UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VIRTUS PHARMACEUTICALS, LLC,
Plaintiff,
v.
MERRICK GARLAND, *et al.*,
Defendants.

Civil Action No. 21-2308 (CKK)

MEMORANDUM OPINION
(September 22, 2021)

Virtus Pharmaceuticals, LLC ("Virtus") is a "virtual" drug manufacturer. As part of its business model, Virtus owns the technical applications necessary to produce various pharmaceuticals regulated under the Controlled Substances Act. But because Virtus is not itself registered with the United States Drug Enforcement Agency ("DEA") to handle controlled substances, the company outsources its manufacturing and distribution operations to third parties that are registered with the DEA. As relevant here, Virtus contracts with a logistics company called Woodfield Distribution, LLC ("Woodfield") for the storage and distribution of Virtus's pharmaceutical products through Woodfield's facilities in both Sugar Land, Texas and Boca Raton, Florida.

On August 11, 2021, the DEA served Woodfield with an order that immediately suspended Woodfield's registrations to import and distribute controlled substances from its Sugar Land facility. The DEA based this suspension on Woodfield's alleged compliance failures, which facilitated the illicit diversion of controlled substances and threatened public health. In conjunction with that suspension order, the DEA placed all controlled substances at Woodfield's Sugar Land facility under seal, including the pharmaceutical products Woodfield was storing for

Virtus. According to the DEA, Virtus's drugs currently remain under seal at undisclosed DEA facilities for safekeeping. While these drugs remain under seal with the DEA, Virtus is unable to send them to market and the company now contends that this supply shortage is causing it significant financial harm.

To address this alleged harm, Virtus has filed a [2] Motion for a Temporary Restraining Order ("TRO") against the DEA. Therein, Virtus requests a court order compelling the DEA to release Virtus's drug supply to a new third-party distributor, so that that Virtus can resume its sale operations for those drugs. Upon consideration of the pleadings, the relevant legal authorities, and the record as a whole,[1] the Court will **DENY** Virtus's [2] Motion for a Temporary Restraining Order.

I. BACKGROUND

A. Controlled Substances Act

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act, Pub. L. No. 91–513, 84 Stat. 1236, (the "Controlled Substances Act" or "CSA"), with the goal of regulating the manufacture, importation, possession, and distribution of certain controlled substances. 21 U.S.C. § 801 *et seq.*; *see also Gonzales v. Oregon*, 546 U.S. 243, 250 (2006) (discussing the legislative history of the CSA). "A central feature of the CSA is its 'closed system' of distribution in which all persons in the 'legitimate distribution chain' of controlled substances

[1] This Memorandum Opinion focuses on the following documents:

- Compl., ECF No. 1;
- Pl.'s Mem. of P. & A. in Supp. of its Appl. for a Temp. Restraining Order ("Pl.'s Mot."), ECF No. 2-1;
- Def.'s Mem. of Law in Opp'n to Pl.'s Mot. ("Def.'s Opp'n"), ECF No. 9-1;
- Pl.'s Reply Mem. of P. & A. in Supp. of Pl.'s Mot. ("Pl.'s Reply"), ECF No. 11; and,
- Admin. Record (cited as "DEA at __"), ECF No. 13-3.

In an exercise of its discretion, the Court finds that holding oral argument in this action would not be of assistance in rendering a decision. *See* LCvR 7(f).

must register with [the] DEA." *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 542 (D.C. Cir. 2007); *see also* 21 U.S.C. §§ 821, 822; 21 C.F.R. § 1301.11. Entities not properly registered with the DEA under the CSA may not manufacture, distribute, or dispense controlled substances. 21 U.S.C. §§ 822, 823. To carry out and enforce this regulatory regime, the DEA has authority to "promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances . . . " 21 U.S.C. § 821; *see also* 28 C.F.R. § 0.100(b) (delegating authority under the CSA from the Attorney General to the DEA Administrator).

The DEA "closely observes [registrants] to ensure that their operations are 'consistent with the public interest.'" *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212 (D.C. Cir. 2017) (quoting 21 U.S.C. § 824(a)(4)). In the case of registered distributors and manufacturers, for example, the DEA determines whether the registrant maintains "effective control[s] against diversion of particular controlled substances." 21 U.S.C. § 823(a)(1), (b)(1). The DEA also considers whether the registrant complies with state and local laws or has any prior criminal convictions related to the possession of controlled substances. *Id.* at § 823(a)(2)–(4), (b)(2)–(3). More generally, the CSA directs the DEA to take into account "such other factors as may be relevant to and consistent with the public health and safety." *Id.* § 823(a)(6), (b)(5). Relatedly, the CSA's implementing regulations also set forth compliance requirements for DEA registrants. For example, registrants must "design and operate a system to disclose . . . suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b), report instances of theft to the DEA, *id.* at § 1301.74(c), and maintain certain physical security conditions at their facilities, *see id.* at §§ 1301.72–73.

Where such safety and security conditions are not met, the CSA authorizes the DEA to suspend or revoke the registration of a non-compliant entity. *See* 21 U.S.C. § 824(a); 21 C.F.R. §

1301.36(a). For example, the DEA may revoke or suspend registration where a registrant has "committed such acts as would render [its] registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4). Before revoking or suspending an entity's registration, however, the DEA must serve the impacted registrant with "an order to show cause why [its] registration should not be denied, revoked, or suspended." *Id.* at § 824(c)(1). The impacted registrant is then entitled to an administrative hearing before the DEA, for the purpose of submitting evidence regarding the issues involved in the proposed revocation or suspension. *See id.* at § 824(c); 21 C.F.R. §§ 1301.36(d), 1301.42.

But where a registrant poses "an imminent danger to public health or safety," the CSA authorizes the immediate suspension of that entity's registration. 21 U.S.C. § 824(d)(1). Such an "imminent threat to public health and safety" exists where a registrant's conduct presents "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.* at § 824(d)(2). If the DEA effectuates an immediate suspension, it shall include with the show cause order served upon the registrant "an order of immediate suspension which . . . contain[s] a statement of [the DEA's] findings regarding the danger to public health or safety." 21 C.F.R. § 1301.36(e). The DEA possesses the authority to withdraw an immediate suspension order, 21 U.S.C. § 824(d)(1), and it also "may limit revocation or suspension of a registration to the particular controlled substance . . . with respect to which grounds for revocation or suspension exist," *id.* § 824(b).

Importantly, the CSA and its implementing regulations also govern how the DEA may treat the controlled substances affected by a registrant's suspension or revocation. In the event of a suspension or revocation, the DEA may either (1) direct the impacted registrant to "[d]eliver all

controlled substances in [the registrant's] possession to the nearest office of the Administration or to authorized agents of the Administration," or (2) "[p]lace all controlled substances in [the registrant's] possession under seal." 21 C.F.R. § 1301.36(f)(1)–(2); *see also* 21 U.S.C. § 824(f). But in such cases, "[n]o disposition may be made of any controlled substances . . . under seal until the time for taking an appeal [of the suspension or revocation] has elapsed or until all appeals have been concluded, except that a court . . . may at any time order the sale of perishable controlled substances." 21 U.S.C. § 824(f). Where an entity's "registration has expired," however, or where the entity "has ceased to practice or do business in the manner contemplated by [its] registration," the DEA may either place that entity's controlled substances under seal or, alternatively, "seize" the controlled substances. *Id.* at § 824(g).

B. Virtus Pharmaceuticals

As described in its complaint, Virtus Pharmaceuticals, LLC ("Virtus") is "a small, privately held . . . specialty pharmaceutical company that markets safe and effective products by specializing in underserved markets, offering its customers a niche product portfolio covering a range of therapeutic areas." Compl. ¶ 1. Of note, Virtus is the owner of the Abbreviated New Drug Application ("ANDA") for levorphanol tartrate 2 mg tablets ("levorphanol"). *Id.* ¶ 2. Levorphanol is a Schedule II opioid under the CSA, used primarily for patients who are in extreme pain and resistant to other opioid pain medications. Smith Decl., ECF No. 3-2, at ¶¶ 5, 12–14. [redacted]

Virtus is also the owner of the ANDA for "phendimetrazine 35 mg immediate release tablets," as well as a New Drug Application ("NDA") for phendimetrazine 105 mg extended release capsules (collectively, "phendimetrazine"). Compl. ¶ 2; *see also* Smith Decl., ECF No. 3-

2, at ¶ 4. Phendimetrazine is a Schedule III controlled substance "indicated for the management of exogenous obesity as a short term adjunct . . . in a regimen of weight reduction based on caloric restriction" in certain high-risk patients "who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone." Compl. ¶ 24; *see also* Smith Decl., ECF No. 3-2, at ¶ 24.

[redacted]

Virtus, however, does not possess its own DEA registration to manufacture or distribute controlled substances. Compl. ¶ 25; *see also* 21 U.S.C. § 822(a)(1). Accordingly, Virtus itself does not physically or directly handle its pharmaceutical products, including its levorphanol or phendimetrazine. Compl. ¶ 25. Instead, Virtus is a "virtual" drug manufacturer that contracts with third parties for the manufacture and distribution of its drugs. For manufacturing, Virtus currently contracts with Halo Pharmaceutical, Inc. in New Jersey for the production of its levorphanol, *see* Smith Decl., ECF No. 3-2, at ¶ 11, and Epic Pharma in New York for the production of its phendimetrazine, *id.* at ¶ 23. Beyond manufacturing, Virtus outsources all packaging, warehousing, and distribution activities to third-party vendors that are also DEA registrants. *Id.* at ¶ 3.

One such third-party contractor for Virtus is a logistics company called Woodfield Distribution, LLC ("Woodfield"). Woodfield is currently registered with the DEA as a distributor of Schedule II through Schedule V controlled substances under the CSA. *See* Besser Decl., ECF No. 10-2, at ¶ 4. Virtus contracts with Woodfield to provide inventory management and distribution services for Virtus's drugs, including its levorphanol and phendimetrazine, at facilities

in Sugar Land, Texas and Boca Raton, Florida. Smith Decl., ECF No. 3-2, at ¶¶ 7–8; *see also* 3PL Services Agreement, ECF No. 10-1 (Ex. A), at § 1.1 (describing services provided by Woodfield). Virtus allegedly retains title over all of its product while stored at Woodfield's facilities. Smith Decl., ECF No. 3-2, at ¶ 8. And while Woodfield stores Virtus's product, Woodfield is contractually obligated to "comply with all applicable federal and state laws, regulation, and rules," and maintain all "necessary permits, licenses, and other federal . . . authorizations" required to discharge its contractual services for Virtus. 3PL Services Agreement, ECF No. 10-1 (Ex. A), at § 1.3. The Virtus-Woodfield service agreement further requires Woodfield to "indemnify and hold [Virtus] harmless" for damages caused by Woodfield's "negligence" or shortcomings in Woodfield's "regulatory activities and compliance." *Id.* at § 6.1.

C. DEA Enforcement Action

Beginning in at least 2020, the DEA launched an administrative investigation into Woodfield. *See* DEA at 2–11. The DEA's investigation focused on Woodfield's controls against the illicit diversion of controlled substances, including the company's recordkeeping and theft reporting systems. *See id*. As part of this administrative investigation into Woodfield, the DEA became aware that Virtus was one of the customers for whom Woodfield acted as a third-party logistics provider. Mills Decl., ECF No. 10-1, at ¶ 3. Consequently, the DEA's Houston Field Division issued an administrative subpoena to Virtus on April 1, 2021, for the purpose of obtaining additional evidence from Virtus to support the administrative investigation into Woodfield. *Id.* at ¶ 4. Between March 29, 2021 and July 7, 2021, DEA personnel were also in contact with counsel for Virtus regarding the subpoena and the DEA's investigation into Woodfield. *Id.* at ¶ 5.

On August 4, 2021, the DEA issued an Order to Show Cause and an Immediate Suspension Order against Woodfield. *See id.* at ¶ 7; DEA at 1. Therein, the DEA set forth its preliminary

investigative findings, which concluded, among other things, that Woodfield (1) failed to maintain effective controls against the diversion of controlled substances, (2) maintained inadequate records of its inventory of controlled substances, (3) failed to report instances of theft and suspicious orders, and (4) maintained inadequate physical security, as evidenced by multiple observed security lapses. *See* DEA at 2–11. Additionally, the DEA's order concluded that one of Woodfield's commonly owned affiliates ("Woodfield Pharma") has alleged connections to a suspected drug trafficking organization and allegedly supplied that organization with illicit drugs in exchange for compensation. *Id.* at 12–13.

In light of these findings, the DEA initiated an administrative proceeding regarding the potential revocation of Woodfield's DEA registrations for its Sugar Land, Texas facility. *See id.* at 1. On September 10, 2021, Woodfield requested an administrative hearing regarding the grounds for revocation set forth in the DEA's Order to Show Cause. *See* Jt. Notice, ECF No. 14, at 1. This administrative action currently remains pending before the DEA, and, on September 13, 2021, an administrative law judge set an initial disclosure schedule for the hearing and a pre-hearing conference for October 14, 2021. *See* Order, ECF No. 14-2, at 1–4. But while Woodfield's revocation matter remains pending, the DEA has also immediately suspended Woodfield's registrations based on a determination that Woodfield's continued operation of its Sugar Land facility represents an "imminent danger to the public health and safety." DEA at 14 (quoting 21 U.S.C. § 824(d)). Specifically, the DEA suspended the distributor registration (Registration No. [redacted]) and the importer registration (Registration No. [redacted]) associated with Woodfield's Sugar Land facility. *See* DEA at 2, 14.

In conjunction with this these suspensions, the DEA placed all of the controlled substances in Woodfield's Sugar Land facility under seal "by directing Woodfield to deliver those controlled

substances to authorized agents of DEA." Mills Decl., ECF No. 10-1, at ¶ 8; *see also* Besser Decl., ECF No. 10-2, at ¶ 39 ("Upon serving the OTSC/ISO on Woodfield, DEA sealed all of the controlled substances in Woodfield's possession . . . by directing Woodfield to deliver those controlled substances to DEA and removing those controlled substances for safekeeping."). In the DEA's suspension order for Woodfield, the agency cited to § 824(f) of the CSA as authority for its decision to place the drugs stored by Woodfield under seal. *See* DEA at 14. The DEA is now storing these controlled substances—approximately 200 million dosage units in total—under seal in four undisclosed DEA facilities. *See* Mills Decl., ECF No. 10-1, at ¶¶ 9–10.

D. Impact on Virtus

Virtus estimates that approximately [redacted] bottles of the company's phendimetrazine and levorphanol were being stored at Woodfield's Sugar Land facility and are now being held under seal by the DEA. *See* Bass Decl., ECF No. 12-3, at ¶ 21. Virtus asserts that these drugs have a collective market value [redacted] Smith Decl., ECF No. 3-2, at ¶ 10. According to the DEA, Virtus's supply of levorphanol and phendimetrazine is now being stored across three different DEA facilities and is packaged in multiple pallets alongside other controlled substances not at issue in this case. Mills Decl., ECF No. 10-1, at ¶ 18.

On August 12, 2021, counsel for Virtus learned of the DEA's enforcement action against Woodfield and the DEA's decision to place Virtus's pharmaceutical products under seal. *See, e.g.*, Schumacher Decl., ECF No. 2-5, at ¶ 2. In response, counsel for Virtus initiated a dialogue with DEA personnel regarding the status of Virtus's levorphanol and phendimetrazine. *See id.* at ¶¶ 3–4. Counsel for Virtus specifically requested that the DEA limit the scope of the Woodfield suspension order to exclude Virtus's levorphanol and phendimetrazine and then release those drugs to a third-party DEA distributor. *See* LaMagna Decl., ECF No. 2-7, at ¶ 8. On August 26,

2021, however, the DEA refused Virtus's request, expressing its belief that "that the controlled substances possessed by Woodfield at the time of the suspension were properly placed under seal and that a release of these controlled substances by [the] DEA is not appropriate at this time." Email Chain (Ex. C), ECF No. 2-10, at 2; *see also* Schumacher Decl., ECF No. 2-5, at ¶ 7.

Virtus now contends that the DEA's decision to retain its levorphanol and phendimetrazine under seal will cause a serious supply shortage. With regards to levorphanol, Virtus allegedly [redacted] Smith Decl., ECF No. 3-2, at ¶ 15. Moreover, [redacted] Bass Decl., ECF No. 12-3, at ¶ 18. The DEA's enforcement action against Woodfield has also impacted Virtus's supply of phendimetrazine. Virtus allegedly suffered a two-week stock out of phendimetrazine in August, and is now able [redacted] Smith Decl., ECF No. 3-2, at ¶¶ 27–28. Virtus further asserts that it is likely to face a [redacted] *Id.* at ¶ 29.

According to Virtus, this supply shortage threatens the company's financial viability and [redacted] *See id.* at ¶¶ 32–42. Separately, Virtus asserts that its supply [redacted] In particular, Virtus anticipates that the [redacted]

[redacted] *See id.* at ¶ 18. Virtus contends that this shortfall will permanently damage the business of those local pharmacies, *see id.*, and cause serious harm to patients who rely on consistent levorphanol regimens to treat their pain, *see* Bass Decl., ECF No. 12-3, at ¶¶ 19–20.

On August 31, 2021, Virtus filed its present civil action against the DEA. Therein, Virtus asserted two claims against the DEA: (1) a claim under the Administrative Procedure Act ("APA") arguing that the DEA's decision to place and retain Virtus's levorphanol and phendimetrazine under seal was arbitrary and capricious, and (2) a claim that the DEA's seizure and retention of those drugs violated Virtus's procedural due process rights under the Fifth Amendment. Compl. ¶¶ 67–75. That same day, Virtus filed a motion for a temporary restraining order, requesting this Court to issue an order compelling the DEA to "immediately release Virtus's levorphanol and phendimetrazine to a DEA-registered distributor." Pl.'s Proposed Order, ECF No. 2-11, at 2.[2] The Court held an initial hearing on September 2, 2021 and set an expedited briefing schedule. By September 6, 2021, the parties completed briefing on Virtus's motion for a temporary restraining order. On September 7, 2021, the DEA filed the relevant administrative record on the docket. *See* Admin. Record, ECF No. 13-3, at DEA 1–266. Accordingly, Virtus's motion for a temporary restraining order is now ripe for this Court's review.

II. LEGAL STANDARD

A temporary restraining order "is an extraordinary remedy that should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion." *Postal Police Officers Ass'n v. United States Postal Serv.*, 502 F. Supp. 3d 411, 418 (D.D.C. 2020)

[2] Virtus requests functionally the same relief in its complaint. *See* Compl. at Request for Relief. Accordingly, during the September 2, 2021 hearing, the Court asked if the parties would prefer to proceed with briefing on the full merits, as opposed to Virtus's temporary restraining order alone. The parties, however, elected to proceed with briefing on only Virtus's temporary restraining order.

(quoting *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004)). An application for a TRO is analyzed using the same factors applicable to a request for preliminary injunctive relief. *See, e.g.*, *Gordon v. Holder*, 632 F.3d 722, 723–24 (D.C. Cir. 2011) (applying preliminary injunction standard to district court decision denying motion for TRO and preliminary injunction); *Sibley v. Obama*, 810 F. Supp. 2d 309, 310 (D.D.C. 2011) (articulating TRO elements based on preliminary injunction case law).

Preliminary injunctive relief is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)); *see also Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (per curiam) ("[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, by a clear showing, carries the burden of persuasion." (internal quotation marks omitted)). A plaintiff seeking preliminary injunctive relief "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Aamer v. Obama*, 742 F.3d 1023, 1038 (D.C. Cir. 2014) (quoting *Sherley*, 644 F.3d at 392 (internal quotation marks omitted)). When seeking such relief, "the movant has the burden to show that all four factors, taken together, weigh in favor of the injunction." *Abdullah v. Obama*, 753 F.3d 193, 197 (D.C. Cir. 2014) (quoting *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009)) (internal quotation marks omitted). "The four factors have typically been evaluated on a 'sliding scale.'" *Davis*, 571 F.3d at 1291. Under this sliding-scale framework, "[i]f the movant makes an unusually strong showing on one of the factors, then it does not necessarily have to make as strong a showing on another factor." *Id.* at 1291–92.

It is unclear whether the United States Court of Appeals for the District of Columbia Circuit's ("D.C. Circuit") sliding-scale approach to assessing the four preliminary injunction factors survives the Supreme Court's decision in *Winter*. *See Save Jobs USA v. U.S. Dep't of Homeland Sec.*, 105 F. Supp. 3d 108, 112 (D.D.C. 2015). Several judges on the D.C. Circuit have "read *Winter* at least to suggest if not to hold 'that a likelihood of success is an independent, free-standing requirement for a preliminary injunction.'" *Sherley*, 644 F.3d at 393 (quoting *Davis*, 571 F.3d at 1296 (Kavanaugh, J., concurring)). However, the D.C. Circuit has yet to hold definitively that *Winter* has displaced the sliding-scale analysis. *See id.*; *see also Save Jobs USA*, 105 F. Supp. 3d at 112. In light of this ambiguity, the Court shall consider each of the preliminary injunction factors and shall only evaluate the proper weight to accord the likelihood of success if the Court finds that its relative weight would affect the outcome.

III. DISCUSSION

For the reasons set forth below, the Court concludes that Virtus has not carried its burden of demonstrating a likelihood of success on the merits, a certainty of irreparable harm, or that the balance of the equities and the public interest tilt in its favor. Accordingly, the Court will **DENY** Virtus's motion for a temporary restraining order.

A. Likelihood of Success on the Merits

First, in order to receive a TRO, the moving "party must show, among other things, 'a substantial likelihood of success on the merits.'" *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015) (quoting *Mills v. District of Columbia*, 571 F.3d 1304, 1308 (D.C. Cir. 2009)). The D.C. Circuit has identified a "likelihood of success on the merits" as the "most important factor" for courts to consider when contemplating a motion for preliminary injunctive relief. *Aamer v. Obama*, 742 F.3d 1023, 1038 (D.C. Cir. 2014).

In its motion for a TRO, Virtus advances three substantive claims. *First*, Virtus argues that the DEA violated the APA by arbitrarily declining to exclude Virtus's levorphanol and phendimetrazine from the suspension order issued to Woodfield. *Second*, Virtus claims that the DEA impermissibly "seized" Virtus's levorphanol and phendimetrazine from Woodfield's Sugar Land facility. And *third*, Virtus contends that the DEA's alleged seizure and refusal to release Virtus's drugs violates the company's procedural due process rights. *See* Pl.'s Mot. at 17–22. At this early stage of the litigation, the Court finds that Virtus has not shown a likelihood that any of these three claims will succeed on the merits.

1. The Scope of the DEA's Administrative Order Against Woodfield

Virtus's first substantive claim against the DEA falls under the APA. Virtus, however, *does not* directly challenge the DEA's immediate suspension order against Woodfield or the DEA's proposed revocation of Woodfield's registrations. *See* Pl.'s Mot. at Pl.'s Mot. at 5–6; DEA at 1–14. Instead, Virtus argues that the DEA's decision to place and retain Virtus's levorphanol and phendimetrazine under seal, as a result of the DEA's administrative action against Woodfield, was arbitrary and capricious.[3] *See* Pl.'s Mot. at 17–18. To support this argument, Virtus asserts that the "DEA indicated that Woodfield's [immediate suspension order] did not involve Virtus's . . . actions," nor did it reflect any "concern [regarding Virtus's] levorphanol or phendimetrazine product at Woodfield's [Sugar Land] facility." Pl.'s Mot. at 15. Accordingly, because Woodfield's suspension order from the DEA apparently does "not concern Virtus['s] conduct or

[3] In its opposition brief, the DEA contends that its decision not to exclude Virtus's drugs from the Woodfield suspension order, and its corresponding decision to retain those drugs under seal, is not a "final" agency action subject to APA review. *See* Def.'s Opp'n at 10 (citing 5 U.S.C. § 704 & *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). This Court too has reservations about the "finality" of the agency action challenged by Virtus in this case. Nonetheless, to address Virtus's pending motion for a temporary restraining order, the Court need not resolve this question of APA finality. Instead, the Court finds below that the agency action at issue is committed to the DEA's discretion and, in any event, does not appear to be arbitrary and capricious on the present record. For these independent reasons, Virtus is not "likely" to succeed on the merits of its APA claim.

the sale of [its] products to its customers," Virtus claims that the DEA should have limited the scope of the Woodfield suspension order to exclude Virtus's drugs. *Id.* at 18.

This claim does not support Virtus's request for a TRO. At this early stage of the proceedings, Virtus has not established that its challenge to the scope of the DEA's suspension order is subject to judicial review. Under the APA, "matters committed to agency discretion are not subject to judicial review." *CREW v. FEC*, 993 F.3d 880, 888 (D.C. Cir. 2021) (citing 5 U.S.C. § 701(a)(2)). This exclusion applies "where statutes are drawn in such broad terms that in a given case there is no law to apply" and "when the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Sierra Club v. Jackson*, 648 F.3d 848, 855 (D.C. Cir. 2011) (internal citations and quotations omitted). "Agency actions in these circumstances are unreviewable because the courts have no legal norms pursuant to which to evaluate the challenged action, and thus no concrete limitations to impose on the agency's exercise of discretion." *Id.* "To determine whether a matter has been committed to agency discretion, [courts] consider both the nature of the administrative action at issue and the language and structure of the statute that supplies the applicable legal standards for reviewing that action." *Id.*

As noted above, Virtus is *not* challenging the DEA's decision to suspend Woodfield's registration. *See, e.g.*, Pl.'s Mot. at 5–6; *cf. Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 213, 220–28 (D.D.C. 2012) (addressing direct challenge by a DEA registrant to an immediate suspension order). Rather, Virtus is challenging the DEA's decision not to *limit the scope* Woodfield's suspension order, by excluding Virtus's levorphanol and phendimetrazine from the drugs placed under seal as a result of that order. *See* Pl.'s Mot. at 17–18. To support this argument, Virtus points to § 824(b) of the CSA, which states that the DEA "*may limit* revocation or

suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist." (Emphasis added). But this statutory language is precatory on its face. Indeed, Congress provided no statutory conditions or factors in § 824(b) governing when or how the DEA should limit suspension orders thereunder. Moreover, Congress could have easily *mandated* that the DEA limit suspension orders "to the particular controlled substance" at issue by simply substituting the word "shall" for "may" in § 824(b). Congress, however, included permissive language in § 824(b). This statutory language strongly suggests that the decision to *limit* a suspension order is committed to the DEA's discretion and is not susceptible to a meaningful standard of judicial review. *See* 5 U.S.C. § 701(a)(2); *Sierra Club*, 648 F.3d at 855.

In its reply brief, Virtus argues that the decision to limit a suspension order is not committed purely to agency discretion because clear judicial standards *do apply* to the DEA's authority under § 824(b) of the CSA. *See* Pl.'s Reply at 6–12. Here, Virtus contends that the standards in § 824(a) and § 824(d) of the CSA should be read into § 824(b). The Court is not persuaded by this reading of § 824. Section 824(a) provides the DEA with five factors to consider when making the *foundational decision* of whether to suspend or revoke a registration in the first place. *See, e.g.*, 21 U.S.C. § 824(a)(4) (a registration may be suspended where the registrant "committed such acts as would render his registration . . . inconsistent with the public interest"). Similarly, § 824(d) sets forth the standard governing the DEA's decision to issue an immediate suspension order. Yet, there is no indication in § 824(b) that the standards from § 824(a) or § 824(d) apply to the DEA's secondary decision of whether to limit a suspension order to a particular controlled substance. As noted above, Congress could have provided such constraining factors under § 824(b) or, instead, included mandatory language therein. To the contrary, § 824(b) simply states that: "The Attorney

General *may limit* revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist." (Emphasis added). This language is discretionary and constraining this discretion through an application of the factors in § 824(a) or § 824(d) appears to stretch § 824(b) beyond its plain meaning.

For the reasons set forth above, Virtus has not established a likelihood of success on its APA claim because it has challenged a DEA action committed to agency discretion. But even if the DEA's discretionary decision not to limit Woodfield's suspension order *was reviewable* under the APA, Virtus has not shown that this action was arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A); Pl.'s Mot. at 18. "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Under arbitrary and capricious review, courts will "uphold an agency's action where [the agency] has considered the relevant factors and articulated a rational connection between the facts found and the choice made." *Nat'l Ass'n of Clean Air Agencies v. EPA*, 489 F.3d 1221, 1228 (D.C. Cir. 2007) (citations omitted).

In this case, the DEA issued a thorough administrative order on August 4, 2021, setting forth its findings that Woodfield's Sugar Land facility had failed to maintain effective controls to prevent the diversion of controlled substances. *See* DEA at 2–11. In particular, the DEA's order explains that Woodfield's recordkeeping and inventory system was unable to account for "tens of millions of dosage units." *Id.* at 4. The DEA's order further states that Woodfield failed to report at least 32 missing shipments of controlled substances, comprising "tens of thousands of dosage units," *id.* at 5, and also failed to maintain an adequate system to report suspicious orders, *id.* at 6–8. Finally, the DEA's order indicates that one of Woodfield's commonly owned affiliates ("Woodfield Pharma") has potential connections to a suspected drug trafficking organization and

allegedly supplied that organization with illicit drugs in exchange for compensation. *Id.* at 12–13. Based on these findings, the DEA immediately suspended Woodfield's registrations at its Sugar Land facility because the company's compliance failings posed an imminent danger to public health and safety. *Id.* at 14 (citing 21 U.S.C. § 824(d)). The DEA then ordered its agents to place under seal and remove for safekeeping "all controlled substances" that Woodfield possessed at its Sugar Land facility under the suspended registrations. *Id.*

The Court cannot find, at this early stage of the proceedings, that the DEA's decision to place all of Woodfield's controlled substances under seal (including Virtus's) was arbitrary and capricious. To begin, the CSA expressly authorizes the DEA to place "all" controlled substances "possessed by [a] registrant pursuant to [a suspended] registration" under seal. 21 U.S.C. § 824(f) (stating that where the DEA suspends a registration "all controlled substances . . . owned or possessed by the [suspended] registrant pursuant to such registration at the time of suspension . . . , as the case may be, may, in the discretion of the [DEA], be placed under seal."). Moreover, the DEA's order clearly articulates public safety concerns associated with Woodfield's failure to effectively prevent the diversion of controlled substances, including alleged connections to a drug trafficking organization. *See* DEA at 2–13. Such systemic concerns are reasonably related to Woodfield's possession of *any* controlled substance, rather than a defect in one particular drug. Therefore, the Court cannot find that it was irrational for the DEA to place *all* of the controlled substances possessed by Woodfield (including Virtus's levorphanol and phendimetrazine) under seal for safekeeping. The reasonableness of this agency action is further augmented by the discretionary authority that Congress conferred upon the DEA to prevent imminent danger to public health and safety. *See Cardinal Health*, 846 F. Supp. 2d at 225 ("[G]iven the degree of discretion vested with the Administrator as well as the summary and urgent nature of an ISO, the

Court's review 'must be correspondingly relaxed.'") (quoting *Nat'l Cable Tele. Ass'n v. Copyright Royalty Tribunal*, 724 F.2d 176, 181 (D.C. Cir. 1983)). Accordingly, the Court cannot find that the DEA's decision to include Virtus's drugs within the scope of the Woodfield suspension order was arbitrary and capricious.

As a final matter, Virtus also argues that the DEA's *continued retention* of its levorphanol and phendimetrazine is arbitrary and capricious. *See* Pl.'s Mot. at 18. But this argument is similarly unpersuasive. To start, § 824(f) of the CSA expressly states that "*[n]o disposition may be made of any controlled substances* . . . under seal until the time for taking an appeal has elapsed or until all appeals have been concluded." (Emphasis added). Put otherwise, the CSA affirmatively deprives the DEA of its ability to dispose of any controlled substance placed under seal subject to the suspension of Woodfield's registration, until after Woodfield has concluded its administrative appeals. *See also* 21 U.S.C. § 842(a)(7). Virtus does not argue in its TRO briefing that Woodfield's administrative appeals in this matter have concluded, such that the DEA may now "dispose" of the controlled substances from Woodfield's facility currently held under seal. In fact, the parties jointly notified the Court on September 13, 2021, that Woodfield's administrative appeal of the DEA's proposed registration revocations *remains pending* through at least October 2021. *See* Jt. Notice, ECF No. 14, at 1–2. Accordingly, it appears on the present record that the DEA does not even have the statutory authority to release Virtus's levorphanol and phendimetrazine, as Virtus now requests.

Moreover, the decision to place drugs under seal after the suspension of a registrant's CSA registration is expressly committed to the DEA's discretion. 21 U.S.C. § 824(f) (stating that where the DEA suspends a registration "all controlled substances . . . owned or possessed by the [suspended] registrant pursuant to such registration at the time of suspension . . . , as the case may

be, may, in the discretion of the [DEA], be placed under seal."). Consequently, the attendant decision to retain such drugs under seal during the pendency of an administrative proceeding would also appear to fall within the ambit of the DEA's express discretion—an action, therefore, excluded from judicial review under the APA. *See Sierra Club v. Jackson*, 648 F.3d 848, 855 (D.C. Cir. 2011). Virtus has not adequately addressed these issues at the TRO stage of this proceeding. Consequently, the Court cannot find that Virtus is likely to succeed on a claim that the DEA's continued retention of its levorphanol and phendimetrazine is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

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For the reason set forth above, Virtus has not demonstrated that it is likely to succeed on the merits of its APA claim challenging the DEA's decision to place and retain its levorphanol and phendimetrazine under seal, as a result of the Woodfield suspension order.

2. The DEA's Alleged "Seizure" of Virtus's Drugs

Virtus's second substantive claim is that the DEA impermissibly "seized" the controlled substances taken from Woodfield's facilities, including Virtus's levorphanol and phendimetrazine. Pl.'s Mot. at 19–20. Here, Virtus argues that the CSA allows the DEA to "seal" controlled substances, but not to "seize" them, where a distributor or manufacturer's registration has been suspended under § 824. *Id.* Accordingly, Virtus contends that the DEA's "seizure" of drugs from Woodfield's Sugar Land facility was unlawful and in excess of the agency's statutory authority, *i.e.,* ultra vires. *Id.*

The Court agrees with Virtus's general interpretation of the DEA's "seizure" authority under the CSA. Section 824 of the CSA only authorizes the "seizure" of controlled substances "owned or possessed by a registrant whose registration has expired or who has ceased to practice

or do business in the manner contemplated by his registration." 21 U.S.C. § 824(g). But where the DEA is enforcing a suspension or revocation order under § 824, the CSA only authorizes the agency to place the impacted controlled substances "under seal," pursuant to § 824(f). In turn, the plain language of § 824(f) does not authorize the DEA to "seize" controlled substances where a distributor or manufacturer's registration has been suspended or revoked.[4] And in this case, the DEA's suspension order against Woodfield explicitly relied on § 824(f) when it authorized its agents to "place under seal and remove for safekeeping all controlled substances that Woodfield possesse[d] pursuant to the [suspended] registrations." DEA at 14.

The problem for Virtus, however, is that the present record indicates that the DEA complied with § 824(f) and properly placed the controlled substances at Woodfield's Sugar Land facility "under seal." In particular, the DEA appears to have directly followed its implementing regulations setting forth *how* it may place controlled substances under seal. Those regulations state that upon the service of a suspension or revocation order, the DEA may instruct the affected registrant: (1) to deliver all controlled substances in its possession to the nearest DEA office or to authorized DEA agents, or (2) to place all controlled substances in its possession under seal. 21 C.F.R. § 1301.36(f). In executing the enforcement action against Woodfield, the DEA "direct[ed] Woodfield to deliver [the impacted] controlled substances to authorized agents of the DEA." Mills Decl., ECF No. 10-1, at ¶ 8. The DEA then sealed the controlled substances at undisclosed DEA facilities for safekeeping. *See id.* at ¶ 9; Besser Decl., ECF No. 10-2, at ¶ 39. These actions

[4] Where the DEA "suspends or revokes a registration" *to import or export controlled substances*, "all controlled substances . . . owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the [DEA], be *seized* or placed under seal." 21 U.S.C. § 958(d)(6) (emphasis added). It is notable, that Congress included seizure authority for the suspension of an importer/exporter registration under § 958(d)(6), but omitted such authority for the suspension of a manufacturer/distributor registration under § 824(f). This distinction reinforces the conclusion that the DEA *does not* have seizure authority under § 824(f).

comport with the process set forth in § 1301.36(f), and Virtus does not bring any challenge to the validity of this regulation itself. For these reasons, Virtus has not established that it is likely to succeed on its claim that the DEA unlawfully "seized" controlled substances from Woodfield's storage and distribution facility.[5]

3. Procedural Due Process

Virtus's final substantive claim is one of procedural due process. Here, Virtus asserts that the DEA's decision to place and retain Virtus's levorphanol and phendimetrazine under seal deprived the company of a clear property interest. *See* Pl.'s Mot. at 20–22. Furthermore, Virtus contends that the DEA afforded the company inadequate process, attendant to this alleged property deprivation. *Id.* In this way, Virtus claims that the DEA's actions violated the company's constitutional right to procedural due process. *Id.*; *see also* Pl.'s Reply at 14–18.

"A procedural due process violation under the Fifth Amendment occurs when a government official deprives a person of property without appropriate procedural protections." *N. Am. Butterfly Ass'n v. Wolf*, 977 F.3d 1244, 1265 (D.C. Cir. 2020). When evaluating a procedural due process claim, courts first consider "whether the plaintiff has been deprived of a protected interest in 'liberty' or 'property.'" *Gen. Elec. Co. v. Jackson*, 610 F.3d 110, 117 (D.C. Cir. 2010). If so, courts then determine whether the government's attendant procedures comport with principles of due process. *Id.* This latter inquiry turns on the familiar three-factor balancing test set forth in *Mathews v. Eldridge*, 424 U.S. 319 (1976), which considers: (1) "the private interest that will be affected by the official action," (2) "the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards," and (3) "the Government's interest, including the function involved and the fiscal and

[5] Virtus appears to concede this point by omitting any discussion of this claim from its reply brief.

administrative burdens that the additional or substitute procedural requirement would entail." *Id.* at 335. "There is no one-size-fits-all procedure to protect against the unconstitutional deprivation of property." *Statewide Bonding, Inc. v. DHS*, 980 F.3d 109, 118 (D.C. Cir. 2020). Instead, the concept of due process is ultimately "'flexible and calls for such procedural protections as the particular situation demands.'" *Id.* (quoting *Mathews*, 424 U.S. at 334).

At this early stage of the proceedings, Virtus has not shown that it is likely to succeed on the merits of its procedural process claim. To begin, Virtus has not demonstrated that its private property interest outweighs the strong governmental interest at play in this case. Virtus certainly appears to maintain a property interest in its levorphanol and phendimetrazine. *See* Smith Decl., ECF No. 3-2, at ¶ 8; Waiver of Rights and Interests (Ex. A), ECF No. 2-3. But the contours of this particular property interest are somewhat unclear. Unlike traditional real or personal property, Virtus is prohibited by law from exercising direct possession over its levorphanol or phendimetrazine because it is not registered with the DEA to handle these controlled substances. *See* 21 U.S.C. § 822. Instead, Virtus relies on third-party DEA registrants, like Woodfield, to store its levorphanol and phendimetrazine until the point of sale. *See* Smith Decl., ECF No. 3-2, at ¶ 7. As such, the scope of Virtus's private interest in its levorphanol and phendimetrazine is not connected to the possession of those drugs, but rather to its ability to sell the drugs through third-party intermediaries.

Conversely, the government (here, the DEA) has a substantial interest in regulating the flow of controlled substances and preventing the illicit diversion of those drugs in a timely manner. *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 230 (D.D.C. 2012) ("The government has a strong interest in enforcing the CSA and ensuring that pharmaceutical drugs are not improperly diverted . . . "); Besser Decl., ECF No. 10-2, at ¶¶ 10–15. Indeed, Congress codified

this governmental interest through the CSA and conferred the DEA with authority to place controlled substances under seal in furtherance of public health and safety. *See, e.g.*, 21 U.S.C. § 824(d), (f). And in this case, the DEA placed Virtus's levorphanol and phendimetrazine under seal specifically in furtherance of this public health and safety concern. *See* DEA at 14. Given the DEA's important governmental interest, it is not clear that Virtus's uniquely circumscribed property interest merits additional process in this particular case.

Furthermore, Virtus has not demonstrated how additional process would protect its purported property interest. *Mathews*, 424 U.S. at 335. In fact, Virtus does not specify in its TRO papers what additional procedures should be required to ensure that it receives adequate process before the DEA. *See* Pl.'s Mot. at 21–22; Pl.'s Reply at 14–18. In any event, it is not clear that granting Virtus additional process would reduce the risk of erroneous deprivation. As described above, Virtus's potential "deprivation" is tied to the company's inability to sell its drugs through a third-party registrant (*i.e.*, Woodfield), while the DEA holds those drugs under seal pending that registrant's administrative appeal. *See* DEA at 14; 21 U.S.C. § 824(d), (f). Thus, the risk of an erroneous deprivation that Virtus faces derives directly from the DEA's predicate decision to initiate suspension or revocation proceedings against the DEA registrant holding its drugs. *See id.*

The CSA and its implementing regulations, however, already require that the DEA provide these registrants, like Woodfield, with notice of a suspension or revocation proceeding and a subsequent opportunity to challenge the suspension or revocation at an administrative hearing. *See* 21 U.S.C. § 824(c); 21 C.F.R. § 1301.36(d), (h). And as the target of the suspension or revocation order in question, the impacted registrant is best situated to challenge the suspension or revocation order issued by the DEA. It is unclear, therefore, how providing additional process to interested parties like Virtus would facilitate a more accurate hearing process that reduces the risk of an

erroneous suspension or revocation and, by extension, an erroneous sealing of the impacted registrant's drugs. *See* 21 U.S.C. § 824(f). Conversely, opening a registrant's suspension hearing to third parties that are not themselves the target of the DEA's enforcement action would impose a significant administrative burden on the agency and its attempt to efficiently regulate the flow of controlled substances. *See Mathews*, 424 U.S. at 335. On balance, therefore, the Court is not persuaded that the *Mathews* factor weigh in favor of Virtus's somewhat ambiguous request for additional process in this case.

For the reasons set forth above, the Court cannot find that Virtus has met its burden of demonstrating a likelihood of success on the merits of its procedural due process claim.[6]

4. Redressability

As explained in the foregoing pages, Virtus has not established that either its procedural due process or its APA claims are likely to succeed on the merits. It bears mention, however, that Virtus's substantive claims also encounter a more structural impediment, given the specific relief Virtus requests in this case. In both its complaint and its motion for a TRO, Virtus asks the Court to order the DEA to immediately release its levorphanol and phendimetrazine to another DEA-registered distributor. *See* Pl.'s Proposed Order, ECF No. 2-11, at 2; Compl., at Request for Relief. It is not clear that this requested relief is, in fact, appropriately subject to judicial redress.

First, Virtus's requested relief would place the Court in conflict with the legislative scheme Congress enacted through the Controlled Substances Act. The DEA is holding Virtus's

[6] In its reply brief, Virtus raises for the first time a passing argument about the "vagueness" of the DEA's regulations. *See* Pl.'s Reply at 18. Virtus raises this point within the context of its procedural due process claim and, accordingly, the Court reads Virtus's vagueness argument in support thereof. But to the extent Virtus now attempts to raise a distinct "void for vagueness" challenge, the Court will not consider such a claim raised in a single paragraph, for the first time in Virtus's reply brief. *See, e.g.*, *Lucas v. District of Columbia*, 214 F. Supp. 3d 7, 10 (D.D.C. 2016) (refusing to consider new legal arguments raised in a reply brief) (collecting cases).

levorphanol and phendimetrazine under seal pursuant to § 824(f) of the CSA, and in conjunction with the proposed revocation of Woodfield's DEA registrations. *See* Mills Decl., ECF No. 10-1, at ¶ 18; DEA at 14. Woodfield's administrative appeal of the DEA's proposed revocation currently remains pending through at least October 2021. *See* Jt. Notice, ECF No. 14, at 1–2. But to satisfy Virtus's request for relief, the Court would need to issue an order immediately compelling the DEA to transfer Virtus's drugs to another third-party registrant, while Woodfield's administrative proceeding remained pending. *See* Pl.'s Proposed Order, ECF No. 2-11, at 2. Such an order would contradict the language of § 824(f), which *prohibits* the DEA from disposing of controlled substances under seal until all administrative appeals have concluded. 21 U.S.C. § 824(f); *see also id.* at § 842(a)(7) (making it unlawful for any person "to remove . . . a seal placed upon controlled substances pursuant to section 824(f)"). As the DEA notes in its opposition brief, this Court cannot simply "ignore the judgment of Congress, deliberately expressed in legislation." *United States v. Oakland Cannabis Buyers' Co-op.*, 532 U.S. 483, 497 (2001) (quoting *Virginian R. Co. v. Railway Employees*, 300 U.S. 515, 551 (1937)). Put otherwise, the relief Virtus now requests would place this Court in conflict with the very statute governing this case.

The relief requested by Virtus also raises separation of powers concerns. Virtus is not asking the Court to simply review the DEA's suspension order against Woodfield. Instead, Virtus essentially asks the Court to intervene in the DEA's pending enforcement action against Woodfield, by instructing the agency on how to dispose of certain controlled substances the agency is currently holding under seal for safekeeping. Such an insertion into the *execution* of an agency enforcement action conflicts with this Court's obligation to "keep[] the Judiciary's power within its proper constitutional sphere." *Raines v. Byrd*, 521 U.S. 811, 820 (1997). At bottom, it is the constitutional prerogative of the Executive Branch, here, acting through the DEA, to make

administrative decisions regarding the enforcement of the Controlled Substances Act. *See* Const., Art. II, § 3; *Colonial BancGroup, Inc. v. PricewaterhouseCoopers LLP*, 110 F. Supp. 3d 37, 44 (D.D.C. 2015) (explaining that in furtherance of the "separation of powers" courts should "not unduly intrude into the operations of executive branch administrative agencies"). In turn, Article III courts, like this one, are traditionally limited by "the equitable principles governing judicial action," *Ford Motor Co. v. NLRB*, 305 U.S. 364, 373 (1939), including the precept that courts should not substitute their own judgment in "essentially administrative functions" subject to an agency's technical expertise, *Federal Power Commission v. Idaho Power Co.*, 344 U.S. 17, 21 (1952). Granting Virtus the injunctive relief it now seeks would be in tension with these prudential considerations surrounding this Court's constitutionally circumscribed role.

Altogether, these structural concerns further impede Virtus's attempt to show a likelihood of success on the merits and weigh against this Court granting Virtus the immediate injunctive relief it now seeks.

B. Irreparable Harm

The Court next considers whether Virtus has demonstrated "irreparable harm." *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995). To constitute "irreparable harm," the injury alleged must be "both certain and great, actual and not theoretical, beyond remediation, and of such imminence that there is a clear and present need for equitable relief." *Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 555 (D.C. Cir. 2015) (quotation omitted). And "[p]laintiffs seeking preliminary relief [must] demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis in original) (internal citations omitted). "[P]ossibility of irreparable harm" is not enough. *Id.* "[P]roving 'irreparable' injury is a considerable burden, requiring proof that the

movant's injury is 'certain, great and actual—not theoretical—and imminent, creating a clear and present need for extraordinary equitable relief to prevent harm.'" *Power Mobility Coal. v. Leavitt,* 404 F. Supp. 2d 190, 204 (D.D.C. 2005) (quoting *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)).

Virtus's case for irreparable harm is primarily financial. According to Virtus, the levorphanol and phendimetrazine products taken from Woodfield's Sugar Land facility by the DEA account for approximately [redacted] Smith Decl., ECF No. 3-2, at ¶ 33. And while the DEA retains these drugs under seal, Virtus claims that it is unable to meet its service level commitments on active supply contracts with its customers. *Id.* at ¶ 34. Virtus estimates that these [redacted] *Id.* Virtus separately estimates that its [redacted] *Id.* at ¶ 38. Relatedly, Virtus's Director explains that "[i]f the levorphanol stock out situation is not imminently resolved, [redacted] *Id.* at ¶ 39. Altogether, Virtus contends that its present supply shortage places the company in [redacted] and threatens to permanently damage the company's reputation with customers. *See id.* at ¶¶ 37–42. Virtus [redacted] *Id.* at ¶ 42.

In the normal course, such a claim of "economic loss does not, in and of itself, constitute irreparable harm." *Wis. Gas Co.*, 758 F.2d at 674. Instead, to establish irreparable harm, a

company like Virtus must make "a strong showing that the economic loss would significantly damage its business above and beyond a simple diminution in profits, or demonstrate[] that the loss would cause extreme hardship to the business, or even threaten destruction of the business." *Air Transp. Ass'n of Am., Inc. v. Exp.-Imp. Bank of the U.S.*, 840 F. Supp. 2d 327, 336 (D.D.C. 2012) (internal citations and quotations omitted). "For economic harm to constitute irreparable injury" under this framework, the moving party "must 'adequately describe and quantify the level of harm it . . . face[s]." *Id.* (quoting *Nat'l Ass'n of Mortgage Brokers v. Bd. of Governors of the Federal Reserve System*, 773 F. Supp. 2d 151, 181 (D.D.C. 2011)). On the present record, Virtus's attempt to show such financial harm, while colorable, does not rise to the level of "irreparability" necessary to secure a TRO. *Mexichem*, 787 F.3d at 555.

Despite Virtus's claims of financial hardship, *see* disc. *supra* at 28, the record also reflects countervailing factors which make it less certain whether Virtus's current supply shortage will cause irreversible damage to the company. First, the full scope of Virtus's supply shortage is not clear. For example, Virtus's Director notes that the company has continued at least partial sales of its phendimetrazine product. Smith Decl., ECF No. 3-2, at ¶ 28. And while Virtus claims a complete [redacted], *id.* at ¶ 38, it also asserts that its levorphanol manufacturer requested additional API on August 5, 2021, so that it can resume levorphanol production, *id.* at ¶ 21. Furthermore, the DEA has submitted contradictory record evidence indicating [redacted] *See* Harper-Avilla Decl., ECF No. 9-2, at ¶ 24. This conflicting record evidence calls into question the full scope and duration of Virtus's supply shortage. Consequently, absent more comprehensive financial data from Virtus—such as Virtus's quarterly or annual financial projections—it is difficult for the Court

to find with "certainty" that Virtus's interim losses will severely damage its business, to the point of collapse. *See, e.g.*, *ConverDyn v. Moniz*, 68 F. Supp. 3d 34, 47 (D.D.C. 2014); *Mott Thoroughbred Stables, Inc. v. Rodriguez*, 87 F. Supp. 3d 237, 246 (D.D.C. 2015) (explaining that the absence of "additional financial information, such as operating costs" impeded a finding of irreparable business harm). Even Virtus's Director couches his financial predictions in qualifying language, noting that Virtus [redacted] Smith Decl., ECF No. 3-2, at ¶ 42 (emphasis added).

Beyond this fiscal ambiguity, Virtus's case for irreparable harm is further weakened by its ability to seek compensatory damages directly from Woodfield. In this Circuit, "[t]he possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation weighs heavily against a claim of irreparable harm." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297–98 (D.C. Cir. 2006) (citation omitted). Here, Virtus contracted with Woodfield for the handling and distribution of its levorphanol and phendimetrazine at Woodfield's facilities. *See* 3PL Services Agreement, ECF No. 10-1 (Ex. A), at § 1.1. An express term of the Virtus-Woodfield service agreement requires Woodfield to "maintain all licenses and otherwise comply with all applicable federal . . . laws, regulations, and rules necessary to perform [its] services." *Id.* at § 1.3. Woodfield further represented to Virtus that it would comply with applicable regulations, so as not to interfere with Virtus's ability to "pursue . . . its commercial and business purposes." *Id.* at § 5.1. And crucially, the Virtus-Woodfield service agreement requires Woodfield to "indemnify and hold [Virtus] harmless" for damages caused by Woodfield's "negligence," breach of a representation or warranty, or Woodfield's "*regulatory activities and compliance*." *Id.* at § 6.1 (emphasis added). In this way, Virtus anticipated the potential for Woodfield to cause it damage through regulatory failings and

included a specific contractual remedy to guard against exactly such harm. As such, Virtus's ability to recover its financial losses through a breach of contract action against Woodfield weighs directly against its claim of irreparable harm. *See Taylor v. Resolution Trust Corp.*, 56 F.3d 1497, 1507 (D.C. Cir. 1995) ("[R]ecoverable economic losses are not considered irreparable.")

As a final matter, Virtus also attempts to show irreparable harm through the hardship suffered by downstream pharmacies and their prescription-holders. For example, Virtus contends that its inability to supply local pharmacies could cause those pharmacies to lose patients. *See* Pl.'s Mot. at 24; Smith Decl., ECF No. 3-2, at ¶ 18. Virtus also emphasizes that levorphanol is a unique pain relief medication that should be taken consistently by patients. *See* Pl.'s Reply at 19; Bass Decl., ECF No. 12-3, at ¶ 19. Accordingly, Virtus argues that many prescription-holders will face medical hardship due to the current market shortage of Virtus's levorphanol. *See* Pl.'s Reply at 19; Bass Decl., ECF No. 12-3, at ¶ 10. But these arguments ultimately fall short. While the impact of the DEA's action on third parties like local pharmacies and prescription-holders is not irrelevant, it does not establish that *Virtus* (the sole plaintiff and movant in this case) suffered irreparable harm. *See Alcresta Therapeutics, Inc. v. Azar*, 318 F. Supp. 3d 321, 326 (D.D.C. 2018) ("In addition, to the extent Plaintiffs now invoke this theory as to 'patients' other than Flath, injuries to third parties are not a basis to find irreparable harm."); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 213 (D.D.C. 2012) (holding argument about irreparable harm to consumers "fails because it shows irreparable harm not to [plaintiff], but to third parties"). The third-party considerations presented by Virtus are best considered under the ambit of the "public interest," which the Court does below.

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For the reasons set forth above, the Court finds that Virtus has not carried its burden of establishing certain irreparable harm, absent injunctive relief from this Court.

C. Balance of Harms and Public Interest

"The final two factors the Court must consider when deciding whether to grant a [temporary restraining order] are the balance of harms and the public interest." *Sierra Club v. United States Army Corps of Engineers*, 990 F. Supp. 2d 9, 41 (D.D.C. 2013). Where, as here, the government is a party to the litigation, these two factors merge and are "one and the same, because the government's interest is the public interest." *Pursuing Am.'s Greatness v. Fed. Election Comm'n*, 831 F.3d 500, 511 (D.C. Cir. 2016). "Although allowing challenged conduct to persist certainly may be harmful to a plaintiff and the public, harm can also flow from enjoining an activity, and the public may benefit most from permitting it to continue." *Sierra Club*, 990 F. Supp. 2d at 41. Therefore, when "balanc[ing] the competing claims of injury," the Court must "consider the effect on each party of the granting or withholding of the requested relief." *Winter*, 555 U.S. at 24.

To begin, both parties face plausible sources of hardship. Virtus, as explained above, has a direct financial interest in the levorphanol and phendimetrazine currently held under seal by the DEA. *See* disc. *supra* at 28. These drugs account for a sizeable portion of the company's revenue and, so long as they remain under seal, Virtus will be unable to send them to market. This constitutes a tangible financial hardship for the company. But ordering the release of Virtus's levorphanol and phendimetrazine would also impose a countervailing hardship on the DEA. The DEA is presently storing Virtus's levorphanol and phendimetrazine at three undisclosed facilities. *See* Mills Decl., ECF No. 10-1, at ¶ 18. Transporting Virtus's drugs from these DEA facilities to a third-party registrant would impose a substantial operational and pecuniary burden on the DEA,

as the agency would be required to ensure the security of the drugs while also complying with all attendant regulations. *See id.* at ¶¶ 12–20. Moreover, such a transfer would threaten to disclose the location of the DEA's storage facilities, which is "sensitive law enforcement information." *Id.* at ¶ 13. Given these offsetting concerns, the balance of the hardships does not clearly tip in Virtus's favor.

Next, Virtus raises public interest concerns related to the downstream effects the DEA's enforcement action will have on local pharmacies and prescription-holders. Specifically, Virtus contends that the local pharmacies it supplies may lose business as their pharmaceutical inventory of levorphanol is not replenished. *See* Smith Decl., ECF No. 3-2, at ¶ 18. Virtus also asserts that the DEA's decision to hold its levorphanol 2 mg under seal will deprive [redacted] *See id.* at ¶ 12. And in turn, this shortage could threaten the well-being of prescription-holders who rely on a consistent source of levorphanol for their clinical treatment. *See* Bass Decl., ECF No. 12-3, at ¶¶ 6–11. The Court is appreciative of such concerns, particularly the need for prescription-holders to readily access drugs for clinical purposes.

The DEA, however, has presented conflicting evidence on these points. [redacted]

[redacted] This evidence calls into question whether a levorphanol supply shortage exists and what effect, if any, it will have on local pharmacies and prescription-holders down the supply chain. Accordingly, the Court finds that such public interest concerns stand in equipoise, given the present record.

Finally, the DEA raises public interest concerns regarding public health and safety that tip the scales in the government's favor. Both the DEA and the public have a strong interest in preventing the illicit diversion of controlled substances. Prescription drug abuse has occurred with concerning prevalence in recent years and opioid abuse has been central to this public health crisis. *See* Besser Decl., ECF No. 10-2, at ¶¶ 10–11. Tragically, such drug abuse has also caused numerous overdose deaths. *See id.* at ¶12. To this end, enforcement of the security requirements set forth in the Controlled Substances Act provides the DEA with a meaningful tool to combat the drug diversion exacerbating this prescription drug abuse. *See id.* at ¶¶ 30–37. And in this case, the DEA made an investigative determination that Woodfield failed to comply with multiple recordkeeping and security requirements under the CSA. *See* DEA at 2–11. The DEA further found that one of Woodfield's affiliates has potential connections to a suspected drug trafficking organization. *Id.* at 12–13. Given such findings, the DEA's decision to hold controlled substances from Woodfield's non-compliant facility under seal and prevent their diversion furthers a clear public health and safety interest. *See id.* at ¶¶ 10–15; *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 230 (D.D.C. 2012) ("The government has a strong interest in enforcing the CSA and ensuring that pharmaceutical drugs are not improperly diverted . . . ").

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Overall, and for the reasons as set forth above, the Court finds that the balance of the harms and the public interest tip slightly in favor of the DEA. As such, Virtus has not demonstrated that these factors weigh in favor of its requested TRO.

IV. CONCLUSION

For the reasons set forth in this Memorandum Opinion, the Court concludes that Virtus has failed to satisfy its burden of demonstrating a likelihood of success on the merits, a certainty of irreparable harm, or that the balance of hardships and the public interest weigh in Virtus's favor. Accordingly, the Court will **DENY** Virtus's [2] Motion for a Temporary Restraining Order.

An appropriate Order accompanies this Memorandum Opinion.

Dated: September 22, 2021

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge