UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HOLIDAY CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 12-191 (RBW)
ERIC H. HOLDER, JR., et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

The plaintiffs,[1] Holiday CVS, L.L.C., doing business at two of its pharmacies as CVS Pharmacy Numbers 219 and 5195, bring this action under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-706 (2006), challenging two Orders to Show Cause and Immediately Suspend Registrations issued by the Drug Enforcement Administration ("DEA") on February 2, 2012. Amended Complaint ("Am. Compl.") ¶ 1. The case came before the Court on March 13, 2012, on (1) the Plaintiffs' Motion to Strike or, in the Alternative to Cross Examine Affiant, and (2) the Plaintiffs' Motion for a Preliminary Injunction. Both motions were opposed by the government. After carefully considering the parties' submissions and the arguments made by counsel at the first hearing on the plaintiffs' motions on March 2, 2012, and the second hearing on March 13, 2012,[2] the Court denied the plaintiffs' motions at the March 13, 2012 hearing.

[1] Although it appears from the caption that there is only one plaintiff in this action, Holiday CVS, L.L.C., throughout their briefs the "plaintiffs" refer to themselves in plural terms, presumably because the case involves two pharmacies owned and operated by plaintiff Holiday CVS, L.L.C. The Court will use the plaintiffs' terminology in this memorandum opinion.

[2] In addition to the complaint and the plaintiffs' motions, the Court considered the following filings in rendering its decision: the plaintiffs' Memorandum of Points and Authorities in Support of Motion for Preliminary Injunction ("Pls.' Mem."); the Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction ('Gov't's Opp'n"); the (continued . . .)

This memorandum opinion memorializes the oral rulings issued at that hearing and explains further the reasons for the Court's denial of the plaintiffs' motions.

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 distributing controlled substances must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

Under the DEA's regulations, registered pharmacies must "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). And while "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," a "corresponding responsibility rests with the pharmacist who fills the prescription." Id. § 1301.04(a). Pharmacies are therefore required to ensure that prescriptions for controlled substances are "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Id.

(. . . continued)
Plaintiffs' Reply in Support of Motion for a Preliminary Injunction ("Pls.' Reply"); the Statement of Points & Authorities in Support of Plaintiffs' Motion to Strike or, in the Alternative, to Cross Examine Affiant ("Pls.' Mot. to Strike Mem."); the Defendants' Response to Order to Show Cause Dated February 28, 2012 ("Gov't's Resp."); and the Administrative Record ("AR").

The DEA has authority to revoke or suspend a registration it has issued for a variety of reasons, including on the grounds that a registrant "has committed such acts as would render his [or its] 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).

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 [her] discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where [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

Plaintiff Holiday CVS, L.C.C. is a subsidiary of CVS Caremark Corporation, which is the largest pharmacy health care provider in the United States and is ranked twenty-first in the Fortune 500 list for 2011. Gov't's Opp'n at 30. At issue in this case are two CVS retail pharmacy stores located in Sanford, Florida ("CVS 219" and "CVS 5195"; collectively, the "CVS pharmacies"). Pls.' Mem. at 6. The CVS pharmacies are registered to dispense Schedule II-V controlled substances, as classified by the CSA. Id. Neither pharmacy has previously been the subject of disciplinary action for failing to comply with the controlled substance laws. Id.

The DEA's investigation of CVS 219 and CVS 5195 evolved from the agency's investigation of the pharmacies' main distributor, Cardinal Health, Inc. ("Cardinal").[3] Gov't's Opp'n at 8. This investigation revealed that from January 1, 2008, to October 31, 2011, Cardinal's distribution facility in Lakeland, Florida, sold over 12.8 million dosage units of oxycodone (a Schedule II drug) to its top four pharmacy customers. Id. Two of these top four customers were the CVS pharmacies. Id.

The DEA executed administrative inspection warrants at the CVS pharmacies on October 18, 2011. Pls.' Mem. at 7. The warrants sought documents relating to the dispensing practices and volumes of oxycodone sold at the two pharmacies. Id. The DEA then served administrative subpoenas on the two pharmacies on October 25, 2011, seeking additional documents regarding the prescribing physicians whose patients filled prescriptions at the two pharmacies. Id. The

[3] Cardinal filed a similar case in this Court, also seeking a preliminary injunction of an immediate suspension order issued by the DEA. The Court denied Cardinal's preliminary injunction motion on February 29, 2012, which was later memorialized in a memorandum opinion entered on March 7, 2012. See Cardinal Health, Inc. v. Holder, __ F. Supp. __, __, 2012 WL 718486, at *1 (D.D.C. 2012). Because the issues presented in the two cases overlap in several respects, the Court will frequently reference its Cardinal decision in this memorandum opinion.

DEA also interviewed employees at both pharmacies, as well as individuals with supervisory responsibility over the pharmacies. Id.

After the DEA commenced its investigation, the plaintiffs took a number of remedial steps in response to the agency's concerns. First, in November 2011, the CVS pharmacies suspended filling Schedule II drug prescriptions of 22 physicians for whom the DEA had requested dispensing information from CVS. Id.; Gov't's Opp'n at 23. These 22 physicians accounted for a substantial majority of the oxycodone prescriptions dispensed by the pharmacies. Pls.' Mem. at 7. Second, CVS issued revised dispensing guidelines in January 2012 for filling pain management prescriptions, which have been implemented at CVS pharmacies nationwide. Id. at 8. Third, the CVS pharmacies limited the "geographic area for prescribers and patients for which they will fill prescriptions." Id. Fourth, they reviewed "with pharmacists the regulatory requirements relating to pharmacists' corresponding responsibility to fill prescriptions for a legitimate medical purpose." Id. And fifth, the pharmacies retained "a third party consultant to review recordkeeping and security at both pharmacies." Id. Since the DEA served the warrants in October 2011, dispensing volumes for oxycodone at the two CVS pharmacies have decreased by 86%. Id. at 9.

The DEA issued immediate suspension orders to the CVS pharmacies on February 2, 2012. See Pls.' Mem., Exhibits ("Exs.") A and B (Orders to Show Cause and Immediate Suspension of Registration issued to CVS 219 and CVS 5195 ("CVS 219 ISO" and "CVS 5195 ISO"; collectively, "ISOs")).[4] The allegations set forth in the ISOs are outlined in detail below. Briefly stated, they allege that between 2008 and 2011, the CVS pharmacies purchased

[4] For ease of reference, each ISO will be cited in this opinion by listing "CVS 219 ISO" or "CVS 5195 ISO," followed by the corresponding paragraph number. And because the two ISOs contain nearly identical allegations, they will be collectively cited as the "ISOs."

enormous quantities of oxycodone that "considerably surpassed the amount of oxycodone ordinarily purchased by a retail pharmacy." ISOs ¶ 3. They further assert that since at least 2010, the pharmacies had dispensed controlled substances to customers "under circumstances indicating that the drugs" were illegally diverted. Id. ¶ 4. Finding that this conduct violated the CSA and that continued registration of the CVS pharmacies posed an imminent danger to the public health and safety, the DEA immediately suspended the pharmacies' registrations pursuant to 21 U.S.C. § 824(d). Id. at 2-3.

The plaintiffs filed a complaint and motion for temporary restraining order with this Court on February 6, 2012. Their complaint challenges the ISOs under the APA on the grounds that the orders (1) were issued without statutory authority (Count I), Compl. ¶¶ 43-49; (2) deprived the plaintiffs of their constitutional right to due process of law (Count II), id. ¶¶ 50-55; (3) were arbitrary and capricious (Count III), id. ¶¶ 56-60; and (4) contained inadequate findings to justify an immediate suspension (Count IV), id. ¶¶ 61-64.

After holding a hearing on the plaintiffs' motion for a temporary restraining order on February 7, 2012, and while the undersigned member of this Court was absent from the jurisdiction, Judge Amy Berman Jackson of this Court granted the plaintiffs' motion by order issued that same date. See February 7, 2012 Order, Holiday CVS, L.L.C. v. Holder, Civil Action No. 12-191 (RBW) (D.D.C.). The plaintiffs then moved for a preliminary injunction on February 17, 2012, seeking to enjoin enforcement of the ISOs pending resolution of the administrative proceedings before the DEA. With its opposition to the plaintiffs' preliminary injunction motion, the government submitted declarations of two DEA officials: Deputy Assistant Administrator Joseph Rannazzisi and Administrator Michele Leonhart (the "DEA declarations"). The government purportedly offered these declarations to "distill the voluminous

evidence compiled in the course of DEA's investigation of CVS, and summarize for this Court what informed the Administrator's ultimate decision to issue the ISOs." Gov't's Opp'n at 25 n.8. The plaintiffs thereafter filed a motion on February 28, 2012, to strike the DEA declarations or, in the alternative, to cross examine Administrator Leonhart.

The Court will first address the plaintiffs' motion to strike, and then turn to their preliminary injunction motion.

II. The Plaintiffs' Motion to Strike or, in the Alternative, to Cross Examine Affiant

The plaintiffs move to strike the DEA declarations on the following grounds. First, because the DEA regulations require that ISOs contain "a statement of [the Administrator's] findings regarding the danger to public health or safety," 21 C.F.R. § 1301.36(e), and because the ISOs themselves state that the Administrator's imminent danger findings are made "[u]nder the facts and circumstances described herein," the plaintiffs argue that the ISOs must stand or fall solely based upon the findings stated within the orders. See Pls.' Mot. to Strike Mem. at 4-7. Second, the plaintiffs maintain that the DEA declarations are impermissible post hoc rationalizations for the Administrator's decision to issue the ISOs. Id. at 8. Third, they argue that the DEA declarations include inadmissible hearsay and offer improper testimony regarding "ultimate issues" in this case. Id. at 8-10. In the alternative to striking the declarations, the plaintiffs request that they be permitted to cross examine Administrator Leonhart as an adverse witness at the hearing on the plaintiffs' preliminary injunction motion. Id. at 10-12.

The Court addressed these issues at the hearing on March 2, 2012, during which it expressed its reluctance to consider the DEA declarations without having the administrative record to confirm that the declarations comported with the materials that were before Administrator Leonhart at the time she issued the ISOs. The Court was also hesitant to assess

the merits of the plaintiffs' APA claim based only upon the selective portions of the administrative record that the parties had submitted to the Court at that time. See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 420 (1971) (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") (emphasis added)); Walter O. Boswell Mem. Hosp. v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision."). Accordingly, at the conclusion of the March 2, 2012 hearing, the Court remanded the case to the DEA "for compilation of an administrative record," March 5, 2012 Order, Holiday CVS, L.L.C. v. Holder, Civil Action No. 12-191 (RBW) (D.D.C.), which the DEA thereafter submitted to the Court on March 5, 2012. Then, at the hearing on March 13, 2012, the Court denied the plaintiffs' motion to strike. The following analysis memorializes the oral rulings issued at the March 13, 2012 hearing and explains further the reasons for the Court's denial of the plaintiffs' motion.

A. Consideration of Materials Outside the ISOs

As an initial matter, the Court rejects the plaintiffs' argument that the ISO must stand or fall solely based upon the findings stated therein. First, nothing in the DEA regulation requires the Administrator's imminent danger findings to be comprehensive; it only requires that the ISO contain "a statement of [the Administrator's] findings regarding the danger to public health or safety." 21 C.F.R. § 1301.36(e). Second, this Court already determined in Cardinal that the government's reading of § 1301.36(e) as requiring only a non-exhaustive summary of the factual and legal basis for the immediate suspension decision is entitled to deference, and it will adhere to that ruling here. See __ F. Supp. 2d at __, 2012 WL 718486, at *21-*22 (finding that the

DEA's interpretation of its own ambiguous regulation, advanced in a legal brief, was entitled to deference under Auer v. Robbins, 519 U.S. 452, 461 (1997)). Third, while there is some boilerplate language in the ISOs suggesting that the Adminsitrator's findings of imminent danger are limited to the statements within the ISOs, other parts of the ISOs state that the findings are "non-exhaustive" and "include, but are not limited to" the circumstances stated therein. ISOs at 1, ¶ 4. As in Cardinal, the Court declines to interpret the boilerplate language in the ISOs relied upon by the plaintiffs "to restrict the Administrator's ability to offer further explanation regarding her findings of imminent danger." __ F. Supp. 2d at __, 2012 WL 718486, at *11 n.9.

The Court also rejects the plaintiffs' evidentiary objections to the DEA declarations. The Supreme Court has observed that the decision whether to grant a preliminary injunction is often based on "procedures that are less complete than a trial on the merits." Univ. of Tex. v. Camenisch, 451 U.S. 390, 395 (1981). Following this principle, courts generally permit consideration of hearsay evidence in connection with preliminary injunction motions. E.g., Mullins v. City of New York, 626 F.3d 47, 52 (2d Cir. 2010) (collecting cases from six other circuits). Furthermore, regarding the plaintiffs' request to strike "ultimate issue" testimony contained in Administrator Leonhart's declaration (e.g., Leonhart's statements that the ISOs' findings were "sufficient"), the Court accords no evidentiary value to these conclusory statements and thus disregards them for the purposes of adjudicating the plaintiffs' preliminary injunction motion.

The most substantial challenge raised by the plaintiffs is their claim that the DEA declarations contain impermissible post hoc rationalizations. Under the APA, "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 therefore forbids "ex post supplementation of the record by either side." Walter O. Boswell Mem. Hosp., 749 F.2d at 793 (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).

Nevertheless, when faced with an inadequate administrative record, the "record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency," but "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 (quoting Envtl. Defense Fund v. Costle, 657 F.2d 275, 285 (D.C. Cir. 1981)) (alteration in original); see also Consumer Fed'n of Am. & Pub. Citizen v. U.S. Dep't of Health & Human Servs., 83 F.3d 1497, 1507 (D.C. Cir. 1996) (noting that while the record may be supplemented with "additional background information about the agency's basic rationale," the agency may not submit affidavits offering an "entirely new theory"); Costle, 657 F.2d at 286 ("If anything, a judicial venture outside the record can only serve either as background information, or to determine the presence of the requisite fullness of the reasons given."). And when there is a "contemporaneous explanation of the agency decision . . . [that] indicate[s] the determinative reason for the final action taken[,] . . . [t]he validity of the [agency's] action must stand or fall on the propriety of that finding." Camp, 411 U.S. at 143.

Here, the ISOs plainly were "contemporaneous explanation[s]" for the Administrator's actions, and reveal the following factors that informed the Administrator's "imminent danger" finding: (1) the large and increasing amounts of oxycodone purchased by the CVS pharmacies,

ISOs ¶¶ 2-3; (2) several physicians whose customers filled prescriptions at the CVS pharmacies were under investigation or subjected to disciplinary action for dispensing illegitimate prescriptions for controlled substances, id. ¶ 4(a); (3) the pharmacists in charge at both stores admitted to DEA investigators to dispensing controlled substances under circumstances where they knew or should have known that the substances were abused or diverted by the customer, id. ¶ 4(b); (5) the specific guidance provided to CVS by the DEA (that allegedly was disregarded), id. ¶ 5; and (6) the public information readily available regarding the oxycodone epidemic in Florida, id.

Upon close inspection, the Court finds that many of the statements in the DEA declarations are merely "explanatory" of and provide "background information" for the contemporaneous findings in the ISOs. The DEA declarations are also supported by the certified administrative record produced by the DEA,[5] thus corroborating the Administrator's sworn statement that the circumstances described in her declaration "formed the basis for [her] decision to issue the ISOs to CVS 5195 and CVS 219" on February 2, 2012. Gov't's Opp'n, Declaration of Michele M. Leonhart ("Leonhart Decl.") ¶ 12.[6] The Court thus deems it appropriate to consider these statements in assessing the likelihood of success of the plaintiffs' APA claims. The Court will, moreover, consider statements in the DEA declarations that provide "evidence of whether all relevant factors were examined by the agency," AT&T Info. Sys. Inc., 810 F.2d at

[5] Although the declarations are post hoc in the sense that they were issued after the agency's decision and thus should be "viewed critically," Overton Park, 401 U.S. at 420, the Court is able to critically assess the declarations by comparing them to the administrative record that was before the agency at the time it issued the ISOs.

[6] For ease of reference, this document will be cited as the "Leonhart Decl.," followed by the corresponding paragraph number.

1236, particularly since the plaintiffs claim that the Administrator failed to adequately consider all such factors.[7] Accordingly, the plaintiffs' motion to strike the DEA declarations is denied.

B. The Plaintiffs' Alternative Request to Cross Examine Administrator Leonhart

The Court also denies the plaintiffs' alternative request to cross examine Administrator Leonhart because "such inquir[ies] into the mental processes of administrative decisionmakers [are] usually to be avoided," Overton Park, 401 U.S. at 420 (citing United States v. Morgan, 313 U.S. 409, 422 (1941)), and the plaintiffs have showed no reason to depart from that principle here. In addition, Local Civil Rule 65.1(d) reflects a policy disfavoring the presentation of live testimony at hearings on preliminary injunction motions, and gives the Court discretion in deciding whether to permit such testimony. See Local Civ. R. 65.1(d) (providing that "[t]he practice in this jurisdiction is to decide preliminary injunction motions without live testimony where possible," and granting the Court discretion "to decline to hear witnesses at the hearing where the need for live testimony is outweighed by considerations of undue delay, waste of time, or needless presentation of cumulative evidence."). For these policy reasons and the fact that the Court has determined that the representations in Administrator Leonhart's declaration are supported by the administrative record that existed when the ISOs were issued, cross-examination of the Administrator is unnecessary.

[7] It bears emphasizing that although the plaintiffs' motion to strike urges the Court not to look beyond the findings in the ISOs in evaluating the DEA's actions, see Pls.' Mot. to Strike Mem. at 7, the plaintiffs' preliminary injunction motion asks the Court to do just the opposite in regards to evidence they request the Court to consider. Namely, the plaintiffs challenge the DEA's finding of "imminent danger" on the grounds that after the DEA served their administrative inspection warrants in October 2011, the CVS pharmacies "took decisive, effective action to address the issues raised by [the] DEA," and the ISOs ignore these facts. Pls.' Mem. at 14-17. Of course, since these remedial measures are not mentioned in the ISOs, the Court necessarily has to look outside of the ISOs to consider the plaintiffs' arguments. This serves only to confirm the need to consider materials outside of the ISOs to determine "whether all relevant factors were examined by [the] agency." AT&T Info. Sys. Inc., 810 F.2d at 1236.

III. The Plaintiffs' Motion for a Preliminary Injunction

"'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).[8]

[8] 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 decide 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 (continued . . .)

A. Likelihood of Success on the Merits

The plaintiffs raise three challenges to the ISO in their amended complaint. First, they claim that the DEA's issuance of the ISO violated various provisions of the APA. See Am. Compl. ¶¶ 43-49, 56-60. Second, they allege 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. ¶¶ 61-66. Third, they assert that the DEA's issuance of the ISOs deprived them of due process in violation of the Fifth Amendment of the United States Constitution. See id. ¶¶ 50-55; Pls.' Mem. at 25-27. The Court will address these claims in turn.

1. The Plaintiffs' APA Claims Challenging the Issuance of the ISOs (Counts I and III)

a. 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 Court adopted this position in Cardinal and adheres to it now. See __ F. Supp. 2d __, 2012 WL 718486, at *9. 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 the CVS pharmacies'

(. . . continued)
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.

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 therefore "presume the validity of agency action." Am. 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).

b. Whether the DEA's Actions Were Arbitrary and Capricious

The ISOs identify several factors that formed the basis for the Administrator's immediate suspension decision, which are amplified by the DEA declarations and supported by the administrative record. When viewed collectively, these factors demonstrate that the ISOs had a reasoned basis and were not arbitrary or capricious.

i. The Rampant Problem of Oxycodone Abuse in Florida.

The ISOs note that the "public information readily available regarding the oxycodone epidemic in Florida" played a role in the Administrator's immediate suspension decision. ISOs ¶ 5; see also AR at 8190-8245 (Florida Department of Law Enforcement 2010 Report on Drugs

Identified in Deceased Persons by Florida Medical Examiners); id. at 8192 (listing oxycodone as one of the "four most frequently occurring drugs found in decedents" statewide in 2010); id. at 8391-8392 (July 1, 2011 Press Release from Florida Department of Health declaring "Public Health Emergency Regarding Prescription Drug Abuse Epidemic" and noting that "[m]ore [o]xycodone is dispensed in the state of Florida than in the remaining states combined."). Administrator Leonhart's declaration adds that she has "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. Leonhart Decl. ¶ 8. The Court finds this information highly relevant in assessing the reasonableness of the DEA's decision to issue the ISOs. Indeed, it lays 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.

ii. Large and Increasing Volumes of Oxycodone.

The ISOs assert that the CVS pharmacies dispensed "enormous quantities of oxycodone" that "considerably surpassed the amount of oxycodone ordinarily purchased by a retail pharmacy." ISOs ¶ 3. Specifically, the ISO for CVS 219 alleges that between January 1, 2008, and December 31, 2011, the store "purchased over 5.8 million dosage units of oxycodone from its distributors." CVS 219 ISO ¶ 2. From 2008 to 2009, the store's oxycodone purchases increased by 75%, and from 2009 to 2010, its oxycodone purchases increased by 62%. Id. ¶ 3. In 2011 alone, the pharmacy "purchased over 1.8 million dosage units of oxycodone." Id. Similarly, the ISO for CVS 5195 asserts that between January 1, 2008, and December 31, 2011, the store "purchased over 2.2 million dosage units of oxycodone." CVS 5195 ISO ¶ 2. The ISO

notes increases in oxycodone purchases of 56% from 2008 to 2009, and 748% from 2009 to 2010. Id. ¶ 3. And the pharmacy "purchased over 1.2 million dosage units of oxycodone" in 2011 alone. Id.; see also AR at 3637-3736 (detailing purchase history of oxycodone at the CVS pharmacies).

Administrator Leonhart found these volumes "alarming." Leonhart Decl. ¶ 20. She "considered it to be highly suspect that two pharmacies in a city of only 53,570 residents could alone be dispensing over 8 million dosage units over an approximately three year period." Id. ¶ 22. Again, this determination is entitled to deference from the Court.

iii. Specific Guidance from the DEA.

The ISOs claim that the two CVS pharmacies failed to fulfill their statutory obligations despite "specific guidance provided" by the DEA. ISOs ¶ 5. Regarding this "specific guidance," Administrator Leonhart had information before her indicating that DEA officials met with representatives of CVS twice—first in December 2010 and again in August 2011—"to discuss the recent diversion trends in Florida, primarily the pill mill epidemic." Leonhart Decl. ¶ 15.[9] The DEA purportedly stressed to CVS at these meetings that "its pharmacies located in Sanford, Florida[, i.e., CVS 219 and CVS 5195,] were dispensing an alarming volume of oxycodone." Id.; see also AR at 3737-3740 (internal DEA email chain and summary document regarding meetings with CVS representatives). Despite this guidance, Leonhart found that the CVS pharmacies "continued to dispense oxycodone at an alarming rate." Leonhart Decl. ¶ 15.

[9] Plaintiffs' counsel clarified at the March 13, 2012 hearing that CVS, not the DEA, initiated the December 2010 meeting. But regardless of who prompted the meeting, the plaintiffs do not dispute that the DEA raised concerns at the meeting regarding the "alarming" volumes of oxycodone being distributed by the plaintiffs.

iv. Evidence of Illegitimate Prescriptions Being Dispensed at the CVS Pharmacies and Failure to Detect Warning Signs.

The ISOs allege that "[s]ince at least 2010, CVS has dispensed controlled substances to customers under circumstances indicating that the drugs are diverted from legitimate channels, misused[,] or abused." ISOs ¶ 4. As an example of these "circumstances," the ISOs assert that the "DEA and the State of Florida have taken criminal, civil[,] or administrative action against at least 20 physicians, whose customers fill their controlled substances at [the CVS pharmacies] for activities resulting in the diversion of controlled substances, including for inappropriately prescribing excessive and inappropriate quantities of controlled substances and issuing prescriptions" for illegitimate purposes. ISOs ¶ 4(a). Administrator Leonhart viewed this evidence as supporting the conclusion that the CVS pharmacies were "contributing to the pharmaceutical drug diversion epidemic ravaging Florida." Leonhart Decl. ¶ 18.

As another example of the circumstances indicating that the CVS pharmacies were dispensing illegitimate prescriptions, the ISOs recount DEA interviews with the "Pharmacist[s] in Charge" at CVS 219 and CVS 5195. ISOs ¶ 4(b). The CVS 219 ISO alleges that the pharmacist in charge of that store, Paras Priyadarshi, "admitted to DEA investigators that CVS 00219 dispensed controlled substances where the pharmacy knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose." CVS 219 ISO ¶ 4(b). The CVS 5195 ISO indicates that the pharmacist in charge of that store, Jessica Merrill, made similar admissions, and "further stated that she set daily limits of how many oxycodone prescriptions CVS 05195 would fill each day to ensure that she had enough oxycodone for the 'real pain patients.'" CVS 5195 ISO ¶ 4(b); see also AR at 277-281 (Report of Investigation re Interview of Paras Priyadarshi on October 28, 2011); id. at 239-243 (Report of Investigation re Interview of Jessica Merrill on October 18, 2011).

Administrator Leonhart was made aware of these interviews before she issued the ISOs and they "gravely concerned" her. Leonhart Decl. ¶¶ 16-17. In particular, she learned that during her interview with DEA officials, Ms. Merrill "described many of her customers as 'shady' and admitted that some of the oxycodone prescriptions she filled were probably not legitimate." Id. ¶ 17. Administrator Leonhart also highlighted Ms. Merrill's statement regarding her imposition of daily limits on oxycodone prescriptions so she had enough oxycodone for "real pain patients." Id. As for Mr. Priyadarshi, she found that he "did not exhibit an understanding of basic warning signs of diversion." Id. "He reported, among other things, that customers often request certain bands of oxycodone using street slang; that he did not see anything wrong with two individuals living at the same address receiving the exact same 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. According to Administrator Leonhart, "the results of th[e]se interviews factored heavily into [her] conclusion that CVS 5195 and CVS 219 posed a high risk of diversion." Id. And, at least as of the date when the ISOs were issued, she noted that Mr. Priyadarshi and Ms. Merrill continued to be employed at the CVS pharmacies. See id ¶¶ 12, 19.

v. The Plaintiffs' Remedial Efforts.

The plaintiffs contend that the Administrator ignored remedial efforts undertaken by the CVS pharmacies that diminished any threat to the public health and safety, including the following: (1) after the DEA executed the Administrative Inspection Warrants in October 2011, CVS suspended dispensing Schedule II drugs in Florida for prescriptions written by 22 physicians; (2) the pharmacies implemented revised dispensing protocols in January 2012; and (3) the volume of oxycodone dispensed at the CVS pharmacies decreased by at least 86% from

October to December 2011. See Pls.' Mem. at 13-17. The DEA declarations indicate that the agency considered these mitigating factors before issuing the ISOs, but ultimately concluded that the CVS pharmacies still posed an imminent danger to public health and safety for the following reasons:

- Following the execution of the Administrative Inspection Warrants in October 2011, "[b]oth CVS pharmacies continued to purchase comparatively large amounts of oxycodone through December 2011." Leonhart Decl. ¶ 20. Specifically, Administrator Leonhart was "informed that CVS 219 purchased, on average, nearly 80,000 dosage units of oxycodone per month for the three-month period from October 2011 through December 2011." Id. This amount "exceeded what an average retail pharmacy in Florida purchased in a full year." Id. (emphasis in original). "Similarly, for that same three month period following the issuance of the [Administrative Inspection Warrant], CVS 5195 ordered more than 88,000 dosage units of oxycodone." Id. The Administrator found even these reduced volumes of oxycodone "alarming." Id.
- "In general, [Administrator Leonhart] gives less weight to remedial measures and decreased purchases that occur following the execution of an [Administrative Inspection Warrant]." Id. ¶ 21. This is because, in her experience, "[i]t is not uncommon for registrants to make efforts to cooperate with [the] DEA after coming under investigation." Id. Although she "gave these efforts some weight" in deciding to issue the ISOs, she did "not view them as dispositive evidence" that the CVS pharmacies had brought themselves "into full compliance with the requirements of the CSA, or that [their] continued operation [did] not pose an imminent danger to public health or safety." Id.

- According to Deputy Administrator Rannazzisi, "CVS's November 2011 decision that it would no longer fill Schedule II narcotic prescriptions for twenty-two Florida practitioners . . . was not a proactive measure taken by CVS/Caremark, Inc. after making an independent determination that the twenty-two practitioners at issue may be issuing invalid prescriptions. Rather, it was simply a reaction to heightened scrutiny by [the] DEA, and one made only after [the] DEA requested dispensing information on these very same practitioners." Gov't's Opp'n, Declaration of Joseph Rannazzisi ("Rannazzisi Decl.") ¶ 55; see also AR at 3741-3747 (correspondence between DEA investigator and counsel for CVS from October and November 2011 reflecting CVS's suspension of distribution to twenty-two prescribing doctors identified by the DEA); Leonhart Decl. ¶¶ 11-12 (noting that Rannazzisi conducted the underlying investigation of the CVS pharmacies and that Leonhart relied upon information from Rannazzisi in deciding to issue the ISOs).
- CVS's implementation of revised dispensing guidelines in January 2012 was "granted little weight" by the DEA because (1) "many of the revised guidelines . . . were simply a reiteration of the guidelines listed in CVS/Caremark, Inc.'s previous policies and training"; and (2) "the interviews conducted with employees at CVS 219 and CVS 5195 showed that the pharmacies were dispensing controlled substances even with the existence of the 'warning signs' listed in the company's previous . . . guidelines and training." Gov't's Opp'n, Rannazzisi Decl. ¶¶ 49, 56. Thus, because the CVS pharmacies had failed to follow the dispensing guidelines in the past, "DEA had no reason to believe that the implementation of revised controlled substance dispensing guidelines would do anything to change the practices employed at CVS 219 and CVS

5195."[10] Id. ¶ 56; see also AR at 1378-1379 (December 2010 CVS Dispensing Guidelines); id. at 1381-1442 (various CVS training materials concerning diversion prevention from 2010 and 2011); id. at 1443-1449 (January 2012 CVS Dispensing Guidelines).

- In deciding to suspend the CVS pharmacies' distribution of all controlled substances (rather than just Schedule II substances, such as oxycodone), the Administrator determined that the pharmacies' failings concerning Schedule II drugs were sign of inadequate protocols for lower-schedule drugs as well. Leonhart Decl. ¶ 23. As she concluded, "[o]xycodone is an extremely potent Schedule II narcotic and is one of the most abused prescription drugs in the nation . . . [I]f CVS 5195 and CVS 219 were unwilling or unable to maintain appropriate controls over oxycodone, a potent Schedule II controlled substance, then their handling of controlled substances in lesser scheduled (III through V) was even more suspect." Id.[11]

Having examined the rationale for the Administrator's decision, it is important to emphasize the scope of the Court's review under the APA. Although judicial review under the

[10] In challenging this finding, the plaintiffs maintain that the DEA overlooked that the revised dispensing guidelines were significantly different than the prior guidelines and addressed many of the DEA's concerns. Pls.' Reply at 9-11. Although there were some changes in the guidelines concerning "red flags" of illegitimate prescriptions, it was not arbitrary and capricious for the DEA to conclude that these new guidelines would have been disregarded just as the old ones allegedly were, particularly since the pharmacists-in-charge whom the DEA interviewed in October 2011 remained employed at the two stores. See Leonhart Decl. ¶ 19; 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.").

[11] The plaintiffs also assert that the Administrator's imminent danger finding is undercut by remedial efforts undertaken by the CVS pharmacies after the ISOs were issued, such as their pledge to voluntarily cease distributing Schedule II drugs pending resolution of the administrative procedures before the DEA. Pls.' Mem. at 15. But under the APA, the Court must examine the agency's actions based on the information it had at the time it issued the ISOs. See Walter O. Boswell Mem. Hosp., 749 F.2d at 792-93. Accordingly, the plaintiffs' post-ISO remedial measures are irrelevant to the APA analysis. It should be noted, moreover, that if the plaintiffs' position were correct, any registrant subject to an ISO could voluntarily cease distributing controlled substances and then ask a court to dissolve the ISO because no imminent danger presently exists. That cannot be what Congress envisioned when it conferred immediate suspension authority to the Attorney General.

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 scope of what can amount to "imminent danger," the Act vests the Administrator with discretion to make such determinations. And the statute contemplates that an ISO will be issued in emergency circumstances, prior to an administrative hearing and prior to the development of a formal evidentiary record. Thus, given the degree of discretion accorded to the Administrator as well as the summary and urgent nature of an ISO, the Court's review "must be correspondingly relaxed." Nat'l Cable Tele. Ass'n, 724 F.2d at 181.

Applying these principles here, the DEA's issuance of the ISOs easily passes the arbitrary and capricious standard of review. When viewed collectively, the factors considered by Administrator Leonhart—including (1) the rampant pharmaceutical drug abuse problem in Florida, (2) the large and increasing amounts of oxycodone dispensed at the pharmacies from January 2008 to December 2011, (3) the DEA's earlier specific guidance to CVS that apparently was not heeded, (4) the evidence of illegitimate prescriptions being dispensed at the CVS

pharmacies, and (5) the pharmacists' admitted failure to detect warning signs as recently as October 2011—provided a reasonable basis for her conclusion that the CVS pharmacies' continued registrations 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 43. Furthermore, her consideration and rejection of the CVS pharmacies' remedial efforts shows that she adequately considered all of the available information before rendering her decision. See id.

The plaintiffs raise several challenges to the Administrator's findings, but none are availing. First, they assert that the DEA's allegations regarding past conduct cannot support a finding of imminent danger under § 824(d). Pls.' Mem. at 13-14. For this point, they rely on cases involving a provision of the Prison Litigation Reform Act, id. at 14, which restricts "frequent filer" inmates from filing lawsuits unless they are "under imminent danger of serious physical injury," 28 U.S.C. § 1915(g); see, e.g., Ciarpaglini v. Saini, 352 F.3d 328, 330 (7th Cir. 2003) ("[T]o meet the imminent danger requirement of 28 U.S.C. § 1915(g), . . . [a]llegations of past harm do not suffice; the harm must be imminent or occurring at the time the complaint is filed." (internal quotation marks and citations omitted)). But the plaintiffs overlook a key difference between the two statutes: whereas § 1915(g) of the Prison Litigation Reform Act authorizes courts to determine whether an imminent danger exists, § 824(d) of the CSA vests the Administrator with the authority to make that finding, and courts must review that finding deferentially. See supra at 14 (citing cases stating that the arbitrary and capricious standard of review applies to challenges to ISOs). Doing so here, the Court finds nothing arbitrary and capricious with the Administrator's consideration of sales trends from January 2008 to December

2011 and her reliance on the interviews with CVS pharmacists from October 2011 in support of her finding of imminent danger on February 2, 2012. 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."); cf. Alra Labs. Inc., 54 F.3d at 452 ("An agency rationally may conclude that past performance is the best predictor of future performance.").[12]

Second, the plaintiffs maintain that the DEA's reliance on sales data from as far back as 2008 and the agency's delay in enforcement undermines its imminent danger finding. Pls.' Reply at 6-7. Yet, 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. And the DEA's delay between the execution of its warrant and its issuance of the ISOs is reasonably attributed to the agency's review of information produced as a result of that warrant. See Gov't's Opp'n at 21-22. 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. See id.

Third, the plaintiffs contend that the ISOs are arbitrary and capricious because they are overbroad. Pls.' Reply at 7. They note that the ISOs prevent the pharmacies from dispensing all

[12] Moreover, and to reiterate, as far as the Administrator knew when she issued the ISOs, the two pharmacists-in-charge whom the DEA interviewed still worked at the CVS pharmacies. See Leonhart Decl. ¶ 19. This allegation certainly supports a finding of imminent danger, inasmuch as the agency had evidence before it indicating that these pharmacists routinely filled prescriptions under circumstances where they knew or should have known that the customer was using them for an illegitimate purpose.

controlled substances based largely on allegations relating to oxycodone. Id. In support of this argument, the plaintiffs note that under DEA regulations, "[t]he Administrator may limit the revocation or suspension of a registration to the particular controlled substance, or substances, with respect to which grounds for revocation or suspension exist." 21 C.F.R. § 1301.36(c) (emphasis added). However, the plaintiffs' arguments overlook allegations in the ISO regarding general deficiencies in the pharmacies' dispensing practices that are applicable to all controlled substances, not just oxycodone. See ISOs ¶ 4. Administrator Leonhart also reasoned that the CVS pharmacies' deficient handling of oxycodone, a Schedule II drug subject to strict regulation, indicated to her that the pharmacies' handling of lesser-scheduled drugs "was even more suspect." Leonhart Decl. ¶ 23. There is nothing irrational about this conclusion. Finally, § 1301.36(c) plainly states that the Administrator "may" limit the scope of the ISO in her discretion. The plaintiffs do not explain why the APA requires the Administrator to offer any explanation regarding her decision not to exercise this clearly permissive authority.

Most of the plaintiffs' arguments challenge the accuracy of the factual conclusions underlying the Administrator's imminent danger finding. But while her "initial findings of fact may turn out to be incorrect in certain respects after completion of a thorough investigation and review of the evidence presented at the administrative hearing" before the DEA, the Administrator's "analysis and conclusions were reasoned, not arbitrary and capricious." Novelty Distributors, Inc, 562 F. Supp. 2d at 29. Under the applicable "highly deferential" standard of review, Me. Pub. Utils. Comm'n v. FERC, 454 F.3d 278, 286 (D.C. Cir. 2006), the plaintiffs are not likely to succeed on the merits of their claim that the DEA acted arbitrarily and capriciously in immediately suspending their registrations.

3. The Plaintiffs' APA Claim Challenging the Facial Adequacy of the ISOs (Count IV)

Count IV of the amended complaint challenges the facial adequacy of the ISOs. See Am. Compl. ¶¶ 61-66. Noting that the DEA regulations direct that ISOs "shall contain a statement of [the Adminsitrator's] findings regarding the danger to public health or safety," 21 C.F.R. § 1301.36(e), the plaintiffs claim that the statements of findings in the ISOs here are inadequate, Am. Compl. ¶ 65. The plaintiffs thus contend that the ISOs were issued "without observance of procedure required by law," in violation of APA § 706(2)(D).

As noted, the plaintiffs' position that ISOs must contain a comprehensive (or at least a nearly comprehensive) statement of the Adminsitrator's suspension decision has already been rejected by this Court. See Cardinal, __ F. Supp. 2d at __, 2012 WL 718486, at *21-*22 (holding that the government's reading of § 1301.36(e) as requiring only a non-exhaustive summary of the factual and legal basis for the immediate suspension decision is entitled to deference under Auer v. Robbins, 519 U.S. 452, 461 (1997)). Accordingly, for the reasons set forth in Cardinal, this claim is not likely to succeed on the merits.

4. The Plaintiffs' Procedural Due Process Claim (Count II)

Count II of the amended complaint asserts that the ISOs deprived the plaintiffs of their property interests in their DEA registrations without due process of law. Compl. ¶¶ 50-55. The due process theory set forth in the amended complaint asserts that the ISOs were signed on February 2, 2012, but were not served on the CVS stores until Saturday, February 4, 2012, which prevented the plaintiffs from seeking judicial relief to contest the ISOs' allegations for two days. Id. ¶ 53. However, the plaintiffs make no mention of this theory in their briefs in support of their preliminary injunction motion, and have consequently failed to carry their burden of making a

"clear showing" that they are likely to succeed on this specific claim. See Cobell, 391 F.3d at 258.

The plaintiffs, however, assert a different due process theory in their briefs, which can be summarized as follows: (1) the plaintiffs have a protected property interest in their DEA registrations; (2) the Fifth Amendment prohibits a person from being deprived of a protected property interest without due process of law; (3) consistent with constitutional requirements of due process, the CSA requires the DEA to provide a registrant with a pre-deprivation hearing before revoking its registration, unless the DEA can demonstrate in an ISO that there is imminent danger to the public health or safety; (4) because the plaintiffs have shown that the ISOs demonstrated no such imminent danger, the DEA's actions as applied in this case deprived the plaintiffs of their constitutionally protected due process rights. See Pls.' Mem. at 25.

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 the plaintiffs were deprived of protected property interests in their DEA registrations. 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)). The statutory framework of 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.").

The plaintiffs do not dispute this point, as they have not raised a facial challenge to the CSA. See Pls.' Mem. at 26 (acknowledging that the CSA's immediate suspension procedure may be constitutional in some cases). They instead raise an as-applied due process challenge to the DEA's actions in this case, arguing that because the DEA failed to set forth sufficient findings of imminent danger in the ISOs, it violated the CSA, and that this violation of the CSA amounted to a violation of their due process rights. Pls.' Reply at 14-15.

There are several flaws with the plaintiffs' reasoning. First, it rests on a misinterpretation of the CSA. Section 824(d) of the CSA 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). Contrary to the plaintiffs' contention, the statute does not require the Administrator to "demonstrate" imminent danger in an ISO with any degree of particularity; it instead vests her with the discretion to issue an ISO where she "finds" such a danger exists. And even assuming the Administrator did have a statutory obligation to "demonstrate" the existence of an imminent danger in an ISO,[13] the plaintiffs do not explain why the Administrator's failure to comply with such an obligation would necessarily entail a violation of the plaintiffs' due process rights. They simply assume, without any

[13] While the DEA regulations require the Administrator to provide a statement of her findings regarding imminent danger to the public, 21 C.F.R. § 1301.36(e), the CSA imposes no such requirement. The plaintiffs' due process arguments invoke the statute, not the regulation. See Pls.' Mem. at 25.

supporting legal analysis, that an ISO issued without the requisite findings of imminent danger (regardless, apparently, of whether an imminent danger actually exists) amounts to an unconstitutional deprivation of due process. This falls well short of the plaintiffs' burden of making a "clear showing" that they are likely to succeed on this claim. See Cobell, 391 F.3d at 258.

Furthermore, insofar as the plaintiffs are challenging the propriety of the DEA's finding of imminent danger and its invocation of the CSA's immediate suspension procedure (rather than the DEA's statement of those findings), their due process claim is likely doomed for failure. When reviewing governmental decisions to invoke emergency procedures that forgo pre-deprivation process, the courts of appeals have been very deferential. See, e.g., Elsmere Park Club, L.P. v. Town of Elsmere, 542 F.3d 412, 418 (3d Cir. 2008); Catanzaro v. Weiden, 188 F.3d 56, 62-63 (2d Cir. 1999); Herwins v. City of Revere, 163 F.3d 15, 19 (1st Cir. 1998); Harris v. City of Akron, 20 F.3d 1396, 1404 (6th Cir. 1994). The Second and Third Circuits, for example, apply the following test: "'where there is competent evidence allowing the official to reasonably believe that an emergency does in fact exist . . . [,] the discretionary invocation of an emergency procedure results in a constitutional violation only where such invocation is arbitrary or amounts to an abuse of discretion.'" Elsmere Park Club, L.P., 542 F.3d at 418 (quoting Catanzaro, 188 F.3d at 63) (alterations in original). This standard prohibits "an exacting hindsight analysis" that would "encourage delay and thereby potentially increase the public's exposure to dangerous conditions," but also ensures that the government does not deprive "due process to citizens by arbitrarily invoking emergency procedures." Catanzaro, 188 F.3d at 63. Here, it has already been determined that the DEA's imminent danger finding was not arbitrary and capricious for the purposes of APA review. That rationale applies with equal force to the

plaintiffs' procedural due process claim, and the claim is therefore not likely to succeed on the merits.

In sum, the plaintiffs have failed to show a likelihood of success on the merits for any of their claims.

B. Irreparable Injury

Having failed to show a likelihood of success on the merits, the plaintiffs must, under the sliding scale analysis, make an exceedingly strong showing of irreparable harm in order to obtain a preliminary injunction. See Davis, 571 F.3d at 1291-92. In fact, the Circuit "has set a high standard for irreparable injury" whenever injunctive relief is sought. 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 Wisc. 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. (emphasis in original and citation omitted). 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 Wisc. Gas Co., 758 F.2d at 674).

The plaintiffs claim that absent an injunction, they will suffer irreparable injury in the form of economic harm, loss of customer goodwill and loyalty, and deprivation of their due process rights. Pls.' Mem. at 19-27. For the reasons that follow, none of these purported harms pass the high bar for irreparable injury.

1. Economic Harm and Lost Customers

"The loss of business opportunities, market share, and customer goodwill are typically considered to be economic harms." Air Transp. 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 Wisc. 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 harm 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. Wisc. 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); see also Wisc. Gas, 758 F.2d at 675 (rejecting argument that "recoverable economic injury" constituted irreparable harm and noting that the plaintiffs had failed to show "that the alleged loss [was] unrecoverable," thus indicating that unrecoverable economic loss could support a finding of irreparable harm (emphasis added)). 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. Nat'l Mining Ass'n, 768 F. Supp. 2d at 53; 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).

An initial issue that must be addressed is whether, and to what extent, the Court should consider the economic status of the subsidiary company which owns and operates the two CVS pharmacies, plaintiff Holiday, CVS, L.C.C. ("Holiday"), and Holiday's parent company, CVS Caremark Corporation ("CVS"). The government focuses solely on the economic status of the parent company, Gov't's Opp'n at 30, while the plaintiffs assert that the two pharmacies independently, not CVS, are the aggrieved parties in this case because the ISOs were issued to them and they will suffer the economic consequences, Pls.' Reply at 13. Although it is true that the two CVS pharmacies are the parties most directly affected by the ISOs, it does not necessarily follow that the Court should simply ignore the parent and subsidiary companies in evaluating irreparable injury. On the contrary, courts in this Circuit and elsewhere have found the economic status of a plaintiff's parent corporation to be highly relevant when a plaintiff seeks to show irreparable economic harm. See, e.g., LG Elecs., USA, Inc. v. Dep't of Energy, 679 F. Supp. 2d 18, 36 (D.D.C. 2010) (finding no irreparable economic harm based in part on fact that the plaintiff was "a subsidiary of a $45 billion global technology leader"); Ajilon Prof'l Staffing, PLC v. Kubicki, 503 F. Supp. 2d 358, 362 (D.D.C. 2007) ("Given the size and prominence of Ajilon and its parent corporation, there is no reason to believe that Ajilon's alleged loss of revenue threatens the company's ability to stay in business." (emphasis added)); Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) ("Sandoz is a part of Novartis AG, one of the largest pharmaceutical companies in the world and whose annual sales exceeds $32 billion."); Mediplex of Massachusetts, Inc. v. Shalala, 39 F. Supp. 2d 88, 99 (D. Mass. 1999) ("[T]he presence of a wealthy parent company may mitigate a finding of irreparable harm to Mediplex because of financial losses."); Ortho Diagnostic Sys. v. Abbott Lab., Inc., 822 F. Supp. 145, 151 (S.D.N .Y. 1993) (finding that the plaintiff could "sustain any loss of business which might occur" and

nonetheless survive in part because it was a "subsidiary of Johnson & Johnson," and distinguishing cases involving the "destruction of 'mom and pop' businesses"). Indeed, when pressed at the March 13, 2012 hearing on this issue, counsel for the plaintiffs conceded that she could find no authority in support of the proposition that a court should disregard the economic status of a retail store's parent company, much less the subsidiary company which directly owns and operates the store, for the purposes of determining whether economic loss constitutes irreparable harm.

The Court will therefore consider the wealth of the plaintiffs' parent corporation as a relevant factor in evaluating their claimed economic injury.[14] Moreover, although the plaintiffs urge the Court to focus exclusively on the ISOs' impact on the two CVS pharmacies, those pharmacies are owned and operated by plaintiff Holiday, the subsidiary company, and the Court must therefore consider the effects of the ISOs on that company as well.

The Court is not convinced that a temporary suspension of the two pharmacies' DEA registrations would "threaten the very existence of [their] business." Wisc. Gas, 758 F.2d at 674. In other words, the plaintiffs have not shown that the ISOs would likely cause the two pharmacies to shut down. And they have provided absolutely no evidence regarding the anticipated impact of the ISOs on Holiday, much less have they shown that the ISOs would threaten the very existence of Holiday's business. Moreover, CVS is one of the largest retail pharmacy chains in the nation and ranked twenty-first on the Fortune 500 list for 2011. Gov't's Opp'n at 30. Its revenues exceeded $107 billion in 2011. Id. The company has over 7,300 retail pharmacy stores in 44 states, and in Florida alone has 700 retail pharmacies. Id. The economic

[14] The Court would also have considered the economic status of Holiday, but neither party has provided financial information concerning that company.

status of CVS undermines to a significant degree the showing of irreparable economic harm to the plaintiffs, as the parent company's substantial resources are likely to mitigate any financial losses incurred by the two CVS pharmacies as a result of the temporary suspension of their DEA registrations. Ignoring these facts would require the Court to set aside commonsense; after all, it is not as if the CVS pharmacies are self-sustaining "mom and pop" stores which live or die based solely on the revenue they independently generate.

The plaintiffs nonetheless seek to show that the ISOs will cause substantial economic loss to the CVS pharmacies, which would be unrecoverable due to the government's sovereign immunity. They rely on the following data. In 2011, pharmacy sales amounted to roughly 85% of total revenue at CVS 219, while it comprised 72% of CVS 5195's revenue. Pls.' Reply, Declaration of Christopher Cox ¶ 4. Of these pharmacy sales, 25% consisted of controlled substances. Pls.' Mem., Supplemental Declaration of Crystal Thibeault Pike ¶ 5. In addition to claiming a baseline loss of 25% of all controlled substances sales, the plaintiffs anticipate that the ISOs will have a negative spillover effect on both non-controlled substances and general retail merchandise because "customers typically prefer to buy both controlled and non-controlled substances from a single pharmacy." Pls.' Mem., Declaration of Mark Kolligan ¶ 2, 6-7. Regarding lost sales of general retail products, the plaintiffs note that 2011 data from a CVS store in Florida (but not necessarily either of the CVS pharmacies in this case) shows that 47% of customers who filled prescriptions at that store purchased another $14 to $17 worth of general retail products. Id. ¶ 5. And regarding lost sales of non-controlled substances, the plaintiffs assert that "[o]f those customers that fill prescriptions for controlled substances at Stores 219 and 5195, 62% also simultaneously filled prescriptions for non-controlled substances at least once during 2010 and 2011," and that "30% always filled prescriptions for non-controlled substances

simultaneously with controlled substances." Pls.' Mem., Declaration of Crystal Thibeault Pike ¶ 12.

While the plaintiffs have submitted a flurry of data to the Court, they have not sufficiently quantified their anticipated economic loss. See Nat'l Ass'n of Mortg. Brokers v. Bd. of Gov'rs of Fed. Reserve Sys., 773 F. Supp. 2d 151, 181 (D.D.C. 2011) (For "[u]nrecoverable economic harm [to] constitute irreparable injury," a plaintiff must "adequately describe and quantify the level of harm" it faces); accord Air Transp. Ass'n of America, Inc.., __ F. Supp. 2d at __, 2012 WL 119557, at *6. Specifically, the plaintiffs have failed to provide any estimates concerning how a temporary suspension of the pharmacies' DEA registrations would affect their sales revenues.[15] Without such a projection, the Court cannot compare the pharmacies' anticipated losses to its total revenues, and, consequently, cannot determine whether the plaintiffs will suffer economic harm of the magnitude necessary to constitute irreparable injury. At most, the plaintiffs' projections indicate that they will temporarily lose, for some undefined period, 25% of their controlled substances sales (which comprises a lesser percentage of their total pharmacy sales), in addition to some indeterminate and speculative percentage of sales of non-controlled substances and general retail products. These estimates fall short of showing unrecoverable economic harm to the CVS pharmacies that is certain, actual, and great.[16] Nor

[15] That is not to say that the plaintiffs are unable to offer such estimates because their economic harm is too difficult to quantify. See CSX Transp., Inc. v. Williams, 406 F.3d 667, 673 (D.C. Cir. 2005) (finding irreparable harm based in part on difficulty of "plac[ing] a dollar value" on the plaintiff's claimed injury). On the contrary, the plaintiffs could have gauged their anticipated economic loss based on an analysis of (1) the data they provided to the Court, and (2) a reasonable projection of the duration of the administrative proceedings before the DEA (which the government anticipates will be roughly six months, Gov't's Opp'n at 38). They simply failed to offer such a projection.

[16] In their reply brief, the plaintiffs contend that under agreements the CVS pharmacies have with third-party insurers, suspension of a DEA registration is a basis for the insurer to decline reimbursing the pharmacies for prescriptions filled for their beneficiaries. Pls.' Reply at 13 (citing id., Declaration of R. John Zevzavadjian ¶¶ 5-6). Because the plaintiffs raised this argument for the first time in their reply brief and had not previously submitted Zevzavadjian's declaration, the Court declines to consider this argument. See Rollins Envtl. Servs. v. EPA, 937 (continued . . .)

does the plaintiffs' data provide any indication as to the ISOs' expected financial impact on either Holiday or CVS.

The plaintiffs also claim that the temporary suspension of the CVS pharmacies' DEA registrations will cause the pharmacies to permanently lose customers. But the evidence offered in support of this claim is based on mere conjecture. See Pls.' Mem., Declaration of Mark Kolligan ¶ 8 (stating, without explanation or supporting data, that "once a customer goes to another pharmacy to fill prescriptions it dramatically increases the likelihood that they will not return"); id, Supplemental Declaration of Jessica Merrill ¶ 8 ("The pharmacy business is comprised to a large degree of long-term relationships between the pharmacy and patients. These long-term relationships at Store 5195 may likely be permanently disrupted by the [ISO]." (emphasis added)); id, Declaration of Susan Masso ¶ 27 ("[I]f Store 219 is prohibited from filling prescriptions for all controlled substances, . . . some patients will likely decide to take their pharmacy business to another pharmacy, including possibly a pharmacy other than CVS." (emphasis added)). Like the plaintiffs other economic harm arguments, these projections are speculative at best, and thus insufficient to support a finding of irreparable injury.

2. Harm to Customers

The plaintiffs also claim that the "ISOs' effect of rerouting of customers to other pharmacies will result in delays and possibly will prevent patients from receiving controlled substance prescriptions, thereby disrupting patient therapy and putting patients at risk." Pls.' Mem. at 21. This argument fails because it shows irreparable harm not to the plaintiffs, but to

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(. . . continued)
F.2d 649, 653 n.2 (D.C. Cir. 1991) ("Issues may not be raised for the first time in a reply brief."); Aleutian Pribilof Islands Ass'n, Inc. v. Kempthorne, 537 F. Supp. 2d 1, 12 n.5 (D.D.C. 2008) ("[I]t is a well-settled prudential doctrine that courts generally will not entertain new arguments first raised in a reply brief.") (citing Herbert v. Nat'l Acad. of Scis., 974 F.2d 192, 196 (D.C. Cir. 1992)).

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 the plaintiffs' consumers will therefore be considered under the public interest prong of the preliminary injunction analysis.

3. Deprivation of the Plaintiffs' Due Process Rights

The plaintiffs further argue that they will suffer irreparable injury absent an injunction because the ISOs violated their due process rights. Pls.' Mem. at 25. "It has long been established that the loss of constitutional freedoms, 'for even minimal periods of time, unquestionably constitutes irreparable injury.'" Mills v. District of Columbia, 571 F.3d 1304, 1312 (D.C. Cir. 2009) (quoting Elrod v. Burns, 427 U.S. 347, 373 (1976) (plurality opinion)). However, to invoke this principle, the plaintiffs would have to show that their due process claim is likely to succeed on the merits. See id. (citation omitted). Because the Court has determined that this claim is not likely to succeed, the plaintiffs cannot show irreparable injury based a deprivation of their due process rights.

C. Balance of Hardships and the Public Interest

Having found no likelihood of success on the merits on any of the plaintiffs' 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 weighs in the government's favor because the plaintiffs' 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.

Nor does the public interest factor weigh in favor of granting a preliminary injunction. The plaintiffs offer a tenuous theory that legitimate patients may be deprived altogether of controlled substances if the two CVS pharmacies' DEA registrations are temporarily suspended. See Pls.' Mem. at 25, 28. But there are other pharmacies in Sanford, Florida that can service customers with a legitimate need for controlled substances. See Gov't's Opp'n, Rannazzisi Decl. ¶ 51 (noting that there are two major pharmacies within one mile of CVS 219 and one major pharmacy within two miles of CVS 5195). Furthermore, there is a strong 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. The plaintiffs argued at the hearing on March 13, 2012, that because the CVS pharmacies have voluntarily agreed to suspend distribution of all Schedule II drugs pending resolution of the administrative proceedings before the DEA, the public interest in preventing diversion would not be compromised by a preliminary injunction. Yet, as noted above, the DEA's imminent danger finding was based in part on the CVS pharmacies' dispensing practices with respect to all controlled substances, not just Schedule II drugs. The public interest factor therefore tips in the government's favor.

IV. Conclusion

The balance of the preliminary injunction factors weighs in favor of denying the plaintiffs' motion. Without a showing of likely success on the merits or irreparable harm, the plaintiffs 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 the plaintiffs have failed to make an adequate showing on any of the four preliminary injunction factors, their motion for a preliminary injunction must be denied.

SO ORDERED this 16th day of March, 2012.[17]

REGGIE B. WALTON
United States District Judge

[17] The Court previously issued an order consistent with this memorandum opinion on March 13, 2012.