IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

OAK HILL HOMETOWN PHARMACY

Petitioner,

v. CIVIL ACTION NO. 2:19-cv-00716

UTTAM DHILLON, et al.,

Respondents.

MEMORANDUM OPINION AND ORDER

On October 30, 2019, this court **DISSOLVED** the Order of Immediate Suspension of Registration ("ISO") issued by the United States Drug Enforcement Administration ("DEA") pursuant to 21 U.S.C. § 824(d)(1) of Oak Hill Hometown Pharmacy's ("the Pharmacy") registration to dispense controlled substances. [ECF No. 17]. On November 27, 2019, the respondents, Uttam Dhillon and the DEA, filed a Motion to Alter or Amend that October 30, 2019 Order pursuant to Federal Rule of Civil Procedure 59(e) [ECF No. 20]. The petitioner, the Pharmacy, has responded [ECF No. 25] and the matter if ripe for adjudication. The court **DENIES** the respondents' Motion to Alter or Amend the Judgment.

I. Introduction

On October 21, 2019, the Pharmacy filed what was styled as a motion for Temporary Restraining Order ("TRO") against the ISO. [ECF No. 4]. This court held a hearing on the motion on October 23, 2019 and October 24, 2019. [ECF Nos. 9, 10]. On October 30, 2019, this court issued an order dissolving the ISO, finding that the DEA had not demonstrated that the immediate suspension of the Pharmacy's registration was necessary to prevent an "imminent danger to public

health and safety." [ECF No. 17]. In that order, the court found, based on the enabling statute, that it was more appropriate to dissolve the ISO rather than grant temporary relief. The enabling statute states, "a suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction." 21 U.S.C. § 824(d). The United States District Courts are the courts of "competent jurisdiction." *See* Barry M. Schultz, M.D.; Decision and Order, 76 Fed. Reg. 78,695 (Dec. 19, 2011) (finding that an ISO is not reviewable by an administrative law judge); *Novelty Distributors, Inc. v. Leonhart*, 562 F. Supp. 2d 20, 27 (D.D.C. 2008); *Norman Bridge Drug Co. v. Banner*, 529 F.2d 822, 824 (5th Cir. 1976). Therefore, the plain language of the statute vests the United States District Courts with the power to dissolve, meaning terminate, an ISO. The October 30, 2019 Order was thus a final judgment.

On November 27, 2019, the respondents filed a Motion to Amend or Alter the October 30, 2019 Order. [ECF No. 20]. The respondents base this motion on a newly certified administrative record, which they contend constitutes evidence unavailable at the time of the dissolution hearing. The respondents ask this court to "reconsider the judgment entered on October 30, 2019, pursuant to Rule 59(e), deny OHHP's [the Pharmacy] Motion for "TRO," and schedule further proceedings regarding OHHP's Petition for Injunction to Dissolve Immediate Suspension Order." Resp'ts Mem. in Supp. of Mot. to Alter or Am., 3 [ECF No. 23].

II. Legal Standard

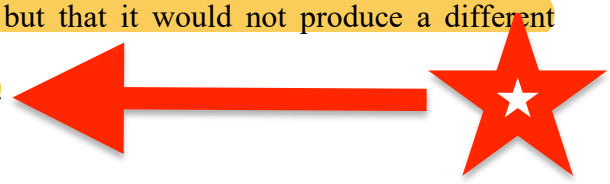
Federal Rule of Civil Procedure 59(e) allows for a party to motion to alter or amend a final judgment. Granting a Rule 59 motion is an extraordinary remedy that should be used sparingly. *Pac. Ins. Co. v. Am. Nat. Fire Ins. Co.*, 148 F.3d 396, 403 (4th Cir. 1998). Although the Rule itself does not provide a standard under which a district court may grant such a motion, the Fourth Circuit

recognizes three grounds for amending or altering a final judgment: "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." *Id.* at 403; *Hutchinson v. Staton*, 994 F.2d 1076, 1081 (4th Cir.1993). "Rule 59(e) motions may not be used, however, to raise arguments which could have been raised prior to the issuance of the judgment," nor may they be used to relitigate the merits of the case. *Pac. Ins. Co.*, 148 F.3d at 403; *see also* Wright et al., 11 Fed. Prac. & Proc. § 2810.1 Grounds for Amendment or Alteration of Judgment (3d ed. 2019).

A party who brings a Rule 59(e) motion based on newly discovered evidence "must produce a legitimate justification for not presenting the evidence during the earlier proceeding." *Pac. Ins. Co.*, 148 F.3d at 403 (quoting *Small v. Hunt*, 98 F.3d 789, 798 (4th Cir.1996)). And must show that the new "evidence is such that is likely to produce a new outcome if the case were retried, or is such that would require the judgment to be amended." *Boryan v. United States*, 884 F.2d 767, 771 (4th Cir. 1989).

III. Discussion

The respondents' Motion to Alter or Amend turns on two primary questions: (1) whether the newly certified administrative record constitutes new evidence not available at the time of the dissolution proceeding, and (2) if it does, is the administrative record likely to produce a new outcome or require the judgment be amended. *See id*. For the following reasons, I find that the administrative record does constitute new evidence but that it would not produce a different judgment. Thus, the respondents' motion is **DENIED**.



a. New Evidence

During the expediently scheduled dissolution proceeding it was unclear to me as to what was contained in the administrative record. At that hearing, it was argued that the administrative

record definitely contained: (1) "the immediate suspension order itself;" (2) "the West Virginia Board of Pharmacy and prescription drug monitoring program ('PDMP') data;" and (3) the DEA expert's report. TRO Hr'g Tr. 46:7–8, Oct. 23, 2019 [ECF No. 15]. The Government argued that the court's review should be restricted to those three items. *Id.* At the same time, the Government admitted that the administrative record before the DEA administrator was not necessarily limited to these three sources and could include other material. *See* TRO Hr'g Tr. 5:25; 6:1–5, Oct. 24, 2019 [ECF No. 16].

It is apparent from the filing accompanying the Rule 59(e) motion the DEA considered more material than it previously represented to the court. For example, the Government strongly objected to—among other material—the inclusion in the record of the West Virginia Board of Pharmacy Letter; West Virginia Board of Pharmacy Inspector's Report, and the March 2017 West Virginia Board of Pharmacy Minutes. Relying on the Government's representation that there was no evidence that the DEA had the information from the West Virginia Board of Pharmacy when it issued the ISO, this court granted the respondents' objection and excluded that evidence. [ECF No. 17]. Yet the Declaration of Assistant Administrator of the DEA's Diversion Control Division, William McDermott, explicitly states that "prior to issuing the ISO, DEA was aware of material from the West Virginia Board of Pharmacy." Decl. of William McDermott, 16 [ECF No. 30–1].

This court will not discuss here all forty-two exhibits that now make up the certified administrative record. Suffice to say, I have carefully reviewed all the exhibits. Most repackage information the that I considered in the order to dissolve the ISO—such as maps outlining distances patients traveled to fill prescriptions and specific patient prescriptions records that were reflected in the PDMP data. I will, however, outline new evidence that contains information not previously presented to the court: an excel spreadsheet of all DATA waived practitioners in West Virginia

(Admin. Record Ex. 27); four published DEA administrative decisions and orders (Admin. Record Ex. 33–36); a list of top controlled substances filled by the Pharmacy from 2015 to 2018 (Admin. Record Ex. 39); the West Virginia DHHR, Office of Policy Services, Policy for the Coverage of Suboxone (Admin. Record Ex. 40); and a January 30, 2018 letter from the West Virginia DHHR re: Opioid Response Plan for the State of West Virginia (Admin. Record Ex. 41). Although not part of the official administrative record, the respondents also include the Declaration of the Assistant Administrator of DEA's Diversion Control Division, William T. McDermott, as supplementary background information that helps explain the administrative record. *See AT & T Info. Sys., Inc. v. Gen. Servs. Admin.*, 810 F.2d 1233, 1236 (D.C. Cir. 1987) (holding that reviewing background information or evidence that explain the administrative record is permitted while post-hoc rationalizations are unacceptable).

The respondents argue that although the DEA administrator obviously had the information prior to the court's October 30, 2019 Order, they justifiably could not have organized and formally certified the administrative record because of the procedural posture of a TRO. *See* Resp'ts Mem. in Supp. of Mot. to Alter or Am., 4 [ECF No. 23]. I agree. A motion for TRO under Rule 65 is meant to provide temporary relief before a matter can be fully decided on the merits. *See* Fed. R. Civ. Pro. 65. Since the matter was presented in that procedural posture, the briefing period and hearing on the plaintiff's motion were expedited. I find that this rushed schedule explains the DEA's inability to produce and certify a complete administrative record. I find that the newly certified administrative record thus qualifies as new evidence not available at the time the final judgment was issued. *See Pac. Ins. Co.*, 148 F.3d at 403.

b. Likelihood of Producing a Different Judgment

Simply demonstrating however that the evidence qualifies as new under Rule 59(e) does not mean the motion to amend or alter should be granted. *Boryan*, 884 F.2d at 771. Most importantly, the movant must also show that such new evidence would be likely to result in a new outcome in the judgment. Here, the respondents have failed to do so.

1. Standard of Review

First, the respondents argue that the new administrative record changes the standard of review. Resp'ts Mem. in Supp. of Mot. to Alter or Am., 5 [ECF No. 23]. This is an odd argument. The respondents' brief misstates my reason for reviewing the ISO de novo. I did not apply a de novo standard of review because of the lack of certified administrative record but rather applied de novo review because of the lack of administrative *process* in issuing an *ex parte* ISO and because statutory authority vest the United States District Courts with original jurisdiction to review such emergency orders. A disagreement with the court's reasoning is not a legitimate basis for a Rule 59(e) motion. *Pac. Ins. Co.*, 148 F.3d at 403.

2. Merits of the Case

Second, the contents of the newly certified administrative record do not produce a different outcome or require amending the judgment on the merits of the case. The administrative record filed with the Rule 59(e) motion is made up of hundreds of pages of information which largely restates the argued basis submitted to the court at the dissolution hearing. Nothing contained in the newly filed administrative record evidences a fact not previously considered by the court that supports a substantial likelihood that there exists or did exist at the time of the dissolution an "imminent threat to the public health and safety." This newly filed record continues to rely upon unquantified suspicions. Assuming arguendo, that the behaviors characterized as red flags by the

DEA are sometimes indicators of criminal conduct does not prove the substantial likelihood of "imminent harm to public health and safety" required by the statute. Treatment drugs such as, Subutex and Suboxone, offer the potential for diversion and abuse. After all, they are placed by prescription in the hands of drug abusers—persons addicted to opioids. But mere surmise of diversion does not equate to an "imminent danger to public health and safety."

As the court explained in its previous order, the statute governing the *ex parte* emergency suspension procedure, which immediately suspends registration—without a pre-deprivation hearing—presents a high bar to the Government. 21 U.S.C. § 824(d)(1). To justify an ISO, the DEA administrator must show that the continued registration of the registrant poses an "imminent danger to the public health or safety." *Id.* In 2016, Congress amended the statute, imposing an even higher threshold for issuing this emergency suspension procedure. *See* Ensuring Patient Access and Effective Drug Enforcement Act of 2016, Pub. L. No. 114-145, § 2, 130 Stat. 353 (codified as amended at 21 U.S.C. § 824(d)(2)). That amendment defined "imminent danger to the public health or safety" as requiring a showing of "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration." *Id.*

Simply demonstrating an unquantified risk of illegal drug use is not a finding of imminent danger. Here, the certified administrative record does not point to a single instance of a violation of the law. The newly filed administrative record does not contain any new evidence that any patient abused or diverted Subutex or Suboxone. The DEA yet again simply offers evidence of what it sees as a suspicious pattern of the filling of lawful prescriptions for medication designed to treat opioid addiction, which this court previously found insufficient to justify the ISO.

Turning briefly to the four published DEA administrative decisions and orders included in the record that the respondents rely on to show that the Pharmacy's practices present red flags for abuse and diversion, there are several reasons why these decisions are unpersuasive. Most importantly, none of the cases evaluate pharmacy practices under the standard of "imminent harm to public health and safety" because none of the cases involve a review of an ISO. *See Edge Pharmacy*, 81 fed. Reg. 72,092 (2016) (Admin. Ex. 33) [ECF No. 30–5]; *Holiday CVS, L.L.C.*, 77 Fed. Reg. 62,316 (2012) (Admin. Ex. 34) [ECF No. 30–6]; *Trinity Pharmacy II*, 83 Fed. Reg. 7,304 (2018) (Admin. Ex. 35) [ECF No. 30–7]; *Wheatland Pharmacy*, 78 Fed. Reg. 69,441 (2013) (Admin. Ex. 36) [ECF No. 30–8]. All four of the cases arise under the procedure outlined in 21 U.S.C. §824(a)(4), meaning the administrative court in those cases evaluated whether the pharmacies' registration would "be inconsistent with public interest." Assessing whether registration would be inconsistent with the public interest is starkly different than determining whether continued registration poses "an imminent danger to public health and safety." *See* John J. Mulrooney, II & Katherine E. Legel, *Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug-Infested Waters*, 101 Marq. L. Rev. 333, 346 (2017).

Further, none of the four cases in the administrative record involved medications used to treat opioid addiction. *Edge Pharmacy* involved oxycodone and hydromorphone. Admin. Ex. 33, at 1 [ECF No. 30–5]. *Holiday CVS* involved alprazolam and oxycodone. Admin. Ex. 34, at 1 [ECF No. 30–6]. *Trinity Pharmacy II* involved benzodiazepine, fentanyl, and muscle relaxers. Admin. Ex. 35, at 1 [ECF No. 30–7]. *Wheatland Pharmacy* involved hydrocodone, acetaminophen, promethazine, codeine, and Xanax. Admin. Ex. 36, at 1[ECF No. 30–8]. As I emphasized in the October 30, 2019 Order, legal pain management opiates are the primary culprits in the opioid epidemic. The set of controlled substances used to medically treat pain are a far different species

of opiate than Suboxone and Subutex—necessary to treat addiction. Evaluating "imminent danger to public health and safety" is a two-sided inquiry. Considering the "imminent danger to public health and safety" posed by shutting down access to MAT therapy was an essential part of my reasoning in the previous order. Thus, the fact that these four DEA administrative decisions do not involve treatment medication make them materially dissimilar from this case.

The Government is correct that these four cases do indicate that some of the prescriptions the Pharmacy in this case filled presented "red flags." The courts in those cases find that traveling long distances to receive or fill a prescription, paying in cash for prescriptions, and filling prescriptions that are characteristic of "pattern prescribing" —when multiple people present prescriptions for the same drug, on the same day, issued by the same provider— are "red flags" for abuse or diversion. But none of these cases explain or even contend that these "red flags" constitute an "imminent harm to public health and safety." These cases serve only to confirm that the Pharmacy engaged in several suspicious practices. But the statute requires more than suspicion to suspend registration without process. Therefore, these cases are unpersuasive and would not produce a different outcome in judgment from the October 30, 2019 Order.

Moreover, the new administrative record does not address the imminence requirement inherent in the statute governing the issuance of an ISO. The statute by its own terms requires the DEA factually establish that the continued operation of the Pharmacy poses an imminent danger. This standard means that there must be evidence that the Pharmacy was filling prescriptions that patients were abusing or diverting at the time the agency issued the ISO in August 2019. In the October 30, 2019 Order, this court emphasized that the Pharmacy substantially curtailed filling prescriptions that the DEA flagged as indicative of abuse and diversion after the administrative warrant was served on November 28, 2018. That fact demonstrates that any danger posed by the

Pharmacy was not imminent. The Pharmacy accepted only three new out-of-state prescriptions for Subutex after November 28, 2018. This court previously held that the Pharmacy's "red flag" activity since the administrative warrant appears quite limited. The Pharmacy's practices after the administrative warrant was served in November 2018 simply do not support a finding of imminent danger almost nine-months later in August 2019, when the ISO was issued.

The DEA clearly disagrees with the court's assessment of the continued risk the Pharmacy posed at the time the ISO was issued. But in rearguing its opinion on the imminence of harm, the Government again points to the PDMP data, evidence it acknowledges the court already considered in its October 30, 2019 Order. *See* Resp'ts' Reply to Pet'r's Resp. to Mot. to Alter or Amend the Oct. 30, 2019 J. Order, 12 [ECF No. 32]. Rule 59(e) is not a vehicle for parties to relitigate its theories of the case after a final judgment. The Government does not use the *new* evidence contained in the administrative record to show that the court would likely reach a different outcome on the imminence of harm issue.

I am disturbed that Mr. McDermott, in his declaration, infers that there is a correlation between patients receiving Medicaid and patients diverting or abusing controlled substances. I will not spend time here explaining the logical fallacies this surmise embraces. Suffice it to say "poverty and substance use problems operate synergistically" for a multitude of complex reasons. Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to its Social and Economic Determinants*, Am. J. Pub Health 182–186 (February 2018). The suggestion, however, that an addicted patient's qualification for Medicaid indicates in any way a propensity for diversion or substances abuse is repugnant. Service to low income communities can be no part of a government decision to suspend a pharmacy's registration.

Access to treatment was a focal point of this court's October 30, 2019 Order. Evaluating the "imminent danger to public health and safety" required the court to determine whether the continued registration of the Pharmacy posed a "substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur." Therefore, I also contemplated the dangers of further limiting the number of pharmacies in West Virginia willing to provide much needed treatment medication. The underlying reality of MAT therapy is that it requires pharmacies to fill prescriptions of controlled substances for people addicted to opiates—a group of people who frequently face a significant amount of stigma and suspicion

The DEA would suggest that filling lawful prescriptions for Subutex, when they believe that Suboxone is more appropriate, is grounds for revoking a pharmacy's registration without process. From a perusal of all the material from the Government in this case, I conclude that they believe Subutex and Suboxone to be more a part of the problem than part of the solution to the opioid crisis. That mindset ignores the fundamental value of these medications. These treatment drugs are entirely lawful and are to be used by addicts in the treatment of opioid addiction. These drugs should be available by prescription and obtainable at any pharmacy. Discouraging the use of these drugs by revoking the registration of pharmacies who fill prescriptions without any administrative process other than a statement of law enforcement suspicion cannot be consistent with the law.

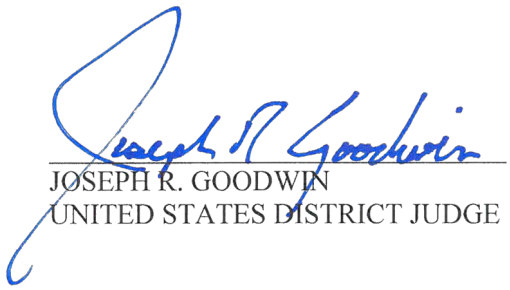
IV. Conclusion

The DEA largely appears to be using Rule 59(e) to relitigate the merits of its case. Much of its memorandum in support of its motion and its reply memorandum merely state its disagreement with the court's findings and reargue its position based on evidence it acknowledges was presented to the court before its October 30, 2019 Order. *See* Resp'ts' Reply to Pet'r's Resp.

to Mot. to Alter or Amend the Oct. 30, 2019 J. Order, 12 [ECF No. 32]. The respondents are of course free to appeal this court's decision to the Fourth Circuit Court of Appeals but using Rule 59(e) as an excuse to re-present its case is inappropriate. The court therefore **DENIES** the respondents' Motion to Alter or Amend the October 30, 2019 Judgement Order.

The court **DIRECTS** the Clerk to send a copy of this Order to the defendant and counsel, the United States Attorney, the United States Probation Office, and the United States Marshal.

ENTER: December 23, 2019



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE