageID 94582, *citing* ECF No 852-1, PageID 25794; ECF No. 924, PageID 31135).

Likewise, Dr. Lubarsky found fault with Dr. Antognini's misuse of the term "complete anesthetic." "A complete anesthetic, as the term is commonly used in the scientific community, is a drug that can achieve all **four** end-points of anesthesia, unconsciousness, amnesia, analgesia, and akinesia." (ECF No. 2005, PageID 94582.) "By implicitly changing definitions of a commonly used terms [sic], Dr. Antognini presents misleading, scientifically invalid information to the Court." *Id*. Dr. Antognini fails to acknowledge the difference between "unconsciousness," which he does not define but which is a state of sedation that can be interrupted by noxious stimuli, and "anesthesia" a state during which a person is not arousable by painful stimuli. *Id*. Dr. Lubarsky cited several studies that illustrate Dr. Antognini's failure to recognize the difference between those two medical terms. *Id*. at PageID 94583-84.

In his declaration, Dr. Antognini cited four studies he stated support his opinion that midazolam can render a person so deeply unconscious that she cannot experience pain. (ECF No. 1983, PageID 88447.) Dr. Lubarsky noted in his rebuttal report that all four of those studies defined unconsciousness as failing to respond to a verbal command or mild physical stimuli and that none of the studies subjected the patients to painful stimuli. (ECF No. 2005, PageID 94584.) He stated that although Dr. Antognini admitted as much in his earlier testimony in this consolidated litigation, he failed to amend his declaration to reflect admission. *Id*.

Essential to the discussion of whether midazolam is a drug capable of meeting the four previously stated goals of anesthesia is that the three stages of anesthesia, which are induction, maintenance, and emergence. *Id*. at PageID 94585. Drugs used in one stage may not be suitable for another stage. *Id*. Dr. Lubarsky stated midazolam may be used as a premedication before inducing anesthesia. *Id*. at PageID 94586. It can be followed by a small dose of a hypnotic drug that acts on $GABA_A$ receptors, inducing a state of sedation from which the patient would be easily

arousable. *Id*. "[G]eneral anesthesia is maintained by a combination of hypnotic agents, inhalational agents, opioids, muscle relaxants, sedatives, and cardiovascular drugs along with ventilatory support." *Id*. No one in these proceedings has denied that midazolam can be used in the induction of anesthesia, but if it is used during the maintenance phase of general anesthesia, it is to provide amnestic effect, not analgesia. *Id*. The four studies upon which Dr. Antognini relies to support his opinion that midazolam can render a patient sufficiently unconscious as to be insensate to pain do not show that the patients reached the plane of general anesthesia, much less remained in that state. *Id*. at PageID 94587. "At most, they were made sleepy." *Id*.

Although Dr. Antognini stated that he has used midazolam to induce anesthesia in patients, he stopped short of saying he used only midazolam to induce or maintain general anesthesia. (ECF No. 2005, PageID 94587-88.) In addition, Dr. Antognini fails to define the end-point of his induction with midazolam. *Id*. at PageID 94588.

Dr. Lubarsky further disagreed with Dr. Antognini's opinion that midazolam can cause unconsciousness deeply enough to mimic an analgesic because studies have shown that only twenty percent of patients given midazolam in various dosages were asleep five minutes after being given the drug. *Id.*, *citing* Gamble J.A., et al., *Evaluation of midazolam as an intravenous induction agent*, ANAESTHESIA 36:868-73 (1981). Dr. Lubarsky stated that "whatever meager effect midazolam has on suppression of consciousness, . . . [it] is inconsistent and has great variability from person to person." *Id*. at PageID 94588.

Dr. Antognini's current position that midazolam has limited analgesic effect at low doses differs from his previously stated opinion that the drug has no analgesic effect at low doses. *Id*. at PageID 94589. Dr. Lubarsky noted that Dr. Antognini cited no new studies that support the change in his opinion. *Id*. He found the same was true of Dr. Antognini's statement that midazolam does

not produce hyperalgesia. *Id*. Dr. Antognini has also apparently changed his opinion from midazolam has some analgesic properties to his current statement that the drug has analgesic properties at various doses and routes of administration. *Id*.

Dr. Lubarsky took issue with Dr. Antognini's definition of "analgesia":

> Analgesia: The full or partial relief of painful perception without affecting consciousness, whether by parenteral, topical, oral mucous membrane, or other routes. In the [emergency department] analgesia is commonly achieved with opioids (e.g., morphine, hydromophone, and fentanyl}, acetaminophen, and/or non-steroidal anti-inflammatory agents (e.g., ibuprofen, ketorolac). . . . '[A]nalgesia' involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not lose consciousness, but does not perceive pain to the extent that may otherwise prevail.

(ECF 2005, PageID 94590-91.) Dr. Lubarsky criticized Dr. Antognini's reliance on those definitions because they involve only local action and are set forth in the context of chronic pain rather than noxious stimuli.

Dr. Lubarsky dismissed Dr. Antognini's criticism of *Miller's Anesthesia*'s statement that benzodiazepines lack analgesic properties, explaining that rather than being an outdated notion in light of "emerging new data," it is an authoritative and well-established fact. *Id*. at PageID 94591. (Recall that Dr. Lubarsky was responsible for the chapter in *Miller's Anesthesia* that deals with benzodiazepines in the fourth through seventh editions of that volume.) In the studies Dr. Lubarsky reviewed that were cited by Dr. Antognini, the definition involved only local action.

In addition, Dr. Lubarsky noted that benzodiazepines' lack of analgesic properties has been established across numerous anesthetic practices:

> a. Treatment of burn pain: "The use of anxiolytic drugs has become commonplace in combination with opioids in the treatment of burn pain, but benzodiazepines should not become substitutes for analgesics, citing C. Gregoretti et al., Analgo-

> Sedation of Patients with Burns Outside the Operating Room, Drugs, December 2008, Vol. 68, Issue 17, 2427-43;
>
> b. Painful procedures requiring moderate sedation: "We must continue to emphasize to our 'anesthesiologically challenged' colleagues that midazolam is neither an analgesic nor a hypnotic, nor is it an anesthetic. . . . The indication for midazolam is not sleep, nor immobilization, nor analgesia. It is conscious sedation and amnesia. I believe anesthesia providers must insist on being present if the patient's pain is so great that immobilization becomes necessary. Patient movement is the hallmark of inadequate pain control; even sedated and sleeping patients respond to pain with movement. Analgesia is indicated under these circumstances – not more sedation," citing Mike Stewart, MS, PNP, CRNA, Chief Nurse Anesthetist, Letter to the Editor: Confusion of Amnesia, Analgesia, and Sedation Really a Safety Issue, Anesthesia Safety Patient Foundation, Vol. 15, No. 1, Spring 2000;
>
> c. Neonatal care: "midazolam provides no pain relief," citing Blank Children's Hospital, Guidelines for the Use of Midazolam (Versed®);
>
> d. Veterinary medicine: "Because they do not provide analgesia, benzodiazepines should not be used alone," citing S. Kaiser-Klingler, Balanced Anesthesia in Small Animals, Anesthesia, Nov. 2007 (Vol. 28, No. 11).

(ECF No. 2005, PageID 94592-93.)

Dr. Antognini discounted the findings of a 2013 study that concluded that "intravenous sedatives may increase pain perception." *See* Michael A. Frölich, *Effect of Sedation on Pain Perception*, ANESTHESIOLOGY, 119(3), 611-21, March 2013. The reports he relied upon in forming his opinion contradicting the Frölich study, however, variously involved different species, different methods of administration, different drugs, and different mechanisms of action. (ECF No. 2005, PageID 94592-93.)

Dr. Lubarsky disagreed with Dr. Antognini's opinion that the application of painful stimuli to a person who has been administered an anesthetic would cause the central nervous system to be

less depressed, but not rouse them into consciousness, depending on the anesthetic level. *Id*. at PageID 94593. Dr. Antognini acknowledged that the person could come close to consciousness, however. *Id*. Dr. Lubarsky stated that rather, "the person's central nervous system would not be depressed very deeply because of midazolam's inherent limitations," and adds that the degree of pain generated from the noxious stimuli would also figure into whether the person would regain consciousness. *Id*. Thus, Dr. Lubarsky opined that a person being executed under Ohio's execution protocol is sure or very likely to regain consciousness upon administration of the paralytic drug and will experience the full brunt of the pain caused by that drug. *Id*. at PageID 94594.

Dr. Antognini's discussion of Rapid Sequence Induction is irrelevant to the execution context according to Dr. Lubarsky, since that procedure is used in emergency situations where amnesia and avoiding hemodynamic instability are secondary concerns. (ECF No. 2005, PageID 94594.)

Dr. Lubarsky also criticized Dr. Antognini for conflating unconsciousness with analgesia, and consciousness checks with reflex checks. *Id*. at PageID 94596. Thus, Dr. Antognini's opinion that nurses and paramedics are qualified and capable of determining levels of consciousness is based on imprecise use of those terms. Dr. Lubarsky allowed that nurses and paramedics are qualified to determine whether a patient is responsive, but not whether the patient's central nervous system is so depressed as to ablate the response to noxious stimuli. *Id*. at PageID 94596-97. He also reminded the Court that the checks used in the execution process are largely benign, response to which can easily be suppressed by a sedative while leaving the pain pathway operative. *Id*.

Report and Testimony of Craig W. Stevens, Ph.D.

On October 26 and November 19, 2018, Craig W. Stevens, Ph.D., filed expert and rebuttal reports, respectively, on behalf of Plaintiff Henness. (Stevens Report III; ECF No. 1949; Stevens Rebuttal III, ECF No. 2007.) He had previously provided two initial and two rebuttal expert reports on behalf of former plaintiffs in this consolidated litigation. (Stevens Report I, ECF No. 836-1; Stevens Rebuttal I, ECF No. 900-1; Stevens Report II, ECF No. 1288-1; Stevens Rebuttal II, ECF No. 1333-1.) He also previously testified, twice in plaintiffs' cases-in-chief and twice in rebuttal. (Hrg. Trs., ECF Nos. 923, 941, 1359, 1363.) In the instant report, he stated that, "since my most recent expert disclosure, I have provided expert testimony, in trial and in a deposition, in an additional case: *Abdur'Rahman v. Parker*, Chancery Court for State of Tennessee, Twentieth Judicial District, Davidson County, TN, Part III, Case No. 18-183-II (III)[,]" but that other pertinent information remained the same from prior reports. (ECF No. 2007 PageID 76584.)

Dr. Stevens's testimony at Henness's hearing on December 13, 2018, was largely consistent with his reports. He had been in the courtroom for the entire testimonies of Drs. Exline, Greenblatt, and Lubarsky, and for the cross-examination of Dr. Edgar. Based on his observations and expertise, he concluded that there was nothing in their respective testimonies (as they pertained to pharmacology) with which he disagreed, and that his opinions were in accord with theirs. (Hrg. Tr., ECF No. 2117, PageID 104433-34.)

His report focused on "The Five Incontrovertible Truths of Midazolam Pharmacology Relating to Lethal Injection Use." (ECF No. 1949, PageID 76584 (emphasis in original).) *First*, the only drugs that can produce analgesia—that is, an absence of pain—"are either opioids like morphine or non-steroidal anti-inflammatory drugs ('NSAIDs') like aspirin." *Id*. Midazolam, as

a sedative-hypnotic drug, fits neither of those categories. *Id*. Indeed, and consistent with the testimonies of Drs. Greenblatt and Lubarsky, "[t]he most authoritative textbook in Anesthesiology states that 'Benzodiazepines lack analgesic properties and must be used with other anesthetic drugs to provide sufficient analgesia.'" *Id*. at PageID 76586-87 n.1, quoting J. Vuyk *et al.*, *Chapter 30: Intravenous Anesthetics*, in 1 RONALD D. MILLER**,** MILLER'S ANESTHESIA 842 (Ronald D. Miller, *et al.* eds.) (8th ed. 2015); Hrg. Tr., ECF No. 2117, PageID 104435-104436. Midazolam's capabilities and limitations were exemplified in studies showing that the drug, when compared with a placebo, can reduce anxiety, but it does not reduce pain, and in some cases, produces *hyper*algesia. *Id*. at PageID 76587 n.3 *citing* M.A. Frölich *et al.*, *Effect of sedation on pain perception*, ANESTHESIOLOGY 118: 611-62 (2013).

Dr. Stevens further explained that "[m]orphine, an opioid, literally binds to and activates opioid drug receptors that sit on the pain neurons. The act of morphine binding to the opioid receptor causes changes inside the pain neuron to stop the neuron from getting excited by incoming pain signals. With no incoming pain signals to the brain, you get analgesia." (ECF No. 1949 PageID 76584-85.) Midazolam and other benzodiazepines, meanwhile, bind to GABA receptors, which induces non-analgesic sedation, *i.e.*, sleep. The deep sleep induced by midazolam is insufficient to protect "against severe pain, such as that caused by the second and third drugs in Ohio's lethal injection protocol." *Id*. at PageID 76585. This opinion is consistent with functional magnetic resonance imaging ("fMRI") studies, which show "that midazolam does not prevent the activation of brain areas that process pain. These areas that process pain are not activated when a true analgesic like morphine or other opioids are given." *Id*. at PageID 76587 n.7, *citing* R.G. Wise *et al.*, *The anxiolytic effects of midazolam during anticipation to pain revealed using fMRI*, MAGNETIC RESONANCE IMAGING 25: 801-810 (2007). "Although midazolam can work

synergistically with morphine to enhance respiration suppression, that is not true as to analgesia. Midazolam given with morphine does not produce a greater analgesic effect than morphine given with saline." *Id*., PageID 76588 nn.8-9, *citing* A. Majidi *et al., Comparison of morphine-midazolam versus morphine injection for pain relief in patients with limb fractures - a clinical trial*, ULUS TRAVMA ACIL CERRAHI DERG[34] 21: 22-26 (2015); Y. Auffret *et al., Does midazolam enhance pain control in prehospital management of traumatic severe pain?* AM J. EMERGENCY MED. 32: 655-659 (2014).

Dr. Stevens's testimony at the January 2017 hearing was largely consistent with his reports and testimony as to Henness. He testified that one of midazolam's "major effects, is the amnesia [*sic*] effect[,]" but that it is not an analgesic drug. (Hrg. Tr., ECF No. 923, PageID 30746.) He discussed how midazolam, once it crosses the blood-brain barrier, "binds to a separate place on that $GABA_A$ receptor, . . . [and] increases the frequency of that opening" for the chloride ions to flow into the neuron, which in turn, "causes the neuron not to fire, and that decreases the activity." *Id*. at PageID 30756. Significantly, however, "midazolam can only work when GABA is present on the receptor." *Id*. at PageID 30757. Thus, no matter how much midazolam is introduced into a person's system, the drug can do nothing unless GABA is present. Barbiturates on the other hand, can work without GABA being present and actually increase the duration of the doors staying open. Thus, they are much more effective in depressing neuron functioning than benzodiazepines. *Id*. at PageID 30760-30761.

Second, the sleep induced by the overdose of midazolam cannot be equated with a state of general anesthesia—"the state of becoming insensate to all incoming sensations including touch, pressure, and pain. It is accompanied by a drug-induced loss of consciousness[.]" (ECF No. 1949,

[34] TURKISH JOURNAL OF TRAUMA AND EMERGENCY SURGERY. http://www.tjtes.org/eng/jvi.aspx (last accessed Jan. 9, 2019).

PageID 76585.) Dr. Stevens differentiated midazolam from general anesthetic drugs (such as propofol), the latter of which "bind and activate the GABA receptor like midazolam, but general anesthetic drugs can turn on GABA receptors in the absence of the neurotransmitter GABA. General anesthetics also affect other systems in the brain, like blocking excitatory pathways that midazolam doesn't affect." *Id.* In his first expert report, rendered on December 19, 2016, in conjunction with the motions for preliminary injunction of Phillips, Otte, and Tibbetts, Dr. Stevens contrasted midazolam, a benzodiazepine, with pentobarbital or sodium thiopental, which are barbiturates, and opined that unlike the barbiturates, midazolam could not bring an inmate to a state of general anesthesia, and could not render an inmate insensate to pain. Such a difference extended to the practical level, too—whereas barbiturates can increase the synthesis and release of GABA, and allow the drugs to bind onto the receptors, benzodiazepines can do neither of those, and must wait until and unless sufficient GABA is released naturally by the body's neurons. This creates midazolam's "ceiling effect" that is not present with barbiturates. (ECF No. 836-1, PageID 24808.) Thus, he opined, "[u]se of midazolam as the first drug in the State's three-drug lethal injection protocol (01-COM-11, eff. Date [*sic*] Oct 7, 2016) is highly likely to cause intolerable and severe pain and suffering in the condemned inmate." *Id.* at PageID 24803.

Midazolam's limited effects mean that it cannot produce the level of unconsciousness of a general anesthetic, a conclusion reached in several studies that measured loss of consciousness "by monitoring the activity of the brain by [electroencephalogram (EEG)] and converting these brain waves to a bispectral index score (BIS); the lower the score, the deeper the level of unconsciousness." (ECF No. 1949 at PageID 76588.) In none of the patients who were administered midazolam did their mean BIS drop below 65—above "the level of unawareness and inability to feel and experience pain found with General Anesthesia (from 40-60 BIS)." *Id.* nn.12-

13, *citing* A.E. Ibrahim, *et al.*, *Bispectral index monitoring during sedation with sevoflurane, midazolam, and propofol*, ANESTHESIOLOGY 95: 1151-1159 (2001); N.A. Sandler, *Additional clinical observations utilizing bispectral analysis*, ANESTHESIOLOGY PROGRESS 47: 84-86 (2000); *accord* Hrg. Tr., ECF No. 2117, PageID 104442. Thus, Dr. Stevens opined, Defendants' argument that a large dose of midazolam, a sedative-hypnotic drug, can induce general anesthesia, is belied by the drug's chemical properties, which make a transformation from sedative to anesthetic impossible. *Id*.

Third, Dr. Stevens stated that midazolam's above-discussed inability to act at the GABA receptors unless GABA is already bound to the receptors limits its efficacy. (ECF No. 1949, PageID 76585.) Specifically, "[i]f there is more midazolam than there are places for it to bind on GABA receptors, because midazolam is already bound to it with some GABA, then that extra midazolam cannot do anything. Increasing the dose of midazolam simply produces extra midazolam floating around the brain with nothing to do." *Id*. In other words, there is a "ceiling effect" on midazolam, and increasing the dosage beyond a certain point will not provide increased sedation. *Id*. Studies have consistently shown a ceiling effect occurring at or below 25 mg of midazolam for a typical 180-pound adult, and that even 25 mg of the drug cannot yield a BIS score of lower than approximately 70. *Id*. at PageID 76589 nn.16-17, *citing* A.E. Ibrahim *et al*., *The influence of parecoxib, a parenteral cyclooxygenase-2 specific inhibitor, on the pharmacokinetics and clinical effects of midazolam*, ANESTHESIA & ANALGESIA 95: 667-673 (2002); K. Kuizenga *et al.*, *Biphasic EEG changes in relation to loss of consciousness during induction with thiopental, propofol, etomidate, midazolam or sevoflurane*, BRIT. J. ANAESTHESIOLOGY 86: 354-360 (2001). M. Bührer *et al.*, *Electroencephalographic effects of benzodiazepines. II. Pharmacodynamic modeling of the electroencephalographic effects of midazolam and diazepam*, CLINICAL

PHARMACOLOGY & THERAPEUTICS 48: 555-567 (1990); M. Bührer *et al.*, *Electroencephalographic effects of benzodiazepines. I. Choosing an electroencephalographic parameter to measure the effect of midazolam on the central nervous system*, CLINICAL PHARMACOLOGY & THERAPEUTICS 48: 544-554 (1990). This limited efficacy, Dr. Stevens opined, is in contrast to barbiturates such as pentobarbital, which act on the GABA receptors regardless of whether GABA is present, and "also block excitatory circuits and further decrease neuron activity and eventually depress the brain enough to shut down the neurons that drive breathing[,] . . . leading to respiratory depression and death at higher doses." *Id*. at PageID 76586.

Most importantly, the existence of a ceiling effect means that:

> *No amount of midazolam* can render someone into a state of sufficiently deep unconsciousness to where the person is unconscious and insensate to the painful stimuli of drugs #2 and #3 in the Ohio lethal injection protocol. It is not in the nature of midazolam to produce that depth of unconsciousness to have concomitant insensateness, and midazolam does not have analgesic properties.

Id. at PageID 76589 (emphasis added).[35] The above is consistent with Dr. Stevens's January, 4, 2017, testimony that based on his calculations, the 500 mg of midazolam used in Defendants' protocol is "about 2.192 times higher than the concentration [of] midazolam that produces the ceiling effect." (Hrg. Tr., ECF No. 923, PageID 30798-99.) This was significant, Dr. Stevens opined, because beyond that ceiling point, "greater dosages won't produce a greater effect." *Id*. at PageID 30799; *see also* Hrg. Tr., ECF No. 941, PageID 32058 (Contrary to Dr. Buffington's previous testimony, "it doesn't matter the potency of a benzodiazepine because it has to have GABA present to work, it will always tail off because there is not an infinite amount of GABA. It's limited by our brain neurons[.]").

[35] Dr. Stevens previously determined that IV midazolam had a ceiling effect at 228 mg (*See* Stevens Report I, ECF No. 836-1, PageID 24817-28 (citations omitted) (methodology and calculation of ceiling effect).)

In his most recent testimony, Dr. Stevens expressed disappointment that Dr. Antognini's report did not discuss how midazolam acts—and does not act—on the GABA receptors (Hrg. Tr., ECF No. 2117, PageID 104448.) Absent such an explanation, Dr. Stevens opined, Dr. Antognini's conclusion that midazolam could have analgesic effects is spurious, in addition to being contrary to the scientific consensus that "[m]idazolam, by its mechanism of action, cannot [a]ffect pain processing." *Id*. at PageID 104448-49. On cross-examination, Defendants introduced a decision in a Mississippi lethal injection case in which Dr. Stevens conceded, in an expert declaration, that midazolam had produced BIS as low as 65 in patients, which represents "deep sedation," but higher than the range that qualifies as "general anesthesia." *Id*. at PageID 104460-61, *citing Loden v. State*, No. 17-DR-00870-SCT, ¶¶ 18-19 (Miss. 2018). Dr. Stevens also testified on cross-examination regarding a study in which, while the mean BIS score of a subject injected with midazolam was 70, and he conceded that at least two subjects in that study had a BIS approaching 60, although he termed those data points "outliers," because they were at least two standard deviations below the mean. *Id*. at PageID 104462-63, 104473, 104488.

Fourth, Dr. Stevens opined that, in addition to midazolam lacking analgesic properties, "it cannot produce the depth of unconsciousness to the point where the patient is unconscious, insensate, and immobile"—the commonly-accepted definition of anesthesia. (ECF No. 1949, PageID 76586.) In support, he notes that studies of patients who overdosed on benzodiazepines have consistently shown responsiveness to pain stimulus. *Id*. at PageID 76590 nn.19-20, *citing* M.D. Allen *et al.*, *Pharmacokinetic study of lorazepam overdosage*, AM. J. PSYCHIATRY 137:1414-1415 (1980); David J. Greenblatt *et al.*, *Acute Overdosage with Benzodiazepine Derivatives*, CLINICAL PHARMACOLOGY & THERAPEUTICS 21(4): 497-514 (Apr. 1977). He distinguished between midazolam's ability to suppress response to non-noxious stimuli—what

some studies, including those relied upon by Dr. Antognini term "unconsciousness"—and its inability to render an individual insensate to pain or noxious stimuli. (Hrg. Tr., ECF No. 2117, PageID 104442.) Specifically, the Glass study defined "unconsciousness as when the patient no longer responds to their name repeatedly or loudly spoken, but still responds to mild shaking and prodding and still responds to noxious stimulus." *Id*. at PageID 104443-44, *citing* P.S. Glass *et al., Bispectral analysis measures sedation and memory effects of propofol, midazolam, isoflurane and alfentanil in healthy volunteers*, ANESTHESIOLOGY 86(4): 836-47 (1997). This level of consciousness, termed "sedation" by the American Society of Anesthesiology, is distinct from the level created in a general or surgical plane of anesthesia, and those levels have different BIS scores. *Id*. at PageID 104445-46.

Dr. Stevens's report and testimony in this case were consistent with his previous reports and testimonies. In his first report, Dr. Stevens discussed the "four levels defined for the Continuum of Depth of Sedation. . . : Minimum Sedation Anxiolysis, Moderate Sedation/Analgesia ('Conscious Sedation'), Deep Sedation/Analgesia, and General Anesthesia." (ECF No. 836-1, PageID 24809). The first "three levels of sedation are characterized by response to pain and drug-induced *depression* of consciousness and less awareness but *without loss* of consciousness. Only at the level of General Anesthesia is a person rendered unaware and insensate to pain." *Id.* (emphasis in original). He noted that the authors of the chapter on hypnotics and sedatives in the authoritative pharmacological textbook stated that: "The clinical literature often refers to the anesthetic effects and uses of certain benzodiazepines, but those drugs do not cause true general anesthesia because awareness usually persists." *Id*. at PageID 24811 (emphasis removed), quoting S.J. Mihic and R.A. Harris, *Ch. 17 Hypnotics and Sedatives*, in GOODMAN & GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 460 (Laurence L. Brunton *et al.*,

eds., 1st ed. 2010). Similarly, Dr. Stevens testified in rebuttal on January 6, 2017, that, while it is sometimes difficult to parse levels of consciousness in going from mild to moderate to heavy sedation, anesthesia was a "bright line" that revealed sharply different EEG patterns—and consequently, BIS values—above and below the line (Hrg. Tr., ECF No. 941, PageID 32067.)

On January 4, 2017, Dr. Stevens testified that, with barbiturates, you can decrease functioning so much that you can introduce and "maintain anesthesia. You can get all the way to coma and death." (Hrg. Tr., ECF No. 923, PageID 30764-65.) With benzodiazepines, however, "at some dose . . . [y]ou get a plateau. And in this case, it's . . . just below anesthesia." *Id*. at PageID 30766. Dr. Stevens emphasized that his definition of "anesthesia" was similar to that of the American Society of Anesthesiology: one in which "you have loss of consciousness, and no response to noxious stimulus." *Id*. at PageID 30767-68. Someone who is merely sedated, however, will eventually respond to noxious stimuli, no matter how deep that sedation is. *Id*. at PageID 30770-71. Further, while there have been no studies on the effects of 500 mg of midazolam, Dr. Stevens testified that "[t]here is no evidence" that that amount or any other could transform the drug's ceiling from sedation to anesthesia; "[n]o matter how much you give of it, it's still a benzodiazepine." *Id*. at PageID 30773, 30776. Because of that, Dr. Stevens testified that it would not be, in his opinion, "acceptable medical practice to give the second or third drugs" in the execution protocol "to someone who is not in the state of general anesthesia." *Id*. at PageID 30780.

Similarly, in his first rebuttal report, Dr. Stevens noted that Dr. Buffington[36] did not

[36] In the two previous hearings, Dr. Buffington's expert reports were accepted, and he was permitted to testify, and those reports and testimonies are among the materials being considered by the Court with respect to Henness. Thus, to the extent that Stevens Rebuttals I and II pertain to the opinions of Dr. Buffington, the Court sets them forth here. Stevens Rebuttals I and II were also directed at previous expert opinions filed by Dr. Antognini. However, Dr. Antognini's opinions were largely the same across his three reports, and thus, the Court discusses those portions of Stevens Rebuttals I and II only to the extent that they discuss material unique to Dr. Antognini's first or second report.

elaborate on his statement that 500 mg of intravenous midazolam would render an individual unconscious "nor provide any data to support his bold assertion, and I am not aware of any that could support it." (ECF No. 900-1, PageID 30151.) Indeed, Dr. Stevens opined, the lack of any comatose or lethal blood range renders Dr. Buffington's statement dubious. *Id*. at PageID 30151-30152, *citing* R. Regenthal *et al.*, *Drug levels: therapeutic and toxic serum/plasma concentrations of common drugs*, J. CLINICAL MONITORING AND COMPUTING 15: 529-44 (1999). Further, Dr. Stevens argued that "Dr. Buffington continues to confuse the states of sedation and General Anesthesia[.] . . . There are no clinical studies that support the assertion that midazolam can produce loss of consciousness and unawareness to noxious stimuli." *Id*. at PageID 30153. He then noted that Dr. Buffington's own report relied upon studies showing that midazolam did not lower BIS below 66, above the range between 40 and 60 consistent with a state of general anesthesia. *Id*., *citing* Buffington Report I, ECF No. 852-2, PageID 25830-31. He opined that Dr. Buffington's assertion that midazolam's ceiling effect had never been observed in humans was belied by the studies cited in his (Dr. Stevens's) initial report, and only pertained to sedation, not general anesthesia. *Id*., *citing* Stevens Report I, ECF No. 836-1, PageID 24826; Buffington Report I, ECF No. 852-2, PageID 25831. Dr. Stevens concluded that he was "not aware of any scientifically accepted approach that would support [Dr. Buffington's] conclusion" that, with a sufficient overdose of midazolam, one's consciousness could be suppressed to a level consistent with that of general anesthesia. *Id*., *citing* Buffington Report I, ECF No. 852-2, PageID 25832.

Consequently, while the FDA has approved midazolam for anesthetic induction and as a co-anesthesia drug—*i.e.*, in conjunction with a general anesthetic drug—it has not approved midazolam or any benzodiazepine as the sole drug to induce anesthesia. (ECF No. 836-1, PageID 24812.) As Dr. Stevens explained, "Anesthetic Induction is a procedure to **start the anesthesia**

process[;] this use does not mean that midazolam can produce a state of unawareness and inability to feel and experience pain at the level of a state of General Anesthesia." *Id*. at PageID 24813 (emphasis in original); Hrg. Tr., ECF No. 1359, PageID 50824. Moreover, while midazolam can be used for preoperative or outpatient sedation, neither use is "germane to drug use for lethal injection." *Id*.; *see also* Hrg. Tr., ECF No. 1359, PageID 50905 (distinguishing between "induction of anesthesia," which is "a process," whereas "general anesthesia is a state of being of the patient").

Finally, Dr. Stevens, stated that the high-volume acidic nature of the 100 mL midazolam solution called for in Defendants' protocol "results in pain by acting on specific acid-sensing ion channels (ASIC) in blood vessels. Human studies of acid drug IV injection confirm the pain that occurs with the IV administration of acid solutions comparable to the midazolam solution." (ECF No. 1949, PageID 76586.) Given that "midazolam formulation must be in a low acid pH of 3-4 pH in order to keep the midazolam soluble in water[,]" and that "ASIC acid receptors respond to pH changes when decreasing from a normal pH of 7.4 and respond maximally at pH4[, a]ctivation of ASIC acid receptors directly excites pain fibers." *Id*. at PageID 76591 nn.26-27, *citing* M. Hesselager *et al.*, *pH Dependency and desensitization kinetics of heterologously expressed combinations of acid-sensing ion channel subunits*, J. BIOLOGICAL CHEMISTRY 279: 11006-101 (2004); N.G. Jones *et al.*, *Acid-induced pain and its modulation in humans*, J. NEUROSCIENCE 24: 10974-79 (2004). Indeed, the manufacturer of the injectable midazolam solution put on the label that the solution would have a pH between 2.5 and 3.5. (Hrg. Tr., ECF No. 2117, PageID 104481.) This activation of ASIC receptors and excitement of pain fibers was demonstrated by a study of users of intravenous heroin, which, like midazolam, is made heavily acidic prior to injection of between 0.2 and 2.0 mL solution, a much smaller amount than the 100 mL of the midazolam solution called for in the execution protocol. *Id*. at PageID 104451. Thus, a recipient of 500 mg

of midazolam will be in severe pain even before pulmonary edema begins. (ECF No. 2117, PageID 104450-51, 104483.) Dr. Stevens noted a recent study of individuals injecting heroin intravenously, which, in solution, has a pH between 2.1 and 3.5: "Heroin users reported severe pain upon heroin IV injection; one user describing it as 'it stung like f***k when you shot it up.'" (ECF No. 1949, PageID 76591 n.28 (alteration in original), *citing* Ciccarone D., Harris M., *Fire in the vein: Heroin acidity and its proximal effect on users' health.* INT'L J. DRUG POL'Y 26: 1103-10 (2015).)

While the study of heroin users was the only one of which he was aware that studied the pain of an acidic solution upon injection, the levels of pain reported by respondents was significant, because the maximum solution injected by the subjects was 2.0 mL, whereas the lethal injection protocol called for 100.0 mL of midazolam solution. Thus, Dr. Stevens opined, to a reasonable degree of scientific certainty, Henness was sure or very likely to suffer severe pain upon injection of midazolam. (Hrg. Tr., ECF No. 2117, PageID 104453-104454.) On cross-examination, Dr. Stevens conceded that, in his original reports and testimony in this consolidated litigation, he had not opined that the acidic nature of the midazolam solution was sure or very likely to cause severe pain to inmates. *Id*. at PageID 104469. However, he felt "one hundred percent confident" making that causal connection because the surrounding science had evolved. *Id*. at PageID 104471, 104489.

In his most recent rebuttal report, Dr. Stevens identified five significant flaws in the report of Defendants' expert, Dr. Antognini (ECF No. 2007, PageID 94874-78.)[37] *First*, he claimed that "Dr. Antognini's assertion that midazolam produces certain effects—'unconsciousness' (left undefined) and analgesia, for example—are given without pharmacological underpinnings. . . . No

[37] Like Dr. Stevens, Dr. Antognini has twice provided expert reports in the consolidated litigation (Antognini Report I, ECF No. 852-1; Antognini Report II, ECF 1317-19.)

explanation of how midazolam produces the asserted effects is given, nor are the asserted effects tied back to midazolam's mechanism of action." *Id*. *Second*, he opined that Dr. Antognini's statements that midazolam can be used as the "sole medication" in painful medical procedures is irrelevant and misleading, because it has only been used as the sole medicine for procedures such as laryngoscopy or endotracheal intubation—neither of which is remotely as painful as injection with the second and third drugs of Ohio's execution protocol. *Id*. Further, he argued that Dr. Antognini's citation of an article co-authored by Dr. Stevens regarding intrathecal administration of midazolam *and morphine* to rats, for the proposition that "midazolam has analgesic properties, as demonstrated by antinociceptive effects at the spinal cord[,]" (ECF No. 1983, PageID 88447, *citing* A.Yanez , *et al*., *Interaction of midazolam and morphine in the spinal cord of the rat*, NEUROPHARMACOLOGY 29: 359-64 (1990)), was misleading. "There was not clear evidence of an analgesic effect in this animal study[.]" (ECF No. 2007, PageID 94875). The study could not determine whether the rats staying on the hot plate was a function of not feeling as much pain or simply because their motor functions were so degraded that they could not move off the plate even if they were experiencing pain. (Hrg. Tr., ECF No. 2117, PageID 104439-40.) Moreover, as indicated by the article's title, "the authors' main thrust of the study was examining morphine effects with a small dose of midazolam. *This paper did not show that midazolam alone was analgesic*." (ECF No. 2007, PageID 94875 (emphasis added).) This is because "midazolam hits GABA, which are inhibitory and can produce CNS depression. . . . But unlike morphine, which hits opioid receptors which are tied to pain neurons and pain pathways, the GABA receptors do not produce analgesia." (Hrg. Tr., ECF No. 1359, PageID 50884.)

In sum, Dr. Stevens opined that, as to Dr. Antognini's opinion that midazolam has analgesic properties, he is "iconoclastic in that belief. In other words, he is an outlier, perhaps

even an extreme outlier, because everything I have read, *Miller's Anesthesia* book and all the classic and well-known authoritative texts do not say that midazolam has any analgesic action." (Hrg. Tr., ECF No. 1359, PageID 50883.)

Third, Dr. Stevens opined that Dr. Antognini's assertion that midazolam can induce "unconsciousness" is ambiguous and immaterial to the execution context, as not one of the studies Dr. Antognini cited used the term "unconsciousness" to mean "insensation" or "unconsciousness sufficient to protect the inmate from the severe pain and suffering associated with the drugs in Ohio's lethal injection protocol." (ECF No. 2007, PageID 94876 (citations omitted).) Consequently, Dr. Antognini's assertions that midazolam's induction of "unconsciousness" was sufficient to shield an inmate from the pain of the paralytic and potassium chloride are unfounded. *Id*. at PageID 94877-78; *see also* Hrg. Tr., ECF No. 1359, PageID 50889-50890 (Dr. Steven's testimony that, contrary to Dr. Antognini's statements, administering 30 mg of midazolam prior to the administration of the paralytic would not render an inmate unconscious, because midazolam cannot produce general anesthesia).

Fourth, Dr. Stevens opined that Dr. Antognini's opinion that midazolam is itself a lethal drug is belied by the sole study he cites for that assertion, which found that a high dosage of midazolam *when combined with an opioid* posed a high risk of hypoxemia and apnea. (ECF No. 2007, PageID 94877 (emphasis added), *citing* Antognini Report III, ECF No. 1983, PageID 88449, 88453; P.L. Bailey *et al.*, *Frequent hypoxemia and apnea after sedation with midazolam and fentanyl*, ANESTHESIOLOGY 73:826-30 (1990).) Subsequently, Dr. Stevens noted that "in the latest compendium of therapeutic, toxic, and fatal blood levels of over 1,000 drugs[,]" there was no fatal level listed for midazolam. In other words, unlike, *e.g.*, pentobarbital, it should not be possible for someone to die simply from the volume of midazolam consumed (ECF No. 836-1, PageID 28415-

16, *citing* M. Schulz *et al.*, *Therapeutic and toxic blood concentrations of nearly 1,000 drugs and other xenobiotics*, CRITICAL CARE 16: R136 (2012).) In fact, Dr. Stevens testified, benzodiazepines "have largely replaced the barbiturates because they are so safe." (Hrg. Tr., ECF No. 941, PageID 32076.)

Further, "Dr. Antognini ignores Dr. Greenblatt's studies of benzodiazepine overdose, which show that the subjects of those overdoses all recovered from massive overdoses of benzodiazepines and were sensitive to painful stimuli when they entered the hospital with those massive overdoses in their systems." (ECF No. 2007, PageID 94877.) Thus, Dr. Antognini's seeming insinuation that an overdose of midazolam might kill an inmate before the paralytic or potassium chloride takes effect is nonsensical. *Id.* *Finally*, Dr. Stevens disagreed with Dr. Antognini's statement that sedation occurs within thirty to sixty seconds of intravenous administration of midazolam, a statement for which Dr. Antognini offers no support and one that is belied by other research in the field. *Id*. at PageID 94878, *citing* Stevens Report II, ECF No. 1288-1, PageID 47115-19; Antognini Report III, ECF No. 1983, ¶ 12, PageID 88445[38]; *accord*: Hrg. Tr., ECF No. 1359, PageID 50881 ("As a scientist, I believe in evidence-based opinions, and I did not see them here.").

On October 9, 2017, Stevens filed an expert report on behalf of former Plaintiffs Tibbetts and Campbell (ECF No. 1288-1), and later filed a rebuttal report, again in response to expert reports filed by Drs. Antognini and Buffington. (ECF No. 1333-1.) On October 24, 2017 (in Plaintiffs' case-in-chief) and October 27, 2017 (in rebuttal), Dr. Stevens testified at Campbell and

[38] Dr. Stevens's rebuttal report also discusses the report of Defendants' expert Daniel Buffington, Pharm.D., as to Henness. (Buffington Report III, ECF No. 1985.) However, Dr. Buffington's report was struck by this Court (Decision and Order, ECF No. 2068), and to the extent that Dr. Stevens's rebuttal report is directed at the report of Dr. Buffington, the Court did not consider that portion.

Tibbetts's hearing for preliminary injunction; those testimonies were largely consistent with the reports. (Trs., ECF Nos. 1359, 1363.)

In the initial report, Dr. Stevens focused on the fact that "[a]fter midazolam is administered by the IV route, **the drug takes a non-trivial period of time to begin to exert its pharmacological effects**." (ECF No. 1288-1, PageID 47710 (emphasis in original).) Specifically, it takes slightly less than two minutes after infusion for a recipient to lose "verbal and other non-reflexive responses[,]" and between 2.0 and 3.7 minutes to produce a loss of the eyelid reflex. *Id*. at PageID 47710, 47714 nn. 5-7, *citing* L. Gehrke *et al.*, *Diazepam or midazolam for orotracheal intubation in the ICU?*, REV. ASSOC. MÉD. BRASILEIRA 61: 30-34 (2015); M.E. Crawford *et al.*, *A randomized comparison between midazolam and thiopental for elective cesarean section anesthesia*, ANESTHESIOLOGY AND ANALGESIA 68: 229-233 (1989); R.J. Fragen *et al.*, *A water-soluble benzodiazepine, RO21-3981 [midazolam], for induction of anesthesia*, ANESTHESIOLOGY 49: 41-43 (1978). Finally, it takes between three and five minutes after administration for sedation to be achieved, and the drug's "maximal (peak) sedative effect occurs between 10 and 20 minutes after IV administration." *Id*. at PageID 47710, 47115 nn.8, 10 (emphasis removed), *citing* J.W. Mandema *et al.*, *Pharmacokinetic-pharmacodynamic modelling of the EEG effects of midazolam in individual rats: influence of rate and route of administration*, J. PHARMACOLOGY 102: 663-668 (1991); H. Allonen *et al.*, *Midazolam kinetics*, CLINICAL PHARMACOLOGY & THERAPEUTICS 30: 653-661 (1981). Meanwhile, peak depression of the central nervous system, as measured by EEG, did not occur until between 7 and 15 minutes after administration, and during that time, "brainwaves in the range of 11.5-30 Hz (*beta* frequency) are actually *increased*." *Id*. at 47715-16 nn.9, 11 (emphasis added), *citing* J.W. Mandema *et al.*, *Pharmacokinetic-pharmacodynamic modelling of the central nervous system effects of midazolam and its main metabolite alpha-*

hydroxymixazolam in healthy volunteers, CLINICAL PHARMACOLOGY & THERAPEUTICS 51: 715-728 (1992).

In his initial testimony, Dr. Stevens reiterated that "circulation delay" prevents intravenous drugs, including midazolam, from being immediately effective:

> So even though a drug is given directly into the bloodstream with IV administration, it doesn't go instantaneously into the brain for -- in this example. It has to go through the circulation. So it gets mixed, some of it is bound to proteins that are in the blood. It has to start, for example, in the right arm, go to the right side of the heart, right ventricle, out [the] right atrium first and right ventricle, and then out to the lungs, gets oxygenated, and then comes back to the heart from the lungs, left atrium, left ventricle, and then goes out to the aorta and then can start from there.
>
> So after that time, it can actually then start to get distributed or transported to the site of action.

(Hrg. Tr., ECF No.1359, PageID 50851.) He emphasized that the site of action for midazolam—the brain—was particularly difficult due to the blood-brain barrier, despite the drug's lipophilic properties. *Id*. at PageID 50852. This circulation delay is based on "a number of factors that contribute to the variability of how fast a drug would even get to the blood-brain barrier." *Id*. at PageID 50853. Additionally, differences in metabolic rates across individuals mean that different amounts of the drug will be metabolized in the bloodstream before it crosses the barrier. *Id*.

Also, as the loss of the verbal response and eyelid reflex occurs prior to "the loss of response to stimuli such as pressure pain or pain of being stuck with a pin[,] . . . lack of response to any of the methods that [Defendants] use[] does not indicate that the inmate has reached a state of unconsciousness characterized by lack of awareness to pain." (ECF No. 1288-1, PageID 47710 (emphasis removed), 47121 n.20, *citing* J.B. Gross, *Induction dose-response curves for midazolam and ketamine in premedicated ASA Class III and IV patients*, ANESTHESIOLOGY AND ANALGESIA 64: 795-800 (1985).) Dr. Stevens then testified as to studies using thiopental and propofol, which

showed that the eyelid reflex and loss of verbal response both disappeared long before the loss of ability to respond to pain (Hrg. Tr., ECF No. 1359, PageID 50868-50869.) Thus, if Defendants chose to use the eyelid reflex test and/or responses to verbal cues as one or both of their required consciousness checks, an inmate's lack of response would indicate nothing as to whether he can feel pain. *Id*. at PageID 50869-71.

This is particularly problematic, Dr. Stevens opined, because the written execution protocol does not specify the particular consciousness checks to be used, and Execution Team Member 21 testified that the medical team chose not to perform some of the more aggressive consciousness checks (*i.e.*, applying the more noxious stimuli), without giving any scientific justification for its decision to forego those other stimuli (ECF No. 1288-1, PageID 47122-26, *citing* TM 17 Depo., ECF No. 1073-1, PageID 41142-43, 41201-03, 41212; TM 21 Depo., ECF No. 1073-2, PageID 41265-66 (other citations omitted).) Dr. Stevens testified that, based on his review of the deposition testimonies of Team Members 17 and 21, the two consciousness checks "that [DRC] apparently used or will use are ones that are not necessarily correlated with lack of response to more noxious stimuli. And I would say they are the more minor reflex or verbal tests that can be used." (Hrg. Tr., ECF No. 1359, PageID 50819-50820.) Moreover, the consciousness check is deemed satisfied if an inmate does not demonstrate a "meaningful reaction" to a stimulus, as determined solely by the execution team member. (ECF No. 1288-1, PageID 47126-27, *citing* Team Member 17 Depo., ECF No. 1073-1, PageID 41195-97.) Dr. Stevens testified that, based on his reviews of the depositions of Team Members 17 and 21, there appeared to be a lack of "any training or common thought put into what is a positive response or a negative response to those assessments" on the part of Defendants, and the fact that the assessments used on Phillips—the eyelid reflex and nailbed assessment, are "less rigorous" than other options available, including

the trapezius squeeze or sternum rub. (Hrg. Tr., ECF No. 1359, PageID 50877-78.) In sum, the small time between the administration of midazolam and the second and third drugs makes it all but certain that an inmate will suffer severe pain, and the consciousness checks performed in between the administration of midazolam and rocuronium bromide provide no guarantee that he is protected from that pain.

Dr. Stevens relied on the FDA's own prescription label for midazolam, which states that "Sedation in adult and pediatric patients is achieved within 3 to 5 minutes after intravenous (IV) injection." (ECF No. 1288-1, Page DI 47112 (emphasis removed) (citation omitted).) Further, he noted studies that have shown that a therapeutic dose of midazolam (0.3 mg/kg, compared to the roughly 7 mg/kg called for in the execution protocol) takes approximately twenty seconds to be administered intravenously, and from that point, it took almost two minutes before recipients stopped responding to simple verbal commands. *Id*. at PageID 47113 nn.3-4, *citing* J.W. Dundee *et al., Pretreatment with opioids: the effect of thiopentone induction requirements and the onset of action of midazolam*, ANAESTHESIA 41: 159-161 (1986); N.J. Halliday *et al., Influence of plasma proteins on the onset of hypnotic action of intravenous midazolam*, ANAESTHESIA 40: 763-766 (1985). Importantly, in a study in which different doses of midazolam (6.6 mg, 10 mg, and 15 mg) were given to patients, "the onset time of sleep was 1.7 minutes, and did not differ among the low, medium, and high midazolam doses." *Id*. n.2, *citing* F.H. Sarnquist *et al., A bioassay for a water-soluble benzodiazepine against sodium thiopental*, ANESTHESIOLOGY 52: 149-153 (1980). Thus, "[a]lthough it may be counter-intuitive, larger drug doses do not lead to faster time of effect." *Id*. at PageID 47718-19 n.17 (emphasis removed), *citing* J.A.S. Gamble *et al., Evaluation of midazolam as an intravenous induction agent*, ANAESTHESIA 36: 868-873 (1981). Dr. Stevens also testified the time required to cross the blood-brain barrier—and thus, achieve sedation and

peak effect—was not dose dependent. Rather, one could hasten those states only by changing the drug's actual formulation. (Hrg. Tr., ECF No. 1359, PageID 50854-55.) While administering morphine or another opioid narcotic in conjunction with midazolam could decrease the time from administration to onset of sedation, no such drug is provided for in Ohio's execution protocol. *Id*. at PageID 50856-50857.

Finally, Dr. Stevens examined the execution logs from the Phillips and Otte executions, which showed that: (a) consciousness checks were conducted less than one minute after the midazolam was administered; (b) rocuronium bromide is administered between 70 and 100 seconds after administration of midazolam; and (c) potassium chloride was administered barely two minutes after the rocuronium bromide. (ECF No. 1288-1, PageID 47119.) Thus, the inmate is feeling the effects of those drugs before he has even achieved a state of sedation, and long before midazolam has its peak sedative effect. Consequently, an inmate executed with this three-drug protocol, with the three drugs administered so closely together, "presents a risk that is sure or very likely to cause serious pain and suffering." *Id*. at PageID 47111 (emphasis removed). Significantly, even if Dr. Antognini's testimony were accurate, and the onset of sedation occurred between 1.9 and 2.4 minutes after the administration of midazolam, an inmate would experience pain from the paralytic prior to midazolam's sedative effect. (Hrg. Tr., ECF No. 1359, PageID 50888.)

In his rebuttal report, Dr. Stevens examined Dr. Buffington's assertion that the Reves article demonstrates that greater doses of midazolam results in more rapid sedation (Stevens Rebuttal II, ECF No. 1333-1, PageID 49222, *citing* Buffington Report II, ECF No. 1312-1, ¶ 6, PageID 47546-47; J.G. Reves *et al*., *Comparisons of two benzodiazepines for anaesthesia induction: midazolam and diazepam*, CANADIAN ANAESTHESIOLOGY SOC'Y J. 25(3): 211-14

(1978)). For several reasons, Dr. Stevens opined, Dr. Buffington's assertion is unfounded. *First*, the study underpinning the article was conducted with a small group of subjects—three for small dose (0.1 mg/kg), five for medium dose (0.15 mg/kg), and ten for large dose (0.2 mg/kg), and while the large dose group had the fastest average induction time, the difference was only statistically significant compared against the small dose group. *Id*. *Second*, the small number of subjects makes the results sensitive to an individual result, particularly to a result that would be treated as an outlier in a larger study. *Id*. at PageID 49222-23. *Third*, the fact that the same people were not in the same groups means that the study did not—and could not—account for variation in how individuals responded to any amount of midazolam. Thus, differences in the speed of the subjects' respective circulations may account for the variation, *rather than the particular, different dosages of midazolam*. "If the Reves study had given differing doses to the *same* patients and had observed different onset times for the *same* people depending on differing doses, that *might* be scientifically valid information . . . . But the study did *not* do even that[.]" *Id*. at PageID 49223 (emphasis in original); *see also* Hrg. Tr., ECF No. 1363, PageID 51487 (the small experimental groups meant that it was "not a robust study . . . this paper would not be published today.").

In light of the above shortcomings, Dr. Stevens concluded, the Reves study does not alter "the overwhelming evidence against dose dependence[.]" (ECF No. 1333-1, PageID 49223.) "Moreover," the consistent body of scientific "studies demonstrating a lack of dose dependency for midazolam's time of onset are consistent with principles of pharmacology which show that the onset of drug effect and time of peak effect of the drug are not correlated to the dose of the drug." *Id*. at PageID 49224 (citations omitted); Hrg. Tr., ECF No. 1359, PageID 50916 ("in the case of the studies that I cited . . . for midazolam across the range of doses, all the way, I believe, from 6.6 to 21.7 [mg] . . . more than a threefold range of doses, and they all end up with the same onset

time."). Specifically, in a commonly accepted pharmacological formula "to determine the time it takes a drug to reach peak blood circulation[,] . . . There is no parameter in the equation to enter the dose of the drug." *Id*. at PageID 49225 (emphasis removed). Taken together, Dr. Stevens opined, Ohio's lethal injection protocol was sure or very likely to cause severe pain, because: (a) midazolam cannot produce a state of general anesthesia or analgesia; (b) even if it could, the paralytic is injected before the midazolam has a chance to take full effect, meaning the inmate is still likely to experience severe pain.; and (c) Defendants' consciousness checks are insufficient to determine whether an inmate can still feel pain. (Hrg. Tr., ECF No. 1359, PageID 50891-50894.)

Defendants' Expert Opinions on the First Prong of *Glossip*

Reports and Testimony of Joseph F. Antognini, M.D.

A brief summary of the history of the participation of Joseph F. Antognini, M.D., M.B.A., in this consolidated litigation may be helpful. His first declaration was filed on December 21, 2016. (ECF Nos. 852-1, 2022-5.) The next month, he testified in the hearing on former Plaintiffs Phillips, Tibbetts, and Otte's motion for a preliminary injunction. (Hrg. Tr., ECF No. 924, PageID 31020-196.) He filed a second declaration on October 19, 2017, (ECF Nos. 1310-1), and testified in a hearing held on Plaintiffs Campbell and Tibbetts's motion for a preliminary injunction on October 23, 2017, (ECF No. 1358, PageID 50562-679). Both declarations and his prior testimony were admitted into evidence in Plaintiff Henness's hearing, albeit over objection as to prior testimony.

Dr. Antognini received his medical degree from the University of Southern California in 1984, and his Master of Business Administration degree at California State University, Sacramento, in 2010. (Curriculum Vitae, ECF No. 2090-1, PageID 103290.) He served his internship and residency at the University of California, Davis, Medical Center from 1984 to 1987. *Id*. at PageID 103290-91. He has taught in the UC Davis School of Medicine's Department of Anesthesiology in various professorial capacities since 1987, and from November 2010 to June 2016, was director of Perioperative Services at the UC Davis Health System. *Id*. He is currently a Clinical Professor of Anesthesiology and Pain Medicine and the Director Emeritus at UC Davis as well as a Physician Surveyor on The Joint Commission at Oakbrook Terrace, Illinois. *Id*. at 103290. Dr. Antognini is a licensed medical doctor in the State of California, a Diplomate of the National Board of Medical Examiners and the American Board of Anesthesiology, and he is certified by the American Board of Anesthesiology.

Dr. Antognini has acknowledged that the majority of his research has been conducted using animal models (Hrg. Tr., ECF No. 924, PageID 31023), and that most of his career had been spent trying to understand how anesthetics produce immobility in those animals (Hrg. Tr., ECF No. 924, PageID 31027). His research did not include studying the consciousness of the animals, nor did he study the effects of midazolam or other benzodiazepines. *Id*. at PageID 31033, 31102-3.

Dr. Antognini's opinion, as expressed in his report for the Henness hearing (ECF No. 1983) and consistent with his testimony is that:

a. Midazolam can be used, and has been used, as the sole medication in a variety of otherwise painful medical procedures, including laryngoscopy, followed by endotracheal intubation, which is very stimulating;

b. Midazolam produces unconsciousness and by itself can be fatal;

> c. Paralysis and lack of breathing following administration of a drug such as vecuronium or rocuronium would not be perceived by a person rendered unconscious by 500 mg [of] midazolam;
>
> d. Intravenous infusion of potassium chloride would not be painful in a person rendered unconscious by 500 mg [of] midazolam;
>
> e. The Ohio lethal injection protocol provides for sufficient time for midazolam to produce unconsciousness before administration of a paralytic drug and potassium chloride;
>
> f. The members of the execution team will be able to adequately determine unconsciousness using medically appropriate methods, to determine whether the condemned inmate has been rendered sufficiently unconscious so as to be unware [sic] of any pain produced by administration of the paralytic drug and the potassium chloride[;]
>
> g. Mr. Henness has various medical conditions (including asthma, COPD, Hepatitis C) but none of these increase his risk for pain and suffering related to the lethal injection protocol[.]

(ECF No. 1983, PageID 88444-45.)

Dr. Antognini explained that midazolam is a short-acting benzodiazepine commonly used in various minor medical procedures, and as a sedative prior to surgery. (ECF No. 1983, PageID 88445.) After describing the usual therapeutic dosages of midazolam, he stated the risks of larger-than-therapeutic dosages as "unconsciousness, respiratory depression, apnea, and death, *citing* the FDA's package insert relating to the drug. *Id*. The onset of action for midazolam is usually thirty to sixty seconds. *Id*.

A primary purpose of midazolam in the clinical setting is to calm a patient's anxiety and act as a "powerful sedative," although Dr. Antognini also stated that the usually desired endpoint is "moderate sedation." *Id*. Midazolam is also an amnesic which prevents the formation of memories surrounding a painful or unpleasant medical procedure. *Id*. at 88446. In his October 2017 voir dire, Dr. Antognini explained that since no studies addressing the effect of 500 mg of

midazolam have been or can ethically be conducted on humans, predicting the drug's effect at that dose involves extrapolation and assumptions based on what is known about it in therapeutic doses. (Hrg. Tr., ECF No. 1358, PageID 50567-68.)

Dr. Antognini reported that midazolam has been used in the past for the induction of anesthesia although not typically so, and that he himself has used it for that purpose. (ECF No. 1983 PageID 88447.) He notes that studies and reports relating to the use of midazolam in the induction of anesthesia are important in the current litigation because they can shed light on midazolam's ability to reduce or eliminate the pain from a part of the induction-of-anesthesia process which is the placement of an endotracheal tube. *Id.* Dr. Antognini states that that procedure is "very stimulating and painful in an awake person" And that just because midazolam is perhaps not the first choice to use in the induction of anesthesia does not negate that it can be used for such purpose. *Id.*

Now, and in both of his previous reports in this consolidated litigation, Dr. Antognini opines that midazolam possesses analgesic properties. (ECF No. 1983, PageID 88447; ECF No. 852-1, PageID 25786, 25792-93.) Dr. Antognini uses the term "analgesia" to describe the relief from pain in somebody who is awake. (Hrg. Tr., ECF No. 2120 PageID 104851.)

At the instant hearing on Henness's motion for an injunction, Dr. Antognini testified that "the administration of five hundred milligrams of midazolam as called for in the Ohio protocol would render a person unconscious to the extent that they would not be able to sense or experience pain that might occur from the administration of the other two drugs." (Hrg. Tr., ECF No. 2120, PageID 104842.) He explained that the reason midazolam is not classified as an analgesic is because in the clinical setting, there are better drugs for pain relief, drugs such as morphine and fentanyl, and that they would be preferred to midazolam. *Id.* at PageID 104845. He does not

believe it is necessary to administer a drug classified as an analgesic if a patient is in a state of general anesthesia, or essentially unconscious to the point of being insensate to pain. *Id*. at PageID 104859.

Dr. Antognini testified that there are two components of pain: one that can be thought of as the "ouch . . . it hurts" part, and an emotional component. (Hrg. Tr., ECF No. 2120, PageID 104850.) One study using a benzodiazepine other than midazolam in humans showed that that drug affected the emotional component of pain, which he distinguished from the physical component of pain. *Id*. Another showed that humans given midazolam and tested with a pain stimulus had lower amounts of pain. *Id*.

In support of his opinion that midazolam possesses some analgesic properties, Dr. Antognini began by defining "analgesia" as the "[a]bsence of pain in response to stimulation that would normally be painful," *citing* the International Association for the Study of Pain's website. *Id*. The same site defines "pain" as "[a]n unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." (ECF No. 1983, PageID 88446-47.) Although benzodiazepines are not classified as analgesics, Dr. Antognini opined that the drug's ability to produce unconsciousness "removes the ability to experience the pain." *Id*. He cited four studies he indicated support his opinion that midazolam produces unconsciousness. *Id*. Dr. Antognini acknowledged that determining the analgesic properties of midazolam in humans has been challenging because the dosages used to effect analgesia and deep sedation/unconsciousness are similar. *Id*.

Dr. Antognini cited animal studies in which a low dose of midazolam was administered intrathecally and was shown to have an analgesic effect. (Hrg. Tr., ECF No. 2120, PageID 104854.) The effect was admittedly less than the effect of morphine, but it was an effect

nonetheless. *Id*. The language used by the authors of the study was that "intrathecally administered midazolam alone displayed weak but clear antinociceptive actions." *Id*. at 104852-55, *quoting* A. Yanez, *et al.*, *Interaction of Midazolam and Morphine in the Spinal Cord of the Rat*, NEUROPHARMACOLOGY, Vol. 29, No. 4, p. 362 (1990).

Dr. Antognini consistently opined that to a reasonable degree of medical and scientific certainty a 500 mg dose of midazolam, which he calculates is 100-200 times the usual therapeutic dose, would render a person "completely unconscious and insensate to pain and noxious stimuli." (ECF No. 1983, PageID 88449; ECF No. 1310-1, PageID 47501; ECF No. 852-1, PageID 25794; Hrg. Tr., ECF No. 1358, PageID 50577, 50607.) He stated with the same certainty and consistency that the risk that an inmate to whom a 500 mg of midazolam had been administered would experience any pain from the administration of rocuronium bromide or potassium chloride would be "exceedingly small." (ECF No.1983, PageID 88449-50; ECF No. 1310-1, PageID 47501; ECF No. 852-1, PageID 25794. Rather, that dosage "would produce a state of anesthesia comparable to levels of anesthesia considered adequate and sufficient for otherwise noxious and painful medical procedures performed on a daily basis." (ECF No. 1983, PageID 88450; ECF No. 1310-1, PageID 47501; ECF No. 852-1, PageID 25794-95.)

Dr. Antognini testified in the October 2017 hearing that his opinion that the amount of midazolam used in Ohio's Execution Protocol is not consistent with the FDA-approved package insert for the drug with regard to the onset of action. (ECF No. 1358, PageID 50580.) He explained:

> [The package insert states that midazolam] is to be infused or given over two minutes. And then the onset of action later describes – is described as being, I believe, around two to three minutes. But that is a very long infusion, so to speak, or time of administration, to give it over two minutes. So the FDA, when they – I wasn't there when they approved this so, again, I am having to extrapolate, as I said,

> but the time frame that they provide in that package insert in terms of an onset of action is two to three minutes, I think. Again, I am not sure of the exact number of minutes, but it was based on, it seems, an administration of two minutes.
>
> But in the clinical setting, we give this drug . . . rapidly, I mean over one or two seconds.

(Hrg. Tr., ECF No. 1358, PageID 50580-81.) He did not clarify how that opinion is inconsistent with the FDA package insert, but on cross-examination in that same hearing, he testified that giving a larger dose of midazolam will result in its taking effect faster. *Id*. at PageID 50670. In other words, the onset of action is dose dependent. Dr. Antognini did not provide, nor could he identify any article that supports his view, and he acknowledged that the FDA's package insert for midazolam does not back up his opinion on this point. *Id*.

Dr. Antognini noted that Henness's reported medical conditions do not increase his risk for suffering pain during his execution since some of those risks can be ameliorated by using a wedge-shaped cushion Ohio has used in previous executions and others have been resolved or are of minor concern. (ECF No. 1983, PageID 88451.)

Dr. Antognini opined that the consciousness checks provided for in Ohio's Execution Protocol, 01-COM-11, are sufficient to assess an inmate's level of consciousness. *Id*. at 88451-52; (ECF No. 1310-1, PageID 47502; Hrg. Tr., ECF No. 2120, PageID 104866.) He further stressed that "a reflex withdrawal (in response to noxious stimulation) is NOT considered purposeful movement." (ECF No. 1983, PageID 88452; Hrg. Tr., ECF No. 2120, PageID 104877). He did not identify what kinds of responses to noxious stimuli would be considered purposeful movements or whether such movements, whether or not purposeful, would indicate reaction to pain. In his earlier report filed in this consolidated litigation, Dr. Antognini explained that phenomenon, stating that as the dose of an anesthetic is increased, the "percent of patients who

retain memory and consciousness decreases to zero, but these same patients will move to noxious stimulation." (ECF No. 852-1, PageID 25790.) In the January 2017 hearing, he stated that anesthesia acts on the spinal cord to achieve immobility, and that it is not uncommon for patients to move during surgery, even though they are unconscious. (Hrg. Tr., ECF No. 924, PageID 31133, 31138, 31027-28.) Such movements can even reach the point of violent thrashing about or "bucking," vigorous coughing, or movement of the arms and legs. *Id*. at PageID 31043-44.

Dr. Antognini was asked on direct examination about the Richmond Agitation-Sedation Scale, or RASS, which involves applying certain stimuli to patients to determine their level of consciousness. (Hrg. Tr., PageID 104867-68.) There are a variety of stimuli that can be used in assessing consciousness under RASS, such as talking to the patient, shaking them, squeezing the trapezius muscle, lifting the eyelid, actually touching the eyeball, and pinching. *Id*. The techniques used in Ohio's Execution Protocol are very similar to those in the RASS. *Id*. at PageID 104868.

Dr. Antognini describes "air hunger" as the "sensation a conscious person would have when they are unable to breathe sufficiently." (ECF No. 1983, PageID 88452, ECF No. 1310-1, PageID 47504.) He then defined "sensation" as "a mental process . . . resulting from the immediate external stimulation of a sense organ often distinguished [sic] from a conscious awareness of the sensory process," and concludes that air hunger is a sensation for which one must be awake to experience. (ECF No. 1983, PageID 88452-53, ECF No. 1310-1, PageID 47505.) An inmate injected with 500 mg of midazolam would "clearly" not be awake to experience air hunger, according to Dr. Antognini. (ECF No. 1983, PageID 88453.) Midazolam, like all sedative and anesthetic drugs, does cause respiratory depression not unlike that caused by opiates. *Id*. at PageID 88453. On that, Dr. Antognini and Plaintiff's expert witness Dr. Lubarsky agree. *Id*. at 88449. Dr. Antognini found illogical the idea that after being administered a respiration-depressing drug,

one can simultaneously stop breathing and suffer from air hunger. (ECF No. 1983, PageID 88449; ECF No. 1310-1, PageID 47505.) He posited instead that it is most logical that the sedative or anesthetic drugs remove the sensation of air hunger and discusses a study in which extended periods of apnea were induced in patients who were unconscious and "adequately anesthetized," and that the patients reported no complaints following the apneic period. (ECF No, 1873, PageID 88449; ECF No. 1310-1, PageID 47506.) He concluded that apnea is not a potent noxious stimulus during anesthesia and would not cause an anesthetized patient to wake up. (ECF No. 1983, PageID 88453-54; ECF No. 1310-1, PageID 47506.) From that study, he extrapolated that "the lack of breathing is not stimulating enough to awaken a subject when a large dose of midazolam is administered." (ECF No. 1983, PageID 88454; ECF No. 1310-1, PageID 47506.)

Dr. Antognini cited three studies that he states support his opinion that midazolam can render an inmate insensate to the pain caused by rocuronium bromide and potassium chloride. (ECF No. 1983, PageID 88454; ECF No. 1310-1, PageID 47509-10.) One study found that midazolam or a mixture of midazolam and ketamine were "safe and effective induction agents for emergency surgery" which may have had advantages over thiopental, which is a complete anesthetic, in such situations. *See* Paul F. White, *Comparative Evaluation of Intravenous Agents for Rapid Sequence Induction – Thiopental, Ketamine, and Midazolam*, ANESTHESIOLOGY 57:279 (1982), (ECF No. 1983-1, PageID 88647, ECF No. 1310-1, PageID 47509.) In the White study, the patients' heart rates increased during induction in all groups, but the increase was significantly less in the midazolam-ketamine group. (ECF No. 1983-1, PageID 88647.)

Another study cited by Dr. Antognini compared the effects of a bolus of midazolam to one of propofol on the QT intervals in the patients' hearts and on the patients' blood pressure during tracheal intubation, and concluded, among other things not relevant here, that the patients' heart

rates and blood pressure increased significantly in both groups following intubation. *See* D.G. Michaloudis, *The effects of midazolam or propofol followed by suxamethonium on the QT interval in humans*, EUROPEAN JOURNAL OF ANAESTHESIOLOGY 13, 364 (1996), (ECF No. 1983-1, PageID 88578, ECF No. 1310-1, PageID 47509.) Midazolam was administered intramuscularly to all patients in Michaloudis's study. (ECF No. 1983, PageID 88455.) In the recent hearing, Dr. Antognini directed the Court's attention to a sentence in the Michaloudis paper indicating that "[a]ll patients were completely anaesthetized" with either midazolam or propofol. (Hrg. Tr., ECF No. 2120, PageID 104864, *quoting* Michaloudis, at 365.) He noted that endotracheal intubation is an "incredibly noxious stimulus," but that the dose of midazolam was "quite high," at 0.4 mg per kilogram. *Id*. at PageID 104864. It bears mentioning, however, that in the January 2017 hearing, Dr. Antognini testified that having no memory of the pain of intubation does not mean the patient did not experience the pain during the procedure. (ECF No. 924, PageID 31117.)

Finally, Dr. Antognini cited A.M. Zbinden, *Anesthetic Depth Defined Using Multiple Noxious Stimuli during Isoflurane/Oxygen Anesthesia*, ANESTHESIOLOGY 80:253-260 (1994), stating that the drug used in that study, even in high doses, increased the patients' heart rates by about thirty-six beats per minute. (Hrg. Tr., ECF No. 2120, PageID 104862-63; 2017 Decl., ECF No. 1310-1, PageID 47509-10.) Although the patients' heart rates increased in both the White and the Michaloudis studies, Dr. Antognini stated that "[t]he fact that midazolam blunts the cardiovascular response to intubation . . . relative to isoflurane suggests that patients given induction doses of midazolam . . . are well anesthetized." (ECF No. 1983, PageID 88455; ECF No. 1310-1, PageID 47510.) Dr. Antognini concluded from these studies that to a reasonable degree of medical and scientific certainty, midazolam administered at 500 mg produces unconsciousness, blunts responses to noxious stimuli, and produces analgesia. (ECF No. 1983,

PageID 88455-56; ECF No. 1310-1, PageID 47510.) His hearing testimony was closely in line with this section of his report. (Hrg. Tr., ECF No. 2120, PageID 104853-64.)

In contrast to other experts who testified at Henness's hearing on his motion for an injunction, Dr. Antognini disputed the claim that midazolam can produce hyperalgesia, or a heightening of painful sensation. (ECF No. 1983, PageID 88456, ECF No. 1310-1, PageID 47510.) Specifically, at the October 2017 hearing, Dr. Antognini testified that a person experiencing hyperalgesia at a particular dose of midazolam does not mean that same person will experience hyperalgesia at any dosage of the drug. (ECF No. 1358, PageID 50607.) He also explained, however, that along the spine there are sites where the drug may act differently. *Id*.

Dr. Antognini testified that midazolam could be used to induce general anesthesia. (ECF No. 2120, PageID 104858-59.) The induction of general anesthesia, however, is not the same as the achievement of general anesthesia. The induction of anesthesia is a process that takes place over the period of time between the first introduction of any amount of the chosen drug and the end result of general anesthesia.[39] Dr. Antognini testified in January 2017 that beginning the process of anesthetization is called the "induction of anesthesia." (ECF No. 924, PageID 31047.) In the October 2017 hearing, Dr. Antognini testified that "induction" of anesthesia is separate from the maintenance of anesthesia in that "[t]hey are separate in a temporal basis but they are not necessarily separate in the state or the stage of anesthesia that [is] achieved." (ECF No. 1358, PageID 50615.) He further acknowledged that benzodiazepines as a class of drugs are the most commonly used drugs for premedication in preparation for surgery. *Id*. at PageID 50624.

Thus, there is little dispute that midazolam can be used in the process of inducing anesthesia, but Dr. Antognini acknowledges that it is not typically used for that purpose since there

[39]https://www.tabers.com/tabersonline/view/Tabers-dictionary/736481/0/induction?q=anesthesia+induction+of, last viewed on January 8, 2019.

are better drugs available for induction. (ECF No. 2120, PageID 104845.) Despite its infrequent use in that context, midazolam has been approved by the FDA for use in the induction of anesthesia, as well as being approved for use as sedation and hypnosis. *Id*. at PageID 104858. The reason midazolam has fallen out of favor in that context is because patients awaken from other sedatives more quickly. (Hrg. Tr., ECF No. 2120, PageID 104866.)

Dr. Antognini reviewed the autopsy reports of inmates' executions in which midazolam was used, observing that pulmonary edema is commonly found in individuals who have died of a drug overdose. (ECF No. 1983, PageID 88457-58.) It is his opinion that the high dose of midazolam used in the Ohio protocol will produce unconsciousness "well before the full 500 mg dose is administered." *Id*. at PageID 88458. He estimated that the inmate will lose consciousness when approximately 10% of the full dose has been administered, and that if pulmonary edema were to manifest, it would not be sensed by the inmate. *Id*.

Dr. Antognini's Rebuttal to Plaintiff's Expert Witnesses

Included in various places throughout his declaration are Dr. Antognini's rebuttals to Plaintiff's expert witnesses. Dr. Antognini stated that midazolam has been shown to produce analgesia when administered intravenously, intrathecally, intraperitoneally, and intraarticularly in humans, rats, mice, and rabbits, contrary to Plaintiff's expert witnesses' opinions that midazolam possesses no analgesic qualities at all. In fact, Dr. Antognini said, Plaintiff's expert Dr. Stevens has published animal work showing that "midazolam has analgesic properties, as demonstrated by antinociceptive effects at the spinal cord." (ECF No. 1983, PageID 88447.) And he noted that Dr. Greenblatt has testified in a different case that midazolam has "weak analgesic effects, citing the

Tennessee Chancery Court case *Abdur'Rahman v. Parker*. *Id*. at PageID 88447-48. Dr. Antognini added that Dr. Greenblatt has in fact written that midazolam has antinociceptive effects related to the drug's spinal cord action. *Id*. at PageID 88448.

Dr. Antognini insisted that midazolam produces anesthesia in humans at the spinal and supraspinal level via intravenous and intrathecal administration, although he acknowledged that the leading textbook on anesthesia, *Miller's Anesthesia*, 8th Edition, 2015, Page 842, states that "[b]enzodiazepines lack analgesic properties." *Id*. He attempted to discredit that entry in the text by stating that "[t]his [1990] statement has been carried over from one edition to the next, without proper consideration of emerging new data." *Id*. It is not evident, however, that Dr. Antognini knows how much "proper consideration" has been devoted to the "ample evidence that [midazolam] has analgesic properties a various doses and routes of administration." *Id*.

Dr. Antognini disagreed with Dr. Edgar's declaration and testimony in which the latter states midazolam is highly acidic; painful upon injection in the dose required by the Ohio Protocol; and that it is sure or very likely to cause pulmonary edema in the inmate, causing substantial pain and suffering. Dr. Antognini opined that given the time over which the 500 mg of midazolam is administered, approximately two minutes, and the rate human blood is capable of buffering the acid in the midazolam, the small amount of hydrogen ions will be counteracted, and therefore not cause the pain Dr. Edgar believes will result. *Id*. at PageID 88458. For the same reason, Dr. Antognini stated that midazolam is unlikely to produce pulmonary edema in inmates executed under the current Ohio protocol. *Id*. Midazolam is preferred over diazepam, in fact, because it "enjoys this property of 'painless' injection relative to other intravenous anesthetic drugs." *Id*. Dr. Antognini attributed the lurching, heavy breathing, gasping, and coughing reported by witnesses to past executions to "breathing efforts of an unconscious person, similar to what occurs in people

who snore heavily." *Id*. at PageID 88459. He further stated that the autopsy reports on four Arkansas inmates executed in 2017 with a three-drug cocktail beginning with midazolam had sufficient concentrations of midazolam in their blood to produce unconsciousness before death. *Id*.

Dr. Antognini found it "hard to know" what Dr. Lubarsky was talking about when the latter stated midazolam does not act on the body's pain receptors and therefore has no analgesic effect. (Hrg. Tr., ECF No. 2120, PageID 104844.) But then Dr. Antognini qualified his criticism by stating that he was reading that "just in isolation or even further on." *Id*. In spite of the unanimity of Henness's expert witnesses on that point, however, Dr. Antognini testified that that "there's really not much there to support [Dr. Lubarsky's] statements around that." *Id*.

Dr. Antognini also disagreed with Dr. Lubarsky as to the goals of general anesthesia. During Henness's voir dire of Dr. Antognini, the doctor acknowledged his belief that general anesthesia entails immobility, amnesia, and unconsciousness. (Hrg. Tr., ECF No. 2120, PageID 104824; Hrg. Tr., ECF No. 924, PageID 31026.) Dr. Lubarsky testified that proper anesthesia renders a patient insensate, immobile, unconscious, and amnestic. (Hrg. Tr., ECF No. 2113, PageID 104278.) Dr. Antognini's opinion is that unconsciousness subsumes insensation. (ECF No. 2120, PageID 104842; 104859; Hrg. Tr., ECF No. 924, PageID 31027.)

Some of Henness's experts, particularly Drs. Greenblatt and Stevens, testified that the midazolam solution itself is very acidic and would cause significant pain to an inmate when administered intravenously. Dr. Antognini disagreed. He stated that midazolam, being water soluble, is much less painful on injection, regardless of dose, than its predecessor diazepam, which is dissolved in propylene glycol. (Hrg. Tr., ECF No. 2120, PageID 104870.) When asked if an inmate's blood would have the buffering capacity to render 500 mg of an acidic drug like

midazolam less painful on injection, Dr. Antognini said, "The pH of midazolam in solution is around a pH of three, and that is considered to be acidic, but it's just the acidic nature, acidic, the pH that you have to look at because a lot of drugs that we administer to patients can be . . . acidic." *Id*. at PageID 104872. He went on to clarify that answer, stating that in the 90-120 seconds it takes the execution team to inject 500 mg of midazolam into the inmate, the entire five or so liters of blood in his body will have circulated throughout his body twice. *Id*. at PageID 104874. Dr. Antognini testified to a medical and scientific certainty that the time it takes to inject the midazolam into the inmate is sufficient for the drug to be dissolved or buffered in his blood. *Id*.

Report and Testimony of Robert H. Davis, M.D., Ph.D.

Defendants also called Dr. Robert H. Davis, M.D., Ph.D. – a board certified Pathologist with Anatomic Pathology and Clinical Pathology certifications, who has served for the last thirty-five years as the Director of Laboratory and Medical Services at Mary Rutan Hospital in Logan County, Ohio. (Hrg. Tr., ECF No. 2120, PageID 104919, 104920.) Dr. Davis testified that over his entire professional career, he has conducted approximately 400 autopsies, including approximately twenty-five in which death resulted from apparent drug overdose. *Id.* at PageID 104922.

Dr. Davis's Expert Report is at ECF No. 1984. Defendants retained him to review Dr. Edgar's Report. Dr. Davis recounted his educational background, training, and experience (Hrg. Tr., ECF No. 2120, PageID 90623-24), as well as the materials he reviewed. *Id*. at PageID 90624. He further stated that all of the opinions he expressed in his report "are stated to a reasonable degree of medical and scientific certainty unless otherwise noted." *Id*.

During *voir dire* Plaintiff's counsel established that Dr. Davis no longer performs autopsies on a regular basis as he once did. (Hrg. Tr., ECF No. 2120, PageID 104924.) On Plaintiff's objection to treating Dr. Davis as an expert, the Court ruled that, "[t]he witness will be accepted on the basis of the foundation laid for such weight as may be appropriate to give his opinions. Again, we do not have a jury present." *Id*. PageID 104942. Later, during cross examination, Dr. Davis agreed that one need not be a *forensic* pathologist in order to assess findings from an autopsy report prepared by someone else, and that an anatomical pathologist is capable of doing so and of reading and interpreting histology slides. *Id*. at PageID 104951-52.

Dr. Davis, in his own report, recounted Dr. Edgar's expert opinion "'based on autopsy data that the condemned inmates developed acute pulmonary edema in 24 of 28 executions in which IV-injected midazolam was used as part of the execution protocol.'" (ECF No. 1984, PageID 90625.) Noting that Dr. Edgar had not stated that the autopsy data showed to a reasonable degree of medical certainty that the pulmonary edema he found was *caused* by IV-injected midazolam, Dr. Davis stated in his report that "no such opinion would be scientifically supportable." *Id*. Dr. Davis pointed first in his report to literature demonstrating that "[p]ulmonary edema can be identified in most deaths related to barbiturates, opioids, as well as midazolam…." *Id*. Dr. Davis testified consistently with his report in this regard and offered his opinion that it is not possible to render an opinion to a reasonable degree of medical certainty that the pulmonary edema indicated was caused by the massive dose of acidic midazolam. (ECF No. 2120, PageID 104933.)

Dr. Davis opined several times on direct examination that it is not the acidic nature of the midazolam that caused the pulmonary edema, but the midazolam itself. (ECF No. 2120, PageID 104934, 104942.) Dr. Davis later confirmed during cross-examination that benzodiazepine overdoses can cause pulmonary edema. (ECF No. 2120, PageID 104944.) Dr. Davis appeared to

base that opinion on his experience with seeing indications of pulmonary edema from other overdose deaths in which a benzodiazepine, an opioid, or a barbiturate was ingested orally. (ECF No. 2120, PageID 104934-35, 104947.) During cross-examination, Dr. Davis confirmed his opinion that it is not possible to reach a conclusion about what specifically from the overdosed drugs may have caused the pulmonary edema based on review of autopsy reports alone. (ECF No. 2120, PageID 104950.)

During cross-examination, Dr. Davis agreed that he relied on only two published sources in rendering the opinions in his Expert Report. (Hrg. Tr., ECF No. 2120, PageID 104959-60.) With respect to an opinion in paragraph 4-a of his report, relying on an article by H. Chen and Joyce deJong, that pulmonary edema can be identified in most overdose deaths involving barbiturates, opioids, and midazolam, Dr. Davis agreed that the 500 mg IV-injected dose of midazolam prescribed in Ohio's lethal injection protocol would qualify as an overdose. *Id*. at PageID 104957 (*citing Increased Lung Weights in Drug Related Fatalities*, H. Chen and Joyce deJong, D.O. (2017). In paragraph 5-b, Dr. Davis cited an untitled article that appeared to be from the journal Clinical Endoscopy to support his opinion that IV-injected doses of 500 mg of midazolam do not cause burning sensations in executed inmates because thousands of individuals, including children, receive IV injections of midazolam every day for medical procedures with no reports of those sensations. *Id*. at PageID 104958. Dr. Davis agreed that the article upon which he relied did not involve an IV-injected dose of 500 mg of midazolam, or data from overdoses of midazolam at any level, but only therapeutic doses of midazolam. *Id*. at PageID 104949-50. Dr. Davis also agreed on cross-examination that he identified no published studies to refute the claim that 500 mg of IV-injected midazolam is causing severe, burning pain upon injection. *Id*. at PageID 104960-61. When asked whether he had identified any published studies to refute the

theory that 500 mg of IV-injected midazolam is causing destruction of pulmonary blood vessels in executed inmates, Dr. Davis answered, "There are none." *Id*. at PageID 104963. Later, on re-direct examination, Dr. Davis agreed that he did seek out relevant studies in preparing his report, and that when he did not find any relevant studies, he was satisfied that he had taken efforts to determine whether any existed. *Id.* at PageID 105008-09.

In his report, Dr. Davis characterized as unfounded Dr. Edgar's expert opinion that injecting large doses of midazolam intravenously will cause severe burning sensations in the blood vessels due to the highly acidic nature of midazolam in injectable solution form. (ECF No. 1984, PageID 90627.) According to Dr. Davis, Dr. Edgar failed to utilize available procedures for detecting damage to the blood vessels of the lungs in connection with his autopsy of Robert Van Hook. "If Midazolam is so toxic and acidic as Dr. Edgar describes," Dr. Davis opined, "it would cause destruction of delicate cells lining the blood vessels of the lungs, as well as other blood vessels of the body." *Id*. at PageID 90627-28.

Returning to paragraph 4-a of his report, where Dr. Davis, relying on the Chen and deJong study, stated his opinion that the main histological findings were that pulmonary edema caused increased lung weights, Dr. Davis agreed on cross-examination, however, that the Chen and deJong article did not actually discuss histological findings and mentioned pulmonary edema only twice in reference to other studies. (Hrg. Tr., ECF No. 2120, PageID 104963-64.)

Dr. Davis also pointed in his report to what he characterized as Dr. Edgar's failure, in correlating the lung weights in autopsies he reviewed exclusively to pulmonary edema, to take into account the congestion of blood vessels within the lungs. Dr. Davis explained that, "[a]t the time of death, blood stasis in the pulmonary arteries and veins dilates these vessels due to pump failure and causes increased weight in the lungs." (ECF No. 1984, PageID 90625.) With respect to the

autopsy data noting that Robert Van Hook had a heart weight of 475 grams, Dr. Davis stated in his report, "[t]he normal heart weight is approximately 350 grams and this weight reveals some degree of cardiomegaly not mentioned by Dr. Edgar." *Id*. at PageID 90625-26. But on cross-examination, Dr. Davis admitted that a 2014 study by Vanhaebost set forth an updated reference for normal heart weights that factored in the person's body weight, and that Dr. Davis did not take that recent science into consideration when drawing conclusions about Van Hook's heart weight. (ECF No. 2120, PageID 104986-89.)

"In addition," Dr. Davis continued in paragraph 4-c of his report, "it appears that this inmate had some degree of congestive heart failure (right heart failure) due to the fact that the right ventricular wall thickness was 0.2 cm and the average should be .05 cm." (ECF No. 1984, PageID 90626.) When asked on cross-examination whether *Cardiology Pathology*, Third Edition, 2001, stated that normal right ventricular wall thickness can vary widely, and that 0.2 cm fell within the normal range, Dr. Davis stated that he did not accept that source or data "in this case." (Hrg. Tr., ECF No. 2120, PageID 104991.) Dr. Davis maintained that 0.5 was normal wall thickness but could point to no source supporting his opinion. *Id.* at PageID 104993-94. Dr. Davis also conceded on cross-examination that he did not review Van Hook's medical records for evidence that Van Hook suffered congestive heart failure and took note that Dr. Edgar had reviewed those records. *Id.* at PageID 104994-95.

Dr. Davis next questioned in his report Dr. Edgar's failure, in reviewing the autopsies performed by other pathologists, to take into account any medications or other medical history of the executed inmates. Dr. Davis explained that, "[p]atients with congestive heart failure have, in many instances, congestion involving the lungs (blood stasis) as I have just explained." (ECF No. 1984, PageID 90626.) Dr. Davis stated that a patient's history is of "critical importance" in

surgical pathology and the autopsy. *Id*.

In his report, Dr. Davis also questioned Dr. Edgar's conclusion, with respect to data showing that inmate Kimbrough had marked vascular congestion (blood stasis in lungs) and mild alveolar edema; specifically, that this data could confirm Dr. Edgar's opinion that Kimbrough died of pulmonary edema. According to Dr. Davis, "[t]he cited data does not justify such a finding to a reasonable degree of scientific certainty." (ECF No. 1984, PageID 90626.) "Marked vascular congestion," Dr. Davis explained, "is pump failure (heart) and is an indication of 'mild pulmonary edema.'" *Id*. Dr. Davis concluded, "[i]n other words, the correlation which supposedly confirms his findings is NOT established." *Id*. On cross-examination, however, Plaintiff's counsel established that Dr. Davis was mistaken in attributing to Dr. Edgar a conclusion that inmate Kimbrough, or *any* of the executed inmates, had *died* of pulmonary edema, as opposed to having *developed* pulmonary edema. (Hrg. Tr., ECF No. 2120, PageID 104968-70.)

Dr. Davis next turned in his report, specifically in paragraph 4-f, to the inmates whose autopsies yielded insufficient data for Dr. Edgar to conclude that those inmates developed pulmonary edema, which Dr. Edgar conceded. (ECF No. 1984, PageID 90226.) Dr. Davis specifically noted that inmate Melson's autopsy revealed "normal crepitus" in both lungs, meaning that the lungs had air in the alveoli (air sacs of the lungs). That finding, Dr. Davis averred, is *inconsistent* with pulmonary edema. Dr. Davis also noted that inmate Moody's autopsy indicated congestion in both lungs and interstitial pigment in the lung tissue, "which suggests that Inmate Moody may have been a smoker." *Id*. at PageID 90627. "In a seeming attempt to nevertheless suggest that the data may still support his opinion, Dr. Edgar states that pulmonary edema cannot be ruled out. Of course, Dr. Edgar's speculation does not support his opinion." *Id*.

On cross-examination, Plaintiff's counsel questioned Dr. Davis about several apparent

mistakes in paragraph 4-f of Dr. Davis's report. (ECF No. 2120, PageID 104975-86.) First, Dr. Davis alleged that Dr. Edgar found the autopsy data from the execution of inmate Christopher Brooks was insufficient for Dr. Edgar to conclude that the inmate developed pulmonary edema. *Id*. at PageID 104976-80. Dr. Davis admitted, however, that the sentence purported to include a quotation from Dr. Edgar with no citation as to where Dr. Edgar is alleged to have made that statement. *Id* Earlier during cross-examination, Dr. Davis acknowledged that Dr. Edgar did identify four inmates whose autopsy reports Dr. Edgar did not include in the group of autopsy reports supporting a finding of the development of pulmonary edema. *Id*. at PageID 104974-75. To that point, Dr. Davis agreed that for those four inmates, Dr. Edgar did not say that the autopsies found no pulmonary edema, only that the autopsy data did not show anything one way or the other about pulmonary edema. *Id.* at PageID 104975-76. Later during cross-examination, Dr. Davis did not dispute that pulmonary edema was identified in 24 of the 28 inmates whose autopsy reports were reviewed. *Id*. at PageID 104986.

Continuing with paragraph 4-f of his report, where Dr. Davis recounted Dr. Edgar's conclusion that autopsy data from inmate Christopher Brooks' execution was insufficient for Dr. Edgar to conclude that Brooks developed pulmonary edema, Dr. Davis conceded upon re-review of Dr. Edgar's Report that Dr. Edgar *actually concluded* that Brooks' autopsy data *confirms* Dr. Edgar's conclusion that Brooks developed acute pulmonary edema during his execution. (Hrg. Tr., ECF No. 2120, PageID 104981-986.)

In paragraph 4-g of his report, Dr. Davis next characterized as "unwarranted criticism" Dr. Edgar's "speculation" that the absence of data does not undermine his opinions because other pathologists may have overlooked the "'subtle microscopic evidence of pulmonary edema.'" (ECF No. 1984, PageID 90627.) Dr. Davis's opinion is "that it is unlikely that a certified pathologist

would overlook or fail to note when pulmonary edema is present histologically." *Id.* On cross examination, Dr. Davis admitted that paragraph 4-g of his report included another instance of a quotation attributed to Dr. Edgar but with no citation. (Hrg. Tr., ECF No. 2120, PageID 104996.) Dr. Davis also reiterated that he thought Dr. Edgar's statement about the possibility that other pathologists overlooked subtle evidence was an insult to all pathologists and that Dr. Davis felt personally offended. *Id*. at PageID 104997. Plaintiff's counsel also established on cross-examination that where Dr. Davis's report purported to quote Dr. Edgar's reference to "***micro***scopic evaluations," Dr. Edgar's report actually referenced "***macro***scopic evaluations" *Id*. at PageID 104998-5000 (emphasis added).)

On re-cross examination Dr. Davis agreed that if data shows a "common incident" in 24 of 28 executions, that would be "highly concerning" to him as a scientist. (ECF No. 2120, PageID 105015.)

Dr. Davis continued in his report, "[m]y review of Dr. Edgar's qualifications and experience indicates that Dr. Edgar is not qualified to render an expert opinion on whether the pulmonary edema he discerned based on autopsy findings may be related to the chemical properties of midazolam." (ECF No. 1984, PageID 90628.) To that point, Dr. Davis also opined that "no such relation can be established to a reasonable degree of scientific certainty based solely on a pathologist's autopsy findings." *Id*. at PageID 90628-90629.

Court's Evaluation of the Evidence on the First Prong of *Glossip*

The quality of the evidence presented on the first prong of the *Glossip* standard has increased dramatically since the January 2017 hearing for former Plaintiffs Phillips, Otte, and

Tibbetts. The evidence, both designated from prior hearings and newly introduced, now establishes several factual propositions material to the first prong of *Glossip*.

First of all, the Court finds that midazolam at any dosage level has no analgesic properties. Dr. Stevens testified in the January 2017 hearing that midazolam is not an analgesic drug (Hrg. Tr., ECF No. 923, PageID 30746), and he has not wavered from his opinion or his explanation of why he holds this opinion, which is based in the neuropharmacology of benzodiazapenes. Dr. Antognini has also not wavered from his contrary position (*see, e.g.*, ECF No. 1983, PageID 88447), but his opinion is now shown to be an outlier in the field of anesthesiology by the testimony of Doctors Greenblatt, Exline, Lubarsky, and Stevens. Although the Court declined to exclude Dr. Antognini as an expert witness under Fed.R.Evid. 702, that does not imply his opinion is entitled to as much weight as those of the many opinions which oppose it. Particularly persuasive is the opinion of Dr. Greenblatt, who was there at the "birth" of midazolam as an FDA-approved drug (Hrg. Tr., ECF No. 2113, PageID 104172-73), has continued to study it intensively, and has persuaded many others to rely on his studies.

Because midazolam has no analgesic properties, it cannot prevent the pain incident to the second and third drugs from reaching the brain of the condemned inmate, based on the GABA receptor mechanism Drs. Stevens, Lubarsky, Exline, and Greenblatt all identified and which is unrebutted. This Court has already found that injection of the second and third drugs into a fully conscious person would surely or very likely cause severe pain and needless suffering to the person being executed and the Sixth Circuit accepted that finding. *Fears v. Morgan*,860 F.3d at 886. That being so, the State must do something first to prevent the inmate from suffering that severe pain.

Second, the Court finds that midazolam at the 500 mg dose used by Ohio as an initiatory drug is certain or very likely to cause pulmonary edema. Dr. Edgar examined twenty-eight autopsy

reports from persons executed with midazolam and confirmed the presence of pulmonary edema in twenty-four of them. Twenty-eight appears to be the entire number of such autopsy reports that were available to be examined.[40] When more than eighty-five percent of the entire possible sample has a confirmed diagnosis, it is good science to infer that midazolam caused it, since they all were executed with midazolam. The Court further finds credible Dr. Edgar's explanation as to how he came to the conclusion that the pulmonary edema was caused by the midazolam.

The fact that overdoses of other drugs, including barbiturates, will also cause pulmonary edema, as Dr. Davis testified (Hrg. Tr., ECF No. 2120, PageID 104931), does not undermine this finding because other drugs cannot have caused pulmonary edema in executed inmates when they were not injected with those other drugs; it has to have been the midazolam. The Court finds Dr. Edgar's explanation of Eighty-five percent is enough for the Court to conclude that midazolam is "sure or very likely" to cause pulmonary edema.

Third, the Court finds that pulmonary edema itself certainly or very likely causes severe pain and needless suffering. In all the hearings in this case, the Court has heard lay descriptions of labored breathing of various sorts by condemned inmates after injection of midazolam, commonly referred to as air hunger. Dr. Edgar has now provided a medical explanation of air hunger: it comes from pulmonary edema, which means the airways in the lungs are filling up with fluid instead of air. All medical witnesses to describe pulmonary edema agreed it was painful, both physically and emotionally, inducing a sense of drowning and the attendant panic and terror, much as would occur with the torture tactic known as waterboarding.[41]

In sum, Plaintiff has established that midazolam cannot prevent the physical pain known

[40] The Court learned during the hearing that Ohio does not perform autopsies on executed inmates, which is why Dr. Edgar had to be retained to perform the Van Hook autopsy and why the Otte autopsy is not publicly available.
[41] Dr. Lubarsky expressly likened the effect to that of waterboarding (Hrg. Tr., ECF No. 2113, PageID 104292.)

to be caused by injection of the paralytic and the potassium chloride. Moreover, midazolam itself is certainly or very likely causes pulmonary edema, which is both physically and emotionally painful to a severe level.

Henness has not shown that the Eighth Amendment requires that a condemned inmate be rendered insensate to pain, but only that midazolam will not achieve insensation. In *Fears v. Morgan*, the Sixth Circuit formulated the relevant question as "whether an inmate who receives a 500-milligram dose of midazolam is 'sure or very likely' to be conscious enough to experience serious pain from the second and third drugs in the protocol." 860 F.3d at 886, *quoting Glossip*, 135 S.Ct. at 2737.[42] Based on the testimony at the hearing, we can now add to the relevant question whether an inmate who has received the 500 mg dose is sure or very likely to be conscious enough to experience the severe pain from pulmonary edema.

The key question, it appears to this Court, is whether "sensate to pain" and "conscious enough to experience pain" are equivalent. In his Motion for Preliminary Injunction, Henness characterized this as a scientific question:

> But that framing of the purported "relevant question" is a direct manifestation of the scientific inaccuracies in this case that cry out for re-evaluation and correction. As stated, the inquiry misstates the actual relevant scientific question; it conflates three unique and distinct concepts—consciousness, awareness, and sensation—into just "consciousness." This Court consequently misinterpreted evidence demonstrating sensation; the significance of that evidence; the critical distinction between consciousness and sensation of pain; and the scientific truth that being unconscious does not prevent a person from experiencing pain in the absence of a true analgesic agent.

(ECF No. 1929, PageID 74876.)

The ultimate question, of course, is legal: what level of experience of pain constitutes cruel

[42] Rephrased as "the likelihood that the inmate is conscious enough to experience that serious pain, whether physical or psychological" in *Campbell v. Kasich*, 881 F.3d at 450 (emphasis removed).

and unusual punishment? The scientific contributions to deciding that question are informing the courts what causes pain, what blocks pain, and how can we determine what level of pain is being experienced by the inmate.

The Court disagrees with Defendants' assessment that the evidence presented in the December hearing is no different in quality than that presented before. If the evidence were just "cumulative" in the sense in which that word is used in evidence law, it would have been proper to exclude it altogether. But, as Plaintiff argues, science operates on the accumulation of new data. Indeed it is the essence of the scientific method to continue to test previously reached conclusions against newly accumulated data. See *Daubert*, 509 U.S. at 593, *citing* CARL G. HEMPEL, PHILOSOPHY OF NATURAL SCIENCE 49 (1966); KARL POPPER, CONJECTURES AND REFUTATIONS: THE GROWTH OF SCIENTIFIC KNOWLEDGE 37 (5th ed. 1989). A scientific theory that cannot be tested is not scientific at all.[43] A hypothesis that survives testing against new data becomes thereby stronger.

The December hearing produced significant new opinion testimony, provided by experts who were not just qualified, but in many cases preeminent in their fields of specialization. They examined the data that was available as of January 2017 and the data accumulated since then, particularly the autopsy reports on inmates executed with midazolam, and testified to a consensus about the insufficiencies of midazolam to prevent severe pain and needless suffering.

An appellate court case that considers science as it exists at a given point in time does not freeze that science into the law for all future cases. For example, the Supreme Court in *Glossip* did not hold that a lethal injection execution that begins with 500 mg of midazolam can never be

[43] Karl Popper contrasted Einstein's theory of relativity which could be tested against data with Freud's theories of psychoanalysis, which could not and were therefore not scientific in Popper's view. See DAVID GOODSTEIN, HOW SCIENCE WORKS IN REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 49 (3d ed. 2011) (Federal Judicial Center & National Research Council).

shown to prevent the experience of severe pain. Rather, it held the district court in *Glossip* "did not commit clear error when it found that midazolam is highly likely to render a person unable to feel pain during an execution[.]" *Fears v. Morgan*, 860 F.3d at 886, *quoting Glossip*, 135 S.Ct. 2739. But deference under a clearly erroneous standard depends on the evidence presented in the trial court and the scientific evidence on the effects of midazolam is not limited by the record developed in the Oklahoma district court in *Glossip*. To put it another way, the task of this Court is not to reweigh the *Glossip* evidence or the evidence before it in January 2017, but rather to weigh all the evidence now in the record here.

Based on the evidence presented here, both at the December hearing and as designated from prior hearings, the Court finds as a matter of fact that it is certain or very likely that a 500 mg IV-injected dose of midazolam cannot reduce consciousness to the level at which a condemned inmate will not experience the severe pain associated with injection of the paralytic drug or potassium chloride or the severe pain and needless suffering that is certain or very likely to be caused by the pulmonary edema which is very likely to be caused directly by the midazolam. This finding of fact is independent of the hypothesis that it is the acidic state of injected midazolam that causes pulmonary edema.

Has Plaintiff Proven an Appropriate Alternative Method of Execution? (The Second Prong of *Glossip*)

In *Fears v. Morgan*, the *en banc* circuit court restated the second prong of an Eighth Amendment claim under *Glossip* "which requires [a plaintiff] to prove that an alternative method of execution is 'available,' 'feasible,' and can be 'readily implemented,' among other things." 860

F.3d at 890, *citing Glossip*, 135 S.Ct. at 2737. Although this Court had found that the alternative proposed by former Plaintiffs Phillips, Otte, and Tibbetts, met the second prong of *Glossip*, the Sixth Circuit strongly disagreed, concluding this Court "was seriously mistaken as to what 'available' and 'readily implemented' mean."[44] "[F]or that standard to have practical meaning," the circuit court held, "the State should be able to obtain the drugs [needed for the alternative method] with ordinary transactional effort." 860 F.3d at 891.

Plaintiff's Position on the Second *Glossip* Prong

Henness's Preliminary Injunction Motion does not revisit with new evidence the alternative methods advocated, unsuccessfully, by former Plaintiffs Phillips, Tibbetts, and Otte. Instead, Henness proposes two methods of execution (1) oral injection of ten grams of secobarbital in four ounces of a sweet liquid or (2) oral injection of 3.75 grams of midazolam, 100 milligrams of digoxin, 15 grams of morphine sulfate, and 2 grams of propranolol, along with, in either alternative, use of a wedge pillow to hold the inmate up from the prone position on the execution gurney. He asserts these alternatives are available, feasible, and readily implemented with ordinary transactional effort (Motion for Preliminary Injunction, ECF No. 1929, PageID 74954-74.)

Defendants have already used or agreed to use a wedge pillow in prior executions adjudicated in this consolidated case, so that element requires no analysis.

[44] The circuit court denominated this as legal error, evoking *de novo* review, as opposed to the more deferential clearly erroneous standard that would be applicable to findings of fact. *Fears v. Morgan*, 860 F.3d at 890, *citing Highmark Inc. v. Allcare Health Mgmt. Sys. Inc.*, 572 U.S. 559, 563 (2014).

Defendants' Position on the Second *Glossip* Prong

In opposing Henness's Preliminary Injunction Motion on the second *Glossip* prong, Defendants argued that the four-drug, midazolam-digoxin-morphine-propranolol ("MDMP II")[45] method would be infeasible because of the length of time from drug ingestion to death. (Memo in Opp., ECF No. 1934, PageID 75027.) They also note that Henness's medical records show an allergy to codeine which could cause an allergic reaction to the morphine in the MDMP II mixture, resulting in nausea and vomiting. *Id.* They argue from several perspectives that oral ingestion of execution drugs does not constitute an "injection" within the meaning of Ohio's method of execution statute, Ohio Revised Code § 2949.22(A). *Id.* at PageID 75028-29.

In their written Closing Argument, Defendants argue Henness failed to prove there was a readily available source of the drugs for their proposed alternatives that was both able and willing to sell the drugs to Ohio, noting that the source identified[46] by Henness does not presently have a Terminal Distributor of Dangerous Drugs or Wholesale Distributor of Dangerous Drugs license as issued by the Ohio Board of Pharmacy. (ECF No. 2105, PageID 103520-21.) Defendants compare this lack of licensure to the long delay, not yet ended, in the Drug Enforcement Administration's consideration of an import license for the State of Ohio. *Id.* at PageID 103521.

Defendants also assert Henness had not proved "either alternative is feasible and readily implemented" because neither has ever been used to carry out an execution. *Id.* at PageID 103522. Defendants repeated their argument that oral ingestion does not constitute an "injection" under

[45] An unspecified amount of midazolam, between fifty and one hundred mg digoxin; fifteen grams morphine sulfate; and two grams propranolol (ECF No. 1947, PageID 75589-91).

[46] The identification was made under seal to obviate issues of possible harassment of the source identified by Judge Frost as ground for a protective order in 2015 (ECF No. 629, upheld by the Sixth Circuit in *Fears*, 845 F.3d 231).

Ohio Revised Code § 2949.22. Basing their argument on Dr. Blanke's testimony about variability in the medical assistance in dying process, Defendants argue the alternatives are unpredictable in their results, particularly as to time from ingestion to death. Lastly, they argue Henness has not shown his alternatives would reduce pain because both involve the use of drugs which, per Dr. Edgar's testimony, could cause pulmonary edema. *Id.* at PageID 103525-26.

Expert Opinion on the Second Prong of *Glossip*

Charles D. Blanke, M.D.

To carry his burden of proof on the second *Glossip* prong, Henness relied on the testimony of Dr. Charles Blanke who opined that Henness's proposed alternative methods—(1) a combination of ten grams of secobarbital and four fluid ounces of "sweet liquid"; and (2) the four-drug "MDMP II" method—are virtually one hundred percent effective at inducing a pain-free death, and, consequently, pose much less of a risk of pain and suffering than does Defendants' three-drug protocol. (ECF No. 1947,PageID 75595-96.) Dr. Blanke based his report on his status as "a practicing end-of-life specialist," *id*. at PageID 75583, nearly thirty years of practice as a licensed oncologist, authoring more than 440 academic works, and serving as the medical aid in dying ("MAID") consultant for the State of Hawai'i and the Province of Ontario. *Id.*

As discussed in both his expert report and testimony—which was consistent with said report—Dr. Blanke has been present on more than 125 occasions when MAID patients self-administered secobarbital or DDMP II drugs (substituting diazepam for midazolam), which he believes is "more MAID procedures than any other doctor in the United States." (ECF No. 1947,

PageID 75585; Hrg. Tr., ECF No. 2117, PageID 104609-10.) He also authored a recent, peer-reviewed journal article based on data published annually by the State of Oregon from 1998 through 2015 regarding MAID procedures in the state, which in subsequent academic presentations, he has supplemented with similar data from the State of Washington. (Hrg. Tr., ECF No. 2117, PageID 104610-11, *citing* Charles D. Blanke *et al.*, *Characterizing 18 Years of Death with Dignity in Oregon*, JAMA ONCOLOGY (accepted Jan. 17, 2017).) Dr. Blanke opined that Oregon's data is the best, most comprehensive source from which to draw inferences, because: (a) it was the first state to legalize MAID, and has been collecting data for the longest time; (b) its statute has served as the model for other jurisdictions that have legalized MAID via statute or ballot initiative; (c) the statute requires an extensive amount of information to be reported with respect to each assisted suicide; and (d) the data are published annually and are made publicly available. *Id*. at PageID 104615-18. However, he conceded on cross-examination that, for the majority of MAID cases occurring after the Oregon law was amended around 2010 to make reporting of the length of time from ingestion to death optional, those data were not reported. *Id*. at PageID 104712-13.

In his report, Dr. Blanke stated that the secobarbital method has been used in more than 1,000 MAID cases since 1998 (ECF No. 1947, PageID 75586-88, *citing* Oregon Death with Dignity Act 2017 Data Summary ("DWDA 2017"), ECF No. 1947-1, PageID 75669), and he opined that the means by which the method is administered in the MAID context is "essentially analogous" to Henness's proposed method. *Id*. at PageID 75589. He stated that the DDMP II method "was used in approximately 72 cases in Oregon between 1998 and 2017." *Id*. at PageID 75589, *citing* DWDA 2017, ECF No. 1947-1, PageID 75669. Further, he opined that the "MDMP II" method proposed by Henness, *i.e.*, replacing diazepam (a benzodiazepine) with midazolam

(also a benzodiazepine) would not be a material change. *Id*. at PageID 75591; Hrg. Tr., ECF No. 2117, PageID 104736-37.

Dr. Blanke's expert opinion and testimony subsequently described the administration of the secobarbital and four-drug methods. He testified that oral, over-the counter medications are sometimes given to a patient prior to administration of the MAID drugs to ease fears of patient nausea or regurgitation of the drugs. (Hrg. Tr., ECF No. 2117, PageID 104718.) He stated that 100 capsules of 100 mg of secobarbital are emptied into a syringe, mixed with four ounces of sweet liquid (*e.g.*, apple juice), and swallowed as a mixture. (ECF No. 1947, PageID 75593), and that the four medications used in the DDMP II method naturally form a liquid when mixed together; the mixture is then injected orally via depressing a syringe. *Id*. at PageID 75593-95; *see also id*. at PageID 75599-606. Despite neither the secobarbital nor the four-drug method having been used outside of the MAID context, Dr. Blanke testified that the evidence from MAID may be readily applied in the execution context, since the drugs "would act in the same fashion." (Hrg. Tr., ECF No. 2117, PageID 104619.) As both are injected via nasogastric or orogastric tube into the stomach, neither of the methods will require specialized training or skills on the part of execution team members. He then stated that neither the secobarbital nor four-drug method requires any specialized skills or training to prepare and could be done by any responsible pharmacist. *Id*. at PageID 104648-59; *accord* (Blanke Report, ECF No. 1947 at PageID 75594-95.) The ease of preparation and administration of these methods, along with their efficacy, have produced, "among practitioners, particularly specialists," an "absolute consensus that these are the best medications and that they are humane." *Id*. at PageID 104651.

In his testimony, Execution Team Member 31, a licensed paramedic, confirmed that he has been trained and believes himself competent to insert either a nasogastric or orogastric tube (Hrg.

Tr., ECF No. 2117, PageID 104511-12.) While Team Member 31 stated that there was a risk of non-cooperation by the patient which could complicate the insertion of a tube, *id*. at PageID 104529, Dr. Blanke testified that, in approximately 100 MAID cases in Oregon, secobarbital had been administered via tube, specifically with patients suffering from amyotrophic lateral sclerosis, and he had never encountered any such resistance with a patient. *Id*. at PageID 104663-64; *accord* ECF No. 1947, PageID 75602. Further, he opined that the risk resulting from an inmate's non-cooperation is much less with a tube than with attempting to insert a needle for intravenous administration of drugs, in which a small movement by a recalcitrant inmate could cause the intravenous infusion to be ineffective and even dangerous. *Id*. at PageID 104665. Finally, once placement of the tube "is verified, for example, there is almost no risk of accidentally administering the drug into tissue (as opposed to that risk when attempting to administer the drug into a vein by IV injection)." (ECF No. 1947, PageID 75602.)

In his report, Dr. Blanke opined that, from his experience and publicly available data from the State of Oregon between 2008 and 2017, the median time from ingestion of secobarbital to becoming comatose is five minutes, and the median time from ingestion to death is approximately twenty-five minutes, although the actual range was between two minutes and two days. However, he was unable to confirm or deny Defendants' reading of a report that, of 200 Canadian MAID patients who used the secobarbital method, the "average time from ingestion to death . . . was sixty-eight minutes." (Tr., ECF No. 2117, PageID 104727.) Based on that same experience and data, the median time from ingestion of the DDMP II drugs to unconsciousness is approximately twenty-five minutes, and the average time from ingestion to death is approximately 125 minutes (ECF No. 1947,PageID 75595-96, *citing* Oregon Health Auth., Ctr. For Pub. Health Prac., Pub. Health Division, "Median Times for DWDA Deaths Resulting from Ingestion of Secobarbital or

DDMP II, Oregon 2008-2017" (Sept. 12, 2018), ECF No. 1947-1, PageID 75659.) On re-direct examination, however, he stated that patients, even those who take a long time to die after ingestion, "are deeply asleep, unaware, and not in pain," and "[t]here is no risk of pain or suffering or severe pain or suffering regardless of the duration." (Hrg. Tr., ECF No. 2117, PageID 104753.) As evidence of such, he testified that, at the request of families, he will subject the patient to noxious stimuli, "and there is no evidence of any response[.]" *Id*. at PageID 104756. Specifically, as to the preparation and administration of the four-drug cocktail, Dr. Blanke stated that digoxin may be "given in advance of the other three to hasten the death of the patient." *Id*. at PageID 104639. He testified that the benzodiazepine (either diazepam or midazolam) "will act in a similar fashion as the barbiturate in terms of respiratory, breathing suppression, possibly brain function[,] and nervous system action." *Id*. at PageID 104639, 104646. However, it is the morphine—and only the morphine—that produces analgesia, and consequently, a "death that is painless and free of suffering." *Id.* at PageID 104643.

Dr. Blanke stated that, while he has never encountered complications with patients self-administering MAID drugs, in the event that the initial doses are not effective, a second administration of the drugs could be administered with no danger of pain or complications to the patient. (ECF No. 1947, PageID 75597-98.) Dr. Blanke claimed, based on the data available and his personal experience, that the drugs are over 99% effective at causing death, and 100% effective in rendering pain-free death. *Id.* at PageID 75596-98. He further stated that, because neither protocol contains a paralytic or potassium chloride, the risks of suffocation and intravenous pain, respectively, resulting from Ohio's execution protocol are absent as to either of the proposed alternatives. *Id*.at PageID 75597, 75606. However, when asked about the prospect of a patient or inmate suffering pulmonary edema as a result of the administration of secobarbital or the four-

drug method, Dr. Blanke lacked a basis to offer an opinion, as no autopsies were performed on MAID patients. (Hrg. Tr., ECF No. 2117, PageID 104687.)

Any discomfort from the insertion of the tube, Dr. Blanke claimed, would be ameliorated by the application of a topical anesthetic, such as lidocaine, but an inmate would feel pain if such an anesthetic was not used. (Hrg. Tr., ECF No. 2117, PageID 104661, 104735.) He also stated that an "injection," in both the medical and statutory sense, involves "the forcing of a fluid into a vessel, tissue, or cavity." (ECF No. 1947, PageID 75603 (citation omitted).) There is no requirement that a needle pierce the body; nor must an injection necessarily be done intravenously. *Id*. at PageID 75603-04. Thus, he stated, "administering either of the alternative drugs by forcing the drugs through a syringe (a vessel) into the passages (mouth) or cavities (abdominal) of the inmate's body is properly considered 'injection,' regardless of whether a needle of any kind is used." *Id*. at PageID 75604. Dr. Blanke previously testified in *Hamm v. Dunn*, in which the district court ruled on the issue of whether the administration of execution via depressed syringe and a tube constituted an "injection" under the State of Alabama's execution protocol. (Hrg. Tr., ECF No. 2117, PageID 104653-54, *citing* 302 F. Supp. 3d 1287 (N.D. Ala. 2018), *vacated and remanded by Hamm v. Comm'r*, No. 18-10473, 2018 WL 2171185 (11th Cir. Feb. 13, 2018.) He reiterated that, based on his reading of Ohio's lethal injection statute, administration via nasogastric or orogastric tube would constitute an injection, clarifying that while "[n]eedles are commonly cited as examples of injections . . . there's no requirement for a needle to meet the medical definition of injection." *Id*. at PageID 104657. Dr. Blanke then testified as to the insertion of such a tube, and that he analyzed "randomized trial data, experimental data, suggesting [that] with appropriate use of anesthetic, it is relatively painless[.]" *Id*. at PageID 104661.

Dr. Blanke testified that cases of actual allergies to specific drugs occur in less than one

percent of the population, making the State's argument that Henness is allergic to codeine, in his opinion, a dubious one (Hrg. Tr., ECF No. 2117, PageID 104743; *see also* ECF No. 1947, PageID 75607 (describing Henness's purported codeine allergy).) While the allergy, if accurate, would require the replacement of morphine—like codeine, an opioid—from the MMDP II method, *id*. at PageID 104744, that allergy would not implicate secobarbital, a barbiturate; nor, consequently, the secobarbital method. (ECF No. 1947,PageID 75607.) Finally, in his report, Dr. Blanke opined that he knows of at least one medical source willing to sell secobarbital, digoxin, morphine, and propranolol for the purpose of executions, and that Defendants could obtain those drugs with ordinary transactional efforts and at a reasonable expense (between $3200 and $3700 for secobarbital, and between $400 and $700 for the MDMP II compound). *Id*. at PageID 75609-11; Hrg. Tr., ECF No. 2117, PageID 104679-104680. He also testified as to his familiarity with the process by which an out-of-state pharmacy could obtain a TDDD license in Ohio, which would enable the pharmacy to sell the lethal drugs to Defendants for use in executions, but he only obtained that familiarity by visiting the State of Ohio Board of Pharmacy website and viewing the application (Tr., ECF No. 2117, PageID 104624, 104630-32).

Dr. Antognini's Opinion on Plaintiff's Proposed Alternative of Oral Administration of Secobarbital

Dr. Antognini anticipates trouble with Plaintiff's proposed alternative of oral administration of secobarbital. First, he disputes Dr. Blanke's description of insertion of a nasogastric tube through which to administer the drug as "painless." (ECF No. 1983, PageID 88457.) "[I]n the absence of topical anesthesia, pain was rated, on average, around 50-60 on a 100-point scale, where 100 is the most pain imaginable." *Id*., *citing* Lor, *et al*., 2018, Defendants'

Exhibit FF; ECF No. 2022-3. Another study cited by Dr. Antognini, however, concludes that the pain arising from the insertion of a nasogastric tube can be significantly decreased by pretreating the inmate's nose and throat with a topical anesthetic and vasoconstrictors. Adam J. Singer, *Comparison of Topical Anesthetics and Vasoconstrictors vs Lubricants Prior to Nasogastric Intubation: A Randomized, Controlled Trial*, ACADEMIC EMERGENCY MEDICINE, Vol. 6, No. 3 (March 1999)(ECF No. 2022-3, PageID 95969). It is true, as Dr. Antognini states, that there are risks to insertion of a nasograstric tube, such as gagging or choking, vomiting, perforation of the nasopharynx and esophagus, misplacement of the tube in the trachea, nosebleed, and damage to the nasal passages. (ECF No. 1983, PageID 88457.) But Dr. Antognini offers no opinion and points to no studies on the frequency or severity of any such incidents that one might encounter when placing a nasogastric tube. Thus, the degree of risk and the severity of any injury to the inmate remains unknown.

Court's Evaluation of the Evidence on the Second Prong of *Glossip*

In evaluating Dr. Blanke's report and testimony, the Court gives particular weight to his significant experience with both the secobarbital and DDMP II methods—he has likely been involved with more MAID cases than anyone else in the United States. In light of his experience, and the substantial empirical data upon which he bases his conclusions, the Court finds credible his conclusions that both methods, if administered to Henness, would likely render him insensate and allow him to die in a pain-free manner. The Court finds that pain from the insertion of a nasogastric or orogastric tube could be effectively mitigated by the application of a topical anesthetic and finds concerns—raised by Defendants' attorneys on cross-examination—that

administering oral, pre-execution drugs for nausea would start the execution clock to be specious, and an unreasonable reading of 01-COM-11. From his report and testimony, the Court is satisfied that the administration of either the secobarbital or MDMP II via nasogastric or orogastric tube would constitute a "lethal injection" as contemplated by Ohio Revised Code § 2949.22(A).

However, the Court cannot conclude, from this testimony, that either method is "feasible, readily implemented, and in fact significantly reduce[s] a substantial risk of severe pain." *Glossip v. Gross*, 135 S.Ct. 2726, 2737 (2015) (internal quotation marks and citation omitted). As Dr. Davis testified, pulmonary edema can be caused by overdoses of "numerous other drugs, such as opiates, not only the benzodiazepines, but also barbiturates." (Hrg. Tr., ECF No. 2120, PageID 104931.) No evidence has been presented to the contrary. In addition, as no autopsies are conducted on MAID patients, there is no evidence that the secobarbital method did not itself produce pulmonary edema—precisely the pain that the Court has found midazolam is sure or very likely to cause. While Dr. Blanke offers a conclusory statement in his expert report that "[t]he secobarbital method does not pose a risk of causing acute pulmonary edema during the execution[,]" (Blanke Report, ECF No. 1947, PageID 75606), he is not a pulmonologist or pathologist, and he simply lacks the knowledge to render such an opinion to a reasonable degree of scientific or medical certainty. Moreover, he cites no source in support of his statement.

The four-drug method, as opined and testified to by Dr. Blanke, raises two similar concerns. *First*, unlike secobarbital's relatively short time from ingestion to death of twenty-five minutes, the median time from ingestion of the DDMP II drugs to death of over two hours creates a logistical impossibility for Defendants. As testified to by Warden Ron Erdos, an execution that would last more than one hour:

> [L]ogistically, we couldn't accommodate that. We couldn't accommodate the witnesses, the team members, the people that are

> carrying out the process, or the people that we have over in the death house at that time for an extended period of time. . . . [W]e just don't have the facilities to accommodate that[.]

(Hrg. Tr., ECF No. 2117, PageID 104593-94.) Henness has offered no testimony, from Dr. Blanke or anyone else, that would give the Court reason to question the credibility of Erdos's testimony on that point. *Second*, Dr. Blanke concedes that, if Henness is indeed allergic to codeine, Defendants would need to "substitute another narcotic that is unrelated to morphine" to account for that allergy. (Hrg. Tr., ECF No. 2117, . at PageID 104744.) While Dr. Blanke describes that as among the "small changes" to be made to the four-drug method, he does not identify the drug that should replace morphine. This is of particular concern, given that it is the morphine in the second alternative that produces analgesia. Moreover, whereas substituting midazolam for diazepam could be done with no effort, since it is undisputed that Defendants are in possession of midazolam, Dr. Blanke's inability even to identify a replacement narcotic means Henness has not shown that that drug could be obtained by Defendants through ordinary transactional effort. These issues, alone or in conjunction, mean that neither of the proposed alternatives, as introduced by Dr. Blanke, can satisfy the second prong of *Glossip*.

Finally, the Court has not been provided with proof of the ease or difficulty of obtaining a Terminal Dangerous Drug Distributor license. While the Court suspects that Ohio's difficulty in obtaining an import license from the DEA is not completely analogous, there is no evidence that obtaining such a license would be properly characterized as "ordinary transactional effort," whether conducted by the potential supplier or by ODRC on the supplier's behalf.

Conclusion

It is undisputed that Warren Henness will suffer irreparable harm without preliminary injunctive relief and that a stay pending trial would not harm others. The public interest favors resolution of serious constitutional issues on the merits. Thus Henness satisfies three branches of the general test for a preliminary injunction.

To obtain a preliminary injunction, then, Henness must show that it is likely he would prevail at trial on his Eight Amendment claim. That likelihood depends on his meeting the standard in *Glossip*, *supra*. He has shown he is likely to prevail at trial on the first prong of the *Glossip* test: executing him by Ohio's current three-drug protocol will certainly or very likely cause him severe pain and needless suffering because the dose of midazolam intended to be used will not render him sufficiently unconscious as to prevent him from suffering the severe pain caused by injection of the paralytic drug or potassium chloride or the severe pain and needless suffering caused by pulmonary edema from the midazolam itself. However, he has not satisfied the second prong of *Glossip* because has not proved that the alternative methods he proposes are available, feasible, and can be readily implemented.

This is not a result with which the Court is comfortable. In 2017, this Court heard extensive evidence that midazolam was not achieving the intended result of blocking the severe pain caused by the second and third drugs. *In re Ohio Execution Protocol Litig. (Otte, Phillips, Tibbetts)*, 235 F. Supp. 3d 892 (S.D. Ohio 2017). The case against midazolam is now much stronger. We now know on the best expert testimony available that it does not have any analgesic effect. Moreover, we have good evidence that midazolam will cause the "waterboarding" effects of pulmonary edema. If Ohio executes Warren Henness under its present protocol, it will almost certainly subject

him to severe pain and needless suffering. Reading the plain language of the Eighth Amendment, that should be enough to constitute cruel and unusual punishment. As Justice Sotomayor wrote in *Glossip*, Oklahoma's protocol, the same one being used by Ohio, was saved from Eighth Amendment condemnation only by "imposing a wholly unprecedented obligation on the condemned inmate to identify an available means for his or her own execution." *Glossip*, 135 S.Ct. at 2797. Despite what we now know of the inadequacies of midazolam as an execution drug, the *Glossip* majority commands that a death row inmate must also plead and prove an appropriate alternative method of execution. That Henness has not done.

The Motion for Preliminary Injunction (ECF No. 1929) is DENIED.

January 14, 2019.

s/ *Michael R. Merz*
United States Magistrate Judge