

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

_____)	
In the Matter of the)	
Federal Bureau of Prisons’ Execution)	
Protocol Cases,)	
)	
LEAD CASE: <i>Roane et al. v. Barr</i>)	Case No. 19-mc-145 (TSC)
)	
THIS DOCUMENT RELATES TO:)	
)	
<u><i>Nelson v. Barr, et al., 20-cv-557</i></u>)	

**DEFENDANTS’ RESPONSE TO PLAINTIFF KEITH NELSON’S REQUEST TO
CLARIFY AND/OR AMEND ORDER AND ISSUE NEW INJUNCTION**

This Court entered judgment for Plaintiff Keith Nelson on Count XI of the Amended Complaint and enjoined Defendants from proceeding with the execution of Nelson, scheduled for 4 p.m. today, “until the government can comply with the requirements of the [Federal Food, Drug and Cosmetic Act (FDCA)].” ECF No. 213. Upon Defendants’ emergency motion to stay or vacate the permanent injunction issued by the Court, the D.C. Circuit vacated the injunction on the basis that “inter alia, there are insufficient findings and conclusions that irreparable injury will result from the statutory violation found by [this] court.” *Roane v. Barr*, No. 20-5260 (D.C. Cir. Aug. 27, 2020) (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), and *Withrow v. Larkin*, 421 U.S. 35, 44-45 (1975)). Nelson now asks the Court to “clarify or amend the Order pursuant to Fed. R. Civ. P. 60(a) (or issue a new order) to include specific findings and conclusions concerning the irreparable injury that will result from the statutory violation found by this Court and enjoin the Government from proceeding with his execution scheduled for 4:00 pm today.

Nelson cannot establish that he will suffer irreparable injury to justify issuance of a permanent injunction. According to Nelson, he faces irreparable injury if he is executed with the administration of a drug both without the benefit of prescription (and thus physician involvement) and without the benefit of using an approved (not compounded) drug – and the labeling, approval and manufacturing quality requirements that apply to approved drugs – including, among other

things, a scientifically established expiration date. Mot. at 2-3. His argument essentially is that it is per se harm to be executed with a drug in violation of the FDCA. But the D.C. Circuit's order and the cases cited make clear that violations of the law are not per se irreparable harm, and that further concrete irreparable injuries must be demonstrated to establish equitable entitlement to injury. The Ninth Circuit's recent ruling in *United States v. Mitchell* is instructive. There the inmate argued that he would "suffer an irreparable harm, due to the possibility that he 'could be executed by means of an illegal protocol.'" 2020 WL 4815961 at *2 (9th Cir. Aug. 19, 2020). The Ninth Circuit rejected this argument, concluding that Mitchell had not "carried his burden of showing that it is more probable than not that he will suffer any irreparable harm." *Id.* at *4. The court's rejection of Mitchell's irreparable harm argument necessarily meant that Mitchell's then-impending execution, standing alone, cannot irreparable harm, and that a technical statutory violation—whether of the FDPA as in Mitchell's case, or the FDCA here—does not constitute irreparable harm even if the inmate will be executed.

As for Nelson's suggestion that because the FDCA regulation is intended to ensure a drug is "safe and effective for its intended use" and thus any violation of such regulations would be irreparable injury, that is incorrect in the death penalty context, where the "intended use" is actually to kill the "patient" – *i.e.*, the drug has certainly *not* "function[ing] as intended" unless Nelson dies. Even assuming arguendo that the FDCA nevertheless applies, Nelson would still need to show that violation of the specific prescription and compounding requirements poses a risk of harm separate and apart from his death. Indeed, courts have so held. *See Ringo v. Lombardi*, No. 09-cv-4095, 2009 WL 1406980, at *3 (W.D. Mo. May 19, 2009) (denying stay of execution because "it is uncertain how mere compliance with the CSA and FDCA would impact" inmate's execution); *Ringo v. Lombardi*, No. 09-cv-4095, 2010 WL 4103201, at *1–2 (W.D. Mo. Oct. 18, 2010) ("[A]ny harm to Mr. Nunley from being executed with a drug that is not prescribed by a physician or approved by the FDA for the purpose of execution, is relatively small in comparison to the State of Missouri's interest in having its death penalty enforced."); *Durr v. Strickland*, No. 10-cv-288, 2010 WL 1610592, at *4 (S.D. Ohio Apr. 15, 2010) (describing alleged FDCA

violation as “a technical violation of federal law” that suggests at most “an injury to” the state officials, “not to” the inmate,” because the state officials could be prosecuted for violating federal law), *aff’d*, 602 F.3d 788 (6th Cir. 2010).

As for the two specific risks Nelson identifies – notably, he identifies *none* from the mere absence of a prescription in this context – neither suffices to establish irreparable injury. First, Nelson argues that the drug BOP intends to use will be beyond their “scientifically established expiration date.” Nelson did not identify this risk in his cross-motion for summary judgment and therefore the Court should not consider it. Even if the Court were to consider it, Nelson has produced no evidence that BOP intends to use expired drugs. In fact, as the Administrative Record makes clear, BOP’s “General Guidelines for Compounding and Testing Pentobarbital Sodium for Use in Executions” explicitly state that it will only use an injectable solution of pentobarbital for an execution if “its expiration date has not passed.” AR at 1085; *see also United States v. Mitchell*, C.A. No. 20-99009, DE 15 (9th Cir. Aug. 19, 2020) (Decl. of Rick Winter ¶ 7) (representing to the Ninth Circuit that “BOP will only use chemicals in the execution of Lezmond Mitchell that have an expiration date or beyond-use date that is after the date on which his execution will be carried out”). Nelson cites no facts to indicate that BOP will deviate from its Guidelines, much less facts that would overcome the well-settled presumption of good faith to which agencies like BOP are entitled in carrying out their duties.

Second, Nelson argues that he would be harmed because the drug is compounded, and thus, not FDA “approved.” Mot. at 2. Any risk of using an unapproved drug is purely speculative given that the Administrative Record clearly shows that the drugs BOP intends to use have passed quality assurance testing, *see* AR 970–1015, 1075–1083, by two independent laboratories. Moreover, BOP’s Guidelines specify that BOP will not use an injectable solution of pentobarbital for an execution unless “it has passed quality assurance testing conducted by at least one independent laboratory.” AR1085. Again, Nelson cites no facts to indicate that BOP will deviate from its Guidelines and therefore cannot overcome the well-settled presumption of good faith to which agencies like BOP are entitled. *See Sussman v. U.S. Marshals Serv.*, 494

F.3d 1106, 1117 (D.C. Cir. 2007); *see also Riggs Nat'l Corp. & Subsidiaries v. Comm'r*, 295 F.3d 16, 20 (D.C. Cir. 2002).

To the extent Nelson is concerned about the risk of using a drug from a compounding pharmacy, the Administrative Record makes clear that BOP's contractor pharmacy is subject to the FDA's "Current Good Manufacturing Practice ('CGMP') requirements," 21 C.F.R. Pts. 201 & 211, it ordinarily must comply with CGMP requirements, is inspected by the Food and Drug Administration (FDA), and must meet certain other conditions, such as reporting adverse events. The FDA's CGMP regulations require the Pharmacy to subject samples from each batch of compounded injectable solution it produces to quality assurance testing by an independent laboratory to ensure that the batch meets appropriate specifications and statistical quality control criteria before it is released. AR1084. Nelson has identified no facts to suggest that any of these safety measures would be enhanced by a prescription from a physician.

Furthermore, it would not be proper at this point in the litigation for the Court to credit Nelson's claims of injury from an alleged FDCA violation. In order to conclude at the summary-judgment stage that there is a risk of irreparable harm resulting from Nelson's FDCA claim, as is required for a permanent injunction, the Court would need to weigh the competing evidence and conclude that there is no "genuine issues of material fact." *Cobell v. Norton*, 391 F.3d 251, 261 (D.C. Cir. 2004) (reversing injunction entered without evidentiary hearing in the face of disputed facts as an "abuse of discretion). The government strongly contests Nelson's allegations of harm resulting specifically from any violation of the FDCA, and, as discussed above, the evidence in the record strongly suggests that no such harm will result. And simply crediting Nelson's evidence over the government's, without a hearing or the opportunity for the government to test Nelson's claims would be improper. *See id.* (concluding that the district court erred by entering a preliminary injunction without holding an evidentiary hearing given disputed issues of fact). Nor would it be proper for the Court to enter an injunction at this late stage in order to conduct the further fact-finding that would be required in order to credit Nelson's evidence. *See Dunn v.*

McNabb, 139 S. Ct. 369 (2017) (vacating injunction of execution for failure to satisfy “all of the requirements of a stay” (quoting *Hill v. McDonough*, 547 U.S. 573, 584 (2016))).

Finally, the course of events until now strongly reinforces the absence of any cognizable irreparable harm. In litigation surrounding the July executions, this Court expressly declined to rely on the inmates’ FDCA claim when it issued an injunction on July 13, the day of Daniel Lee’s planned execution. If the court’s position was that lack of a prescription actually constituted cognizable irreparable harm even in the context of lethal injection, the court presumably would have issued such a holding before Lee was executed. It did not do so. Moreover, Supreme Court’s vacatur of that FDCA-based preliminary injunction, which permitted Wesley Purkey and Dustin Honken’s executions to proceed despite identical alleged harm, underscores the propriety of staying or vacating the injunction here. See No. 20A10. If Nelson’s contentions were correct, four federal inmates executed without a pentobarbital prescription in the last two months -- Lee, Purkey, Honken, and Lezmond Mitchell, who was executed two days ago—would all have been subjected to irreparable harm. Nelson cannot explain how to square that position with this Court’s decisions in those cases.

As the D.C. Circuit’s Order yesterday made clear, the lack of a factual finding of irreparable injury is only one of the deficiencies in the permanent injunction issued by this Court. In addition to irreparable injury, a plaintiff seeking a permanent injunction must also show that “considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and that the public interest would not be disserved by a permanent injunction.” *eBay Inc.* 547 U.S. at 390. Nelson cannot make that showing.

The Supreme Court has repeatedly warned against last-minute injunctions in the death penalty context, including in this case, *see Lee v. Barr*, No. 20A8 at 3, 591 U.S. __ (2020) (“Last-minute stays’ like that issued this morning ‘should be the extreme exception, not the norm.’”). This case is not an extreme exception. Pentobarbital has been used in over one hundred executions over the last ten years without incident. *Id.* In none of those cases was the purported FDCA violation at issue here found to provide just cause to stop an execution at the last minute. This

case should not be the first, particularly in light of the fact that the Supreme Court already vacated this Court's preliminary injunction on the same grounds without a noted dissent in another last minute order last month. *Purkey v. Barr*, 20A12, 591 U.S. ____ (2020). Nelson cannot dispute the government's overwhelming interest in the enforcement of the criminal sentences imposed by unanimous federal juries after fair trials and upheld through extensive appellate and post-conviction proceedings in federal courts. See *Bucklew*, 139 S. Ct. at 1123. The American people have chosen to make capital punishment available in the federal system; if that decision is to be given meaningful effect, sentences must be enforced in cases like these. Although this Court asserted that "the potential harm to the government caused by a delayed execution is not substantial," Mem. Op. at 14, the Supreme Court has rejected that view, emphasizing that "[b]oth the [government] and the victims of crime have an important interest in the timely enforcement of a [death] sentence," *Bucklew*, 139 S. Ct. at 1133 (quoting *Hill*, 547 U.S. at 584); see also *Calderon*, 523 U.S. 556 (explaining that once post-conviction proceedings "have run their course . . . finality acquires an added moral dimension"). "Only with an assurance of real finality can the [government] execute its moral judgment in a case," and "[o]nly with real finality can the victims of crime move forward knowing the moral judgment will be carried out." *Calderon*, 523 U.S. at 556. Unduly delaying executions can frustrate the death penalty by undermining its retributive and deterrent functions. See *Bucklew*, 139 S. Ct. at 1134; *id.* at 1144 (Breyer, J., dissenting). For these reasons, Judge Katsas concluded in his concurrence that this Court erred in finding that the balance of equities was in Plaintiffs' favor. See *In re Fed. Bureau of Prisons' Execution Protocol Cases*, 955 F.3d at 126 ("In this case, the district court failed to recognize the important governmental and public interest in the timely implementation of capital punishment."). At base, having ended ten-year-old Pamela Butler's life by raping her and strangling her with a wire, Nelson demands that his execution by the sedative pentobarbital be halted until it is accompanied by a prescription. Pamela's mother and other loved ones are currently waiting in Terre Haute, Indiana for the implementation of a lawful sentence issued over eighteen years ago in response to that horrific

crime. The equities here do not come close to warranting the truly last-minute injunction Nelson seeks.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court deny Nelson's request to enjoin his execution scheduled for today at 4:00 pm.

Dated: August 28, 2020

Respectfully submitted,

MICHAEL R. SHERWIN
Acting United States Attorney

DANIEL F. VAN HORN
Civil Chief, U.S. Attorney's Office

ALAN BURCH (D.C. Bar 470655)
Assistant United States Attorney
U.S. Attorney's Office
for the District of Columbia
Washington, D.C. 20530
202-252-2550
alan.burch@usdoj.gov

DAVID M. MORRELL
Deputy Assistant Attorney General

PAUL R. PERKINS
Special Counsel

/s/ Jean Lin
JEAN LIN
Special Litigation Counsel
BRADLEY P. HUMPHREYS (D.C. Bar 988057)
JONATHAN KOSSAK (D.C. Bar 991478)
CRISTEN C. HANDLEY (MO Bar 69114)
Trial Attorneys
Federal Programs Branch
Civil Division, Department of Justice
1100 L Street, N.W.
Washington, D.C. 20005
(202) 514-3716
Jean.lin@usdoj.gov
Jonathan.kossak@usdoj.gov
Cristen.handley@usdoj.gov
Bradley.humphreys@usdoj.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on August 28, 2020, I caused a true and correct copy of foregoing to be served on all counsel of record via the Court's CM/ECF system. Pursuant to this Court's August 20, 2019 Order, below is a list of all plaintiffs' counsel of record (as most recently identified in the signature pages of the Consolidated Amended Complaint, ECF No. 92):

Alan E. Schoenfeld (admitted *pro hac vice*)
Ryan M. Chabot (admitted *pro hac vice*)
WILMER CUTLER PICKERING HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, New York 10007
(212) 230-8880
Alan.Schoenfeld@WilmerHale.com
Ryan.Chabot@WilmerHale.com

Andres C. Salinas (DC Bar No. 156118)
WILMER CUTLER PICKERING HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
(202) 663-6289
Andres.Salinas@WilmerHale.com

Counsel for Wesley I. Purkey

Joshua C. Toll
D.C. Bar No. 463073 King & Spalding LLP
1700 Pennsylvania Avenue, N.W.
Washington, DC 20006
(202) 737-8616
jtoll@kslaw.com

Margaret O'Donnell
P.O. Box 4815
Frankfort, KY 40604
(502) 320-1837
mod@dcr.net

Counsel for Plaintiff Anthony Battle

Ginger D. Anders (Bar No. 494471)
Jonathan S. Meltzer (Bar No. 888166546)
Brendan Gants (Bar No. 1031419)
MUNGER, TOLLES & OLSON LLP

1155 F Street N.W., Seventh Floor
Washington, D.C. 20004-1357
(202) 220-1100

Counsel for Plaintiff Brandon Bernard

Alex Kursman, Assistant Federal Defender
Shawn Nolan, Chief, Capital Habeas Unit
Federal Community Defender Office, E.D. Pa.
601 Walnut Street, Suite 545 West
Philadelphia, PA 19106
Telephone - 215-928-0520
Email – alex_kursman@fd.org

Counsel for Plaintiff Alfred Bourgeois

Joseph Luby, Assistant Federal Defender
Federal Community Defender Office, E.D. Pa.
601 Walnut Street, Suite 545 West
Philadelphia, PA 19106
Telephone - 215-928-0520
Email – joseph_luby@fd.org

Counsel for Plaintiff Chadrick Fulks

Amy Lentz (DC Bar No. 990095)
Steptoe & Johnson, LLP
1300 Connecticut Avenue NW
Washington, DC 20036
202.429.1320

Counsel for Plaintiff Orlando Hall

Scott W. Braden
Assistant Federal Defender
Arkansas Federal Defender Office
Ark Bar Number 2007123
1401 West Capitol, Suite 490
Little Rock, Arkansas 72201
(501) 324-6114
Scott_Braden@fd.org

Jennifer Ying (DE #5550)
Andrew Moshos (DE #6685)
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 N. Market St.
P.O. Box 1347
Wilmington, Delaware 19801

(302) 658-9300
jying@mnat.com
amoshos@mnat.com

Counsel for Plaintiff Norris G. Holder, Jr.

Jon Jeffress
KaiserDillon PLLC
1099 14th Street NW
8th Floor West
Washington, DC 20005
Telephone - 202-640-2850
Email - jjeffress@kaiserdillon.com

Timothy Kane, Assistant Federal Defender
Shawn Nolan, Chief, Capital Habeas Unit
Federal Community Defender Office, E.D. Pa.
601 Walnut Street, Suite 545 West
Philadelphia, PA 19106
Telephone - 215-928-0520
Email – timothy_kane@fd.org
Email – shawn_nolan@fd.org

Counsel for Plaintiff Dustin Lee Honken

Donald P. Salzman (D.C. Bar No. 479775)
Charles F. Walker (D.C. Bar No. 427025)
Steven M. Albertson (D.C. Bar No. 496249)
Skadden, Arps, Slate, Meagher & Flom LLP
1440 New York Avenue, N.W.
Washington, D.C. 20005
(202) 371-7983
donald.salzman@skadden.com

Counsel for Plaintiff Corey Johnson

David S. Victorson
Hogan Lovells US LLP
Columbia Square
555 13th Street NW
Washington, DC 20004
(202) 637-5600
(202) 637-5910 (fax)
david.victorson@hoganlovells.com

Pieter Van Tol (admitted *pro hac vice*)
Hogan Lovells US LLP
390 Madison Avenue

New York, NY 10017
(212) 918-3000
(212) 918-3100 (fax)
pieter.vantol@hoganlovells.com

Counsel for Plaintiff Daniel Lewis Lee

Kathryn L. Clune
Crowell & Moring LLP
1001 Pennsylvania Avenue NW
Washington D.C. 20004-2595
(202) 624-2705
kclune@crowell.com

Harry P. Cohen (pro hac vice application pending)
Michael K. Robles (pro hac vice application pending)
James Stronski (pro hac vice application pending)
Crowell & Moring LLP
590 Madison Avenue New York, NY 10022
(212) 223-4000
(212) 223-4134(fax)
hcohen@crowell.com
mrobles@crowell.com
jstronski@crowell.com

Jon M. Sands (pro hac application to be filed)
Dale A. Baich (pro hac application to be filed)
Jennifer M. Moreno
Federal Public Defender
District of Arizona
850 West Adams Street, Suite 201
Phoenix, Arizona 85007
602-382-2816
602-889-3960 (fax)
dale_baich@fd.org
jennifer_moreno@fd.org

Counsel for Plaintiff Keith Nelson

Shawn Nolan, Chief, Capital Habeas Unit
Federal Community Defender Office, E.D. Pa.
601 Walnut Street, Suite 545 West
Philadelphia, PA 19106
Telephone - 215-928-0520
Email – timothy_kane@fd.org
Email – shawn_nolan@fd.org

Counsel for Plaintiff Jeffrey Paul

Paul F. Enzinna
D.C. Bar No. 421819
Ellerman Enzinna PLLC
1050 30th Street, NW
Washington, DC 20007
202.753.5553

Counsel for Plaintiff James H. Roane, Jr.

Amy Karlin
Interim Federal Public Defender
Celeste Bacchi
Jonathan C. Aminoff
Deputy Federal Public Defenders
321 E. Second Street
Los Angeles, CA 90012
(213) 894-2854

Counsel for Plaintiff Julius O. Robinson

Gerald W. King, Jr. Ga. Bar No. 140981
Jeffrey Lyn Ertel Ga. Bar No. 249966
FEDERAL DEFENDER PROGRAM, INC.
101 Marietta Street, Suite 1500
Atlanta, Georgia 30303
404-688-7530
(fax) 404-688-0768
Gerald_King@fd.org
Jeff_Ertel@fd.org

Stephen Northup
VSB #16547
Troutman Sanders LLP
P.O. Box 1122
Richmond, Virginia 23218-1122
(804) 697-1240
(fax) (804) 698-5120
steve.northup@troutmansanders.com

Frederick R. Gerson VSB #39968
Bank Of America Center
1111 East Main Street, 16th Floor Richmond,
Virginia 23219
(804) 482-1121
fgerson@dagglaw.com

Counsel for Richard Tipton, III.

Evan Miller (DC Bar # 219310)
Vinson & Elkins LLP
2200 Pennsylvania Avenue, NW
Suite 500 West
Washington, D.C. 20037
(202) 639-6605
(202) 478-1815 (fax)
emiller@velaw.com

Counsel for Bruce Webster

/s/ Bradley P. Humphreys
Attorney for Defendants