

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PDK LABS INC.,
Plaintiff,

v.

JANET RENO, et al.,

Civil Action 00-2894 (HHK)

MEMORANDUM OPINION AND ORDER

PDK Labs Inc. (“PDK”) is a New York corporation that manufactures over-the-counter pharmaceutical and vitamin products. Ephedrine is an ingredient that is used in the manufacture of these products. Unfortunately, ephedrine can also be used to produce illegal controlled substances, most notably methamphetamine, when extracted from lawful over-the-counter medicines. This process is known as “diversion.” Because of this possibility, the government classifies ephedrine as a List I chemical and regulates its importation into the United States.

In October of the year just ended, Indace, Inc., a company registered with the Drug Enforcement Administration to import List I chemicals, notified DEA of its intention to import three metric tons of ephedrine from India and that PDK was the purchaser of the ephedrine. The Drug Enforcement Administration blocked the importation of the ephedrine and continues to do so, an action which PDK claims is unlawful and is causing it irreparable injury.

PDK brings this case¹ against the Attorney General of the United States and the Administrator

¹ This case is comprised of two cases that are consolidated in an order accompanying this opinion.

of the Drug Enforcement Administration, in their official capacities, as well as against the United States Department of Justice and the Drug Enforcement Administration (collectively “defendants” or “DEA”), seeking injunctive and declaratory relief and a writ of mandamus. PDK maintains that DEA has (1) violated the Administrative Procedure Act (Counts I through IV); (2) deprived PDK of its property and liberty interests in violation of the Fifth Amendment’s due process clause (Count V); and (3) failed to perform its statutory duties (Count VI). Presently before the court is PDK’s motion for a preliminary injunction and defendant’s motion to dismiss. Upon consideration of the motions, the respective oppositions thereto, the oral arguments of counsel at a hearing and the testimony presented at that hearing, and the record in this case, the court concludes that each motion should be granted in part.

I. BACKGROUND

A. Importation Approval Process

Pursuant to section 6053 of the Chemical Diversion and Trafficking Act (“CDTA”), Pub. L. 100-690, 102 Stat. 4181 (1988), codified as amended at 21 U.S.C. § 971 (“the statute” or “§ 971”), DEA regulates the importation of certain listed chemicals. Importers are required to notify DEA at least 15 days prior to the scheduled date of arrival of such chemicals. 21 U.S.C. § 971(a). Notification consists of the filing of an Import Declaration Form 486. 21 C.F.R. § 1313.12(b). Following notification, the statute and its implementing regulations permit DEA to issue a notice of suspension of importation based on evidence that the chemical may be diverted to the clandestine manufacture of controlled substances. A suspension order must contain the legal and factual basis for its issuance. 21 U.S.C. § 971(c)(1). After a suspension order has been issued the regulated person may not carry out the transaction. However, a regulated person to whom a suspension order applies has 30 days in

which to request a hearing, and upon such request a hearing must be held within 45 days. 21 U.S.C. § 971(c)(2); 21 C.F.R. § 1313.52, 1313.54.

Several countries, of which India is one, will not permit the export of listed chemicals until they have received a letter-of-non-objection (“LONO”) acknowledging that the importer’s government does not object to the shipment. The LONO is as an outgrowth of a 1994 international initiative among several nations, including the United States, and the International Narcotics Control Board (“INCB”), a UN-based entity. Subsequently, in addition to the formal regulations concerning suspension orders, DEA created a process enabling those importers who need a LONO to obtain one. If an importer needs a LONO for a particular transaction it files a Form 486 importation request accompanied by a written request that a LONO issue.

Upon request for a LONO, DEA will either issue one, in which case the transaction continues normally, or will decline to do so because it perceives a threat of downstream diversion for illicit purposes. When a LONO is not issued, the importer is notified and provided three options. The importer can either (1) withdraw its request for a LONO and cancel its Form 486, or (2) take no action and in 30 days DEA will deem the request withdrawn, or (3) request in writing its desire to pursue the matter further, in which case a suspension order is issued. If the importer elects option three, and a suspension order is issued, only then will DEA allow the importer the opportunity to obtain a hearing as provided for in § 971(c)(2). DEA maintains that the LONO process is standardized and consistent with the law; however, both parties recognize that it is not explicitly authorized in any statute or regulation.

B. Factual Allegations

On October 18, 2000, Indace, Inc., submitted a Form 486 notifying DEA of its intention to import three metric tons of ephedrine on November 14. The completed Form 486 specifically identified PDK as the purchaser of the ephedrine. On October 25, DEA informed Indace that a LONO would not be issued because there were grounds to believe the shipment would be diverted downstream for illegal uses, and notified Indace of the three courses it could pursue.²

Indace informed DEA on November 1, that PDK planned to elect option three and pursue the matter further. Thereafter, on November 10, PDK wrote to DEA indicating that it was awaiting the issuance of a formal order of suspension. Indace then notified DEA on November 14, that it was not withdrawing its request because it was aware that PDK had elected to persist in its effort to obtain the ephedrine. In a November 17 telephone call with PDK's counsel, and a subsequent November 22 letter, DEA expressed its position that under 21 U.S.C. § 971(c), PDK did not have standing to pursue this matter, and that therefore a suspension order could not be issued to PDK.

On December 4, PDK filed this case. In light of DEA's position, Indace notified DEA on December 5, that it regarded this matter as solely between "PDK and DEA," and that "Indace has no intent to exercise Option 3." As a result on December 11, DEA notified Indace that since 30 days had passed after the denial of the LONO with no action by Indace, DEA considered the request for importation to be withdrawn.

II. LEGAL ANALYSIS

A. Defendants' Rule 12(b)(1) Motion to Dismiss

² PDK maintains that a DEA official told Indace, in a telephone conversation, that PDK would be permitted to participate in a suspension hearing. Defendants dispute the conversation, however.

Defendants move to dismiss PDK's APA and Mandamus claims for lack of subject matter jurisdiction pursuant to Fed. R. Civ. P. 12(b)(1). When deciding a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction, "allegations of the complaint should be construed favorably to the pleader." *Walker v. Jones*, 733 F.2d 923, 925-26 (D.C. Cir. 1984) (quoting *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). When necessary, however, the court may properly look beyond the complaint to the undisputed facts evidenced in the record, or may resolve disputed facts. *See Herbert v. National Academy of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992).

I. Review by United States District Court

First, defendants assert that under 21 U.S.C. §§ 877 and 965, exclusive jurisdiction to review final determinations of the Attorney General under the CDTA rests with the D.C. Circuit. Section 877 states that "[a]ll final determinations, findings, and conclusions of the Attorney General under [subchapter I of the CDTA] shall be final . . . except that any person aggrieved by a final decision of the Attorney General may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located."³ Citing the plain terms of § 877, defendants maintain that this court is without jurisdiction to review the action which is the subject of this suit.

PDK responds that while pursuant to § 877 jurisdiction to review generally lies with the Court of Appeals, § 877 does not apply in this case. PDK argues that DEA, in effect, issued a "de facto suspension" without complying with the requirements of § 971. *See* Compl. ¶¶ 58, 65, 78. Far from

³ Section 877 expressly applies only to decisions made under subchapter I of the CDTA. Pursuant to § 965, however, § 877 also applies to subchapter II of the CDTA, which includes § 971. Thus, final actions taken under § 971 are subject to the judicial review limitation in § 877.

constituting a final action under § 971, PDK alleges that DEA simply failed to follow § 971.

Consequently, PDK argues, the LONO denial cannot constitute a final action of DEA subject to review only in the Court of Appeals. Rather, this action is properly before this court as a federal question under 28 U.S.C. § 1331.

Defendants counter that DEA's decision not to grant PDK a hearing was based on DEA's "final determination that PDK does not have standing under the clear language of sections 971(a) and (c)(2) to have an administrative hearing to contest DEA's denial of the LONO." Pl.'s Mem. at Ex. I, Letter from DEA to PDK's counsel, Nov. 22, 2000. DEA maintains that the conclusiveness and finality of its position are clear. Indeed, the letter itself states that it is DEA's "final determination" regarding PDK's right to a hearing. Defendant's position, however, cannot be sustained.

Although an agency's characterization of its own action is never conclusive, it does carry some weight. *See American Portland Cement Alliance v. EPA*, 101 F.3d 772, 776 (D.C. Cir. 1996) ("An agency's characterization of an administrative action, though not dispositive of reviewability, may provide guidance."). However, even if the court accepts the November 22 letter which DEA wrote to PDK's counsel as DEA's final statement regarding PDK's right to a hearing, that statement does not constitute a final determination, finding, or conclusion within the meaning of § 877. At best, DEA's letter is considered as its final interpretation of § 971(c), as opposed to a final action under the CDTA as contemplated by § 877. Therefore, the court concludes that 21 U.S.C. § 877 does not preclude this court from exercising jurisdiction over this suit.

2. *Standing*

Defendants also claim that plaintiff lacks standing to bring its APA claims because (1) PDK is

not an intended beneficiary of § 971's procedures, and (2) the interests underlying PDK's claims are not within the "zone of interests" protected by § 971. Section 971 provides that "*a regulated person* to whom a[] [suspension] order applies under paragraph (1) is entitled to an agency hearing on the record." 21 U.S.C. § 971(c)(2) (emphasis added). As defined in § 802 and incorporated by reference in § 971, "regulated persons" include manufactures, distributors, importers, and exporters of listed chemicals. 21 U.S.C. § 802(38). It is undisputed that as both a manufacturer and distributor PDK is a regulated person within the meaning of § 802. Nonetheless, defendants assert that the overall statutory scheme and congressional purpose of § 971 make clear that the right to a hearing extends only to importers. Because PDK is not an importer, defendants argue, PDK is neither an intended beneficiary of § 971, nor are its interests within the "zone of interests" protected by the statute. Defendants' position is without merit. PDK is clearly either an intended beneficiary of § 971, or at the least its interests fall within the "zone of interests" protected under the section.

First, the express language of § 971 supports the conclusion that PDK is an intended beneficiary of the statute. Section 971 uses both the terms "importers" and "regulated persons." Congress easily could have limited the right to a hearing in § 971(c)(2) exclusively to "importers to whom an order applies," but chose not to do so—instead extending this right to "regulated persons." The specific use of the term "regulated persons" in § 971(c)(2) at least suggests that Congress intended to permit a regulated entity to whom an order applies—including a manufacturer like PDK—to obtain judicial review.

DEA itself previously adopted a similar reading in *Yi Heng Enterprises Development Co.*, 64 Fed. Reg. 2234, 2235 (1999), a case in which a suspension order was reviewed by the Deputy DEA

Administrator. Although *Yi Heng* arose in a different context, mainly because it involved the interests of two importers rather than an importer and a manufacture, the Deputy DEA Administrator concluded that § 971 “does not specify that only one party in a transaction is entitled to a hearing.” *Id.* at 2235. The *Yi Heng* decision recognized that “the statute provides the opportunity for a hearing to ‘a regulated person to whom an order (suspending shipment) applies,’ not necessarily the person to whom the order was issued.” *Id.*

Even if the court were to find that PDK is not an intended beneficiary of the statute, it is clear that its interests are within the “zone of interests” protected in § 971. Generally the APA allows persons “adversely affected or aggrieved by agency action” to seek review. *See Block v. Community Nutrition Institute*, 467 U.S. 340, 345 (1984) (quoting 5 U.S.C. § 702). The “zone of interests” analysis is useful in determining “whether, in view of Congress’ evident intent to make agency action presumptively reviewable, a particular plaintiff should be heard to complain of a particular agency decision.” *Clark v. Securities Industry Ass’n*, 479 U.S. 388, 399 (1987). The court must decide if “the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.” *Association of Data Processing Service Organizations, Inc., v. Camp*, 397 U.S. 150, 153 (1970).

To determine if a statute precludes judicial review a court may look to the language of the statute, the statute’s overall scheme, the nature of the action involved, and legislative objectives and intent. *See Block*, at 345. This test is not demanding. Although the presumption in favor of judicial review is overcome where “congressional intent to preclude judicial review is fairly discernible in the statutory scheme. . . . there need be no indication of congressional purpose to benefit the would-be

plaintiff.” *Clarke*, at 399-400 (internal quotations omitted).

The statutory language of § 971 does not express any congressional intent to preclude judicial review by manufacturers directly affected by a suspension order. To the contrary, the phrase “regulated person to whom any order applies” is evidence that a manufacturer affected by a suspension order is protected under § 971’s review provision. Furthermore, defendants’ contentions about the overall statutory scheme are unpersuasive. There is no indication that Congress intended to preclude judicial review by manufactures or distributors to whom a suspension order applies.

The conclusion that PDK’s interests fall within the “zone of interests” protected by § 971(c) is confirmed by the standard DEA uses, and the actions it takes, when investigating Form 486 requests for importation. The statute permits DEA to suspend proposed imports when there are grounds to conclude “that the chemical may be diverted to the clandestine manufacture of a controlled substance.” 21 U.S.C. § 971(c)(1). To make this inquiry DEA must look to the eventual destination of the chemicals after importation into the United States. For this reason many importers list on the Form 486 the name of the company to which the goods will be sold upon arrival. Indace did just this, and listed PDK as the intended recipient of the ephedrine proposed for importation on November 14. Even if an importer does not initially disclose the intended recipient of the chemicals, DEA must ascertain this information in order to determine if the goods may be diverted. Thus DEA’s election to suspend importation hinges largely on the identity of the eventual purchaser. In this case it is clear that DEA denied the LONO because PDK was the intended recipient of the ephedrine, not because Indace was the importer. The fact that DEA’s action was based largely on its assessment of PDK reinforces the conclusion that under the statutory scheme PDK is entitled to a hearing.

Additionally, unlike in *Block v. CNI*, where allowing judicial review by the plaintiff created a risk that any consumer would be able to seek review, here review is limited to only “regulated persons to whom an order applies.” While the term “regulated persons” encompasses a large number of entities, only persons to whom an order applies may obtain a hearing. It is undisputed that PDK was the intended beneficiary of the ephedrine, and it is clear that DEA’s objection relates to alleged problems with PDK, not with the importer Indace. Under these circumstances, allowing PDK to obtain a hearing does not open the floodgates to intervention by an unlimited number of downstream users or customers. Thus, either as an intended beneficiary, or under the “zone of interests” test, PDK has prudential standing to bring its claims. Defendants’ motion to dismiss for lack of subject matter jurisdiction will therefore be denied.

B. Defendants’ Rule 12(b)(6) Motion to Dismiss

Defendants move to dismiss PDK’s Fifth Amendment and Mandamus claims for failure to state a claim upon which relief can be granted under Fed. R. Civ. P. 12(b)(6). A court reviewing a motion to dismiss for failure to state a claim upon which relief may be granted, must accept as true the allegations in the plaintiff’s pleadings, and view them in a light most favorable to the plaintiff. *See Conley v. Gibson*, 355 U.S. 41, 45-46 (1957); *Sinclair v. Kleindienst*, 711 F.2d 291, 293 (D.C. Cir. 1983). A Rule 12(b)(6) motion to dismiss should be granted only when it is clear that the plaintiff can prove no set of facts which would entitle her to relief under her claims. *See Conley*, 355 U.S. at 45-46.

1. Fifth Amendment Claim

Plaintiff maintains that it has been deprived of property and liberty in violation of the Due

Process Clause of the Fifth Amendment. PDK asserts that it has a property interest in the importation of the chemicals and a liberty interest in preserving its status as a reliable and legitimate business.

Accordingly, it claims that DEA's use of the LONO process and corresponding refusal to grant PDK a hearing constitute a due process violation.

For PDK to make out a due process claim it must show that (1) it has a protected interest, (2) the government deprived it of this interest, and (3) the deprivation occurred without proper procedural protections. *See Indus. Safety Equip. Ass'n, Inc. v. EPA*, 837 F.2d 1115, 1122 (D.C. Cir. 1988). Defendants' argue that PDK is unable to prevail on its due process claims because PDK had no right to import the ephedrine and, thus had no protected interest in it, and the alleged damage to PDK's business occasioned by PDK not receiving the chemical is insufficient to rise to the level of a protected liberty interest.

PDK first argues that as a registered manufacturer of List I products, it has an implied "adjunct right to obtain List I chemicals." Pl.'s Reply Mem. at 20. Derived from its status as a manufacturer of List I products, PDK maintains that it has a property interest in the importation of List I chemicals subject only to the express limitations proscribed in § 971. Defendants, however, respond that no such right exists because § 971 grants DEA broad discretion to suspend imports, and therefore the right to import does not constitute a protected property interest. PDK's position cannot be sustained.

In order for a constitutionally protected property interest to exist, a party must have "a legitimate claim of entitlement to it." *Board of Regents v. Roth*, 408 U.S. 564, 577(1987). A statute may create such an entitlement by conferring certain rights upon a party. However, where a statute leaves discretion with the government in awarding benefits, no constitutionally protected property

interest is created. Conversely, a statute may create a protected property interest if it places “substantive limitations on official discretion” to grant the requested relief. *Washington Legal Clinic for the Homeless v. Barry*, 107 F.3d 32, 36 (D.C. Cir. 1997). The Supreme Court has described substantive limitations as those which “contain ‘explicitly mandatory language,’ i.e., specific directives to the decision maker that if the regulations’ substantive predicates are present, a particular outcome must follow.” *Tarpeh-Doe v. United States*, 904 F.2d 719, 723 (D.C. Cir. 1990) (quoting *Kentucky Dep’t of Corrections v. Thompson*, 490 U.S. 454 (1989)). Where an agency has discretion to determine which individuals qualify for a benefit, however, no constitutionally protected interest exists. *See Roth*, 408 U.S. at 567.

Section 971 does not sufficiently limit official discretion to restrict importation so as to create an entitlement of an entity to import chemicals. The statute permits DEA to deny an importation request where it has “grounds” to believe that the shipment “may be diverted.” 21 U.S.C. § 971(c)(1). This standard vests broad discretion with the agency for determining which importation requests will be approved or denied. It can hardly be said that this constitutes a substantive limitation of DEA’s discretion sufficient to create a constitutionally protected property right. Although § 971 does contain some procedural safeguards, “legislative provision of procedural safeguards cannot in itself create a property interest for purposes of due process analysis.” *Griffith v. FLRA*, 842 F.2d 487, 495 (D.C. Cir. 1988) (citing *Olim v. Wakinekoma*, 461 U.S. 238, 250-51 (1983)). Nothing in the overall scheme of the CDTA justifies the finding that PDK is has an entitlement to import List I chemicals. Therefore, with respect to PDK’s Fifth Amendment property interest allegation, defendants’ motion to dismiss must be granted.

Turning to PDK's alleged liberty interest, the Court of Appeals for this Circuit has held that a company may have a "liberty interest in avoiding the damage to its reputation and business caused by a stigmatizing suspension." *Reeve Aleutian Airways, Inc. v. United States*, 982 F.2d 594, 598 (D.C. Cir. 1993) (finding that suspending an airline creates a lasting blemish on the company's reputation equivalent to the "scarlet letter pinned across the heart of Hester Prynne"). Mere harm to reputation alone, however, is insufficient; the harm must be in conjunction with or stem from "some tangible change in status." *O'Donnell v. Barry*, 148 F.3d 1126, 1141 (D.C. Cir. 1998). Defendants submit that the damage, if any, to PDK is purely harm to its reputation, an injury that is unaccompanied by a change in PDK's status.

This is a close question. And, at first glance PDK's allegations regarding its business status, even if true, do not seem to rise to the level of a protected liberty interest. Upon further analysis, however, it appears that a company which is "labeled not worthy of being trusted with common chemicals . . . is severely stigmatized and . . . would appear to be entitled to some sort of notice and hearing." *Chemicals for Research and Industry v. Thornburgh*, 762 F. Supp. 1394, 1398-99 (N.D. Cal. 1991) (in a case where DEA denied a company the ability to purchase chemicals under 21 U.S.C. § 830 without a hearing or due process, finding that DEA's actions impairing the company's ability to obtain chemicals created a stigma similar to criminal prosecution). Furthermore, DEA's actions have the "broad effect of largely precluding" PDK from pursuing its core business. *Kartseva v. Dep't of State*, 37 F.3d 1524, 1528 (D.C. Cir. 1995) (discussing due process violations in the individual employment context). This is sufficient to constitute a "tangible change in status" and implicate a protected liberty interest. The complaint goes on to sufficiently allege that this liberty interest was

deprived absent adequate procedural safeguards. Therefore, with respect to PDK's Fifth Amendment liberty interest allegation defendants' motion to dismiss shall be denied.

2. *Petition for Mandamus*

In Count VI, PDK asserts that defendants failed to perform their non-discretionary duties under 21 U.S.C. § 971 and failed to adhere to their regulations governing the importation of listed chemicals. By effectively blocking the ephedrine shipment without formally issuing a suspension order and denying the opportunity for a hearing, PDK argues that DEA failed to perform its duty. PDK therefore asks the court to issue a writ of mandamus pursuant to 28 U.S.C. § 1361 to compel defendants to perform their statutory and regulatory obligations.

Although under 28 U.S.C. § 1361 a district court may issue a writ of mandamus, it remains “a drastic [remedy], to be invoked only in extraordinary situations.” *Northern States Power Co. v. Dep't of Energy*, 128 F.3d 754, 758 (D.C. Cir. 1997) (quoting *Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 34 (1980)). Mandamus relief is appropriate only if “(1) the plaintiff has a clear right to relief; (2) the defendant has a clear duty to act; and (3) there is no other adequate remedy available to plaintiff.” *Council of and for the Blind of Delaware County Valley, Inc. v. Regan*, 709 F.2d 1521, 1533 (D.C. Cir. 1983) (*en banc*). Additionally, the duty to be performed by the agency must be “ministerial and the obligation to act peremptory, and clearly defined. The law must not only authorize the demanded action, but require it; the duty must be clear and indisputable.” *13th Regional Corp. v. Dep't of Interior*, 654 F.2d 758, 760 (D.C. Cir. 1980) (quoting *United States ex rel. McLennan v. Wilbur*, 283 U.S. 414, 420 (1931)). The law places the burden on the party seeking mandamus to demonstrate “its right to issuance of the writ.” *Gulfstream Aerospace Corp. v. Mayacamas Corp.*,

485 U.S. 271, 289 (1988) (internal quotations and citations omitted).

In this case, the mandamus relief sought by plaintiff is essentially identical to that which plaintiff seeks under the APA. Mandamus is an extreme measure, to be invoked only when no other adequate remedies are available to plaintiff. Moreover, even if all three factors are satisfied, it is within the court's discretion to deny mandamus. *See 13th Regional Corp.*, 654 F.2d at 760 (“[E]xercise of the power of mandamus is a matter committed to the sound discretion of the trial court.” Quoting *Cartier v. Secretary of State*, 506 F.2d 191, 199 (D.C. Cir. 1974), *cert. denied*, 421 U.S. 947 (1975)). The court, therefore, elects to analyze plaintiff's entitlement to relief under its other claims, and defendants' motion to dismiss count VI shall be granted.

C. PDK's Request for a Preliminary Injunction

A party requesting a preliminary injunction must sufficiently demonstrate four elements: (i) likely success on the merits; (ii) irreparable harm if the injunction is not granted; (iii) that relief would not impair the rights of other parties; and (iv) that relief would be in the public interest. *See e.g., CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 746 (D.C. Cir. 1995); *see also Sea Containers Ltd. v. Stena AB*, 890 F.2d 1205, 1208 (D.C. Cir. 1989). "These factors interrelate on a sliding scale and must be balanced against each other." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1318 (D.C. Cir. 1998). Nevertheless, "some showing of irreparable injury is always required, since 'the basis for injunctive relief in the federal courts has always been irreparable harm.'" *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 215 (D.D.C. 1996) (quoting *Sampson v. Murray*, 415 U.S. 61, 88 (1974)); *see Sea Containers Ltd.*, 890 F.2d at 1208.

1. Likelihood of Success on the Merits

With respect to its APA claims, PDK alleges that by using the LONO process to effectively bar the importation of ephedrine destined for PDK, DEA: (1) acted in excess of statutory authority; (2) acted contrary to the law and the scheme created by Congress and DEA regulations; (3) deviated from established practice by not issuing the LONO upon timely and repeated requests; and (4) acted in an arbitrary and capricious manner by refusing to issue a LONO without formally acting to suspend the importation.

PDK contends that the statute does not mention the LONO process, and only contemplates formal suspension orders. Therefore, the LONO system is in excess of DEA's authority. Furthermore, PDK maintains that the LONO process is contrary to law because it supplants the suspension order formula contemplated in both the statute and DEA's own regulations. *See Fla. Inst. of Tech. v. FCC*, 952 F.2d 549, 553 (D.C. Cir. 1992) ("an agency's failure to follow its own regulations is fatal to the deviant action").

Defendants argue that the LONO process is a "standardized" process fully consistent with the requirements of § 971. Furthermore, defendants claim it is merely a procedural process, the basic formulation of which is left to the agency's discretion. *See Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 524, 543 (1978). Although no statutory provision specifically authorizes the LONO process, defendants assert that DEA has "inherent authority to establish internal procedural rules." Defs.' Sur-Reply at 18. Relying on congressional directives to reduce diversion and considerations of international comity, defendants maintain that the LONO process is reasonable and lawful exercise of DEA's authority to establish procedural rules.

It is clear that an agency may adopt its own procedural rules. In fact, in order to give agencies

“latitude in organizing their internal operations,” § 533 of the APA specifically exempts rules of procedure or practice from formal rulemaking requirements. *American Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (quoting *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980)). In addition to its ability to establish procedural rules, Congress has also directed DEA to “maintain an active program, both domestic and international, to curtail the diversion of precursor chemicals and essential chemicals used in the illicit manufacture of controlled substances.” 21 U.S.C. § 872. Similarly, DEA is instructed to make an effort to “decrease the movement of methamphetamine and methamphetamine precursors into the United States.” See Comprehensive Methamphetamine Control Act of 1996, Pub. L. 104-237, 110 Stat. 3100 (“CMCA”).

Although the underlying goals of the laws cited by defendants are easily understood, these goals fail to justify DEA’s application of the LONO process to deny PDK a hearing. Furthermore, it is of little significance whether the LONO process is characterized as substantive or procedural, because an agency may not exercise its inherent authority in a manner that conflicts with the procedures created by Congress. “[W]here Congress prescribes the form in which an agency may exercise its authority, [a court] cannot elevate the goals of an agency’s action, however reasonable, over that prescribed form.” *Amalgamated Transit Union v. Skinner*, 894 F.2d 1362, 1364 (D.C. Cir. 1990). Both agencies and courts “are bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.” *MCI Telecommunication Corp. v. American Tel. & Tel. Co.*, 512 U.S. 218, 231 n.4 (1994). In cases where Congress has clearly provided the agency with a process to follow, courts may not “authorize substitution of a potentially more effective method.” *Beverly Enterprises, Inc. v. Herman*, 119 F. Supp. 2d 1, 11

(D.D.C. 2000).

The critical question is not DEA's authority to issue LONOs, but rather whether the process is inconsistent with the law. Section 971 grants the Attorney General, and thereby DEA, the authority to issue suspension orders as a means of formally preventing the importation of certain chemicals. The statute further provides that "a regulated person to whom an order applies" may obtain an expedited hearing. As discussed *supra*, PDK is a "regulated person to whom an order applies" within the meaning of § 971. As such, it is entitled to an expedited hearing of formal suspension orders that apply to it. By refusing the request that a LONO issue for the proposed November 14 shipment, DEA de facto suspended the shipment without either issuing a suspension order or providing PDK an opportunity for a hearing. This use of the LONO process is not only in direct conflict with, but supplants the form prescribed by Congress for the suspension of List I imports.

Even assuming that in evaluating LONO requests DEA applies the same standard as contained in § 971 for suspension orders, it seems clear that DEA has at least circumvented the formal process created by Congress. It should be noted that LONOs themselves are not inconsistent with § 971. PDK even acknowledges as much in that it requests that a LONO issue. However, when defendants refuse to issue LONOs, they must do so in accordance with the suspension process contained in § 971 and the regulations. An informal suspension that sidesteps the congressionally-mandated scheme is contrary to law. Because this finding alone is sufficient to justify the conclusion that PDK has a substantial likelihood success in demonstrating that DEA has utilized the LONO process in a manner contrary to law or in excess of its statutory authority, the court will not address the remaining elements of PDK's APA claims.

The court turns next to PDK's remaining claims, the alleged Fifth Amendment violations contained in Count V. Given the conclusions reached above, it is clear that PDK cannot succeed on its claim that its property rights were violated without due process. However, for the same reasons discussed in reference to the motion to dismiss, PDK has demonstrated a likelihood of success on the merits of its claim that it has been deprived of a liberty interest without the process that is due. Overall, PDK has met its burden of demonstrating to this court that it has a likelihood of success on at least some of its underlying substantive claims.

2. *Irreparable Harm*

The next element of the preliminary injunction analysis is irreparable harm. Affidavits submitted by PDK makes several important showings. First, products containing List I chemicals constitute approximately 75% of PDK's revenue. Affidavit of Reginald Spinello ¶ 5 ("Spinello Aff."). Second, roughly 60% of PDK's employees are directly involved in the manufacturing and packaging of List I products. *Id.* ¶ 6. Third, as a result of DEA's conduct in this case PDK is unable to supply its full range of products to roughly 90% of its customers, and has already laid off 14 employees, 10-12% of its workforce. *Id.* ¶¶ 37, 38. Fourth, a second round of lay offs is scheduled for January, 2001. *Id.* ¶ 39. This situation directly threatens PDK's business reputation, jeopardizes its customer base, and compromises its ability to remain fully operational. *Id.* ¶¶ 31-36; Supp. Spinello Aff. ¶ 4.

Although defendants do not concede that PDK has suffered irreparable injury, they make little effort to contest the point. Defendants' only response is to suggest that List I chemical products are only a portion of PDK's business. *See* Defs.' Opp'n & Mot. to Dismiss at 29-30. However, they make no suggestion that the numbers submitted by PDK are inaccurate, and do not contest the estimate

that 75% of PDK's revenue is derived from List I products. In short, based on the written evidence before it, the court concludes that PDK is threatened with irreparable injury. As a direct result of DEA's actions PDK faces not only the risk of substantial monetary losses, but more importantly the genuine possibility of imminent devastation.

3. *Defendants' Rights and the Public Interest*

Lastly, the court must examine the remaining two factors to be weighed in assessing the request for a preliminary injunction. First, PDK has demonstrated that defendants' rights will not be impaired by the entry of a preliminary injunction. The more difficult question is whether the issuance of a preliminary injunction is in the public interest. In this regard the court must proceed with caution. Neither of the parties in this case express any doubt that the diversion of ephedrine to clandestine methamphetamine labs is a serious problem contrary to the public interest. That having been said, it is DEA, not this court, that Congress has entrusted to protect the public from this danger. In this case, DEA denied the request to import ephedrine destined for PDK because it had "grounds to believe that the proposed importation may be subject to diversion." Pl.'s Mem. at Ex. D. The court doubts that it possesses more expertise than DEA in making such a determination, and is reluctant to order DEA to permit the importation of chemicals that may be used to manufacture illegal drugs. At the same time, however, the court cannot turn a blind eye to defendants' improper conduct. The public also has an interest in requiring agencies to operate within their statutory and regulatory mandates.

The court has discretion when balancing the factors which must be considered in determining whether PDK has made a showing that entitles it to injunctive relief. However, the court's use of its equity power is restricted by the proposition that "[a]n injunction should issue only where the

intervention of a court of equity is essential in order effectually to protect property rights against injuries otherwise irremediable.” *Sea Containers, Ltd.*, 890 F.2d at 1208 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)) (internal quotations omitted). The court’s equity jurisdiction is unique in its flexibility. *See Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). In weighing the competing interests of PDK, defendants, and the public, the court should reach a “nice adjustment and reconciliation between the competing claims” by balancing “the conveniences of the parties and possible injuries to them according as they may be affected by the granting or withholding of the injunction.” *Romero-Barcelo*, 456 U.S. at 312 (internal citations and quotations omitted). Having considered the relevant factors, the court finds that PDK is entitled to some, but not all, of the relief it seeks.

It would be inappropriate in this case for the court to require a LONO to issue with respect to the November 14 shipment. Upon consideration of the evidence and balancing the hardships on all concerned parties, including the public, the appropriate remedy at this juncture is for the court to reinstate PDK’s LONO request for the November 14 shipment and direct DEA to either grant the LONO request or issue a suspension order within a reasonable time, and in any event within 15 days of the docketing of this memorandum. Should DEA elect to issue a suspension order, PDK is then entitled to an expedited hearing as provided for under § 971(c)(2).

Although DEA has not waived its right to object to the November 14 shipment, its objection in the form of only a LONO denial is improper. Essentially DEA acted to suspend the shipment without providing either a sufficient written order or allowing PDK to participate in a hearing. Nevertheless, the statute does not require DEA to permit the shipment to proceed. This court shall only require DEA to

comply with the statute. The DEA may elect to continue with its objection to the proposed November 14 shipment, but it must do so in compliance with the statutory process created by Congress.⁴

Furthermore, during the pendency of this litigation DEA shall comply with the suspension procedures contained in § 971(c)(2) and the implementing regulations, and refrain from blocking proposed imports of List I chemicals by any other means. As noted above, LONOs are not per se invalid. However, defendants may not act to prevent a shipment by refusing to issue a LONO, unless they follow the congressionally prescribed suspension process contained in § 971. Lastly, the court deems it appropriate to declare PDK to be a real party in interest at any hearing relating to the suspension of a List I chemical sought to be imported on its behalf.

IV. CONCLUSION

For the foregoing reasons, it is this 16th day of January, 2001, hereby,

ORDERED that defendants' motion to dismiss for lack of subject matter jurisdiction is **DENIED**; and it is further

ORDERED that defendants' motion to dismiss for failure to state a claim is **GRANTED** with respect to the property interest violation in Count V and Count VI; and it is further

⁴ This relief is coextensive with the relief plaintiff would be entitled to on its mandamus claim. DEA has discretionary power under which it "may" issue a suspension order. However, "if the DEA decides to block a shipment -- by LONO or otherwise -- it must do so in accordance with the statute." Pl.'s Reply Mem. at 23. As provided in §§ 971(c)(1) and (c)(2), DEA through power delegated by the Attorney General, "may" act to suspend a proposed importation of List I chemicals. Written notice of such a suspension order must include "a statement of the legal and factual basis for the order." 21 U.S.C. § 971(c)(1). Following issuance of an order, a "regulated person to whom an order applies" may request an expedited hearing. 21 U.S.C. § 971(c)(2). In this case DEA acted to effectively prevent the importation of ephedrine without either issuing a suspension order or granting PDK a hearing. While DEA has no legal obligation to allow the proposed importation, it must comply with the law in suspending a shipment.

ORDERED that defendants' motion to dismiss for failure to state a claim is **DENIED** with respect to the liberty interest violation in Count V; and it is further

ORDERED that plaintiff's motion for a preliminary injunction and declaratory relief is **GRANTED IN PART**; and it is further

ORDERED that with respect to the November 14 shipment, defendants are enjoined from not complying with 21 U.S.C. § 971 and the accompanying regulations, and accordingly shall either grant the LONO request for the November 14 shipment or issue a suspension order within 15 days from the date of this memorandum; and it is further

ORDERED that with respect to future importation notices, defendants are enjoined from blocking or causing the blockage of proposed imports of List I chemicals to be imported on PDK's behalf by means not set forth in 21 U.S.C. § 971 and the accompanying regulations; and it is further

ORDERED that this court deems PDK to be "a regulated person to whom an order applies" under 21 U.S.C. § 971(c)(2) with respect to the suspension of List I chemicals to be imported on PDK's behalf.

Henry H. Kennedy, Jr.
United States District Judge