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.

RESPONDENT'S BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER AND PETITION FOR A PRELIMINARY INJUNCTION

I. INTRODUCTION

Buprenorphine is an opioid medication, which the U.S. Food and Drug Administration ("FDA") has approved for, *inter alia*, the treatment of narcotic addiction. *See* Exhibit 1, Buprenorphine Drug Information, Drug Enforcement Administration, Diversion Control Division.[1] There are two types of buprenorphine in sublingual tablet form. The first type is Subutex, which is a single entity buprenorphine product (also known as a "buprenorphine-mono-product"). *Id.* The other is Suboxone, which is a combination product containing buprenorphine and naloxone. *Id.* The combination of buprenorphine and naloxone, to form Suboxone, is intended to block the euphoric high resulting from the injection of the drug by narcotic abusers.

Following FDA approval, the U.S. Drug Enforcement Administration ("DEA") classified buprenorphine, in all forms, as a Schedule III controlled substance. *Id.*; *see also* 21 C.F.R. § 1308.13(e)(2)(i). Buprenorphine is approximately 20 to 30 times more potent than morphine as an analgesic. Like morphine and other commonly abused opioids, buprenorphine is capable of

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[1] Also available at https://www.deadiversion.usdoj.gov/drug_chem_info/buprenorphine.pdf [hereinafter referred to as Buprenorphine Drug Info.].

producing significant euphoria. *See* Buprenorphine Drug Info. Data indicates that buprenorphine has been abused by various routes of administration (sublingual, intranasal, and injection) and has gained popularity as a heroin substitute and as a primary drug of abuse. The potential for abuse of buprenorphine in general, and Subutex in particular, has led a number of states to prohibit the prescribing of Subutex, except in those circumstances where naloxone (included in Suboxone) will harm a patient (i.e. pregnancy and/or a naloxone allergy). Among these states are Kentucky, Ohio, and Virginia. 201 Ky. Admin. Regs. 9270; Ohio Admin. Code 4731-33-03; 18 Va. Admin. Code § 85-21-150.

For these reasons, the DEA has focused its efforts on stopping the diversion of Subutex and other buprenorphine products from legitimate channels into the illegal market at various points along the drug pipeline, including the improper prescribing and dispensing of buprenorphine by registrants. In this case, to further that objective, DEA investigated the dispensing practices of Oak Hill Hometown Pharmacy ("OHHP").

II. PROCEDURAL HISTORY

The Acting Administrator of the DEA, Uttam Dhillon, signed the Immediate Suspension Order ("ISO") on August 6, 2019, immediately suspending OHHP's DEA registration pending a final resolution of administrative proceedings. The ISO was served on OHHP on August 8, 2019. (ECF No. 1-1 at 1.) Nearly two months later, on October 2, 2019, OHHP filed a pleading styled as a Petition seeking an order for an injunction to dissolve the ISO. (ECF No. 1.) Almost three weeks later OHHP filed a Motion for a Temporary Restraining Order ("TRO") on October 21, 2019. (ECF No. 4.)

The procedural history of this matter would be incomplete without noting that the ISO and OHHP's registration are the subjects of an administrative proceeding pending before an

administrative Law Judge ("ALJ"). *See* Exhibit 2, Declaration of Katherine Steele, DEA Attorney. The administrative hearing was originally scheduled for October 14, 2019. *Id*. During a prehearing conference held on October 1, 2019, the ALJ and DEA agreed to move the administrative hearing up to October 7, 2019. *Id*. However, OHHP declined the option to begin the administrative hearing on October 7. *Id*. The hearing is now set to commence on November 5, 2019. *Id*.

III. FACTUAL BACKGROUND

OHHP is registered with the DEA to fill prescriptions for controlled substances classified in Schedules II through V. (ECF No. 1-2 at ¶ 1.) The investigation of OHHP began in 2018 after DEA received intelligence that OHHP was filling an unusually large number of prescriptions for buprenorphine-mono-products (i.e. Subutex). The vast majority of these prescriptions were written by prescribers located in Western Pennsylvania for individuals who resided in the Southern District of West Virginia but not in close proximity to OHHP. (ECF No. 1-1 at 3–4.) On November 28, 2018, the DEA executed an Administrative Inspection Warrant ("AIW") at OHHP. (*Id.* at 8.)

A. Pharmacy expert opined that OHHP should not have filled Subutex prescriptions.

From at least December 2016 to March 2019, OHHP's pharmacists filled approximately 2,000 prescriptions for Subutex, a widely-abused Schedule III controlled substance. (*Id.* at 3.) The DEA consulted with a pharmacy expert who opined that buprenorphine is an opioid derivative and, therefore, poses a significant risk of abuse and diversion. (*Id.* at 3–4.) To prevent buprenorphine from being abused, it is frequently combined with naloxone, which is an opioid antagonist that blocks or reverses the effects of opioids if the user attempts to abuse the drug. The DEA's expert indicated that because buprenorphine/naloxone products (i.e. Suboxone) have a lower abuse potential than buprenorphine-mono-products (i.e. Subutex), buprenorphine/naloxone

products should be prescribed as the first-line treatment for narcotic addiction, unless the patient is pregnant or allergic to naloxone. (*Id.*) Accordingly, the DEA's expert opined that a pharmacist should not fill a Subutex prescription unless the patient is pregnant or allergic to naloxone. (*Id.*) The DEA's expert also indicated it is highly unlikely that all of the patients who presented these 2,000 Subutex prescriptions at OHHP were pregnant or allergic to naloxone. (*Id.*) In fact, approximately half of these prescriptions were written for men. (*Id.*) According to the DEA's expert, it is highly improbable that all of these men were allergic to naloxone as naloxone allergies are relatively rare. (*Id.*)

B. The Subutex prescriptions at issue displayed numerous "red flags."

All of the prescriptions addressed in the ISO presented no less than five red flags, each of which was an indication that the prescriptions should not have been filled. In the context of prescriptions for controlled substances, a "red flag" is a sign or indication that there is a substantial risk of abuse or diversion of the prescribed drug. *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 827–28 (11th Cir. 2018); Drug Enforcement Administration, *Pharmacists Manual: An Informational Outline of the Controlled Substances Act*, 30 (2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf. (*See also* ECF No. 1-1 at 3.) The red flags associated with the prescriptions presented at OHHP included, but were not limited to, the following:

1. The prescriptions were for Subutex (a buprenorphine-mono-product), a widely abused controlled substance.

2. The prescriptions were written by prescribers outside of West Virginia.

3. Approximately 96% of the prescriptions were paid for with cash.

4. The patients/customers, who resided in southern West Virginia, traveled great distances to Western Pennsylvania to obtain the prescriptions.

5. Most of the patients/customers traveled a significant distance to have the prescriptions filled at OHHP, and in doing so, eschewed pharmacies much closer to their homes.

6. Many of the prescriptions were not filled entirely at the first presentment. Instead, OHHP routinely filled the prescriptions piecemeal over multiple visits.[2]

7. The Pennsylvania prescribers in question appeared to be "pattern prescribing."[3]

(ECF No. 1-2 at 3–8.)

C. DEA issued the ISO.

The Acting DEA Administrator issued the ISO based, in part, on the foregoing facts and circumstances. When the DEA has reason to believe that a registrant's continued operation would pose "an imminent danger to the public health or safety," the DEA has discretion to suspend the registration immediately, prior to an administrative hearing, through an ISO. 21 U.S.C. § 824(d). The CSA provides that "imminent danger to the public health or safety" means that, *inter alia*, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant, there is a substantial likelihood of an immediate threat that abuse of a controlled substance will occur in the absence of an immediate suspension of the registration. 21 U.S.C. § 824(d)(2). The DEA must provide the basis for the suspension in an order to show cause. *Id.*; 21 C.F.R. § 1309.44(a). An ISO need not contain the entire basis for the suspension. Instead, The ISO can consist of a non-exhaustive summary. 21 C.F.R. § 1301.73(c) (order need only contain a "summary of the matters of fact and law asserted"); *Boston Carrier,*

[2] The DEA's expert indicated that it can be a red flag of abuse and diversion if a patient has a pattern of obtaining partial fills of a drug with a high street value and paying for the partial fills in cash. (ECF No. 1-1 at 9.)
[3] The DEA's expert opined that "pattern prescribing" is a red flag of abuse and diversion for which pharmacists must monitor. It refers to a provider who prescribes widely-abused drugs, often in the same dosages and quantities, to numerous patients. "Pattern prescribing" is a red flag of abuse and diversion because it indicates that the physician is focused on distributing drugs with high street value rather than on examining his patients and developing individualized treatment. (ECF No. 1-1 at 7.)

Inc., v. ICC, 746 F.2d 1555, 1560 (D.C. Cir. 1984) (stating that "an agency is not required to give every [Respondent] a complete bill of particulars as to every allegation that [it] will confront").

The DEA's expert reviewed Subutex prescriptions filled by OHHP, along with other information. (ECF No. 1-2.) He concluded that from December 14, 2016, to November 28, 2018, OHHP filled approximately 2,000 prescriptions that presented many, if not all, of the aforementioned unresolvable red flags of drug abuse and diversion. (ECF No. at 3.) Therefore, these prescriptions were filled in violation of 21 C.F.R. § 1306.04(a) and W. Va. Code R. § 15-1-19.3.1. (ECF No. at 2.)

D. OHHP's stated basis for belatedly seeking a TRO is factually inaccurate.

In its motion, OHHP claims that the failure to seek a TRO prior to October 21, 2019, was because it only recently obtained certain evidence from the DEA, in the course of the parallel administrative proceeding, which purportedly reveals that the ISO "was predicated on factual allegations which the DEA knew or should have known at that time to be false." (ECF No. 4 at 1.) OHHP's presentation of this evidence is correct.

The evidence in question is prescription drug monitoring program data ("PDMP Data") curated and provided by the West Virginia Board of Pharmacy. OHHP claims that during the discovery phase of the ongoing administrative proceedings, DEA lawyers initially produced the PDMP Data in a "completely unusable format." (ECF No. 4-1 at 12.) What OHHP means by this characterization is that DEA produced the PDMP Data in Adobe Acrobat PDF format. Adobe Acrobat PDF format is a widely used format and is used by attorneys on a daily basis to file documents with this Court. OHHP wanted the PDMP Data produced as an Excel Spreadsheet, presumably because it is easier to sort and manipulate the data in the Excel format. It is not clear

why OHHP did not convert the PDF document to an Excel Spreadsheet.[4] However, there is no dispute that the DEA produced the PDMP Data. OHHP contends that "[o]ver the DEA's strenuous objection, the ALJ in that Administrative Proceeding ordered the government to produce the PDMP data in a useable, excel format, and did so after OHHP had already filed this action." (*Id.*) The fundamental problem with this contention is that it is not accurate. During a Prehearing Conference before the ALJ on October 1, 2019, the parties and the ALJ sorted through various issues, including discovery issues. *See* ALJ's October 2, 2019 Prehearing Ruling, attached hereto as Exhibit 3. The ALJ's Prehearing Ruling addresses the PDMP Data issue as follows:

> During the conference, and as noticed in its prehearing statement, Respondent requested that the Government produce its P[D]MP data in Excel format, rather than in a PDF document. **Respondent recognized that there is no general right to discovery in these proceedings**, but argued that searching for data in an Excel file is significantly faster than using a PDF document. Respondent further noted that having access to the information in Excel format would facilitate the process of agreeing to stipulations. **Despite its initial objections, the Government stated that it has the P[D]MP data in Excel format and will provide the data in that format to Respondent**.

Exhibit 3 at 3 (emphasis added). It is evident that DEA lawyers produced the PDMP Data to OHHP in PDF format prior to October 1, 2019. More importantly, it is apparent that DEA readily agreed to produce the PDMP Data to OHHP in the desired Excel format as part of the Prehearing Conference process of resolving outstanding issues and concerns. *Id.*

Moreover, OHHP's suggestion that PDMP Data produced in Excel format after it filed its Petition for a Preliminary Injunction on October 2, 2019, revealed new evidence is not supportable.

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[4] Typically, PDF documents can be readily converted to Excel spreadsheets. Information on how to do so is publically available, including through the following websites:
https://www.digitaltrends.com/computing/how-to-convert-a-pdf-into-an-excel-document/
https://acrobat.adobe.com/us/en/acrobat/how-to/pdf-to-excel-xlsx-converter.html
https://altoconvertpdftoexcel.com/
https://powerspreadsheets.com/pdf-excel-convert/
https://smallpdf.com/blog/how-to-convert-pdf-to-excel-without-converter

OHHP had all the information in the Excel version of the PDMP Data long before the Petition for a Preliminary Injunction was filed. Indeed, OHHP had the data and information long before the ISO was issued. The Controlled Substances Act ("CSA"), 21 U.S.C. § 801, *et seq.*, requires that registrant pharmacies maintain records of the controlled substances they dispense. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.22(c). Thus, OHHP had all of its dispensing data on hand even before the DEA obtained it. Furthermore, on September 26, 2019, OHHP produced to DEA a 158-page "[s]preadsheet of all buprenorphine prescriptions dispensed at OHHP between November 1, 2016 and August 7, 2019, based on OHHP data." *See* OHHP's Prehearing Statement, attached hereto as Exhibit 4. In other words, OHHP had assembled a spreadsheet of all buprenorphine prescriptions it had filled and disclosed it as part of the administrative proceedings on or before September 26, 2019. Finally, the DEA provided the PDMP Data to OHHP in PDF format on September 16, 2019. *See* DEA's Prehearing Statement, attached hereto as Exhibit 5. Stated succinctly, it is not accurate for OHHP to claim that the decision to seek a TRO was based on evidence obtained only recently. While not only inaccurate, this assertion is clearly being offered by OHHP as a specious explanation for not filing a motion for a TRO prior to October 21, 2019.

E. OHHP has mischaracterized the PDMP Data for Subutex prescriptions filled after DEA executed the AIW.

In its Motion for a TRO, OHHP claims that the ISO was "predicated on false allegations" of improper dispensing conduct that continued after the DEA executed the AIW on November 28, 2018. It is important to note that the ISO was predicated on conduct following execution of the AIW *and* OHHP's historical dispensing practices prior to the AIW. Nonetheless, OHHP has incorrectly described the DEA Administrator's findings regarding OHHP's dispensing conduct following execution of the AIW. The DEA Administrator found that OHHP curtailed the filling of Subutex prescriptions after the DEA served the AIW in November 2018. (ECF No. 1-2 at 8.)

However, the DEA Administrator also found that OHHP continued to fill a significant number prescriptions for Subutex in the face of obvious red flags of abuse and diversion through at least March 2019. (*Id.*) In the ISO, it is further noted that these red flags were the same unresolvable red flags of abuse and diversion outlined in the historical analysis of OHHP's conduct. (*Id.*)

Specifically, the Administrator found that the DEA's pharmacy expert reviewed 43 prescriptions that OHHP filled from December 2018 to March 2019, and opined that these prescriptions continued to present unresolvable red flags of abuse and diversion. (*Id.*) The DEA Administrator made a number of additional findings regarding these prescriptions, including the following:

> The DEA's expert opined that Subutex has a significant potential for abuse and diversion, and should only be prescribed to patients who are pregnant or allergic to naloxone. Twenty-one of these prescriptions (approximately 50 percent) were written for men, who could not have been pregnant. The DEA's expert opined that it is highly unlikely that all of these men were allergic to naloxone because naloxone allergies are uncommon. Additionally, if these patients had documented naloxone allergies, then they should have been able to obtain Subutex from West Virginia prescribers, rather than having to drive hundreds of miles to obtain it from Pennsylvania prescribers.
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> Twenty-six of these prescriptions (approximately 60 percent) were written by Pennsylvania prescribers. As discussed in more detail above, the DEA's expert opined that it can be a red flag of abuse or diversion if a patient travels a significant distance to a specific physician's office, especially if the patient is not seeking specialized medical treatment. These patients were not seeking specialized medical treatment. They were all receiving Subutex (buprenorphine-only), which may be prescribed by any physician who has been designated by the DEA as a DATA waived physician.
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> The DEA's expert opined that it can be a red flag of abuse and diversion if a patient travels a significant distance to a specific pharmacy, especially if the patient also travels a significant distance to the prescriber's office. The DEA's expert also opined that it can be a red flag of abuse and diversion if a patient has a pattern of obtaining partial fills of a drug with a high street value, and paying for the partial fills in cash. Numerous OHHP customers . . . traveled significant distances to obtain and fill their prescriptions, and frequently obtained partial fills of their prescriptions.

(ECF No. 1-2 at 8–9.) The ISO discusses three specific patients/customers who traveled significant distances to obtain and fill their prescriptions, but the ISO indicates that there were more than three such patients/customers. (*Id.* at 9–10.) Indeed, the prescription data, which has always been readily available to OHHP, shows that there were 22 patients/customers with the particular red flag of traveling significant distances to obtain their prescriptions from Pennsylvania or other out-of-state prescribers. All of the prescriptions presented by these 22 patients/customers had other red flags associated with them. (*Id.*) For example, cash was used to pay for all of the prescriptions. (*Id.*)

OHHP's description of these findings made by the DEA Administrator (regarding OHHP's dispensing conduct following execution of the AIW) bears little to no resemblance to the actual findings. Nevertheless, the DEA Administrator's findings are in the ISO and speak for themselves.

IV. CONTROLLED SUBSTANCES ACT STATUTORY FRAMEWORK

Congress enacted the CSA to prevent "diversion"—the distribution of drugs "out of legitimate channels into the illegal market." H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572. The CSA gives the DEA broad authority to prevent the diversion of pharmaceutical drugs for illicit use. *See* 21 U.S.C. §§ 824(d), 871(a); 28 C.F.R. §§ 0.100, 0.101, 0.104, app. to subpart R § 7(a). As part of that authority, the DEA Office of Diversion Control regulates every link in the prescription drug supply chain. DEA requires every person who manufactures, distributes, dispenses, imports, or exports any controlled substance to obtain a registration from DEA. 21 C.F.R. § 1301.11. Registrant compliance at all levels of the distribution chain is essential to ensure that controlled substances are not diverted from legitimate to illegitimate uses.

When a registrant, such as a pharmacy, fails to adhere to its legal obligations, the DEA has

authority to revoke or suspend its registration. *See* 21 U.S.C. § 823(b), (e). Ordinarily, the DEA must hold a hearing prior to revocation or suspension of an entity's registration. However, as noted above, if the DEA has reason to believe that a registrant's continued operation would pose "an imminent danger to the public health or safety," then the DEA has discretion to suspend the registration immediately and without a hearing, through an ISO. 21 U.S.C. § 824(d).[5] The DEA must provide the basis for its suspension in an order to show cause. *Id.*; 21 C.F.R. § 1309.44(a).

The show cause order initiates an administrative proceeding through which the registrant has the opportunity to demonstrate that the registration should not be revoked. 21 C.F.R. § 1309.46. But a suspension under § 824(d) remains in effect until (a) the DEA issues a final order; (b) the suspension is withdrawn by the Attorney General; or (c) the ISO is dissolved by a court of competent jurisdiction. 21 U.S.C. § 824(d); 21 C.F.R. § 1309.44(c). In other words, the CSA and the attendant regulations create a mechanism through which the DEA Administrator can protect public health and safety from imminent danger (i.e. an ISO) while the revocation of the registration is being litigated administratively.

Thus, an ISO need not contain the entire basis for the suspension. Instead, the ISO need only set forth a non-exhaustive summary. 21 C.F.R. § 1301.73(c) (order need only contain a "summary of the matters of fact and law asserted"); *Boston Carrier, Inc.*, 746 F.2d at 1560 (stating that "an agency is not required to give every [Respondent] a complete bill of particulars as to every allegation that [it] will confront").

[5] The CSA provides that "'imminent danger to the public health or safety' means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II, there is 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." 21 U.S.C. § 824(d)(2).

V. STANDARD OF REVIEW

A. DEA's ISO must be reviewed under the arbitrary and capricious standard.

In order to issue an ISO pursuant to § 824(d), the DEA must determine that a registrant's continued operation would pose "imminent danger to public health or safety." 21 U.S.C. § 824(d); 21 C.F.R. § 1309.44. A court of competent jurisdiction reviews a DEA "imminent danger" determination under an arbitrary and capricious standard. *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 214 (D.D.C. 2012); *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 158 (D.D.C.), *vacated and remanded on other grounds*, 493 F. App'x 108 (D.C. Cir. 2012) (per curiam); *Novelty Distribs., Inc. v. Leonhart*, 562 F. Supp. 2d 20, 29 (D.D.C. 2008) (noting in a challenge to an § 824(d) suspension that "the underlying question on the merits is whether DEA acted arbitrarily and capriciously in suspending [Plaintiff's] registration based on a preliminary finding that its continued operation posed an 'imminent danger to public health or safety'").

In conducting judicial review under the arbitrary and capricious standard, the level of scrutiny employed by a court must be tempered by the context of the agency's action. *See Nat'l Cable Television Ass'n, Inc. v. Copyright Royalty Tribunal*, 724 F.2d 176, 181 (D.C. Cir. 1983). The CSA provides that the DEA Administrator may, in his discretion, issue an ISO in cases where he finds that there is an imminent danger to the public health or safety. 21 U.S.C. § 824(d). Because the CSA and related regulations provide little guidance on what constitutes "an imminent danger to the public health or safety," the CSA vests the DEA Administrator with broad discretion to make such determinations. *Holiday CVS, L.L.C.*, 839 F. Supp. 2d at 163. Moreover, the CSA contemplates that an ISO will be issued in emergency circumstances, prior to an administrative hearing, and prior to the development of a formal evidentiary record. *Id.* Given the degree of discretion afforded to the Administrator, as well as the summary and urgent nature of an ISO, the

Court's review "must be correspondingly relaxed." *Nat'l Cable Television Ass'n, Inc.*, 724 F.2d at 181; *Holiday CVS, L.L.C.*, 839 F. Supp. 2d at 163. In other words, the arbitrary and capricious standard "is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *overruled on other grounds*, *Califano v. Sanders*, 430 U.S. 99, 104–07 (1977); *see also Hughes River Watershed Conservancy v. Johnson*, 165 F.3d 283, 284 (4th Cir. 1999).

The determination by DEA that an "imminent danger" exists is entitled to great deference. As explained in *Cardinal Health*, a court cannot substitute its judgment for that of the DEA Administrator:

> Cardinal does not dispute this point, as it has mounted no facial challenge to the statute. It instead contends that due process requires that a de novo finding of imminent danger be made by the Court, without according any deference to the Administrator's finding. But, as already explained, this reading is inconsistent with the plain meaning of the statute. Congress deemed it appropriate to confer upon the Attorney General (and, by designation, the Administrator of the DEA) the authority to make an emergency determination that a party's continued DEA registration poses an imminent danger to the public. 21 U.S.C. § 824(d). Congress did not grant this Court the power to substitute its own judgment regarding the existence of an imminent danger for the judgment of the Administrator, nor does Cardinal cite any authority or offer any convincing reason why due process requires the Court to do so.

Cardinal Health, 846 F.Supp.2d at 229-30 (footnote omitted). This is consistent with the decisions of the Supreme Court requiring that an agency's decision on such matters within the agency's expertise be given great deference. *Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43.

B. Judicial review is confined to the record and information that was before the DEA Administrator when he issued the ISO.

Furthermore, judicial review is confined to events up to the date DEA issued the ISO and

the information DEA had before it in making the ISO determination. *See Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision."); *Holiday CVS, L.L.C.*, 839 F. Supp. 2d at 154–55. Reviewing "more than the information before the [Administrator] at the time [he] made [his] decision risks our requiring administrators to be prescient." *Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792.

Stated another way, in applying the arbitrary and capricious standard the focus of judicial review must be the administrative record already in existence, not some new record made initially in the reviewing court. *Camp v. Pitts,* 411 U.S. 138, 142, 93 S.Ct. 1241, 36 L.Ed.2d 106 (1973) (per curiam). This rule forbids "*ex post* supplementation of the record by *either side*." *Walter O. Boswell Mem. Hosp. v. Heckler,* 749 F.2d 788, 793 (D.C.Cir.1984) (emphasis added); see *IMS, P.C. v. Alvarez,* 129 F.3d 618, 624 (D.C.Cir.1997) (rejecting the plaintiff's attempt to submit litigation affidavits to supplement the agency record *ex post*); *AT & T Info. Sys. Inc. v. Gen. Servs. Admin.,* 810 F.2d 1233, 1236 (D.C.Cir.1987) (rejecting agency's attempt to submit litigation affidavit to provide *post hoc* rationalization of the agency's action). Although the administrative record may be supplemented to provide background information or evidence of whether all relevant factors were examined by an agency, it is clear that the new material should be merely explanatory of the original record and should contain no new rationalizations. *AT & T Info. Sys., Inc.,* 810 F.2d at 1236 (internal quotation marks, citations, and alterations omitted).

VI. ARGUMENT

The standard for granting a TRO or a preliminary injunction is the same. *Sarsour v. Trump*, 245 F. Supp. 3d 719, 728 (E.D. Va. 2017); *Moore v. Kempthorne*, 464 F. Supp. 2d 519, 525 (E.D. Va. 2006). TROs and preliminary injunctions are extraordinary remedies involving the exercise

of very far-reaching power to be granted only sparingly and in limited circumstances. *MicroStrategy, Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001). A party seeking a TRO or a preliminary injunction must establish: (1) a likelihood of success on the merits; (2) irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the party's favor; and (4) that the injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Pashby v. Delia*, 709 F.3d 307, 320 (4th Cir. 2013); *The Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346–47 (4th Cir. 2009), *vacated on other grounds*, *Citizens United v. FEC*, 558 U.S. 310 (2010), *aff'd*, *The Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355 (4th Cir. 2010) (per curiam).

Each of these four elements must be independently satisfied in order for a preliminary injunction or TRO to issue. *Winter*, 555 U.S. at 20. A failure to establish any of the elements necessary for relief is fatal to the request for a TRO or preliminary injunction. *Id.* OHHP has not carried its burden to show that any of the four factors—let alone all of them—favors a TRO or preliminary injunction. OHHP's action for a TRO or preliminary injunctive relief should be denied.

A. OHHP has failed to demonstrate a likelihood of success on the merits.

It is important to note, as an initial observation, that in its Petition and motion, OHHP fails to discuss or even accurately define the applicable standard for judicial review of an ISO. Instead, OHHP argues that (1) the DEA administrator was not aware of or did not consider some evidence that OHHP deems relevant and important; and/or (2) the Administrator evaluated evidence erroneously. This is not the correct standard or analysis.

In order to demonstrate a likelihood of success on the merits, OHHP must show that the DEA Administrator, in all probability, acted arbitrarily and capriciously in issuing the ISO. In a challenge to an § 824(d) suspension, "the underlying question on the merits is whether DEA acted

arbitrarily and capriciously in suspending [Plaintiff's] registration based on a preliminary finding that its continued operation posed an 'imminent danger to public health or safety.'" *Novelty Distribs, Inc.*, 562 F. Supp. 2d at 29. This is an "extremely narrow" standard of review. *U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 7 (2001). And "[t]he court is not empowered to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43; *Citizens to Preserve Overton Park*, 401 U.S. at 416. The Court must apply a presumption of regularity and consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. *Citizens to Preserve Overton Park*, 401 U.S. at 416. A decision is arbitrary and capricious only "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43.

The dispute between the parties in this case focuses on whether the DEA had a valid basis to determine that OHHP's continued registration posed an "imminent danger to the public health or safety." The DEA issued the ISO on August 6, 2019, after a lengthy investigation into OHHP's dispensing practices. In reaching its decision to suspend OHHP's registration, the DEA relied on several factors, the totality of which led the DEA to conclude that OHHP's continued registration would pose an "imminent danger to the public health or safety." As outlined in the ISO, the DEA considered no fewer than seven serious red flags associated with prescriptions for Subutex, a widely abused Schedule III controlled substance. In analyzing and addressing these red flags, the DEA considered PDMP Data and the opinions of a pharmacy expert.

In accordance with 21 C.F.R. §§ 1301.36 and 1301.37(c), the DEA included in the ISO a

non- exhaustive summary of the facts and law it relied upon and the violations of the law and regulations that it determined OHHP had committed. The ISO clearly demonstrates that the DEA's determination that OHHP poses an imminent danger to public health or safety is reasonable. OHHP must show that the DEA's determination reflects "a clear error of judgment" or is "implausible" in view of the evidence that the DEA had before it when it issued the ISO. OHHP simply cannot carry this demanding burden. The finding of the DEA Administrator that an imminent danger to public health or safety is entitled to great deference. *Motor Vehicle Mfrs. Ass'n of U.S., Inc.*, 463 U.S. at 43; *Cardinal Health*, 846 F.Supp.2d at 229-30.

1. <u>A typo does not render the ISO arbitrary and capricious.</u>

The primary argument that OHHP chose to advance in its memorandum of law is that the ISO "rests entirely" on the preliminary finding that there is a substantial likelihood that OHHP will continue to unlawfully "prescribe" controlled substances. (ECF No. 1-1 at 14.) In essence, OHHP is pointing out that the ISO contains a typographical error, mistakenly using the word "prescribe" on a single occasion rather than the word "dispense" or "fill." (ECF No. 1-2 at 12.) A typographical error cannot possibly render the ISO arbitrary and capricious. In the ISO the DEA Administrator refers to OHHP dispensing Subutex or filling Subutex prescriptions dozens of times throughout the fourteen-page document. It is obvious that the DEA Administrator did not base the ISO on a finding that OHHP will continue to unlawfully "prescribe" controlled substances.

2. <u>DEA did not fail to consider "on-the-ground circumstances" that ostensibly caused OHHP to fill thousands of Subutex prescriptions laden with red flags.</u>

Next, OHHP dismissed the many red flags evident on the Subutex prescriptions by suggesting that "allegations of supposed red flags of diversion do not acknowledge the on-the-ground circumstances that exist in West Virginia . . . ." (ECF No. 1-1 at 14.) OHHP's argument continues by discussing a series of unsubstantiated and self-serving assertions regarding the lack

of medical providers and pharmacies in West Virginia. However, judicial review is confined to events up to the date the DEA issued the ISO and the information the DEA had before it in making the ISO determination. *See Walter O. Boswell Mem'l Hosp.*, 749 F.2d at 792.

Furthermore, an ISO need not contain the entire basis for the suspension. Instead, the ISO can consist of a non-exhaustive summary. 21 C.F.R. § 1301.73(c); *Boston Carrier, Inc.*, 746 F.2d at 1560. In other words, an agency is not required to give a respondent a complete bill of particulars as to every allegation that it will confront. *See* 746 F.2d at 1560. In this case, the ISO accurately and substantially explains the basis for the suspension. It must be recalled that the ISO/show cause order initiated an administrative hearing process through which OHHP has the opportunity to offer new or additional evidence and endeavor to demonstrate that the registration should not be revoked. 21 C.F.R. § 1309.46. This administrative hearing process is in progress. OHHP will have the opportunity to put forth evidence of "the on-the-ground circumstances that exist[ed] in West Virginia" during the administrative hearing, if it can do so. But such evidence, if it exists, was not before the DEA Administrator. Moreover, OHHP has not offered any credible evidence of "on-the-ground circumstances" here, even if it were relevant to the issue before the Court.

3. <u>DEA was not compelled to limit the scope of the suspension.</u>

In the Motion for a TRO and Petition for a Preliminary Injunction, OHHP contends that the ISO was overly broad and should have been narrowly tailored. It seems OHHP abandoned this argument in the Motion for a TRO. Nonetheless, OHHP does not cite any authority to support the contention that the DEA must limit a suspension or revocation to particular controlled substances but leave the registration in place as to other controlled drugs. While the DEA Administrator *may* limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist, there is no mandate to do so. 21 U.S.C.

§ 824(b). Thus, the DEA has explicit discretion to determine the scope of the suspension or revocation. When the Administrator has concluded that a registrant has repeatedly and flagrantly disregarded multiple red flags associated with prescriptions for a widely abused controlled substance, then it is a reasonable exercise of discretion to extend the suspension to all controlled substances. Indeed, it would be irresponsible for an administrator to allow a registrant to continue to dispense oxycodone, morphine, fentanyl, and other opioids when the registrant has improperly dispensed dangerous controlled substances, such as Subutex. In short, the DEA Administrator had the discretion to suspend OHHP's registration in its entirety and acted reasonably in doing so.

B. Plaintiff Has Not Established that It Is Likely to Suffer Irreparable Harm Absent an Injunction.

1. OHHP's claims of harm are speculative.

Equitable relief is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 22. To obtain the extraordinary remedy of a TRO or preliminary injunctive relief, a plaintiff must show that it is likely to suffer irreparable harm if the petition is denied. *Pashby*, 709 F.3d at 328 (citing *Winter*, 555 U.S. at 20). Irreparable harm will not be established if an injury can be redressed by other legal or equitable remedies after trial. *See SAS Inst., Inc. v. World Programming Ltd.*, 874 F.3d 370, 386–87 (4th Cir. 2017) ("[T]he existence of past harm is far from dispositive on the question of irreparable future harm."). "To establish irreparable harm, the movant must make a 'clear showing' that it will suffer harm that is 'neither remote nor speculative, but actual and imminent.'" *Mountain Valley Pipeline, LLC v. 6.56 Acres of Land*, 915 F.3d 197, 216 (4th Cir. 2019) (quoting *Stuller, Inc. v. Steak N Shake Enters.*, 695 F.3d 676, 680 (7th Cir. 2012)); *see also Marietta Mem'l Hosp. v. W. Va. Health Care Auth.*, No. 2:16-cv-08603, 2016 WL 7363052, at *3 n.2 (S.D. W. Va. Dec. 19, 2016). Furthermore, an alleged constitutional harm is not necessarily synonymous with the irreparable harm necessary

for issuance of a TRO or a preliminary injunction. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 112–13 (1983).

In this case, OHHP alleges a number of economic harms that may occur should a TRO or a preliminary injunction not issue. However, OHHP's allegations are speculative. Indeed, OHHP is not prevented from serving customers and dispensing non-controlled prescription medications. Of course, OHHP may contend that opioids and other controlled substances were such a significant facet of its business that it cannot continue operations without the ability to dispense narcotics. This, however, would be a rather incriminating argument to make. If a registrant cannot continue to operate without dispensing controlled substances, then it is evident that the ISO was warranted.

2. <u>OHHP's claims of harm are undercut but unexplained delays in seeking relief</u>.

More importantly, the ISO was served on OHHP on August 8, 2019. For unknown reasons, OHHP waited nearly two months to petition the Court for preliminary injunctive relief. It was an additional nineteen days before OHHP filed the Motion seeking a TRO. Furthermore, there is no indication that OHHP sought relief elsewhere. Given the statutory framework, it seems unlikely that the ALJ would have had the authority to enjoin or stay the ISO pending a resolution of the administrative hearing process. It seems clear, however, that OHHP did not make a meaningful effort to gain relief from the ISO through the administrative process.

Such delays are evidence that swift relief is not needed. *See Quince Orchard Valley Citizens Ass'n, Inc. v. Hodel*, 872 F.2d 75, 79–80 (4th Cir. 1989); *see also Candle Factory, Inc. v. Trade Assocs. Grp., Ltd.*, 23 F. App'x 134, 138 n.2 (4th Cir. 2001) (per curiam). In addition, OHHP initially requested and ultimately was afforded the option of proceeding with the administrative hearing before the ALJ on October 7, 2019. *See* Exhibit 2. DEA counsel agreed to this expedited hearing date. In the end, OHHP demurred and opted for a November 5, 2019 hearing date. While

it was OHHP's right to delay the administrative hearing, doing so undercuts the argument for urgent relief. *Cf. Montrose Parkway Alts. Coal. v. U.S. Army Corps of Eng'rs*, 405 F. Supp. 2d 587 600 n.4, 602 (D. Md. 2005) (denying the plaintiffs' motion for TRO and preliminary injunction and noting that the plaintiffs delay of "nearly one month after the alleged irreparable harm occurred" seemed "to undermine their claim of irreparable harm"); *see also Rovio Entertainment Ltd. v. Royal Plush Toys, Inc.*, 907 F. Supp. 2d 1086, 1097 (N.D. Cal. 2012) ("Parties spurred on by the threat of or actual immediate irreparable harm [must] file for TROs as quickly as possible to head or stave it off.") (collecting cases).

For these reasons, Plaintiff has not established the kind of irreparable harm that would justify the issuance of a TRO or a preliminary injunction, and the motion should be denied.

C. Balancing of the Equities

1. The balancing of equities favors the DEA.

In considering the extraordinary remedy of an injunction or a restraining order, a court must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief. In exercising their sound discretion, courts of equity should pay particular regard for the public consequences. *Winter*, 555 U.S. at 24 (citations omitted); *Sterling Drug, Inc. v. Bayer AG*, 14 F.3d 733, 747 (2d Cir. 1994). Where the defendant is the Government, the Court may consider these final two factors together. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

In its pleadings, OHHP does not address the final two prongs of the test for a TRO or a preliminary injunction. As the party seeking relief, OHHP must show that the DEA would not be unduly harmed by the entry of a TRO or a preliminary injunction. However, OHHP fails to address the harm to DEA if an injunction or TRO were to be issued. Congress expressly granted the DEA

the authority under § 824(d) to suspend a registrant's authority to prescribe controlled substances when there is evidence of abuse or diversion. Courts have recognized that the government has a strong interest in enforcing the CSA and ensuring that controlled substances are not improperly diverted while the administrative proceedings before the DEA are pending. *See Cardinal Health*, 846 F.Supp.2d at 230. There is a significant public interest in preventing the illegal diversion of prescription drugs, particularly in light of the extensive problem of prescription drug abuse in West Virginia. *Id.*

The DEA has made combating diversion a priority and has dedicated significant resources to halt the prescription drug crisis that exists today. More critically, the public interest in the DEA's vigorous enforcement of the CSA and the proper dispensing of narcotic prescriptions militates against a TRO and a preliminary injunction in this case. The balancing of the harms tips in favor of the Government.

2. <u>The ISO does not harm the Oak Hill Community</u>.

OHHP claims that it plays a vital role in the Oak Hill, West Virginia, community. However, there are no fewer than seven other pharmacies within five miles of OHHP. *See* Exhibit 6, Declaration of DEA Diversion Investigator Leanne Koziol. There is at least one chain pharmacy within a mile of OHHP. *Id*. OHHP has not offered anything to show that the Oak Hill community will find it difficult to locate a pharmacy while the administrative process proceeds to its ultimate conclusion. In fact, it is noteworthy that the vast majority of the prescriptions at issue in this matter were presented by individuals who were not part of the Oak Hill community.

To the extent OHHP is suggesting that inconvenience to its customers demonstrates irreparable harm, the Court should reject this point. This argument is irrelevant because it does not show irreparable harm to OHHP. Instead, it implies some harm to third parties. *See*

555 U.S. at 20, 129 S.Ct. 365. In *Winter* the Court held that a plaintiff seeking a preliminary injunction must establish that it, not others, is likely to suffer irreparable harm in the absence of preliminary relief. *Id*; *see also Cardinal Health*, 846 F.Supp.2d at 213.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 22, 2019, I electronically filed the foregoing **RESPONDENT'S BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER AND PETITION FOR A PRELIMINARY INJUNCTION** with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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