UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CARDINAL HEALTH, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 12-185 (RBW)
ERIC H. HOLDER, JR., et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiff Cardinal Health, Inc. ("Cardinal") brings this action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-706 (2006), challenging an Order to Show Cause and Immediate Suspension of Registration issued by the Drug Enforcement Administration ("DEA") on February 2, 2012, with respect to Cardinal's drug distribution facility in Lakeland, Florida. Complaint and Prayer for Declaratory and Injunctive Relief ("Compl.") ¶ 1. The case came before the Court on February 29, 2012, on Cardinal's motion for a preliminary injunction ("Cardinal's Mot."). Upon careful consideration of the parties' submissions and the arguments made by counsel at the first hearing on Cardinal's preliminary injunction motion on February 13, 2012, and the second hearing on February 29, 2012,[1] the Court, in accordance with the oral rulings issued at those hearings and for the reasons set forth below, concludes that Cardinal's motion for a preliminary injunction must be denied.

[1] In addition to the complaint and Cardinal's motion, the Court considered the following filings in rendering its decision: the Memorandum of Points and Authorities in Support of Cardinal Health's Motion for Preliminary Injunction ("Cardinal's Mem."); the Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction ("Gov't's Opp'n"); Plaintiff Cardinal Health's Reply in Support of Motion for Preliminary Injunction ("Cardinal's Reply"); the Defendants' Supplemental Brief in Response to Court Order of February 16, 2012 ("Gov't's Suppl. Brief"); and Plaintiff Cardinal Health, Inc.'s Supplemental Memorandum in Support of Motion for Preliminary Injunction ("Cardinal's Suppl. Mem.").

I. BACKGROUND

A. The Controlled Substances Act

The Controlled Substances Act ("CSA" or the "Act") and its implementing regulations create restrictions on the distribution of controlled substances. See 21 U.S.C. §§ 801-971 (2006); 21 C.F.R. §§ 1300-1321 (2009). The Act authorizes the DEA to establish a registration program for manufacturers, distributors, and dispensers of controlled substances designed to prevent the diversion of legally produced controlled substances into the illicit market. See 21 U.S.C. §§ 821, 822. Any entity that seeks to become involved in the production or chain of distribution of controlled substances must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

Distributors of Schedule I or Schedule II drugs—controlled substances with a "high potential for abuse," 21 U.S.C. §§ 812(b), 812(2)(A)-(C)—must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels," id. § 823(b)(1). In addition, distributors that supply controlled substances to pharmacies must "design and operate a system to disclose to the [distributor] suspicious orders of controlled substances" and, in turn, disclose those suspicious orders to the DEA. 21 C.F.R. § 1301.74(b). "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." Id.

The DEA has authority to revoke or suspend a party's registration for a variety of reasons, including that a registrant "has committed such acts as would render his registration . . . inconsistent with the public interest." 21 U.S.C. § 824(a)(4). Generally, before suspending or revoking a registration, the DEA must issue an order to show cause containing its basis for the proceedings and provide an administrative hearing within 30 days. See id. § 824(c). DEA regulations direct that an "order to show cause shall . . . contain a statement of the legal basis for

such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted." 21 C.F.R. § 1301.37(c).

However, in cases where the DEA has reason to believe that a registrant's continued operation would pose "an imminent danger to the public health or safety," it can suspend that party's registration immediately, prior to an administrative hearing, by issuing an immediate suspension order ("ISO"). See 21 U.S.C. § 824(d) ("The Attorney General [and the DEA Administrator by designation] may, in his [or her] discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he [or she] finds that there is an imminent danger to the public health or safety."). DEA regulations direct that "an order of immediate suspension . . . shall contain a statement of [the Administrator's] findings regarding the danger to public health or safety." 21 C.F.R. § 1301.36(e). An immediate suspension order under § 824(d) remains "in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction." 21 U.S.C. § 824(d).

B. Factual and Procedural Background[2]

Cardinal is one of the nation's largest wholesale pharmaceutical drug distributors. Cardinal's Mot., Amended Declaration of Jon Giacomin ("Giacomin Decl.") ¶ 5. It was founded in 1971 and has been distributing pharmaceuticals since 1979. Id. At issue in this case is its distribution facility in Lakeland, Florida ("Cardinal Lakeland" or "Lakeland Facility"), which distributes Schedule II-V controlled substances. Id.

[2] In this section, the Court relies on several exhibits submitted by the parties in connection with Cardinal's preliminary injunction motion for the limited purpose of providing necessary background information. To be clear, and for the reasons explained below, many of these materials are not considered by the Court in its evaluation of the likelihood of success of Cardinal's APA claims.

This is not the first time the DEA has taken enforcement action against Cardinal, or even against its Lakeland Facility. See Cardinal's Mot., Amended Declaration of Michael A. Mone ("Mone Decl.") ¶ 27. Between November 28, 2007, and December 7, 2007, DEA Administrator Michele Leonhart issued immediate suspension orders to three Cardinal facilities, one of which was the Lakeland Facility. Gov't's Suppl. Brief, Declaration of Michele M. Leonhart ("Leonhart Decl.") ¶ 13. Administrator Leonhart "concluded that the three facilities posed an imminent danger to public health or safety based on a DEA investigation revealing that Cardinal Lakeland failed to maintain effective controls against diversion." Id. (internal quotation marks and citation omitted). And on January 30, 2008, the DEA issued an order to show cause (but not an ISO) to revoke the registration of another Cardinal facility located in Stafford, Texas, again "based on the failure to maintain effective controls against diversion." Id. As a result of these allegations, Cardinal agreed to pay a civil fine of $34 million. Gov't's Opp'n at 9. Cardinal also entered into a Memorandum of Agreement with the DEA in which it agreed to "maintain a compliance program designed to detect and prevent [the] diversion of controlled substances as required under the CSA and applicable DEA regulations." Cardinal's Mot., Exhibit ("Ex.") 1 (Settlement and Release Agreement and Administrative Memorandum of Agreement ("MOA")) at 3.

As the backdrop of the action taken by the DEA that precipitated this case, the government asserts that the volume of oxycodone (a Schedule II drug) distributed to Cardinal Lakeland's top four retail customers—CVS Store 219, CVS Store 5195, Gulf Coast, and CareMed ("the four pharmacies")—has increased exponentially since the parties entered into the MOA in 2008. Gov't's Opp'n at 9. As a result, the government contends that the DEA repeatedly notified Cardinal of its need to exercise greater diligence at the Lakeland Facility to detect suspicious activity by its customers. Id. at 9-10. Cardinal then terminated distribution of

controlled substances to Caremed on September 26, 2011, and Gulf Coast on October 5, 2011, but continued to distribute to the two CVS pharmacies. See Cardinal's Mot., Mone Decl. ¶¶ 42, 46.

On October 18, 2011, the DEA executed Administrative Inspection Warrants at the four pharmacies, after which both Gulf Coast and Caremed voluntarily surrendered for cause their DEA registrations. Gov't's Opp'n at 10. A few days later, on October 26, 2011, the DEA executed a warrant at Cardinal's Lakeland Facility to determine whether Cardinal "failed to report suspicious orders to the DEA." Id. On November 8, 2011, the DEA issued an administrative subpoena to Cardinal for information regarding its sales of oxycodone and other drugs as well as its compliance mechanisms. Id. Cardinal thereafter lowered its oxycodone distribution thresholds for CVS Store 219 on November 10, 2011, and CVS Store 5195 on December 16, 2011. Cardinal's Mot., Mone Decl. ¶ 46.

The government contends that "[t]he DEA's investigation of Cardinal and its top four retail customers revealed a staggeringly high and exponentially increasing rate of oxycodone distribution from the Lakeland facility." Gov't's Opp'n at 11. Based on these high volumes and information gleaned from its investigation of Cardinal and the four pharmacies, the DEA determined that "Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers." Id. Finding that this conduct violated Cardinal's obligations under the CSA and the 2008 MOA, and that Cardinal Lakeland's continued registration posed an "imminent danger to the public health and safety," the DEA issued an order to show cause and immediate suspension order to the Lakeland Facility on February 2, 2012. See Cardinal's Mot., Ex. A (Order to Show Cause and Immediate

Suspension of Registration ("ISO")) ¶¶ 3-5.[3] After receiving the ISO on February 3, 2012, Cardinal temporarily suspended all sales (from any of its nationwide distribution centers) to the two CVS pharmacies. Cardinal's Mot., Mone Decl. ¶ 45.

Cardinal maintains that it has implemented a "comprehensive compliance program" designed to detect and prevent improper diversion. Compl. ¶ 23. As a result of this program, Cardinal asserts that it has suspended shipments of controlled substances to more than 375 customers since December 1, 2007, based on its belief that those shipments posed an unreasonable risk of diversion. Id. ¶ 25. Cardinal adds that it has pledged to cease distributing drugs to any pharmacy alleged to engage in improper diversion and has repeatedly requested information about such pharmacies from the DEA. Id. ¶ 29. Despite these requests, Cardinal contends that as recently as December 2011, the DEA has declined Cardinal's requests for the information. Id.

Upon receiving the ISO on February 3, 2012, Cardinal filed its complaint and motion for a temporary restraining order with this Court. Cardinal's complaint challenges the immediate suspension order under the APA on the grounds that it (1) was issued without statutory authority (Count I), Compl. ¶¶ 46-52; (2) denied Cardinal of its constitutional right to due process of law (Count II), id. ¶¶ 53-58; (3) was arbitrary and capricious (Count III), id. ¶¶ 59-63; and (4) contained inadequate findings to justify an immediate suspension (Count IV), id. ¶¶ 64-69.

After holding a hearing on February 3, 2012 (which counsel for the government did not attend),[4] the Court granted Cardinal's motion for a temporary restraining order. See February 3,

[3] For ease of reference, the Court will cite to this document throughout this memorandum opinion simply by listing "ISO" followed by the corresponding paragraph number.

[4] At the hearing, counsel for Cardinal represented to the Court that he had made reasonable efforts to notify the government of Cardinal's intention to file the motion for a temporary restraining order on February 3, 2012. See Transcript of Motions Hearing [ECF No. 9] at 2:9-20.

2012 Order, Cardinal Health, Inc. v. Holder, Civil Action No. 12-185 (RBW) (D.D.C.). Cardinal thereafter moved for a preliminary injunction on February 6, 2012, seeking to enjoin enforcement of the ISO pending resolution of the administrative proceedings before the DEA. After holding a hearing on Cardinal's motion on February 13, 2012, the Court remanded this case to the DEA "for compilation of an administrative record and further explanation of the factual circumstances that were actually considered by the agency as support for the issuance of the immediate suspension order to Cardinal Health's Lakeland Facility on February 2, 2012." February 16, 2012 Order at 1, Cardinal Health v. Holder, Civil Action No. 12-185 (RBW) (D.D.C.). Following this remand and in accordance with the Court's instructions, the government submitted to the Court an administrative record and a declaration from DEA Administrator Michele Leonhart purporting to explain the circumstances considered by the agency as support for the issuance of the ISO. The parties appeared before the Court for another hearing on February 29, 2012, at the conclusion of which the Court denied Cardinal's motion for a preliminary injunction.[5] This memorandum opinion memorializes the oral rulings made by the Court at the hearings on February 13 and February 29, 2012, and explains further the reasons for the Court's remand to the DEA as well as its denial of Cardinal's motion for a preliminary injunction.

[5] At the conclusion of the February 29, 2012 hearing, after the Court denied Cardinal's preliminary injunction motion, Cardinal orally requested that the Court stay its order pending appeal, which the Court denied. Cardinal also made an oral motion for the Court to limit the ISO in order to allow the Lakeland Facility to supply non-retail customers, such as hospitals. The Court denied this motion as well, reasoning that the Court's denial of Cardinal's preliminary injunction motion necessarily precluded the granting of the type of partial injunctive relief being requested for the first time by Cardinal at the hearing.

II. STANDARD OF REVIEW

"'A plaintiff seeking a preliminary injunction must establish [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest.'" Sherley v. Sebelius, 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008)) (some alterations in original). Because it is "an extraordinary remedy," a preliminary injunction "should be granted only when the party seeking the relief, by a clear showing, carries the burden of persuasion." Cobell v. Norton, 391 F.3d 251, 258 (D.C. Cir. 2004) (citing Mazurek v. Armstrong, 520 U.S. 968, 972 (1997)).

The District of Columbia Circuit has applied a "sliding scale" approach in evaluating the preliminary injunction factors. Sherley, 644 F.3d at 392. Under this analysis,

> [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. For example, if the movant makes a very strong showing of irreparable harm and there is no substantial harm to the non-movant, then a correspondingly lower standard can be applied for likelihood of success. . . . Alternatively, if substantial harm to the nonmovant is very high and the showing of irreparable harm to the movant very low, the movant must demonstrate a much greater likelihood of success. It is in this sense that all four factors must be balanced against each other.

Davis v. Pension Benefit Guar. Corp., 571 F.3d 1288, 1291-92 (D.C. Cir. 2009) (internal quotation marks and citations omitted).[6]

[6] In a series of recent decisions, several members of the Circuit have read the Supreme Court's decision in Winter to cast doubt on the continued validity of the sliding scale approach. See Davis, 571 F.3d at 1296 (Kavanaugh, J., joined by Henderson, J., concurring) ("[U]nder the Supreme Court's precedents, a movant cannot obtain a preliminary injunction without showing both a likelihood of success and a likelihood of irreparable harm, among other things." (emphasis in original)); Sherley, 644 F.3d at 393 ("Like our colleagues, we 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.'" (quoting Davis, 571 F.3d at 1296 (concurring opinion)). But the Circuit has had no occasion to resolve

(continued . . .)

III. ANALYSIS

A. Irreparable Injury

The Circuit "has set a high standard for irreparable injury." Chaplaincy of Full Gospel Churches v. England, 454 F.3d 290, 297 (D.C. Cir. 2006). "First, the injury 'must be both certain and great; it must be actual and not theoretical.'" Id. (quoting Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam). To meet this standard, the injury must be "of such imminence that there is a 'clear and present' need for equitable relief to prevent irreparable harm." Id. (citation omitted). "Bare allegations of what is likely to occur are of no value since the court must decide whether the harm will in fact occur." Wisconsin Gas Co., 758 F.2d at 674 (emphasis in original). In addition, "the injury must be beyond remediation." Chaplaincy, 454 F.3d at 297. As the Circuit has explained:

> The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay are not enough. The 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.

Id. (quoting Wisconsin Gas Co., 758 F.2d at 674).

Cardinal claims that without a preliminary injunction, it will suffer irreparable injury in the form of lost customers, reduced profits, costs associated with rerouting drug shipments from other facilities, and reputational harm, all of which it claims will be unrecoverable due to the government's sovereign immunity. See Cardinal's Mem. at 29-30; Cardinal's Reply at 20. For the reasons that follow, none of these purported harms pass the high bar for irreparable injury.

(. . . continued)
this question because it has not yet encountered a post-Winter case where a preliminary injunction motion survived the less rigorous sliding scale analysis. See Sherley, 644 F.3d at 393 ("We need not wade into this circuit split today because, as in Davis, as detailed below, in this case a preliminary injunction is not appropriate even under the less demanding sliding-scale analysis."). Thus, because it remains the law of this Circuit, the court must employ the sliding scale analysis here.

1. Economic Loss

"The loss of business opportunities, market share, and customer goodwill are typically considered to be economic harms." Air Transport Ass'n of America, Inc. v. Export-Import Bank of the U.S., __ F. Supp. 2d __, __, 2012 WL 119557, at *6 (D.D.C. 2012). And "the general rule" in this Circuit is "that economic harm does not constitute irreparable injury." Davis, 571 F.3d at 1295; see also Wisconsin Gas, 758 F.2d at 674 ("It is . . . well settled that economic loss does not, in and of itself, constitute irreparable harm."). Courts in this Circuit have, however, recognized that economic loss can constitute irreparable injury in at least two circumstances. First, where "monetary loss . . . threatens the very existence of the movant's business," it may qualify as irreparable injury. Wisconsin Gas, 758 F.2d at 674. Second, where the claimed economic loss is unrecoverable (e.g., when the defendant is entitled to sovereign immunity), this is "one factor the court must consider in assessing alleged irreparable harm." Nat'l Mining Ass'n v. Jackson, 768 F. Supp. 2d 34, 53 (D.D.C. 2011). But the "fact that economic losses may be unrecoverable does not, in and of itself, compel a finding of irreparable harm," for the harm must also be great, certain and imminent. Id.; see also Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 42 (D.D.C. 2000) ("Because [plaintiff] is alleging a non-recoverable monetary loss, it must demonstrate that the injury [is] more than simply irretrievable; it must also be serious in terms of its effect on the plaintiff.") (internal quotations and citation omitted).

Cardinal has not come close to showing that the ISO "threaten[s] the very existence of [its] business." Wisconsin Gas, 758 F.2d at 674. Cardinal is a Fortune 20 company with annual revenues in 2011 exceeding $102 billion, profits exceeding $1.5 billion, and several distribution facilities nationwide that continue to hold DEA registrations. Gov't's Opp'n at 32. Because the ISO only affects the Lakeland Facility, Cardinal is free to ship from its other distribution

facilities. In fact, the DEA previously issued ISOs to three Cardinal distribution facilities (one of which was the Lakeland Facility) in 2007, suspending distribution for roughly 10 months, see id. at 34, yet Cardinal's business thrives to this day.

Cardinal thus seeks to show that it will suffer unrecoverable economic harm in the form of lost customers, reduced sales, and costs expended as a result of rerouting shipments. According to Cardinal, the ISO would seriously disrupt its supply chain in Florida, which would cause many customers to "redirect orders to other wholesale distributors, resulting in a serious and permanent loss of revenue and customers for the Lakeland facility[]. . . . All of these damages, moreover, would be unrecoverable in light of sovereign immunity." Cardinal's Reply at 20. Cardinal relies on the declarations of its President of Pharmaceutical Distribution, Jon Giacomin, who "anticipate[s] that some of Cardinal Health's Florida customers experiencing service delays will leave Cardinal Health for other distributors and . . . . [that] these customers will take their entire pharmaceutical business away from Cardinal Health." Cardinal's Mot., Giacomin Decl. ¶ 20. In support of this claim, Giacomin notes that shipping delays incurred by the 2007 ISO of the Lakeland Facility "caused some customers to leave Cardinal Health for other distributors," although he does not specify how many customers stopped purchasing from Cardinal. Cardinal's Reply, Supplemental Declaration of Jon Giacomin ("Suppl. Giacomin Decl.") ¶ 3; see also Cardinal's Mot., Giacomin Decl. ¶ 22 ("[I]t is anticipated that the[] [shipment] delays will cause some of Cardinal Health's customers to leave Cardinal Health permanently for other distributors, as occurred following the 2007 ISO of the Lakeland Facility."). He estimates that the 2007 suspension of the three Cardinal facilities caused the company to lose "roughly $1 billion of lost sales on an annualized basis." Cardinal's Reply, Suppl. Giacomin Decl. ¶ 3. And regarding losses at Cardinal Lakeland specifically, he notes that

the suspension resulted in "depressed" sales, and that "just one portion of these losses—decreased sales to retain independent pharmacies that remained with Cardinal Health—amounted to approximately $100 million." Id. ¶ 4. Giacomin estimates that an ISO at this time would "likely . . . . have an even greater impact" on Cardinal's sales, because its competitors in Florida also faced disruptions in distribution in 2007, which is not the current situation. Id. ¶ 5.

Cardinal has not shown unrecoverable economic loss of the magnitude necessary to constitute irreparable harm. As noted, Cardinal had annual revenues in 2011 exceeding $102 billion. Gov't's Opp'n at 32. But when the DEA suspended three Cardinal facilities in 2007, Giacomin estimates that the company suffered $1 billion of lost sales, see Cardinal's Reply, Suppl. Giacomin Decl. ¶ 3, which is less than 1 percent of its current yearly revenues. Cardinal is hard-pressed to argue that the suspension of its Lakeland Facility alone would come anywhere close to this $1 billion loss. And, even assuming that it could, courts in this Circuit have consistently recognized that financial losses of less than 1 percent of total sales do not rise to the level of irreparable injury. See, e.g., Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) ("A loss of less than 1 percent total sales is not irreparable harm." (internal quotation marks and citation omitted)); Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 220-21 (D.D.C. 1996) (same); see also LG Elecs., USA, Inc. v. Dep't of Energy, 679 F. Supp. 2d 18, 35-36 (D.D.C. 2010) ("Even assuming [the plaintiff] will not be able to recover monetary damages from [the Department of Energy], the financial impact [the plaintiff] claims it will suffer does not rise to the level of irreparable harm" because that impact represents only "a minuscule portion of the company's worldwide revenues."). Agreeing with the position that has been taken by its colleagues, the Court finds that Cardinal has not established irretrievable economic loss that

would be "serious in terms of its effects" on its business. See Mylan Pharms., Inc., 81 F. Supp. 2d at 42.

Nor has Cardinal shown economic harm in certain, non-speculative terms. To gauge its anticipated economic loss, Cardinal relies on losses incurred as a result of the 2007 suspensions of the three facilities, but it offers no concrete estimates regarding lost revenues, customers, or market share that it anticipates would result from a current suspension of just the Lakeland Facility. Even the losses that Cardinal allegedly incurred as a result of the 2007 suspensions are indeterminate, with Giacomin stating only that "some customers" left Cardinal due to delayed shipments, and providing no estimates regarding the total lost sales incurred by the Lakeland Facility in particular. See Cardinal's Reply, Suppl. Giacomin Decl. ¶¶ 3-4. Similarly, Giacomin's declaration states in vague terms that rerouting drug shipments from facilities outside of Florida would "require substantial effort and resources," Cardinal's Mot., Giacomin Decl. ¶ 7, yet he does not quantify the anticipated costs of rerouting the shipments. Cardinal's claimed economic injuries are therefore too vague and speculative to support a finding of irreparable harm.

2. Reputational Harm

Cardinal also claims that that the suspension would tarnish its "business reputation" and customers would "come to view Cardinal Health as unreliable." Cardinal's Mot., Giacomin Decl. ¶ 20. To be sure, "damage" to a business's "good name" may constitute irreparable injury under some circumstances. Armour & Co. v. Freeman, 304 F.2d 404, 406 (D.C. Cir. 1962). "However, as with all other forms of irreparable harm, the showing of reputational harm must be concrete and corroborated, not merely speculative." Trudeau v. Fed. Trade Comm'n, 384 F. Supp. 2d 281, 297 (D.D.C. 2005), aff'd, 456 F.3d 178 (D.C. Cir. 2006).

Cardinal's purported reputational harm does not satisfy the requirement of irreparable injury for several reasons. First, past experience gleaned from the effects of the 2007 ISOs indicates that Cardinal's concerns are exaggerated and uncorroborated. Indeed, Cardinal has made no concrete showing of reputational harm resulting from the larger-scale suspensions that occurred in 2007, apart from losing an unspecified number of customers and less than 1 percent of its current yearly sales. Second, insofar as Cardinal asserts that the ISO's alleged harm to its reputation will cause current customers to leave Cardinal and potential customers to avoid doing business with Cardinal, this position is simply a rephrasing of its economic loss argument, which the Court has already rejected as vague and speculative.

3. Harm to Patients

Cardinal also maintains that the ISO would irreparably harm the legitimate consumers who might receive delayed treatment due to rerouted drug shipments. Cardinal's Mot., Giacomin Decl. ¶¶ 10-13. This argument fails because it shows irreparable harm not to Cardinal, but to third parties. See Winter, 555 U.S. at 20 ("[A] plaintiff seeking a preliminary injunction must establish . . . that he is likely to suffer irreparable harm in the absence of preliminary relief." (emphasis added)). The alleged harm to Cardinal's consumers will be considered by the Court under the public interest prong of the preliminary injunction analysis.

In sum, the Court finds that Cardinal has failed to show irreparable injury. Although the Court recognizes that "[a] movant's failure to show any irreparable harm is . . . grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief," the Court is equally aware of its obligation under Circuit precedent to set forth its reasoning as to all of the preliminary injunction factors. Chaplaincy, 454 F.3d at 297, 305.

Accordingly, the Court will proceed to consider the remaining three preliminary injunction factors.

B. Likelihood of Success on the Merits

Having failed to show irreparable harm, Cardinal must, under the sliding scale analysis, make an exceedingly strong showing of its likelihood of success on the merits in order to obtain a preliminary injunction. See Davis, 571 F.3d at 1291-92. It has made no such showing here.

Cardinal's complaint raises three challenges. First, Cardinal claims that the DEA's decision to issue the immediate suspension order violated the APA. See Compl. ¶¶ 46-52, 59-63. Second, Cardinal alleges that the findings regarding imminent danger set forth in the ISO were inadequate under the DEA's own regulations, and also do not comport with the APA. See id. ¶¶ 64-68. Third, Cardinal asserts that because there was no imminent danger justifying its issuance, the ISO deprived it of procedural due process under the Fifth Amendment of the United States Constitution. See id. ¶¶ 53-58; Cardinal's Mem. at 27-28. Although Cardinal has at various points conflated these claims in presenting its arguments to the Court, in the interests of analytical clarity the Court will address the claims separately.

1. Cardinal's APA Claims Challenging the Issuance of the ISO (Counts I & III)

i. Standard of Review

As courts in this Circuit and elsewhere have recognized, the arbitrary and capricious standard of review applies to APA claims challenging the issuance of an ISO under 21 U.S.C. § 824(d). See, e.g., Novelty Distributors, Inc. v. Leonhart, 562 F. Supp. 2d 20, 29 (D.D.C. 2008) (Collyer, J.) (applying arbitrary and capricious standard in reviewing APA challenge to the DEA's issuance of immediate suspension order); Neil Labs., Inc. v. Ashcroft, 217 F. Supp. 2d 80, 84-85 (D.D.C. 2002) (Urbina, J.) (same); Keysource Medical, Inc. v. Holder, No. 11-cv-393,

2011 WL 3608097, at *6 (S.D. Ohio Aug. 16, 2011) (same); United Prescription Servs., Inc. v. Gonzalez, No. 07-cv-316, 2007 WL 1526654, at *2 (M.D. Fla. May 23, 2007) (same). The undersigned member of this Court agrees, and thus the underlying question on the merits for these claims is whether the DEA acted arbitrarily and capriciously in finding, on February 2, 2012, that Cardinal's continued operation posed an "imminent danger to public health or safety" within the meaning of § 824(d).

"The 'arbitrary and capricious' standard of review as set forth in the APA is highly deferential," and the Court must "presume the validity of agency action." American Horse Protection Ass'n v. Yeutter, 917 F.2d 594, 596 (D.C. Cir. 1990). As the Supreme Court has explained:

> 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. Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made. In reviewing that explanation, we must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Normally, an agency [action] would be arbitrary and capricious 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 Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (citations and quotation marks omitted).

ii. The Materials that the Court Considered in Assessing the Likelihood of Success of Cardinal's APA Claims

There has been much controversy in this case concerning what materials the Court may consider in evaluating whether the DEA acted arbitrarily and capriciously in issuing the ISO to Cardinal Lakeland. Before describing what it did consider, the Court pauses to emphasize a few

tenets of administrative law. First, in applying the APA's arbitrary and capricious standard, "the focal point for 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 (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 record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency," the Circuit "has made 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). Second, judicial review under the APA generally must "be based on the full administrative record that was before the [agency] at the time [it] made [its] decision." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971) (emphasis added). As the Circuit has explained, "[i]f 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." Walter O. Boswell Mem. Hosp., 749 F.2d at 792. "To review less than the full administrative record might allow a party to withhold evidence unfavorable to its case, and so the APA requires review of 'the whole record.'" Id. (quoting 5 U.S.C. § 706)).[7] Finally, an agency's obligation to

[7] While APA § 706 provides that judicial review may be based on either "the whole record or those parts of it cited by a party," 5 U.S.C. § 706 (emphasis added), the Circuit has stated that "[f]or review to go forward on a partial record, we would have to be convinced that the selection of particular portions of the record was the result of mutual (continued . . .)

compile a record applies even in the context of informal adjudications, such as the issuance of the ISO here. See IMS, 129 F.3d at 624 ("It is not necessary that the agency hold a formal hearing in compiling its record, for '[t]he APA specifically contemplates judicial review on the basis of the agency record compiled in the course of informal agency action in which a hearing has not occurred.'" (quoting Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743-44 (1985) (alteration in original)); Gov't's Suppl. Brief at 8 n.4 (recognizing that the issuance of an ISO is an informal agency adjudication).

Here, instead of an administrative record, both parties submitted various sworn declarations for the Court's consideration in assessing Cardinal's APA claims. The government, for example, urged the Court to consider declarations of two DEA officials who participated in the investigation of Cardinal Lakeland. See Gov't's Opp'n, Declaration of Joseph Rannazzisi and Declaration of Ruth A. Carter. Cardinal likewise submitted declarations from one of its Vice Presidents, Michael Mone, which purports to challenge the factual basis for the DEA's finding that Cardinal Lakeland's continued registration posed an imminent danger to the public. See Cardinal's Mot., Mone Decl. ¶¶ 42-56. Although Cardinal wanted the Court to consider Mone's declaration, it challenged the DEA declarations as containing impermissible post hoc rationalizations for the agency's actions. Cardinal's Reply at 13-15. The government, on the other hand, asserted that its declarations merely "explain[ed] why [the] DEA took the action that it did," and did not "offer new reasons, or reasons other than those that caused it to conclude on February [2], 2012, that Lakeland's continued operation posed an imminent danger to public

(. . . continued)
agreement between the parties after both sides had fully reviewed the complete record," Walter O. Boswell Mem. Hosp., 749 F.2d at 792.

health or safety." Reply in Support of Notice of Request to Present Testimony [ECF No. 13] at 2.

The Court addressed these issues at the hearing on February 13, 2012. In view of the general administrative law principles outlined above, the Court was reluctant to accept either party's invitation to consider their declarations and exhibits (while ignoring the other side's submissions). To be sure, the parties' submission of these materials was not surprising, given that an ISO is a unique type of agency action that is issued in emergency circumstances and that necessarily predates an administrative hearing.[8] However, neither party presented any reason to depart from the normal rules of administrative law in this case. And although the government claimed that its declarations were merely explanatory of the record before the agency at the time it issued the ISO and did not contain any impermissible post hoc rationalizations, the Court was unable to confirm that representation because it was not in possession of the administrative record.

The Court thus set aside the parties' various declarations and exhibits, and was left with the ISO as the entirety of the agency "record." This, the Court found, was insufficient by itself to evaluate the agency's action under the applicable APA standard of review. For instance, the Court could not determine from the ISO alone whether the DEA's finding that Cardinal Lakeland's continued registration posed a "imminent danger" to the public "r[an] counter to the evidence before the agency," or whether the agency "entirely failed to consider an important

[8] It is also not surprising that several district courts have considered declarations and even taken testimony in evaluating preliminary injunction challenges to immediate suspension orders brought under the APA. See, e.g., Novelty Distributors, Inc., 562 F. Supp. 2d at 29 (relying on declarations from DEA officials in determining whether the DEA acted arbitrarily and capriciously in issuing suspension order); Keysource Medical, Inc. v. Holder, 2011 WL 3608097, at *1, *4 (relying on live testimony of the plaintiff's employees and DEA officials, as well as declarations and exhibits submitted by both parties, in considering preliminary injunction challenge to suspension order). In contrast to this case, however, the parties in Novelty Distributors and Keysource Medical did not appear to dispute the propriety of the courts' consideration of extra-record materials, and so the courts in those cases were not confronted with the issues facing this Court.

aspect of the problem." State Farm, 463 U.S. at 43. Accordingly, the Court remanded this case to the DEA "for compilation of an administrative record and further explanation of the factual circumstances that were actually considered by the agency as support for the issuance of the immediate suspension order to Cardinal Health's Lakeland Facility on February 2, 2012." February 16, 2012 Order, Cardinal Health, Inc. v. Holder, Civil Action No. 12-185 (RBW) (D.D.C.). Following the Court's remand, the government submitted a certified administrative record together with a declaration from DEA Administrator Michele Leonhart, who authorized the issuance of the ISO to Cardinal Lakeland.

Cardinal protests the DEA's reliance on anything other than the ISO, contending that the agency must defend the ISO solely on the findings stated in that document. Cardinal's Suppl. Mem. at 6. Cardinal asserts that where the agency offers a contemporaneous explanation of its decision, the validity of that decision must "'stand or fall on the propriety of th[e] finding[s]' that appear in that decision." Id. (quoting Camp, 411 U.S. at 142) (alterations in original). It adds that the DEA's own regulations direct that an ISO "shall contain a statement of the [Administrator's] findings regarding the danger to public health and safety." 21 C.F.R. § 1301.36(e) (emphasis added). Cardinal thus contends that the "the ISO must stand or fall based solely on the grounds stated within the ISO's four corners."[9] Id. For related reasons, Cardinal

[9] In further support of its argument that the DEA can only rely on the ISO to defend its actions, Cardinal highlights closing language in the ISO which states that the Administrator's findings of imminent danger were made "[u]nder the acts and circumstances described herein." ISO at 3. This language apparently indicates to Cardinal that the ISO purports to provide an exhaustive summary of the Administrator's findings. See Cardinal's Suppl. Mem. at 6. However, the first page of the ISO states the Administrator's finding that Cardinal Lakeland's continued "registration constitutes an imminent danger to the public health and safety," and goes on to provide that "[t]he basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts." ISO at 1 (emphasis added). In actuality, it appears that both statements are merely boilerplate provisions included in every ISO issued by the DEA. The Court does not interpret the language to restrict the Administrator's ability to offer further explanation regarding her findings of imminent danger.

urges the Court to ignore "new rationalizations" offered in Administrator Leonhart's declaration that do not appear in the ISO. Id. at 11.

Cardinal's position overlooks caselaw recognizing that even where an agency has offered an inadequate "contemporaneous explanation" for its action, "bedrock principles of administrative law preclude [courts] from declaring definitively that [the agency's] decision was arbitrary and capricious without first affording [the agency] an opportunity to articulate, if possible, a better explanation." Cnty. of Los Angeles v. Shalala, 192 F.3d 1005, 1021, 1023 (D.C. Cir. 1999) (collecting cases); see also Am. Bioscience, Inc v. Thompson, 269 F.3d 1077, 1086 (D.C. Cir. 2001) ("We have already directed the district court to remand this case once to compile a record. . . . That is consistent with our practice of remanding without vacating when we are unsure of the grounds the agency asserts to defend its action (and, perhaps, where we perceive that a ground poorly articulated might be sufficient to sustain the action)." (internal citation omitted and emphasis added)). And Cardinal has cited no authority indicating that the normal practice of remanding to the agency without vacating is inappropriate where, as here, the agency is required by regulation to make "findings" in the informal adjudication context, but fails to articulate those findings with the requisite specificity to facilitate APA review. The Court thus deemed it appropriate to remand this case to the DEA for further explanation of the reasons underlying its issuance of the ISO.[10]

[10] It bears emphasizing that in remanding to the DEA, the Court did not conclude that the ISO's lack of factual detail rendered the DEA's issuance of the ISO arbitrary and capricious, for that would suggest that Cardinal did show a likelihood of success on the merits of its APA claim. Rather, the Court found that it had an insufficient basis to assess the likelihood of success of Cardinal's APA claim, and that a remand was therefore necessary for further explanation. See Am. Bioscience, Inc. v Thompson, 243 F.3d 579, 582 (D.C. Cir. 2001) (holding, in preliminary injunction context, that district court should have remanded to agency before assessing likelihood of success of the plaintiff's APA claim).

Furthermore, in view of this Court's remand, Cardinal's contention that Administrator Leonhart's declaration contains impermissible post hoc rationalizations is unavailing. See Menkes v. U.S. Dep't of Homeland Sec., 637 F.3d 319, 337 (D.C. Cir. 2011). In Menkes, the agency submitted to the court a declaration from a Coast Guard official, Paul Wasserman, after the Circuit remanded to the agency for further explanation of its action. Id. The plaintiff challenged this declaration as an impermissible post hoc rationalization. Id. The court found this challenge "meritless," reasoning as follows:

> Wasserman's declaration was presented in response to this court's direction to the Coast Guard to offer an explanation regarding the changed conditions from the 2003 to 2004 navigation season on remand. . . . "Needless to say, if it is appropriate for a court to remand for further explanation, it is incumbent upon the court to consider that explanation when it arrives." Alpharma, Inc. v. Leavitt, 460 F.3d 1, 6 (D.C. Cir. 2006). As we noted in Local 814, International Brotherhood of Teamsters v. NLRB, 546 F.2d 989, 992 (D.C. Cir. 1976) (per curiam):
>
> > The "post hoc rationalization" rule is not a time barrier which freezes an agency's exercise of its judgment after an initial decision has been made and bars it from further articulation of its reasoning. It is a rule directed at reviewing courts which forbids judges to uphold agency action on the basis of rationales offered by anyone other than the proper decisionmakers.
>
> Because Wasserman is a "proper decisionmaker," his declaration—which explains why the agency allowed Menkes's appointment to lapse in 2003—is not an impermissible post hoc rationalization.

Id. at 337; see also Local 814, 546 F.2d at 992 ("The policy of the post hoc rationalization rule does not prohibit [an agency] from submitting an amplified articulation of the distinctions it sees. . . . [In fact,] the logic of the rule requires it. If a reviewing court finds the record inadequate to support a finding of reasoned analysis by an agency and the court is barred from considering rationales urged by others, only the agency itself can provide the required clarification.").

Here, as in Menkes, the Court remanded this case to the DEA for a further explanation of the basis for its issuance of the ISO to Cardinal Lakeland and, in response, the agency provided

Administrator Leonhart's declaration. Leonhart, the DEA administrator and issuer of the ISO, certainly qualifies as a "proper decisionmaker." Menkes, 637 F.3d at 337. As a consequence, having remanded this case to the agency "for further explanation, it is incumbent upon the court to consider that explanation" upon its arrival.[11] Alpharma, Inc., 460 F.3d at 6.

The Court will also consider the administrative record provided by the DEA. "Once an agency presents a certified copy of the complete administrative record to the court, the court presumes that the record is properly designated," and this presumption can be rebutted only by "clear evidence to the contrary." Calloway v. Harvey, 590 F. Supp. 2d 29, 37-38 (D.D.C. 2008); accord Bar MK Ranches v. Yuetter, 994 F.2d 735, 740 (10th Cir. 1993); Marcum v. Salazar, 751 F. Supp. 2d 74, 78 (D.D.C. 2010). The DEA has presented a certified copy of the complete administrative record to the Court, so there is a presumption that it is properly designated. And because Cardinal has not rebutted this presumption by "clear evidence," the Court deems it as the full record that was before the DEA when it issued the ISO.

In sum, the Court will consider both the administrative record and Leonhart's declaration in evaluating Cardinal's APA challenges.

iii. Whether the DEA's Issuance of the ISO was Arbitrary and Capricious

The ISO sets forth the following basis for the DEA's immediate suspension decision:

> 2. On September 30, 2008, Cardinal entered into an Administrative Memorandum of Agreement (MOA) with DEA agreeing to "maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations." Furthermore, Cardinal "acknowledg[ed]" and "agree[d]" that the obligations undertaken . . . do not fulfill the totality of its obligations to maintain effective

[11] Although the Court appreciates that any post hoc rationalization from an agency, even one prompted by a court's remand, must be "viewed critically," Overton Park, 401 U.S. at 420, the Court now has the ability to critically assess the Leonhart declaration because it can compare it to the administrative record provided by the DEA. Having done so, and as shown below, the Court finds that Leonhart's statements are indeed supported by the record that was before the agency at the time it issued the ISO.

controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances."

3. Despite the MOA, the specific guidance provided to Cardinal by DEA, and despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of [the CSA].

4. Since at least 2009, Cardinal's largest purchasers of oxycodone products have been retail pharmacies in the State of Florida engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than legitimate medical purposes and outside the usual course of professional practice.

> a. From January 1, 2008 through December 31, 2011, Automation of Reports and Consolidated Orders System ("ARCOS") data shows that Cardinal's sales of oxycodone products to its top four retail pharmacy customers exceeded 12.9 million dosage units. In 2010 and 2011 alone, Cardinal sold 10.9 million dosage units of oxycodone to its top four customers. From 2008 to 2009, Cardinal's sales to its top four retail pharmacy customers increased approximately 803%. From 2009 to 2010, Cardinal's sales to its top four retail pharmacy customers increased approximately 162%.
>
> The egregious quantities of oxycodone distributed by Cardinal to its top four retail pharmacy customers well exceeded the amount of oxycodone distributed to Cardinal's Florida retail pharmacies, which received, on average, approximately 5,347 dosage units of oxycodone per month.
>
> [subparagraphs 4(b) through 4(e) break down the specific sales numbers of oxycodone from Cardinal to each of the four pharmacies]

5. Notwithstanding the large quantities of controlled substances ordered by Cardinal's top retail pharmacy customers, Cardinal failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels, including Cardinal's failure to conduct due diligence of its retail pharmacy chain customers. Furthermore, Cardinal failed to detect and report suspicious orders of oxycodone by its pharmacy customers, as required by 21 C.F.R. § 1301.74(b). In addition, Cardinal's conduct described herein violated the provisions of the Administrative Memorandum of Agreement [i.e., the MOA].

ISO ¶¶ 2-5.

In addition to the foregoing findings, Administrator Leonhart's declaration outlines several factors that informed her decision to issue the ISO. These factors, when viewed in the aggregate, establish that the DEA's finding that Cardinal's continued registration posed an "imminent danger to the public health or safety" had a reasoned basis and was not arbitrary or capricious.

The Growing Problem of Prescription Drug Abuse in Florida. Administrator Leonhart began her declaration by noting her "firsthand knowledge of the serious diversion problem along the East Coast and in the Midwest whose states have been ravaged by prescription drug abuse," as well as "Florida's ongoing problem with prescription drug abuse" in particular. Gov't's Suppl. Brief, Leonhart Decl. ¶ 8; see also Administrative Record ("AR") at 8768 (internal DEA document noting that "drug overdoses [have] exceeded motor vehicle accidents as a cause of death, starting in 2009," and that "[a]buse of [controlled substances] now eclipses abuse of all illicit drugs combined, except marijuana."); ISO ¶ 3 (alleging that "despite the public information readily available regarding the oxycodone epidemic in Florida, Cardinal has failed to maintain effective controls against diversion"). She added that as a result of her experience "in conducting and leading drug investigations, [she] know[s] that any effective strategy must address the problem at all levels, including distributors and suppliers." Gov't's Suppl. Brief Leonhart Decl. ¶ 9. This is because, in her view, "[a] strategy that fails to attack every link in the chain will only succeed in moving the problem around," and "the sheer volume of practitioners and pharmacies make it impossible to significantly impact the problem by targeting physicians and pharmacies alone." Id. Although both parties gloss over these statements, the Court finds them highly relevant in assessing the reasonableness of the DEA's decision to issue the ISO. Indeed, these statements lay the background for the Administrator's finding of "imminent

danger," and support an inference that her decision was the "product of agency expertise," State Farm, 463 U.S. at 43, which is entitled to deference from this Court.

Cardinal Lakeland's History of Inadequate Controls Against Unlawful Diversion. As noted, the DEA previously issued suspension orders to three Cardinal facilities, including Lakeland, in 2007. Gov't's Suppl. Brief, Leonhart Decl. ¶ 13. In issuing the 2007 ISO to Cardinal Lakeland, the DEA found "imminent danger to public health or safety based on a DEA investigation revealing that Cardinal Lakeland 'failed to maintain effective controls against diversion.'" Id. Specifically, the DEA's investigation revealed that between August 2005 and October 2007, the Lakeland Facility "distributed over 8,000,000 dosage units of hydrocodone combination products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels." Id. ¶ 14. This resulted in Cardinal entering into the 2008 MOA with the DEA. Id. ¶ 17.

According to Leonhart, "Cardinal's prior compliance problems, particularly those at Lakeland, played a significant role in [her] conclusion to issue the Feburary 2, 2012 ISO." Id. ¶ 18. As she reasoned:

> [In the February 2, 2012 ISO,] I found that Cardinal Lakeland had failed to maintain adequate diversion controls, had violated the terms of its 2008 MOA, and posed an imminent danger to public health and safety. DEA's recent investigation indicated that Cardinal Lakeland had been distributing excessive quantities of oxycodone to its top Florida retail pharmacy customers. DEA previously suspended Cardinal Lakeland [in 2007] because of its failure to maintain adequate safeguards against diversion, a conclusion DEA reached after an investigation into Cardinal Lakeland's distribution of hydrocodone to internet pharmacies. Although the drugs and the end customers were different, the common thread was Cardinal Lakeland's inadequate anti-diversion measures. The results of the recent investigation strongly indicated to me that, contrary to its promises in the 2008 MOA, Cardinal had not maintained adequate anti-diversion measures at its Lakeland facility.

Id.

Cardinal contends that allegations of past misconduct are per se insufficient to show "imminent danger" under § 824(d). See Cardinal's Suppl. Mem. at 3. While this argument would have merit if the allegations of past misconduct formed the sole basis for the ISO, the Administrator reasonably considered Cardinal's past infractions—and, in particular, the prior allegations of inadequate diversion controls at the Lakeland Facility—as only one relevant factor in her determination that Cardinal Lakeland's immediate suspension was necessary to prevent imminent harm to the public. Other district courts have reached similar conclusions regarding the DEA's reliance on prior violations in issuing immediate suspension orders. See Easy Returns Worldwide, Inc. v. United States, 266 F. Supp. 2d 1014, 1021 (E.D. Mo. 2003) ("Plaintiff argues that DEA's actions are unjustified because of its reliance on past events . . . . [However], the prior violations serve as a background to the events which ultimately culminated in the suspension of the registration. The basis [for] the DEA's decision to suspend was an on-going examination of the continued violations prior to and during the decision making process."); MediPharm–Rx, Inc. v. Gonzales, No. 06-cv-2223, 2007 WL 601722, at *5 (M.D. Fla. Feb. 16, 2007) (stating that "[t]he prior violations serve as a backdrop to the events that culminated in the DEA's issuance of the Suspension Order."); cf. Alra Labs. Inc. v. DEA, 54 F.3d 450, 452 (7th Cir. 1995) ("An agency rationally may conclude that past performance is the best predictor of future performance.").

Cardinal also asserts that the DEA's reliance on data dating from as far back as 2008, as well as the delay between the execution of its warrant on October 25, 2011, and its issuance of the ISO on February 3, 2012, undermines its conclusion that Cardinal's continued registration presented an "imminent" danger. Cardinal's Reply at 11-13. But, as explained above, the DEA could reasonably rely on sales trends from past years to show a pattern of inadequate anti-

diversion efforts, which ultimately culminated in the need for immediate suspension in February 2012. Moreover, the DEA's delay between the execution of its warrant and issuance of the ISO is reasonably attributed to the agency's review of information gleaned from the warrant and subpoena it served on Cardinal. See Gov't's Opp'n at 28-29. The DEA should not be faulted for conducting an investigation and carefully considering its fruits before taking the significant step of issuing an immediate suspension order.

Large and Increasing Volumes of Oxycodone Shipped to the Four Pharmacies. As detailed above, the ISO lists the units of oxycodone sold by the Lakeland Facility to the four pharmacies from 2008 to December 2011. See ISO ¶ 4. "Compared to the average number of dosage units distributed monthly to Cardinal Lakeland's other Florida retail pharmacies," Leonhart found that "the average monthly distribution to Cardinal Lakeland's top four customers was staggering." Gov't's Suppl. Brief, Leonhart Decl. ¶ 22 (emphasis added). Specifically,

> Cardinal Lakeland's other Florida retail pharmacies received, on average, 5,347 dosage units per month [from Cardinal Lakeland]. In contrast, CVS 5195 received approximately 58,223 dosage units per month from Cardinal Lakeland; Caremed received approximately 59,264 dosage units per month from Cardinal Lakeland; Gulf Coast received approximately 96,664 dosage units per month from Cardinal Lakeland; and CVS 219 received approximately 137,994 dosage units per month from Cardinal Lakeland . . . . The total distribution to Cardinal Lakeland's top four retailers equates to approximately 50 times the amount of oxycodone compared to the average Florida retailer that Cardinal Lakeland services.

Id.; see also ISO ¶ 4(a).

Leonhart added that the volumes of oxycodone that Cardinal shipped to the four pharmacies were not only large, but had drastically increased. Gov't's Suppl. Brief, Leonhart Decl. ¶ 20; see also ISO ¶ 4(a) (noting increases of 803% from 2008 to 2009, and 162% from 2009 to 2010); AR at 8881-8884 (showing increases in oxycodone volumes to the four pharmacies from 2008 to 2011). To be sure, as Cardinal points out, see Cardinal's Suppl. Mem.

18, the data showing an 803% increase in oxycodone sales from 2008 to 2009 is misleading because it compares two months of data in 2008 to an entire year's worth of data in 2009, see AR at 8881-8884. But the administrative record does reveal steady increases in aggregate oxycodone distribution from 2009 to 2011 based on a fair comparison of the yearly data. See id.

Leonhart also "considered the high distribution numbers of controlled substances by Cardinal Lakeland to CVS 219 and 5195 in the context of the pharmacies' location in Sanford, Florida, a city of approximately 53,570 residents." Gov't's Suppl. Brief, Leonhart Decl. ¶ 23. She found it "highly suspect that two of the fourteen pharmacies in a city of only 53,570 residents could alone be dispensing 7.2 million dosage units of oxycodone over an approximately three year period." Id. Based on Leonhart's knowledge and experience, "this quantity grossly exceeded the oxycodone needs for a population of that size." Id.

Failure to Conduct Due Diligence at Chain Pharmacies Despite Warning Signs. Leonhart had "information before [her] that Cardinal Lakeland was improperly relying on chain pharmacies to police themselves, rather than performing independent due diligence, despite having been told that this was unacceptable." Id. ¶ 27; see AR at 8767 (internal DEA document noting that in 2011 "Cardinal Lakeland staff told [DEA personnel] that they had no interaction with chain pharmacies, but that Corporate handled all business with chain pharmacies," and that "CVS staff told [DEA personnel] that they had never had any interaction with Cardinal staff.").

Leonhart also learned of interviews with pharmacists at CVS 219 and 5195 that revealed their pharmacists' failure to understand the "basic warning signs of diversion," which, in turn, cast doubt on Cardinal Lakeland's own anti-diversion protocols. See Gov't's Suppl. Brief, Leonhart Decl. ¶¶ 24, 27. One CVS pharmacist reported that "customers often request[ed] certain brands of oxycodone using street slang"; that he saw nothing "wrong with two

individuals living at the same address receiving the exact prescriptions for controlled substances from the same practitioner; and that no one from CVS corporate had said anything to him about the high volume of oxycodone dispensed at his store." Id. ¶ 24. Another pharmacist "described many of her customers as 'shady' and admitted that some oxycodone prescriptions she filled were probably not legitimate . . . . She also instituted a daily limit on the number of oxycodone prescriptions the pharmacy would fill each day so that she had enough oxycodone for what she described as 'real pain patients.'" Id.; see also AR at 154 (describing an interview with a CVS pharmacist). Leonhart determined that if Cardinal Lakeland had "taken basic steps to investigate [the pharmacies'] activities, it would have detected serious problems with its top four customers." Gov't's Suppl. Brief, Leonhart Decl. ¶ 25. Because "Cardinal Lakeland sold high volumes of oxycodone to [the] CVS stores despite all the warning signs," she concluded that "Cardinal's Lakeland Facility had failed in its obligation to identify, report, and act upon the suspicious nature of the orders placed by these stores." Id. ¶ 24.

Evidence of General Deficiencies Regarding Anti-Diversion Controls. Leonhart's "imminent danger" finding was not limited only to the four pharmacies. Id. ¶ 27. At the time she issued the ISO, she had information demonstrating that Cardinal Lakeland was "distributing significantly higher amounts of oxycodone than the national and Florida average retail pharmacy to more than twenty-five pharmacies, not including the four pharmacies mentioned in the ISO." Id.; see AR at 8905-8906 (listing Cardinal Lakeland's 2011 oxycodone sales to several pharmacies). Furthermore, Leonhart considered information that she viewed as reflecting Cardinal's misunderstanding of the scope of its anti-diversion obligations. For instance, a letter from Cardinal to the DEA dated October 27, 2011, indicated to Leonhart that Cardinal believed that the DEA, and not Cardinal, was obligated to determine which of Cardinal Lakeland's

customers had been engaging in improper diversion, despite the DEA's position that "DEA registrants, including Cardinal Lakeland, have an obligation to monitor their customers for possible diversion of controlled substances." Gov't's Suppl. Brief, Leonhart Decl. ¶ 30. "Cardinal's request for DEA to identify their own problem customers indicated to [Leonhart] that Cardinal Lakeland still did not understand its obligations as a DEA registrant." Id. Likewise, as just noted, Leonhart had information showing that "Cardinal Lakeland was improperly relying on chain pharmacies to police themselves," instead of conducting its own due diligence and on-site visits. Id. ¶ 27. Based on this information, Leonhart "found that Cardinal Lakeland's anti-diversion efforts were inadequate, both with respect to its top four customers, as well as to its customers generally." Id.

The Administrator's Consideration of Mitigating Evidence. Cardinal contends that in deciding to issue the ISO, the DEA ignored Cardinal's cessation of distribution to the Caremed and Gulf Coast pharmacies in September and October 2011, its reduction of distributions to the two CVS pharmacies in October 2011, and other remedial steps taken by the company. See Cardinal's Mem. at 16. Leonhart's declaration indicates otherwise. It states that Leonhart considered these mitigating factors, but ultimately concluded that "Cardinal Lakeland still posed an imminent danger to public health and safety" for the following reasons:

- "The monthly distributions to the CVS stores in late 2011 remained significantly higher than the average Cardinal Lakeland Florida retail pharmacy and the Florida state average." Gov't's Suppl. Brief, Leonhart Decl. ¶ 26.
- "[T]he distributing pattern of sales to all four pharmacies over an extended period of time gave [her] reason to believe that Cardinal Lakeland did not have adequate anti-diversion controls in place with regard to its sales to its more than 5,200 other retail

customers." Id. (emphasis added). In other words, the Administrator's concerns with Cardinal Lakeland were not limited to the four pharmacies.

- She "also did not give great weight to Cardinal Lakeland's cessation of sales to Caremed and Gulf Coast and its reduced sales to CVS 219 and CVS 5195, because [she] was aware of evidence that other Cardinal Lakeland customers were also receiving extraordinarily large amounts of oxycodone from Cardinal Lakeland as well, including other retail chain pharmacies." Id. ¶ 27.
- "In general, [she] give[s] less weight to remedial measures and decreased sales that occur following the execution of an [Administrative Inspection Warrant]," id. ¶ 28, as was the case with Cardinal Lakeland's reduction of oxycodone distribution to the two CVS pharmacies. As Leonhart explained, "[i]t is not uncommon for registrants to make efforts to cooperate with DEA after coming under investigation. While [she] gave these efforts some weight in [her] consideration, [she does] not view them as dispositive evidence that the registrant has brought itself into full compliance with the requirements of the CSA." Id.
- Leonhart also considered an October 27, 2011 letter from Cardinal to DEA explaining Cardinal's national anti-diversion program (which was sent after Cardinal executed its warrant at Lakeland). Id. ¶ 30. This letter "failed to persuade [Leonhart] that Cardinal Lakeland did not pose an imminent danger" because "[i]t focused primarily on Cardinal's national efforts, while DEA's was focused on Cardinal Lakeland." Id. Furthermore, as noted above, Leonhart was "troubled" by the letter's implication that DEA, and not Cardinal, was responsible for identifying potential diversion. Id.

Having examined the Administrator's rationale, the Court pauses to emphasize the scope of its review under the APA. Although judicial review under the arbitrary and capricious standard should be "searching and careful," Overton Park, 401 U.S. at 416, the level of scrutiny employed must be tempered by the context of the agency's action, see Nat'l Cable Tele. Ass'n v. Copyright Royalty Tribunal, 724 F.2d 176, 181 (D.C. Cir. 1983). Indeed,

> [t]he tautness of court surveillance of the rationality of agency decisionmaking . . . depends on the nature of the task assigned to the agency. If Congress sets precise guidelines for agency action, courts must tightly review the agency's directives to determine whether the congressional instructions have been observed. On the other hand, if Congress entrusts a novel mission to an agency and specifies only grandly general guides for the agency's implementation of legislative policy, judicial review must be correspondingly relaxed.

Id.

The Controlled Substances Act provides that the Administrator "may, in h[er] discretion" issue an ISO "in cases where [s]he finds that there is an imminent danger to the public health or safety." 21 U.S.C. § 824(d) (emphasis added). Far from providing "precise guidelines" that restrict the meaning of "imminent danger," the Act vests the Administrator with discretion to make such a determination. In addition, the statute contemplates that an ISO will be issued in emergency circumstances, prior to an administrative hearing or the development of a formal evidentiary record. Thus, given 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." Nat'l Cable Tele. Ass'n, 724 F.2d at 181.

Applying these principles here, the Court concludes that the DEA's issuance of the ISO easily passes the arbitrary and capricious standard of review. When viewed in the aggregate, the factors considered by Administrator Leonhart—including (1) the rampant pharmaceutical drug problem in Florida, (2) Cardinal Lakeland's history of inadequate anti-diversion controls, (3) the

large and increasing amounts of oxycodone distributed by Cardinal Lakeland to the four pharmacies from 2009 to 2011, (4) the sizeable amounts of oxycodone distributed to 25 other pharmacies in 2011 that exceeded state and national averages, and (5) the evidence of Cardinal Lakeland's failure to monitor its chain pharmacy customers, despite clear warning signs of inadequate anti-diversion controls at those pharmacies—provided a reasonable basis for her conclusion that Cardinal Lakeland's continued registration posed an "imminent danger to the public health or safety" under § 824(d). The Administrator "provided a satisfactory explanation for [the DEA's] action including a rational connection between the facts found and the choice made," and her decision does not reflect a "clear error of judgment." State Farm, 463 U.S. at 430. Furthermore, her consideration and rejection of Cardinal's remedial efforts indicates that she adequately considered all of the available information before rendering her decision. See id. Cardinal's APA claim challenging the Administrator's issuance of the ISO as arbitrary and capricious is, therefore, not likely to succeed on the merits.

2. Cardinal's APA Claim Challenging the Facial Adequacy of the ISO (Count IV)

Count IV of Cardinal's complaint asserts an APA claim challenging the facial adequacy of the ISO. See Compl. ¶¶ 67-69. Specifically, Cardinal notes that DEA regulations direct that ISOs "shall contain a statement of [the Administrator's] findings regarding the danger to public health or safety," 21 C.F.R. § 1301.36(e), and that the statement of findings in the ISO here is inadequate, Compl. ¶¶ 67-68. Cardinal therefore contends that the ISO was issued "without observance of procedure required by law," in violation of APA § 706(2)(D).

The question of what type of "findings" must be contained in an ISO to satisfy 21 C.F.R. § 1301.36(e) appears to be one of first impression. Both parties urge the Court to read the §1301.36(e) in pari materia with its accompanying regulations, but obviously reach different

conclusions. Cardinal's position is that the "findings" required by § 1301.36(e) "call[] for a detailed statement of the factual basis for the agency's decision." Cardinal's Suppl. Mem. at 7. In support of this interpretation, it claims that § 1301.36(e) should be read in conjunction with another regulation within the CSA framework, which requires that "findings of fact" be included in "final orders" issued after a formal evidentiary hearing before the DEA. See 21 C.F.R. § 1301.46. This regulation is, however, plainly not comparable to § 1301.36(e), as an ISO is issued prior to a hearing. It would be untenable to require that an ISO contain findings equivalent to those found in a "final order" issued after a hearing.

The government, on the other hand, urges the Court to look to another CSA regulation, 21 C.F.R. § 1301.37(c). Gov't's Suppl. Brief at 2. This regulation governs the contents of an order to show cause, which is the order that initiates revocation and suspension proceedings before the DEA. See 21 C.F.R. § 1301.37(c). Under § 1301.37(c), show cause orders must "contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted." Id. (emphasis added). The government asserts that this regulation should be read together with § 1301.36(e) because immediate suspension and show cause orders are "inextricably bound," and, in accordance with "longstanding DEA practice," are included in one document. Gov't's Suppl. Brief. at 2-3; see also 21 C.F.R. § 1301.36(e) ("If the Administrator so suspends, he/she shall serve with the order to show cause pursuant to § 1301.37 an order of immediate suspension which shall contain a statement of his[/her] findings regarding the danger to public health or safety." (emphasis added)). Reading the two regulations in conjunction, the government maintains that the requisite "statement of . . . findings" in an ISO need only contain a "summary of the legal and factual basis for suspending an entity's registration." Gov't's Suppl. Brief at 3.

Regardless of whether the Court agrees with this interpretation of § 1301.36(e), the Court finds that the DEA's reading of the regulation is entitled to deference. The Supreme Court has made clear that courts must "defer to an agency's interpretation of its own regulation, advanced in a legal brief, unless that interpretation is 'plainly erroneous or inconsistent with the regulation'" or there is any "'reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question.'" Chase Bank USA, N.A. v. McCoy, __ U.S. __, __, 131 S. Ct. 871, 880 (2011) (quoting Auer v. Robbins, 519 U.S. 452, 461 (1997)). The Circuit has noted an additional requirement of so-called Auer deference: "the language of the regulation in question must be ambiguous, lest a substantively new rule be promulgated under the guise of interpretation." Drake v. FAA, 291 F.3d 59, 68 (D.C. Cir. 2002).

Here, because the meaning of the term "findings" is not evident from the text of § 1301.36(e) alone and is open to more than one reasonable interpretation, it is ambiguous. See Humanoids Group v. Rogan, 375 F.3d 301, 306 (4th Cir. 2004) (finding regulatory language "ambiguous" where its "precise import" was "'not free from doubt'" (quoting Martin v. Occup'l Safety & Health Review Comm'n, 499 U.S. 144, 150 (1991)). And the reading offered by the DEA, through government counsel, is not plainly erroneous or inconsistent with the regulation. Indeed, it is plausible for the DEA to conclude that just as a show cause order need only contain a "summary of the matters of fact and law asserted," 21 C.F.R. § 1301.36(e), an immediate suspension order need only contain a "summary" of the Administrator's legal and factual "findings regarding the danger to public health or safety," id. § 1301.36(e), particularly in light of the interrelationship between show cause and immediate suspension orders. This reading is also consistent with the nature of an ISO—an emergency order issued based upon preliminary findings made prior to an administrative hearing—because a "summary" of the Administrator's

findings comports with the urgent nature of the agency action being taken. See Khalid v. Holder, 655 F.3d 363, 367 (5th Cir. 2011) ("[A] statutory provision cannot be read in isolation, but necessarily derives meaning from the context provided by the surrounding provisions, as well as the broader context of the statute as a whole.").

Nor is there a serious "reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question." Auer, 519 U.S. at 461. As Cardinal correctly notes, see Cardinal's Suppl. Reply at 9, the Court should treat DEA's reading of its regulation with some skepticism out of concern that it may be a mere "post hoc rationalization advanced by an agency seeking to defend past agency action against attack," Auer, 519 U.S. at 462. However, "[w]here the agency's litigation position is consistent with its past statements and actions, there is good reason for the court to defer, for then the position seems 'simply to articulate an explanation of longstanding agency practice.'" Drake, 291 F.3d at 69 (quoting Akzo Nobel Salt, Inc. v. Fed. Mine Safety and Health Review Comm'n, 212 F.3d 1301, 1304 (D.C. Cir. 2000)); see also Ass'n of Bituminous Contractors, Inc. v. Apfel, 156 F.3d 1246, 1252 (D.C. Cir. 1998) ("[T]he Commissioner had not, prior to this litigation, carefully explained why he believes that coal contractors may be assigned responsibility under the statute. Yet the Commissioner has consistently made assignments to coal construction companies under the Coal Act, and in doing so must have interpreted the Coal Act to allow that. This litigation offers the Commissioner his first opportunity to explain his decision. We defer to counsel's explanation because it represents the agency's fair and considered judgment." (internal quotation marks and citation omitted)). This rationale applies here. As noted, this case appears to be the first time in which a party has challenged the adequacy of the DEA's "findings" under 1301.36(e), and thus the first opportunity for the DEA to defend its reading of the "findings"

language. It has, moreover, been a "longstanding agency practice" for the DEA to combine show cause and immediate suspension orders, Gov't's Suppl. Brief at 3, and to include the following boilerplate sentence in the introduction of those orders: "The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts," see ISO at 1; AR at 87-99 (examples of several show cause and immediate suspension orders from 2007) (emphasis added). This "non-exhaustive summary of facts" language is consistent with the reading of the regulation currently being advanced by the DEA before this Court. For these reasons, the Court deems it appropriate to apply Auer deference to the DEA's reading of § 1301.36(e).

Applying that reading here, a summary of the factual and legal grounds for the Administrator's determination is all that is needed to provide the required "statement of . . . findings regarding the danger to public health or safety." 21 C.F.R. § 1301.36(e). The ISO passes muster under that standard, for it sets forth the following findings (many of which are couched in conclusory terms): the drastically increasing and large volumes of oxycodone distributed to Cardinal Lakeland's top four customers from January 2008 to December 2011, the readily available public information regarding the oxycodone epidemic in Florida, Cardinal's violations of the 2008 Memorandum of Agreement, Cardinal's failure to conduct due diligence, Cardinal's failure to detect and report suspicious orders, and Cardinal's failure to maintain adequate anti-diversion controls. See ISO ¶¶ 3-5. Accordingly, Cardinal's challenge to the ISO

based on the agency's alleged inadequate statement of findings under § 1301.36(e) is not likely to succeed on the merits.[12]

3. Cardinal's Procedural Due Process Claim (Count II)

Cardinal also claims that the ISO deprived it of its property interest in its DEA registration without due process of law. Compl. ¶¶ 53-58. Cardinal acknowledges that § 824(d) authorizes the DEA to suspend a DEA registration without notice and an opportunity to be heard if the Administrator finds that continued registration poses an imminent danger. Cardinal's Reply at 6. Yet, Cardinal claims that because registrants have a protected property interest in their DEA registrations, an actual imminent danger must be shown by the government in order to satisfy requirements of due process. Cardinal's Mem. at 15. In other words, Cardinal contends that unless the Court determines that a threat of imminent danger presently exists, due process requires that the DEA grant Cardinal a hearing prior to suspending its registration. See Cardinal's Reply at 7 (arguing that the "'imminent danger' standard . . . is a due process floor," and that "after satisfying itself that the agency provided a reasonable explanation [under the APA], the Court must also conclude that a need for emergency intervention actually exists," in order to satisfy due process).

[12] Even if the ISO's statement of "findings" was not adequate to satisfy the DEA regulation, this would not have materially affected the outcome of this case. Specifically, if the Court had determined that the ISO's findings were not adequate to satisfy § 1301.36(e), the Court still would have denied Cardinal's preliminary injunction motion based on its failure to show irreparable injury. To be sure, even without a showing of irreparable injury, if the Court had declared that the ISO did not satisfy § 1301.36(e), Cardinal would have been entitled to relief under the APA. See Am. Bioscience, 269 F.3d at 1084 ("[W]hether or not appellant has suffered irreparable injury, if it makes out its case under the APA it is entitled to a remedy."). But assuming that relief would have consisted of the ISO being vacated and the case being remanded to the agency, the DEA, on remand, would have been free to issue a new ISO to Cardinal Lakeland, presumably including the same information contained in Administrator Leonhart's declaration. Here, the Court deemed the ISO inadequate to conduct judicial review under the APA, and thus remanded to the agency for further explanation. Although the Court did not vacate the ISO in remanding to the DEA, enforcement of the ISO was enjoined as a result of the Court's temporary restraining order, which in effect had the same impact as vacating the ISO. Thus, in all likelihood, the same result ultimately would have been rendered by the Court regardless of whether the ISO was deemed compliant with § 1301.36(e).

This claim is likely to fail for multiple reasons. First, it conflicts with the statute. Section 824(d) provides that the Administrator "may, in h[er] discretion, suspend any registration . . . in cases where [s]he finds that there is an imminent danger to the public health or safety." 21 U.S.C. § 824(d) (emphasis added). The words "[s]he finds" unambiguously indicate that the Administrator, not the Court, is charged with assessing whether there is an "imminent danger" justifying immediate suspension of a DEA registration. Cardinal would have the Court rewrite the statute to only permit an ISO to issue "where there . . . is an imminent danger," based on such a finding by the Court, but that is not what the law provides.

Second, in view of the particular regulatory scheme at issue here, Cardinal's due process claim is not likely to succeed. A due process challenge entails a two-step analysis: (1) whether the plaintiff has been deprived of a protected interest in property or liberty; and (2) if such a deprivation is shown, whether the government's procedures comport with due process. General Elec. Co. v. Jackson, 610 F.3d 110, 117 (D.C. Cir. 2010). Regarding step one, no one disputes that Cardinal was deprived a protected property interest in its DEA registration. Proceeding to step two, there is a "well-recognized principle that due process permits [the government] to take summary administrative action without pre-deprivation process, but subject to a prompt post-deprivation hearing, where such action is needed to protect public health and safety." DiBlasio v. Novello, 413 Fed. App'x 352, 357 (2d Cir. 2011) (citing Gilbert v. Homar, 520 U.S. 924, 930-33 (1997); Hodel v. Va. Surface Mining & Reclamation Ass'n, 452 U.S. 264, 300 (1981)); Soranno's Gasco, Inc. v. Morgan, 874 F.2d 1310, 1318 (9th Cir. 1989) ("It is well-settled that protection of the public interest can justify an immediate seizure of property without a prior hearing."). The statutory scheme in this case, the CSA, comports with "this well-recognized principle," insofar as it permits a pre-hearing suspension based on a finding of "imminent danger

to the public health and safety," 21 U.S.C. § 824(d), and the DEA's regulations provide registrants with a prompt post-deprivation hearing at their request, see 21 C.F.R. § 1301.36(h) ("Any registrant whose registration is suspended under paragraph (e) of this section may request a hearing . . . at a time earlier than specified in the order to show cause. . . . This request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.").

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.[13] 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.

In short, Cardinal's procedural due process claim is not likely to succeed on the merits.

[13] In support of Cardinal's claim that the Court should make a de novo determination as to whether an "imminent danger" actually exists in evaluating its due process claim, Cardinal cites J.J. Cassone Bakery Inc. v. NLRB, 554 F.3d 1041 (D.C. Cir. 2009). There, the court noted that "in contrast with other aspects of [an agency's] decision, which we review deferentially, 'a reviewing court owes no deference to the agency's pronouncement on a constitutional question.'" Id. at 1044 (citation omitted). Yet, the Court does not discern how the DEA's issuance of the ISO or its finding of "imminent danger" here could be construed as a "pronouncement on a constitutional question" subject to de novo review. Cardinal's unexplained citation to this case is unavailing.

C. Balance of Hardships and the Public Interest

Having found no likelihood of success on the merits on any of Cardinal's claims and the absence of irreparable harm, it is not necessary to engage in a lengthy discussion of the remaining two factors, so the Court will give them only brief consideration.

The balance of hardships weigh in the government's favor because Cardinal's showing of irreparable harm is weak at best, whereas the government has a strong interest in enforcing the CSA and ensuring that pharmaceutical drugs are not improperly diverted while the administrative proceedings before the DEA are pending.

The public interest factor weighs in favor of both parties to some degree. On the one hand, Cardinal makes a substantial showing that there is a public interest in legitimate patients obtaining needed medications in a timely manner. See Cardinal's Reply at 24. On the other hand, there is a weighty public interest in preventing the illegal diversion of prescription drugs, particularly in light of the rampant and deadly problem of prescription drug abuse in Florida. In addition, the facts that other distributors are available to service Cardinal Lakeland's customers in Florida, and that Cardinal itself will be able to serve these customers from other facilities (albeit with some delays in shipments and additional shipping costs), undercut Cardinal's claim that a preliminary injunction is necessary to serve the public interest. Thus, this factor tips in the government's favor.

IV. CONCLUSION

The balance of the preliminary injunction factors weighs in favor of denying Cardinal's motion. Without a showing of likely success on the merits or irreparable harm, Cardinal cannot obtain preliminary injunctive relief. And for what it is worth, the balance of hardships and public interest also weigh in the government's favor. Accordingly, because Cardinal has failed

to make an adequate showing on any of the four preliminary injunction factors, its motion for a preliminary injunction must be denied.

SO ORDERED this 7th day of March, 2012.[14]

REGGIE B. WALTON
United States District Judge

[14] An order consistent with this memorandum opinion was previously issued by the Court on February 29, 2012.