

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

<p>In the Matter of the Federal Bureau of Prisons’ Execution Protocol Cases,</p> <p>LEAD CASE: <i>Roane et al. v. Barr</i></p> <p>THIS DOCUMENT RELATES TO:</p> <p><i>Nelson v. Barr, et al., 20-cv-557</i></p>	<p>Case No. 19-mc-0145 (TSC)</p>
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**PLAINTIFF KEITH NELSON’S NOTICE OF RULING AND REQUEST TO CLARIFY
AND/OR AMEND ORDER AND ISSUE NEW INJUNCTION**

Plaintiff Keith Nelson, by and through counsel, submits this notice of ruling by the D.C. Circuit and requests the relief described below.

By Memorandum and Order dated August 27, 2020 (Dist. Ct. Dkt. No. 213, the “Order”), this Court granted (in part) Mr. Nelson’s cross-motion for summary judgment on Count XI of the Amended Complaint. This Court held that “the government’s use of pentobarbital under the Protocol is contrary to law because it violates the” Food, Drug, and Cosmetic Act (“FDCA”), (Order at 1) and “enjoin[ed] Defendants from executing Keith Nelson until they have met the requirements of the FDCA.” *Id.* at 13.

On the same day (yesterday), the Government filed an emergency motion in the D.C. Circuit asking that court to stay or vacate the Order. By *per curiam* Order dated August 27, 2020, a three-judge Panel of the D.C. Circuit granted the Government’s motion “that the permanent injunction be vacated.” Case No. 20-5260, Doc. No. 1858770. The D.C. Circuit granted the motion based on its finding that the Order “fails to comply with Fed. R. Civ. P. 65(d) in that, inter alia, there are insufficient findings and conclusions that irreparable injury will result from the statutory violation found by the district court.” *Id.* The D.C. Circuit also

directed the Clerk “to issue the mandate forthwith to the district court.” *Id.* The formal mandate has now issued and has been entered. Case No. 20-5260, Doc. No. 1858772.

While Mr. Nelson does not wish to presume what this Court was thinking in issuing the Order, it seems self-evident and implicit in the Order that Mr. Nelson would suffer irreparable injury by being executed illegally by using drugs that do not comply with the FDCA. After all, as the Court duly noted, “the ‘core’ legislative purpose of the FDCA is to ensure that a ‘drug’ is ‘safe and effective for its intended use,’” “[v]iolations of the FDCA carry ‘the risk that the drug[s] will not function as intended,’” and “a lethal injection drug that does not function as intended may ‘result in conscious suffocation, pain, and cardiac arrest.” Order at 6-7 (citations omitted).

Moreover, the compounded drug that the Government will use to execute Mr. Nelson is not approved by FDA and its use, as this Court has ruled, would be in violation of law, *i.e.*, the labeling requirements, approval requirements and manufacturing and distribution requirements of the FDCA. *Id.* at 9. These requirements, among other things, require that approved drugs have expiration dates established by scientific stability studies to avoid the risks of sub-potent drugs. This is no mere academic exercise and has real world implications to Mr. Nelson’s execution because the Administrative Record here lacks a completed stability study or data that would support the Government’s claim that their compounded drugs have a one-year shelf life. Indeed, the limited potency testing in the Administrative Record – far from supporting stability for one-year – demonstrates that after only a couple of months the compounded drug was not stable and sub-potent when stored at elevated temperatures and at room temperature it was

already at the low end of acceptable potency with potency being lost on a monthly basis.¹ Mr. Nelson faces irreparable injury if 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.

By flagrantly violating the FDCA, the Government has admittedly failed to satisfy their “responsibility to comply with federal statutes enacted to ensure that the drugs operate humanely.” *Id.* at 8.

In any event, time is of the essence. Mr. Nelson is scheduled to be executed today at 4:00 pm. Accordingly, Mr. Nelson respectfully requests that this Court, as expeditiously as possible: (1) 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 (2) enjoin the Government from executing Mr. Nelson until they have met the requirements of the FDCA.

¹ The only testing of compounded drug under any storage conditions that the Government has referenced in the Administrative Record took place no more than two or three months after any stability work may have begun in or about May 2019 (i) July 1, 2019 room temperature potency testing with a low end passing result (95.5% in passing potency range of 92% to 108%) (AR 1011), (ii) July 10, 2019 elevated temperature potency testing with failing potency result (90.8% in a passing potency range of 92% to 108%) (AR 1013), (iii) August 21, 2019 room temperature potency testing showing a reduced potency from the July test (94.6% as compared with the earlier 95.5% and in a passing potency range of 92% to 108%) (AR 1014), and (iv) August 21, 2019 elevated temperature potency testing with a very low end passing result (92.2% in passing potency range of 92% to 108%) (AR 1015).

Dated: August 28, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 28, 2020, I caused a true and correct copy of the 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 counsel of record. The names marked with an asterisk (*) have no email provided on the docket and are no longer with the identified firms.

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