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6	IN THE UNITED STATES DISTRICT COURT	
7	FOR THE DISTRICT OF ARIZONA	
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9	Svetlana Burtman,	No. CV-24-00144-TUC-SHR
10	Plaintiff,	Order Denying Temporary Restraining Order
11	V.	
12	Merrick Garland, et al.,	
13	Defendants.	
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16	Pending before the Court is a Motion for Temporary Restraining Order ("TRO	
17	Motion") filed by Plaintiff Svetlana Burtman pursuant to Federal Rule of Civil Procedure	
18	65. (Doc. 2.) Defendants filed a Response. (Doc. 10.) For the reasons stated below, the	
19	Court denies the TRO Motion.	
20	I. BACKGROUND	
21	Plaintiff is a nurse practitioner who owns and operates two medical clinics—one is	
22	in Tucson and the other is in Green Valley. (Doc. 1 at 2–3, 5.) Plaintiff is registered with	
23	the DEA and was permitted to possess, prescribe, administer, and dispense controlled	
24	substances. (Id. at 1.)	
25	On July 19, 2023, the DEA investigated and audited Plaintiff's Tucson Clinic. (Doc.	
26	1 at 5; Doc. 1-2 at 4.) According to th	e Immediate Suspension order ("ISO"),
27	"[i]nvestigators were unable to complete their audit because of missing and incomplete	
28	documentation as to inventory of controlled su	bstances, purchase records, and dispensing

1 logs." (Doc. 1-2 at 4.) The ISO alleges Plaintiff committed the following violations related 2 to the Tucson Clinic: 3 • clinic's dispensing logs were incomplete and inconsistent • unable to provide complete records of your drug purchases 4 from at least two suppliers, Anazao Health Corporation and 5 Henry Schein • failed to conduct an initial inventory of all controlled 6 substances on hand when you first engaged in the 7 dispensing of controlled substances on November 27, 2017 • failed to conduct the required biennial inventories 8 stored non-controlled substances with controlled 9 substances, without written authorization of the DEA Special Agent in charge 10 • failed to properly physically secure controlled substances 11 because controlled substances were found spread across different rooms of the clinic in unsecured cabinets 12 (Doc. 1-2 at 4.) 13 Also on July 19, 2023, the DEA visited Plaintiff's Green Valley Clinic. The ISO 14 alleges the DEA visited this unregistered clinic to answer Plaintiff's questions about 15 registration requirements. (Doc. 1-2 at 3.) According to the ISO, on September 20, 2023, 16 the DEA executed a warrant, collected logs/records, and discovered supplies of 17 testosterone at the unregistered Green Valley clinic. (Id. at 5.) The ISO alleges Plaintiff 18 lied to DEA investigators on July 19, 2023, when she denied ever having or dispensing 19 controlled substances at the Green Valley Clinic. (Id.) The ISO also alleges she "lied to 20 DEA investigators on September 23, 2023, when [she] claimed that the testosterone was 21 only on-site at the Green Valley Clinic because [she was] 'prepping the office.'" (Id. at 5– 22 6.) 23 On December 28, 2023, the DEA issued the ISO, immediately suspending 24 Plaintiff's registration based on the belief Plaintiff's continued registration constituted an 25 imminent danger to the public health and safety. (Doc. 1-2 at 1, 6.) Specifically, the ISO 26 stated: 27 Despite being specifically warned against doing so, you have 28 unlawfully stored and dispensed controlled substances at an

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imminent danger. (Doc. 1-2 at 6.) The ISO also stated:

> It is also the Agency's preliminary finding, based on the facts and circumstances described [in the ISO] and in light of the rampant and deadly problem of prescription controlled substance abuse, that [Plaintiff's] continued registration during the pendency of these proceedings would constitute "an imminent danger to the public health or safety" because of the substantial likelihood of an imminent threat that death, serious bodily harm, or abuse of controlled substances will occur in the absence of this suspension.

unregistered location. You have done so as recently as September 20, 2023. Your ongoing storage and issuance of

controlled substances at the Green Valley clinic poses an

11 || (Doc. 1-2 at 6.)

Plaintiff was served the order to show cause and the ISO on February 29, 2024.
(Doc. 10-2 at 2.) On March 7, 2024, Plaintiff's counsel submitted a hearing request to the
Office of the Administrative Law Judges (ALJ) for review of the DEA's suspension and
issuance of a final order. (Doc. 10-3 at 2.) The same day, Plaintiff's counsel answered the
order to show cause and requested a hearing regarding the summary suspension. (Doc. 10The DEA Office of Administrative Hearing ordered the parties to submit prehearing
statements and set a prehearing conference for April 4, 2024. (Doc. 10-5 at 3-4.)

On March 13, Plaintiff filed a complaint for declaratory and injunctive relief from
the ISO to prevent Defendants—the Attorney General, the Administrator of the DEA, and
the DEA—from enforcing the ISO against her because the DEA's allegations fail to
establish imminent danger. (Doc. 1 at 3.) Plaintiff also seeks to have the Court dissolve
or set aside the ISO under 21 U.S.C. § 824 or 5 U.S.C. § 706. (Doc. 1 at 3, 7–11.)

Also on March 13, Plaintiff filed this TRO Motion seeking a Court order: (1) (1) "[r]estraining DEA from enforcing the [ISO] during the pendency of administrative proceedings pertaining to [Plaintiff's] registration and pending application," and (2) (1) "[r]equiring DEA to immediately return any registrations, licenses, forms, and controlled substances seized." (Doc. 2 at 10.) Defendants filed a response arguing Plaintiff cannot

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meet the standard for obtaining preliminary injunctive relief. (Doc. 10 at 15.)

### II. LEGAL STANDARDS

### A. Registration Requirements for Controlled Substances

The Controlled Substances Act (CSA) and its implementing regulations create restrictions on the distribution of controlled substances. *See* 21 U.S.C. §§ 801–971; 21 C.F.R. §§ 1300–1321. Distributors and prescribers of controlled substances are required to register with the Attorney General. *See* 21 U.S.C. § 823. The Attorney General may suspend and revoke registrations but, normally, it must first serve upon the registrant an order to show cause why the registration should not be denied, revoked, or suspended. 21 U.S.C. § 824(c). The registrant may then request a hearing in front of an ALJ. *Id.* However, "[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings . . . in cases where he finds that there is an imminent danger to the public health or safety." 21 U.S.C. § 824(d)(1).

Under § 824(d), "the phrase 'imminent danger to the public health or safety' means 14 15 that, 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 16 17 of an immediate threat that death, serious bodily harm, or abuse of a controlled substance 18 will occur in the absence of an immediate suspension of the registration." 21 U.S.C. § 19 824(d)(2). A § 824(d) suspension remains in effect until the DEA issues a final order 20 unless the suspension is withdrawn by the Attorney General or dissolved by a court of 21 competent jurisdiction. 21 U.S.C. § 824(d)(1).

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### B. Administrative Procedure Act

Under the Administrative Procedure Act (APA), the Court may set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(a). A decision is arbitrary and capricious if the agency relied on factors Congress did not intend it to consider, failed to account for a significant issue, or offered an implausible explanation or one contrary to the evidence. *Defs. of Wildlife v. Zinke*, 856 F.3d 1248, 1257 (9th Cir. 2017); *see also Evergreen Pharmacy, Inc.* 

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v. Garland, No. 22-03912, 2022 WL 3294842, at \*8 (N.D. Ill. Aug. 11, 2022) ("[T]he 1 2 relevant inquiry is whether [the plaintiff's] infractions demonstrate a pattern and practice 3 of conduct which the DEA could reasonably conclude was inconsistent with public health 4 and safety[;] if so[,] then the ISO is not arbitrary and capricious."). The standard of review 5 is highly deferential, and "[t]he court is not empowered to substitute its judgment for that 6 of the agency." Pac. Dawn LLC v. Pritzker, 831 F.3d 1166, 1173 (9th Cir. 2016) (quoting 7 Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971)). Instead, the 8 court must simply "consider whether the decision was based on a consideration of the 9 relevant factors required by the statute." Id. In other words, the Court must examine 10 whether the agency articulated a rational connection between the underlying facts and the 11 decision made. Solar Energy Indus. Ass'n v. FERC, 80 F.4th 956, 978 (9th Cir. 2023). If 12 so, the agency action must be upheld. Id.

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## C. <u>TRO</u>

14 A TRO is "an extraordinary remedy that may only be awarded upon a clear showing 15 that the plaintiff is entitled to such relief." Winter v. Natural Res. Def. Council, Inc., 555 16 U.S. 7, 24 (2008); see also Stuhlbarg Int'l Sales Co. v. John D. Brush & Co., 240 F.3d 832, 17 839 n.7 (9th Cir. 2001) (TROs are analyzed in substantially the same way as preliminary 18 injunctions). A plaintiff seeking a TRO must establish: (1) she is likely to succeed on the 19 merits; (2) she is likely to suffer irreparable harm in the absence of preliminary relief; (3) 20 the balance of equities tips in her favor; and (4) an injunction is in the public interest. 21 Winter, 555 U.S. at 20. When the government is a party, the last two of the four factors— 22 the balance of the equities and the public interest-merge. Drakes Bay Oyster Co. v. 23 Jewell, 747 F.3d 1073, 1092 (9th Cir. 2014). The first factor, likelihood of success on the 24 merits, is "the most important Winter factor." Disney Enters., Inc. v. VidAngel, Inc., 869 25 F.3d 848, 756 (9th Cir. 2017) ("[I]f a movant fails to meet this threshold inquiry, the court 26 need not consider the other factors."). However, in the Ninth Circuit, a temporary 27 restraining order is warranted where there are "serious questions going to the merits" and 28 a "hardship balance . . . tips sharply toward the plaintiff"—provided the other two elements

of the Winter test are also met. All. for the Wild Rockies v. Cottrell, 632 F.3d 1127, 1132 (9th Cir. 2011); see also Shell Offshore, Inc. v. Greenpeace, Inc., 709 F.3d 1281, 1291 (9th Cir. 2013) (describing serious questions going to the merits as "a lesser showing than likelihood of success on the merits").

#### III. DISCUSSION

# A. Likelihood of Success

Plaintiff argues she is likely to succeed on the merits because she has raised serious questions the ISO issued by the DEA is "arbitrary, capricious, or inconsistent with the law." (Doc. 2 at 4.) According to Plaintiff, the DEA relied on unsupported allegations and failed 10 to establish why an ISO is appropriate in this case. (*Id.* at 2.) Specifically, Plaintiff argues the ISO fails to establish imminent danger to public health or safety because there are no specific allegations showing "anyone has been or is likely to be harmed as a result" of her "technical violations" and the DEA's slow action in the suspension process suggests there is no imminent danger. (Id.)

15 Defendants argue Plaintiff is not likely to succeed on the merits and she also cannot 16 show serious questions about whether the DEA's ISO was arbitrary and capricious. (Doc. 17 Specially, Defendants argue "[d]ispensing controlled substances from an 10 at 6.) 18 unregistered location is significant and dangerous misconduct" that poses an imminent 19 danger to public health and safety.<sup>1</sup> (*Id.* at 8.) Defendants argue actual harm is not required 20to be shown and it is improper to consider the timing of the service of the ISO because the 21 focus should be on the agency's rationale for the ISO. (Doc. 10 at 9–11.)

22 Here, Plaintiff presents a compelling argument of government overreach by relying 23 on Bates Drug Stores, Inc. v. Holder, No. CV-11-0167-EFS, 2011 WL 1750066 (E.D. 24 Wash. May 6, 2011). In *Bates*, the district court issued a temporary restraining order of an 25 ISO because the plaintiff "demonstrated serious questions relating to whether the DEA's 26 finding of an imminent danger in its Suspension Order is arbitrary, capricious, or

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<sup>&</sup>lt;sup>1</sup>At oral argument, Defendants argued imminent danger has been shown because there is a substantial likelihood abuse of a controlled substance will occur, which poses an 28 immediate threat.

inconsistent with law." Id. at \*2-\*4. However, Bates is not binding on this Court and the district court there failed to properly take into consideration the APA's limits on judicial review and the substantial deference afforded to agencies. While the Court may disagree with the DEA's finding of imminent danger, it must give deference to the DEA's conclusion under the APA if the DEA articulated a rational basis for its decision.

6 Notably, in this case, Plaintiff does not contest any of the underlying factual findings 7 in the ISO.<sup>2</sup> Therefore, she concedes she failed to keep proper records of controlled 8 substances, conduct proper inventory, and properly store controlled substances (including 9 keeping controlled substances in secured cabinets). (Doc. 10-1 at 4–5.) She also concedes 10 she stored and dispensed controlled substances at an unregistered location, despite being told she could not lawfully do so, and she concedes lying to DEA investigators about using 12 an unregistered location to dispense controlled substances. (Doc. 10-1 at 5-6). As such, 13 the record establishes Plaintiff was dispensing testosterone out of an unregistered clinic and Plaintiff dispensed the controlled substance before and after speaking with the DEA. 14

15 Contrary to Plaintiff's suggestion, there is nothing requiring a showing of actual 16 harm. Section 824(d)(2) simply requires a substantial *likelihood* of an immediate threat. 17 Based on the record at this early stage in the proceedings, the Court finds Defendants have 18 established there was a rational basis for the DEA to conclude there was imminent danger 19 to public health and safety based on Plaintiff's reckless behavior and blatant flouting of 20federal statutes and regulations. Therefore, Plaintiff has not shown a likelihood of success 21 on the merits or presented serious questions going to the merits.<sup>3</sup>

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#### **B**. **Irreparable Harm**

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Plaintiff argues she will suffer irreparable harm without court intervention because

<sup>&</sup>lt;sup>2</sup>The Court finds it improper to consider the timing of the service of the ISO because 25 under the APA the court's review of an agency action is confined to the record available to the agency at the time of its decision. *Beno v. Shalala*, 30 F.3d 1057, 1074 (9th Cir. 26 1994). The Court also finds the timing between the DEA investigation and issuance of the ISO insignificant.

<sup>27</sup> <sup>3</sup>The failure to satisfy the first *Winter* factor is fatal to Plaintiff's TRO request. All. for the Wild Rockies, 632 F.3d at 1135. But even if Plaintiff had raised serious questions going to the merits of the case, she has not demonstrated she will face irreparable harm or that the balance of equities tips sharply in her favor. See infra sections III(B)–III(C). 28

the ISO is harming her business, staff members, and her reputation.<sup>4</sup> (Doc. 2 at 7-8.) Defendants argue even if Plaintiff raised serious questions regarding the merits of the case there is no irreparable harm because Plaintiff has an adequate remedy at law via the administrative hearing and Plaintiff's financial and reputational evidence is conclusory and insufficient. (Doc. 10 at 11–13.)

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6 Here, Plaintiff provided a declaration avowing the controlled substances in question 7 make up 90% of her business and amount to \$10,000 of revenue per day. (Doc. 2-2 ¶ 6.) 8 Plaintiff claims the ISO has already cost her over \$80,000 in revenue and she has had to 9 lay off two employees due to this lost revenue. (Id. ¶¶ 8, 10.) Plaintiff anticipates having 10 to completely shut down her business within two weeks if the ISO is not lifted. (Id. ¶ 11.) 11 Even if this Court were to assume these statements were enough, monetary injuries are 12 generally not considered irreparable in this circuit. See Doe #1 v. Trump, 957 F.3d 1050, 13 1060 (9th Cir. 2020); Lydo Enters. v. Las Vegas, 745 F.2d 1211, 1213 (9th Cir. 1984) 14 ("Purely monetary injuries are not normally considered irreparable."). Plaintiff fails to cite 15 any binding law in this Circuit indicating the contrary. Moreover, the Court finds 16 Plaintiff's harm to reputation argument speculative and insufficient because she just states 17 she "do[es] not know if [her] clients will return to [her] clinics if and when the [ISO] is 18 lifted." (Doc. 2-2 ¶ 9.) See Titaness Light Shop, LLC v. Sunlight Supply, Inc., 585 F. App'x 19 390, 391 (9th Cir. 2014) (showing reputation might be harmed by an action insufficient to 20 establish irreparable harm is likely). Although the Court is sympathetic regarding layoffs, 21 the focus of the irreparable harm analysis should be on the harm to the plaintiff. See Nat'l 22 Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 886 F.3d 803, 822 (9th Cir. 2018) 23 ("Plaintiffs seeking injunctive relief must show that they themselves are likely to suffer 24 irreparable harm absent an injunction."). Therefore, Plaintiff has not shown irreparable 25 harm.

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## C. Balance of Equities and Public Interest

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Plaintiff argues the balance of equities tips in her favor and the public interest lies

<sup>&</sup>lt;sup>4</sup>At oral argument, Plaintiff focused her irreparable harm analysis on having to shut her business down before the administrative proceedings could be resolved.

1 with her because the DEA has not provided evidence a person has been or could be harmed 2 by her violations, but the ISO has already harmed her business, her patients, and her staff. 3 (Doc. 2 at 8–9.) Defendants argue the government has a strong interest in enforcing the 4 CSA and ensuring pharmaceutical drugs are not improperly diverted while administrative 5 proceedings are pending. (Doc. 10 at 14.) According to Defendants, testosterone is 6 dangerous because it is a Schedule III drug with "a higher tendency for abuse than Schedule 7 IV drugs," research shows high doses can have harmful effects, and "Congress considers 8 these substances serious enough to penalize their unlawful distribution by up to 10 years 9 prison for first time offenders." (Id. at 14–15.)

10 Here, even if Plaintiff could establish irreparable harm, the balance would still favor 11 denying the temporary restraining order. Both parties in this case face plausible sources of 12 hardship. Plaintiff has a financial interest in using the controlled substances seized by the 13 DEA and these substances account for a sizeable portion of Plaintiff's business revenue. However, ordering the release of the controlled substances also imposes a hardship on 14 15 Defendants to return the substances while an administrative proceeding is pending and 16 there is a strong public interest in enforcing the CSA and ensuring controlled substances 17 are not improperly diverted before an administrative decision is made. See Keysource 18 Med., Inc. v. Holder, No. 1:11-cv-393, 2011 WL 3608097, at \*9 (S.D. Ohio Aug. 16, 19 2011) ("Although [plaintiff] has a private financial interest in continuing to sell controlled 20 substances, it is plainly outweighed by the compelling public interest in preventing the 21 distribution of controlled substances without adequate controls against diversion.").

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## **IV. CONCLUSION**

Based upon the record the Court has before it and the balancing interests, the Court
finds the balance tips in favor of Defendants. As such, Plaintiff has not shown these factors
weigh in favor of granting a TRO.

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1	Accordingly,
2	IT IS ORDERED Plaintiff's TRO Motion (Doc. 2) is DENIED.
3	Dated this 28th day of March, 2024.
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7	Honorable Scott H. Rash United States District Judge
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