

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

PDK LABS INC.,

Plaintiff,

v.

**JOHN ASHCROFT, Attorney General of
the United States, et al.,**

Defendants.

Civil Action 00-02894 (HHK)

Civil Action 00-02899 (HHK)

MEMORANDUM OPINION

PDK Laboratories Inc. (“PDK”) brings these actions against the Attorney General of the United States and the Administrator 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. PDK claims that DEA has violated the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*, (“APA”) and deprived PDK of its property and liberty interests in violation of the Fifth Amendment’s Due Process Clause. Presently before the court are the parties’ cross-motions for summary judgment. Upon consideration of the motions, the respective oppositions thereto, the oral arguments of counsel and evidence presented at hearings before this court and related administrative proceedings, the court concludes that plaintiff’s motion must be granted and defendants’ motion must be denied.

I. BACKGROUND

PDK Labs Inc. (“PDK”), a New York corporation, manufactures over-the-counter pharmaceutical and vitamin products that contain ephedrine, a chemical made only outside of the United States.¹ Illegal controlled substances, notably methamphetamine, can be extracted from such products through a process known as “diversion.” Because of this possibility, the government classifies ephedrine as a List I chemical and regulates its importation into the United States under the Chemical Diversion and Trafficking Act (“CDTA”), 21 U.S.C. § 971.

A. Importation Approval Process

Importers of List I chemicals must notify DEA at least 15 days before 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 manufacture 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, the regulated person has 30 days to request a hearing, which, on request, must be held within 45 days. 21 U.S.C. § 971(c)(2); 21 C.F.R. § 1313.52, 1313.54.

Several countries, including India, 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 an outgrowth of a 1994 international initiative among several nations, including the United States, and the International Narcotics

¹ Therefore, all ephedrine that is in the United States was imported at some point.

Control Board (“INCB”), a United Nations-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 along with a written request that a LONO issue.

Upon request for a LONO, DEA will either issue one, in which case the transaction proceeds, or decline to do so because it perceives a threat of downstream diversion for illicit purposes. Usually, the key factor in the DEA’s decision to grant or deny a LONO for a List I transaction is the identity of the intended purchaser of the chemical for whom the importer is importing the product. When it refuses to issue a LONO, DEA notifies the importer and provides 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. Only if the importer elects option three, and a suspension order is issued, does DEA provide the importer a hearing as required by § 971(c)(2). DEA maintains that the LONO process is standardized and consistent with law but concedes that it is not explicitly authorized in any statute or regulation.

Companies that manufacture products with List I chemicals sometimes obtain the chemicals from the domestic spot market, a surplus supply of such chemicals that have lawfully entered the United States. A surplus is created when shipments of ephedrine approved by the DEA under the Form 486 and LONO processes arrive in the United States, but the intended recipient, for a number of reasons, no longer needs the chemicals, e.g., the intended recipient went out of business or no longer needs as much raw List I materials as it ordered. In such

situations, the importer may resell surplus domestic stocks to other manufacturers. DEA has no authority, comparable to the Form 486 process, to prevent transactions in List I chemicals once they are lawfully inside the United States. Nevertheless, a seller faces legal consequences for providing List I chemicals to a buyer with the knowledge, or reason to know, that the buyer was likely part of a chain of distribution that used the chemicals for illicit purposes. *See, e.g.*, 21 U.S.C. § 842(a)(1), (c)(2)(C); 21 U.S.C. § 841(c), (e), (f); 21 C.F.R. § 1310.05(a), (b).

B. Factual Background

On October 18, 2000, Indace, Inc., submitted a Form 486 and LONO request notifying DEA of its intention to import three metric tons of ephedrine on November 14. Indace's Form 486 specifically identified PDK as the buyer of the ephedrine. On October 25, DEA informed Indace that a LONO would not issue 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.

Indace informed DEA on November 1, that PDK elected option three and would pursue the matter further. On November 10, PDK informed DEA that it awaited the issuance of a formal suspension order. Indace then notified DEA on November 14 that it was not withdrawing its request because it was aware PDK had elected to persist in its effort to obtain the shipment of ephedrine. In a November 17 telephone call with PDK's counsel, and a subsequent November 22 letter, DEA expressed its position that under § 971(c), PDK had no standing to pursue this matter, and that a suspension order could not be issued to PDK.

On December 4, PDK filed this case and requested a preliminary injunction against DEA. 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.

On January 16, 2001 this court granted in part PDK’s motion for a preliminary injunction, ordering that PDK be deemed a “regulated person to whom an order applies” under § 971(c)(2) and enjoining defendants from blocking future imports without complying with § 971. The court also granted DEA’s motion to dismiss in part, dismissing PDK’s claim that the LONO process violated its property interests under the Fifth Amendment Due Process Clause and dismissing PDK's request for mandamus relief. Pursuant to this court’s injunction, DEA suspended Indace’s ephedrine shipment and gave PDK a hearing under § 971.

In May 2001, PDK filed its First Amended Complaint, alleging that DEA again violated the APA and Due Process Clause by interfering with PDK’s attempts to purchase ephedrine on the domestic spot market. At the same time, PDK filed another motion for a preliminary injunction. On July 31, 2001, this court orally granted PDK’s motion and enjoined DEA from discouraging importers from selling their domestic stock of ephedrine to PDK. In May 2002, the parties filed the cross-motions for summary judgment presently before the court.

As this matter proceeded in this court, administrative proceedings took place in compliance with this court’s injunction ordering DEA to give PDK a hearing under § 971. In April 2002, an administrative law judge held that DEA failed to prove its case against PDK and ordered DEA to issue the requested LONOs and allow the shipments to proceed. In November 2002, the DEA Administrator issued an order reversing the ALJ’s findings. In March 2004, the D.C. Circuit vacated the DEA Administrators’ findings, holding that PDK had standing to

challenge suspension orders under § 971. *See PDK Labs. v. U.S. Drug Enforcement Admin.*, 362 F.3d 786, 792-93 (D.C. Cir. 2004) (“PDK Labs”). In April 2004, PDK renewed its summary-judgment motion.

II. ANALYSIS

A. Legal Standards

1. Summary Judgment

Under Fed. R. Civ. P. 56, summary judgment shall be granted if the pleadings, depositions, answers to interrogatories, admissions on file and affidavits show that there is no genuine issue of material fact in dispute and that the moving party is entitled to judgment as a matter of law. Material facts are those “that might affect the outcome of the suit under the governing law.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In considering a motion for summary judgment, the “evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Id.* at 255. But the non-moving party's opposition must consist of more than mere unsupported allegations or denials and must be supported by affidavits or other competent evidence setting forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e); *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). The non-moving party is “required to provide evidence that would permit a reasonable jury to find” in its favor. *Laningham v. United States Navy*, 813 F.2d 1236, 1242 (D.C. Cir. 1987). If the evidence is “merely colorable” or “not significantly probative,” summary judgment may be granted. *Anderson*, 477 U.S. at 249-50.

2. Reliance on Prior Findings

In previous orders, the court denied in part and granted in part PDK's motions for preliminary injunctions and DEA's motions to dismiss. The court's previous orders on these motions have certain effects on its consideration of the parties' motions for summary judgment.

A court may grant summary judgment where it carefully fits its previous findings of law or fact from a preliminary injunction to the summary judgment standard. *See Malcolm v. Reno*, 129 F. Supp. 2d 13, 13 (D.D.C. 2000) (Oberdorfer, J.) (granting summary judgment where “[n]othing in the summary judgment pleadings effectively challenge[d] the findings supporting the . . . preliminary injunction or the reasons for it”).² The conversion is especially appropriate if the party requesting summary judgment fails to adduce new evidence suggesting that the court should revisit its grant of a preliminary injunction. *See Remed Recovery Care Ctrs. v. Township of Williston, Chester Cty, Pa.*, 36 F. Supp 2d 676, 682 n.5 (E.D. Pa. 1999) (“Absent presentation of new evidence, a district court may convert an opinion granting a preliminary injunction into one granting a permanent injunction . . . by expressly recasting its findings and conclusions in terms of the proper legal standard applicable to a permanent injunction.”).

A previous motion to dismiss, granted or denied, may also affect the disposition of a later

² *See also Remed Recovery Care Centers v. Township of Williston, Chester Cty, Pa.*, 36 F. Supp 2d 676, 682 n.5 (E.D. Pa. 1999) (allowing a district court to convert an “opinion granting a preliminary injunction into one granting a permanent injunction” if the court “expressly recast[s] its findings and conclusions in terms of the proper legal standard applicable to a permanent injunction.”) (citing *CIBA-GEIGY Corp. v. Bolar Pharmaceutical Co.*, 747 F.2d 844, 847 (3d. Cir. 1984)); *P.T.C. Brands v. Conwood Co. L.P.*, 887 F. Supp. 963, 965 (W.D. Ky. 1995) (“Where we find no reason shown by any party to depart from our previous ruling, we will utilize our earlier findings . . . [b]ut . . . only if it is shown that no genuine issue of material fact exists”); *Spencer v. U.S. Postal Serv.*, 613 F. Supp. 990, 991 (S.D. Ohio 1985) (granting summary judgment where “foundational facts that counselled [sic] our grant of a preliminary injunction . . . remain[ed] unchanged”).

motion for summary judgment. In general, “[t]he ruling on a motion to dismiss for failure to state a claim for relief is addressed solely to the sufficiency of the complaint and does not prevent summary judgment from subsequently being granted based on material outside the complaint.” 10A WRIGHT, MILLER & KANE, FEDERAL PRACTICE & PROCEDURE: CIVIL 3D § 2713 at 233 (2d. ed. 1998).³ However, a summary judgment motion “may not be made on the same grounds and with the same showing that led to the denial of a previous motion to dismiss.” *See id.* (citing *Mayer v. Distel Tool & Mach. Co.*, 556 F.2d 798 (6th Cir. 1977)). Even if different language is used in a summary judgment motion than in a previous motion to dismiss, if the same legal theory supports both motions, the disposition of the motion to dismiss may serve as the law of the case⁴ and on these grounds, a court may similarly dispose of a motion for summary judgment. *See In re Midwest Milk Monopolization Litig.*, 380 F. Supp. 880 (D. Mo. 1974).

B. LONO Process Claims

PDK alleges that, in implementing the LONO process, the DEA violated the APA and deprived it of its liberty interests under the Fifth Amendment Due Process Clause. DEA claims that PDK has no standing to challenge the LONO process under the APA and thus, the court has no jurisdiction to consider the APA claims. The court first analyzes DEA’s jurisdictional argument and then considers PDK’s administrative and constitutional claims in turn.

³ *See also Wilderness Soc’y v. Griles*, 824 F.2d 4, 16 (D.C. Cir. 1987) (“In sum, while a motion to dismiss may be decided on the pleadings alone, construed liberally in favor of the plaintiff, a motion for summary judgment by definition entails an opportunity for a supplementation of the record, and accordingly a greater showing is demanded of the plaintiff.”).

⁴ “'Law-of-the-case doctrine' refers to a family of rules embodying the general concept that a court involved in later phases of a lawsuit should not re-open questions decided . . . by that court or a higher one in earlier phases.” *Crocker v. Piedmont Aviation*, 49 F.3d 735, 739 (D.C. Cir. 1995). However, this doctrine is a prudential, not jurisdictional, rule. *Id.* at 739-40.

1. Standing

DEA maintains that PDK has no standing to challenge the LONO process because only importers of listed chemicals are “regulated persons” under 21 U.S.C. § 971(c)(1). Defs.’ Mot. for Summ. J. at 5-7. This court previously denied DEA’s standing argument. *See Reno*, 134 F. Supp. 2d at 30-31. Subsequently, the D.C. Circuit held conclusively that PDK had both prudential and Article III standing, under § 971(c)(1), to challenge DEA suspension orders. *PDK Labs*, 362 F.3d at 791-94. The D.C. Circuit’s last word, though at times a breathlessly loquacious last word,⁵ is binding. The court, therefore, concludes that PDK has standing to challenge DEA’s LONO processes and denies DEA’s summary judgment motion on this issue.

2. APA

PDK alleges, in four separate counts,⁶ that the LONO process violates the APA because it allows the DEA to effectively suspend shipments without issuing a suspension order or providing an opportunity for a hearing under § 971(c)(2). The court previously found, in granting PDK’s motion for a preliminary injunction, that PDK was likely to prevail on at least

⁵ *See, e.g., PDK Labs*, 362 F.3d at 792 (“The point is so obviously clear and so clearly obvious that it is scarcely worth articulating--if an importer cannot ship a listed chemical, the domestic customer cannot receive it. PDK’s interests are thus arguably, indeed more than arguably, within the zone of interests § 971(c)(1) regulates.”).

⁶ As PDK observes, the court, in its order of January 16, 2001, explicitly considered only the administrative claims under Count I (agency action in excess of statutory authority) and Count II (agency action contrary to law). Under Counts III and IV, PDK alleges that the LONO process was contrary to established agency practice and was arbitrary and capricious. The court does not consider these counts because it is not necessary to do so in order to grant PDK full relief on its administrative challenge to the LONO process.

some of its APA claims. *Reno*, 134 F. Supp. 2d at 36 (“[T]he LONO process is not only in direct conflict with, but supplants the form prescribed by Congress for the suspension of List I imports.”). The court now upholds that finding in favor of PDK on summary judgment.

In its previous order, the court considered at length the question of whether the LONO process is contrary to law. *Reno*, 134 F. Supp. 2d at 29-31, 34-36. While “an agency may adopt its own procedural rules,” DEA is not free to “exercise its inherent authority in a manner that conflicts with the procedures created by Congress.” *Id.* at 35. The court found that PDK was a “regulated person” under § 971(c)(1) and, therefore, entitled to receive notification and an agency hearing for any order—formal or informal—suspending ephedrine imports. *Id.* DEA concedes that the LONO practice affords no such agency hearing to any party other than importers. *See* Defs.’ Mot. for Summ. J. at 8 (“PDK is not entitled to such a hearing under . . . section 971(c)(2) because it was not the importer of listed chemicals, but only a downstream customer.”). While DEA asserts that the LONO process “does not alter the substantive rights of affected parties,” DEA’s erroneously assumes that importers are the only “affected parties.” Defs.’ Opp’n to Pl.’s Mot. for Summ. J. at 8. On this issue, DEA present no arguments⁷ or evidence which this court has not already considered and, therefore, fails to raise a genuine issue of material fact with regard to the finding that the LONO process, as applied to PDK, both violates § 971 and exceeds DEA’s authority under that statute. As a result, the court converts the

⁷ DEA essentially concedes that it has no new arguments to offer. *See* Def.’s Mot. for Summ. J. at 7 & n.4 (referring the court to DEA’ previous pleadings on the issue of the LONO process). Nevertheless, DEA still submits several pages that, with minor cosmetic changes, are the doppelgangers of the arguments it presented previously. *Compare id.* at 7-11 *and* Defs.’ Opp’n to Pl.’s Mot. for Summ. J. at 5-9 *with* Defs.’ Opp’n to Pl.’s Mot. for Prelim. Inj. & Defs.’ Mot. to Dismiss at 18-23 *and* Defs.’ Reply in Support of Defs.’ Mot. to Dismiss at 16-19.

preliminary injunction issued in *Reno*, 134 F. Supp. 2d at 36, 38-39, and now grants PDK's motion for summary judgment and denies DEA's cross-motion for summary judgment on this issue. See *Malcolm*, 129 F. Supp. 2d at 13. While PDK argues that the D.C. Circuit's opinion compels this conclusion,⁸ it suffices to say that the Court of Appeals's decision supports the court's conclusion that the LONO process, as applied to PDK, violates § 971.⁹

3. Due Process Claim

PDK alleges that the LONO process also violates its liberty interests under the Fifth Amendment Due Process Clause. The court previously denied DEA's motions to dismiss and

⁸ PDK maintains that the logical conclusion of the D.C. Circuit's decision—holding that PDK had standing to challenge a *formal* suspension orders and was entitled to a hearing under § 971(c)(2)—is that an *informal* suspension order, pursuant to the LONO process, violates § 971(c)(2) because it does not afford PDK a hearing to challenge DEA's refusal to issue a LONO. Pl.'s Renewed Mot. for Summ. J. at 3.

⁹ DEA contends that the D.C. Circuit only resolved the issue of standing and did not purport to address the LONO process. DEA is technically correct—whether the LONO procedures violate § 971 was not, strictly speaking, before the D.C. Circuit. See *PDK Labs*, 362 F.3d at 794 (“[W]e have avoided placing a judicial interpretation on § 971(c)(2), the hearing provision.”). Nevertheless, though the D.C. Circuit did not mandate that the LONO process violates § 971, nothing in its decision remotely favors DEA on this issue. The D.C. Circuit hinted, but stopped just short of saying directly, that any process having the effect of a suspension order must conform with § 971(c)(2). See 362 F.3d at 794 (finding that “companies in PDK's position have . . . standing to challenge suspension orders, which themselves must contain a ‘statement of the legal and factual basis for the order’”).

granted PDK’s motions for preliminary injunction on this issue.¹⁰ The court again upholds those findings in favor of PDK on PDK’s motion for summary judgment.¹¹ However, it is necessary to clarify the court’s previous findings somewhat.

DEA cites *Conn v. Gabbert*, 526 U.S. 286 (1999), for the proposition that a plaintiff’s liberty interests are at stake only when the government *completely* prohibits her from engaging in a calling or business. *See* Defs.’ Mot. for Summ. J. at 16; Defs.’ Opp’n to Pl.’s Mot for Summ. J. at 10. This is, simply, wrong. *Conn* did not require a plaintiff to show she was completely barred from engaging in her calling or business to prove deprivation of her liberty interests under the Due Process Clause.¹² Rather, a plaintiff may show injury to her liberty interests in one of two ways—either by identifying a government action that “changes her formal legal status” or by

¹⁰ However, the court, in its initial order on PDK’s preliminary injunction, dismissed PDK’s claim that the LONO process violated its property interests under the Due Process Clause. *Reno*, 134 F. Supp. 2d. at 32-33.

¹¹ Again, DEA provides no new evidence or arguments explaining why the LONO process does not infringe PDK’s liberty interests under the Due Process Clause. DEA again simply reproduces or references its previous pleadings. *See* Defs.’ Mot. for Summ. J. at 15 & n. 7 (citing Defs.’ Mot. to Dismiss 1st Am. Compl. at 19-31, Defs.’ Reply In Support of Mot. to Dismiss 1st Am. Compl. at 13-19).

¹² DEA argues that *Conn* requires a plaintiff to allege that she has been completely prohibited from engaging in her calling. Def.’s Opp’n to Pl.’s Mot. for Summ. J. at 10. As support, DEA cites the following passage from the case: “These cases all deal with a complete prohibition of the right to engage in a calling, and not the sort of brief interruption which occurred here.” Defs.’ Mot. for Summ. J. at 16 (citing *Conn*, 526 U.S. at 292).

DEA cites the passage out of context. “These cases” refers to the few cases the plaintiff, an attorney, relied on to support his claim that his liberty interest in practicing law had been violated by a prosecutor who “cause[d] the attorney to be searched at the same time his client [was] testifying before a grand jury.” 526 U.S. at 287. The Supreme Court simply showed that the plaintiff cited cases, involving complete bans on employment, inapposite to proving that a brief interruption in practicing law deprived him of his liberty interests. *Id.* at 292. *Conn* did not purport to articulate a higher standard to prove a deprivation of a liberty interest. Rather, the case narrowly held that the plaintiff’s particular, and peculiar, claim lacked merit. *See id.* at 293.

showing that a government action, not resulting in a change in formal legal status, had the “broad effect of largely precluding” the plaintiff from pursuing a business. *Kartseva v. Dep’t of State*, 37 F.3d 1524, 1528 (D.C. Cir. 1994).¹³ DEA does not dispute that, historically, 75% of PDK’s revenues come from the sale of products containing List I chemicals. *See Reno*, 134 F. Supp. 2d at 37. Neither does DEA dispute evidence that such refusal to issue LONOs for ephedrine imports headed for PDK has the direct effect of preventing PDK from engaging in its core business, and that its refusal threatens PDK’s livelihood as a business. *Id.* Because there is no dispute over these material facts, the court finds that the LONO process also deprives PDK of its liberty interest to engage in its business, grants PDK’s summary judgment motion on this issue, and denies DEA’s cross-motion.

C. Domestic Transactions Claims

PDK also alleges that DEA interfered with its attempts to acquire ephedrine domestically in violation of the APA and Due Process Clause. After analyzing DEA’s jurisdictional challenge, the court analyzes the two claims in turn.

1. Final Agency Action

¹³ DEA repeatedly argues that the cases this court cites do not refer to or address *Paul v. Davis*, 424 U.S. 693 (1976), which held that damage to reputation alone does not implicate a plaintiff’s liberty interests. *See, e.g.,* Defs.’ Opp’n to Pl.’s Mot. for Summ. J. at 9. This is incorrect. *Kartseva* cited *Paul* in acknowledging that reputational injury alone did not constitute an “‘employment foreclosure’ liberty claim.” 37 F.3d at 1527 (citing *Paul*, 424 U.S. at 694). Further, *Kartseva* observed that *Paul*, and cases following it, established that state action resulting in a change in formal legal status was just one of the two ways to prove an infringement of liberty interests under the Due Process Clause. *Id.* at 1527-28. Finally, DEA mis-cites *Taylor v. Resolution Trust Corp.*, 56 F.3d 1497 (D.C. Cir. 1995). DEA claims that *Taylor* requires PDK to show that DEA’s actions resulted in a change in formal legal status. *See* Defs.’ Opp’n to Pl.’s Mot. for Summ. J. at 9 (citing 56 F.3d at 1506). However, *Taylor* acknowledged that either a “sufficiently formal or sufficiently broad” government action may infringe on a plaintiff’s liberty interests. 56 F.3d at 1506 (citing *Kartseva*, 37 F.3d at 1524, 1528, 1529).

DEA contends that the court lacks jurisdiction over PDK's domestic transaction claims because DEA's actions were not final agency actions under the APA, 5 U.S.C. § 704, and cannot be reviewed. Specifically, DEA repeats two arguments,¹⁴ without attempting to raise any new factual issues. First, DEA claims that, under the general rule of finality, its actions were not final because they were executed by subordinate officials. Second, DEA insists that its officials did not engage in final actions because they offered advice on "purely hypothetical" courses of action. The court previously deferred consideration of this issue when it granted PDK a preliminary injunction;¹⁵ it now finds that DEA's arguments are meritless, and that the acts of DEA subordinate officials can be reviewed as final agency actions.

The APA provides for judicial review over "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Generally, an act is not final or binding if it is only the ruling of a subordinate official. *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). However, this factor alone is not dispositive. "Finality" must be interpreted in a flexible and pragmatic way. *See id.* at 796-97 (citing *Abbott Laboratories v. Gardner*, 387 U.S. 136, 152 (1967)). Furthermore, how an agency characterizes its actions does not determine whether they are final. *New York Stock Exch. v. Bloom*, 562 F.2d 736, 740 (D.C. Cir. 1977) ("The label an agency attaches to its actions is not determinative. The

¹⁴ Defs.' Mot. for Summ. J. at 12 (citing Defs.' Mot. to Dismiss 1st Am. Compl. at 14-17; Defs.' Reply in Support of Defs.' Mot. to Dismiss 1st Am. Compl. at 8-13).

¹⁵ *See* Tr. of July 31, 2002 Proceedings at 3 ("July 31 Tr.") (finding that the court "need not specify whether plaintiff's claim under the [APA] will prevail because . . . plaintiff has demonstrated a likelihood of success on its 5th amendment liberty interest claim"); *id.* at 6 (enjoining DEA subordinates from "communicating to [List I] companies . . . not to sell domestic [List I] chemicals to PDK Labs or that DEA disapproves of such sales").

action may be reviewable even though it is merely an announcement of a rule or policy that the agency has not yet put into effect. Indeed, agency action may be reviewable even though it is never to have any formal, legal effect.”). Otherwise agency rulings could escape judicial review simply by virtue of their form (or lack thereof), or because the agency refused to frankly acknowledge their finality. *See Natural Res. Def. Counsel v. EPA*, 22 F.3d 125, 1132-33 (D.C. Cir. 1994) (“NRDC”); *Sabella v. United States*, 863 F. Supp. 1, 3-4 (D.D.C. 1994). Rather, the key issue is whether the agency’s position is “definitive” and has a “direct and immediate effect” on the day to day business of the party challenging the agency. *NRDC*, 22 F.3d at 1132; *Sabella*, 863 F. Supp. at 3.

DEA’s argument on finality is, as a matter of law, meritless. No one disputes that DEA subordinate officials committed the acts challenged by PDK. This fact alone, however, does not compel the conclusion that DEA’s actions were not final and binding. *See NRDC*, 22 F.3d at 1132; *Bloom*, 562 F.2d at 740. Rather, the court must still decide whether DEA’s actions were “definite” and had a direct, immediate impact on PDK’s business. *NRDC*, 22 F.3d at 1132.

DEA contends that its actions were neither definite nor directly and immediately effective because its communications with potential domestic suppliers about engaging in transactions with PDK were “purely hypothetical.” The court has not yet considered, explicitly, this finality argument, *see* Tr. of July 31, 2002 Proceedings at 3 (“July 31 Tr.”). However, the previous preliminary injunction ruling provides the foundation for holding that DEA’s acts were final and binding. DEA claims to raise a genuine issue of fact by arguing that, as a matter of fact, DEA’s communications with PDK’s would-be domestic suppliers were “purely

hypothetical.”¹⁶ However, the evidence they cite specifically says the opposite and indicates that importers with domestic ephedrine stock called specifically to inquire whether they should sell to PDK or not.¹⁷ Further, the court previously found that the statements of DEA subordinates, “whether made in reference to hypothetical Form 486 inquiries or otherwise, undoubtedly have the effect of communicating DEA’s desire for companies to [refrain] from selling domestic stock of [List I] chemicals to PDK.” *Id.* at 4. DEA subordinate officials knowingly discouraged concrete proposals, not purely hypothetical plans, to sell domestic ephedrine stock to PDK. *Id.* The direct and immediate result was that PDK, already unable to import ephedrine, could not buy ephedrine domestically, threatening the existence of PDK as an ongoing concern. *See* ALJ Hrg. Tr. (Apr. 16, 2001) at 2295 (Test. of Reginald Spinello, President of PDK) (noting that because of DEA’s communications with domestic importers, “no one will sell us domestic product”); *id.* at 2294 (“[A]t this point, we’re being suffocated, being strangled by the DEA. We’re going to go out of business if this keeps up.”). As a result, the court finds that the DEA’s acts with regard to PDK’s domestic transactions constituted final agency actions and are, thus, reviewable.

¹⁶ *See* Def.’s Opp’n to Pl.’s Mot. for Summ. J. at 17-20 (citing Uncapher Dep. at 332, 334, 335; Crawford Dep. at 13-14, 31-32, 40, 41-43; Rubbins Dep. at 136, 145-46, 154, 155-156-67, 158, 159-60).

¹⁷ *See* Uncapher Dep. at 328 (“Q: It’s true, is it not, that in PDK’s case, for example, suppliers of domestic chemicals have contacted your office and asked should we sell this product to PDK? A: That’s true.”); Crawford Dep. at 6-10 (acknowledging, after repeated questioning by plaintiff’s counsel, having had discussions with an importer about its intention to sell PDK domestic ephedrine stock); Rubbins Dep. at 156 (admitting that two companies called DEA indicating that they wished to sell domestic stock to PDK).

2. APA Claims

In Counts I and II, PDK alleges that DEA's actions to discourage PDK's attempts to purchase ephedrine domestically exceeded the DEA's statutory authority and were contrary to law under the APA. The court previously found, and DEA concedes, that DEA has no authority to block a domestic shipment of List I chemicals. July 31 Tr. at 3; Defs.' Opp'n to Pl.'s Mot. for Summ J. at 18. However, the issue is whether DEA nonetheless thwarted PDK's attempt to buy ephedrine domestically. The court finds that it did and therefore grants PDK's motion for summary judgment on this issue.

It is uncontested that DEA has no authority to block or interfere with domestic transactions. DEA, however, argues that the actions of its subordinates did not really thwart PDK's attempts to obtain ephedrine domestically. The court previously deferred full consideration of whether DEA's actions were contrary to law. In granting PDK's preliminary injunction, the court found that "[e]vidence in the record supports plaintiff's position that DEA affirmatively indicated to List I chemical[suppliers] that it disapproved of the sale of List I chemicals to PDK." July 31 Tr. at 4. This finding precludes granting DEA's summary judgment on this issue, especially since DEA offers no new arguments or evidence to contradict the court's conclusion.¹⁸ However, the same passage does not say that there was no genuine issue of material fact with regard to whether DEA's actions thwarted PDK's domestic transactions. The

¹⁸ DEA's summary judgment pleadings are nearly identical to what it presented in opposition to PDK's second motion for a preliminary injunction. *Compare* Defs.' Opp'n to Pl.'s Mot. for Summ. J. at 16-23 *with* Defs.' Opp'n to Pl.'s Mot. for Prelim. Inj. Relief at 11-20.

court simply concluded that PDK was likely to succeed. The court must analyze this issue further because DEA purports to raise a disputed issue of fact by characterizing discussions between DEA officials and PDK's would-be domestic suppliers as "purely hypothetical."

The record indicates that DEA's communications with potential suppliers of domestic ephedrine stock did not regard merely hypothetical transactions. *See* Uncapher Dep. at 328; Crawford Dep. at 6-10; Rubbins Dep. at 156. Furthermore, DEA officials admitted that they wished to discourage even these legal domestic transactions. Uncapher Dep. at 329, 331, 336 (conceding that DEA tried to communicate to domestic suppliers that DEA did not want them to ship to PDK); Crawford Dep. at 23-24, 53-55. Finally, DEA's communications had the effect of thwarting of importers' planned transactions with PDK. Uncapher Dep. at 336 (acknowledging that he could not think of instances when an importer supplied PDK "domestic" ephedrine after talking with DEA officials); *see* ALJ Hrg. Tr. (Apr. 16, 2001) at 2295 (Spinello Test.) ("[N]o one will sell us domestic product"). As a result, there can be no dispute that DEA's actions actually frustrated and were intended to frustrate PDK's attempts to obtain ephedrine domestically.

Despite the clarity of the record on this issue, DEA claims that its officials told importers that DEA had no authority to block domestic shipments to PDK. *See* Defs.' Opp'n to Pl.'s Mot. for Summ. J. at 16-21. However, this is consistent with the evidence that, nonetheless, DEA's communications thwarted PDK's transactions. DEA did not need to tell importers explicitly that they could not ship to PDK in order to discourage them from doing so. To understand this requires an explanation of the interaction between Form 486s and domestic transactions.

As mentioned before, there are no purely domestic sources of ephedrine—all ephedrine in the United States was imported at some point. Crawford Dep. at 18-19. Before receiving a shipment, an importer of List I chemicals must get pre-approval from the DEA via the Form 486 and LONO procedures. DEA’s main concern when deciding Form 486 requests is the identity of the intended, eventual recipient of the chemicals. *See* Levinge Dep. at 28 (“[W]hen the 486 is received, the first thing we do is we contact the importer and ask whom are you importing this for.”); Uncapher Dep. at 221-22 (“DEA will not approve a 486 . . . unless it knows who the intended beneficiary is for that [List I] chemical.”). This inquiry allows DEA to prevent downstream diversion of ephedrine. Obviously, if ephedrine is not in the United States, it cannot be diverted to buyers likely to make illegal substances, either.

As a result, the “domestic spot market” poses somewhat of a problem for DEA. Once ephedrine is legally in the United States, the DEA has no authority to prevent a purely domestic transaction from taking place--DEA has already approved the Form 486 and LONO requests for these stocks, understanding that they were intended for recipients posing little threat of diversion in DEA’s eyes. With domestic surplus stocks, an importer may--without a Form 486, LONO or other DEA pre-approval--sell to recipients which DEA believes to pose a great risk of diversion.

However, despite the lack of a pre-approval process, these domestic transaction are not without risk for importers. As entities registered with the DEA, importers face numerous dire consequences under the Controlled Substances Act¹⁹ for completing transactions that they knew

¹⁹ Diversion notices, like the ones PDK received from DEA, include standard citations to statutes and regulations which list the penalties for being part of a chain of distribution that ultimately uses listed chemicals for illegal purposes. *See* Ex. 4 at 2 to Def.’s Mot. for Summ. J. (Uncapher Ltr. To Spinello, Notice of Diversion, Dec. 28, 2000) (citing 21 C.F.R. § 1310.05(a), (b), 21 U.S.C. § 842(a)(1), (c)(2)(C), 21 U.S.C. § 841(d), (f), (g)). Under 21 C.F.R. §

or should have known would result in placing listed chemicals into a chain of distribution that eventually diverted chemicals for illicit purposes. DEA officials know this and sometimes remind importers of the consequences of doing business with suspect buyers:

I think there's another set of regulations that's involved and that is regarding suspicious purchases and sales to individuals who are notified of their product going into illicit markets, okay. I mean there is another set of regulations regarding all people registered to handle list one chemicals, that they must monitor and review their sales to insure that none of them are suspicious. If they are suspicious, they are required by regulation to report those suspicions.²⁰ Our counsel to them at that point is if you're suspicious, why are you going ahead and selling it.

Crawford Dep. at 21. Understandably, then, though there is no pre-approval process, importers seek DEA guidance before selling domestic stock. In asking about domestic transactions with PDK, importers received this as advice:

We are not allowed to tell a supplier who they sell and who they don't sell. *We say it's their responsibility and it's an important responsibility.* And so we make sure that we are all agreed on that because we are, again, we are not allowed to tell a supplier you can make this sale, you can't make that sale. *We say that's your responsibility and you bear the – you know, the consequences of all your distributions, you know.*

Uncapher Dep. at 332 (emphasis added).

When DEA says it will not issue a “hypothetical” Form 486 for domestic transactions

1310.05(a), (b), regulated persons must report to the DEA any regulated transaction involving an extraordinary quantity of listed chemical, uncommon method of payment or delivery or any other suspicious act which may indicate that the listed chemical will be used in violation of the regulation. Under 21 U.S.C. § 842(a)(100), (c)(2)(C), any firm that distributes listed chemicals with reckless disregard for the illegal purposes which the chemicals will be used can receive a civil fine of \$250,000. Under 21 U.S.C. § 841(d), (f), (g)--now 21 U.S.C. § 841(c), (e), (f)--whoever knowingly or intentionally distributes a listed chemical having reasonable cause to believe that its use is for the unauthorized manufacturing of a controlled substances shall be fined or imprisoned.

²⁰ Crawford is apparently referring to 21 C.F.R. § 1310.05(a), (b).

with a particular buyer the message to would-be domestic suppliers is unmistakable—it is notice to a seller that a potential buyer is likely part of a chain of distribution that eventually diverts List I chemicals for illegal purposes. *See* Golubock Decl. ¶ 14 (indicating that the basis for granting a Form 486 request is “the legitimacy of the proposed transaction and the likelihood that the chemicals ‘may be diverted to clandestine manufacture of a controlled substance.’”). Since the consequences for doing business with such a buyer are clear, DEA’s message is more than a simple *caveat vendor*, or seller beware. Rather, it is the proverbial mailed fist in a velvet glove. DEA need only suggest that PDK was a “suspicious buyer,” without mentioning the statutory and regulatory “consequences” of selling chemicals to such a buyer, to scare off PDK’s would-be suppliers. A statement to would-be domestic sellers, such as “we cannot tell you what to do, but do your own due diligence, and you bear the consequences” is, by itself, neutral and appropriate, given that DEA has no statutory authority to prevent domestic transactions in listed chemicals. But by also opining on hypothetical Form 486s, DEA’s advice was no longer neutral—it became a critical signal that, in the eyes of the DEA, PDK’s products were in danger of being diverted. Further, after being told by DEA officials that hypothetical Form 486s would not issue for transactions with PDK, would-be sellers could not later avoid liability or criminal penalties—enforced by DEA—by claiming that they did not know, or have reason to know, that PDK might be a suspect buyer. *See supra* note 19. The hypothetical Form 486 responses by DEA officials were sufficiently clear that, in fact, no domestic supplier would ship ephedrine to PDK. *See* ALJ Hrg. Tr. at 2295 (Spinello Test.). While preventing diversion is laudable, DEA must rely on the retrospective, as opposed to the prospective, mechanisms available to it. DEA may not offer so-called “advice” or “information” that would clearly scare-off would-be

domestic suppliers of List I chemicals. There is no genuine issue of material fact that DEA's actions actually thwarted PDK's domestic transactions, and that DEA had no such authority to prevent such transactions. Such actions are contrary to law and DEA's statutory authority. The court grants plaintiff's motion and denies defendants' summary judgment motion on this issue.

3. Due Process Claims

In Count VI, PDK alleges that DEA's actions with regard to domestic transactions violated its liberty and property interests under the Fifth Amendment Due Process Clause. In its previous decision, the court explicitly found that PDK was likely to prevail on its liberty interest claim. July 31 Tr. at 5. The court finds no reason to revisit that finding here. Indeed, the court's previous analysis in this opinion further supports the conclusion that DEA deprived PDK of its liberty interest by thwarting its attempts to acquire ephedrine domestically. PDK has a liberty interest in receiving imported ephedrine, *see supra* Part II.B.3, and the reasoning leading to that conclusion applies with equal force to PDK's liberty interest in receiving domestic ephedrine. DEA's efforts at making domestic ephedrine unavailable to PDK, because DEA had scared all would-be domestic sellers, had the direct and "broad effect of largely precluding" PDK from engaging in its core business, threatening its survival as an ongoing concern. *See Kartseva*, 37 F.3d at 1528. There is no genuine issue of fact that DEA's actions deprived PDK of its liberty interest in its business of manufacturing products with ephedrine. The court grants summary judgment in favor of plaintiff on this issue.²¹

²¹ In reaching this conclusion, the court does not, and need not, determine whether DEA also deprived PDK of its property interest in obtaining domestic ephedrine.

CONCLUSION

“Run silent, run deep” may be excellent advice for the submariner, but they are poor words to live by for an administrative agency. The DEA applied the LONO process in such a way as to deprive PDK of access to both imported ephedrine and a hearing to challenge DEA’s actions. Similarly, hypothetical Form 486 discussions with would-be sellers allowed DEA to frighten PDK’s domestic suppliers of ephedrine from engaging in transactions while, at the same time, avoiding judicial review by claiming that there was no final agency action. However, the APA is flexible enough to allow for review in such situations. Further, DEA’s actions rose to the level of constitutional deprivations which, in any case, this court may review. DEA’s goals are understandable and laudable. Nevertheless, unlike the submariner, the DEA must run on the surface. For the foregoing reasons, the court grants plaintiff’s motion for summary judgment and denies defendants’ motion. A separate order accompanies this memorandum opinion.

Henry H. Kennedy, Jr.
United States District Judge

Dated: August 27, 2004

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

PDK LABS INC.,

Plaintiff,

v.

**JOHN ASHCROFT, Attorney General of
the United States, et al.,**

Defendants.

Civil Action 00-02894 (HHK)

Civil Action 00-02899 (HHK)

ORDER and JUDGMENT

For the reasons stated in the court's memorandum opinion docketed this same day, it is this 27th day of August, 2004, hereby

ORDERED that **JUDGMENT** is entered in favor of plaintiff and against defendants; and it is further

ORDERED 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; and it is further

ORDERED that defendants and their subordinates are enjoined from communicating to List I companies, through advice or opinions, hypothetical or otherwise, or by any other means,

not to sell domestic List I chemicals to PDK Labs or that DEA disapproves of such sales. This order does not prohibit DEA from disclosing information regarding PDK Labs that is available as a matter of public record and not otherwise prohibited by law from disclosure.

Henry H. Kennedy, Jr.
United States District Judge