No. _____

In The
Supreme Court of the United States

NOVELTY, INC.,

Petitioner,

v.

MICHELLE M. LEONHART, IN HER OFFICIAL CAPACITY AS DEPUTY ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S. DRUG ENFORCEMENT ADMINISTRATION; THE U.S. DEPARTMENT OF JUSTICE; AND THE UNITED STATES OF AMERICA,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The District Of Columbia Circuit

PETITION FOR A WRIT OF CERTIORARI

JONATHAN W. EMORD*
ANDREA G. FERRENZ
PETER A. ARHANGELSKY
CHRISTOPHER K. NIEDERHAUSER
EMORD & ASSOCIATES, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Ph: (202) 466-6937
Fx: (202) 466-6938
jemord@emord.com
**Counsel of Record*

Counsel for Petitioner

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

QUESTIONS PRESENTED

This case involves a D.C. Circuit decision that upholds DEA revocation of a DEA List 1 chemical registration despite a three way conflict that left the court without a majority rationale for decision. Judge Henderson ruled that the DEA properly interpreted "principal place of business" in 21 U.S.C. § 822(e) to require registration of over 100 cross-docking stations used in-transit during shipment of product from the registrant's headquarters to its retail customers. Judges Tatel (concurring) and Brown (dissenting) reasoned that the DEA interpretation was contrary to the statute's plain meaning, but Tatel nevertheless ruled that dicta in the DEA decision questioning whether cross-docks were safe justified a *post hoc* appellate conclusion that the cross-docks were unsafe (an internally inconsistent ruling because Tatel expected security akin to registered facilities for cross-docking stations he agreed did not need to be registered). Thus, the case rests on no rationale for decision acceptable to a majority and should not have resulted in an affirmance. The case thus presents the following questions:

(1) Whether the decision below effectively vests in the Drug Enforcement Administration (DEA) discretionary authority beyond the limits of the Controlled Substances Act (CSA), 21 U.S.C. § 823(h), such that the Deputy Administrator (DA) may revoke the registration of any DEA registrant on almost any

QUESTIONS PRESENTED – Continued

pretext without effective federal judicial review under the CSA or the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(b), in contravention of the decisions of this Court, of the sister circuits, and of the D.C. Circuit.

(2) Whether the decision below is incompetent due to contradictory bases for decision, because no two judges on the panel agreed on a single basis for DEA registration revocation (and the basis articulated by one judge in the majority contradicts the basis articulated by the other).

(3) Whether the decision below upholds the DA's DEA registration revocation based on an impermissible *post hoc* rationalization in contravention of this Court's precedent, that of the D.C. Circuit, and that of all sister circuits, wherein reliance on the court's own *post hoc* rationalization as a substitute for the agency's actual basis for decision is forbidden.

PARTIES TO THE PROCEEDING

All of the parties are listed in the caption of the Petition.

CORPORATE DISCLOSURE STATEMENT

Petitioner Novelty, Inc. ("Novelty"), by counsel and pursuant to Sup. Ct. R. 29(6), states that it has no parent companies. No publicly-held company has any ownership interest in Novelty. Novelty is a distributor of novelty items and other goods sold to convenience stores throughout the United States, including, but not limited to, over-the-counter cold and cough products containing List 1 chemicals under the Controlled Substances Act.

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The D.C. Circuit issued its decision on June 22, 2009, reported at *Novelty, Inc. v. DEA,* 571 F.3d 1176 (D.C. Cir. June 22, 2009) ("D.C. Circuit Decision") (App. 1). That Court's unpublished order denying rehearing, *Novelty, Inc., v. DEA*, No. 08-1296 (D.C. Cir. Filed July 28, 2009) (App. 365), issued on July 28, 2009. The DA's Final Order revoking Novelty's DEA registration issued on September 10, 2009, reported at *Novelty Distributors, Inc.; Revocation of Registration*, 73 FR 52689 (September 10, 2008) ("Order") (App. 59). Administrative Law Judge Gail A. Randall (ALJ) rendered her ruling in favor of Novelty's continued registration on May 21, 2008. *See In Re Novelty Distributors*, DEA Dkt. No. 08-33, Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (May 21, 2008) ("ALJ Decision") (App. 137).

JURISDICTION

The D.C. Circuit entered its decision on June 22, 2009 and denied Novelty's timely Petition for Rehearing and Suggestion for Rehearing En Banc on July 28, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS

The statutes and regulations involved in this case are presented verbatim in the statutory addendum (Sup. Ct. R. 14(f), (i)(v)).

STATEMENT OF THE CASE

This Petition raises questions of great importance for all DEA registered distributors of schedule listed chemicals (SLCs). From 2004 until September 2008, the DA issued 54 consecutive decisions revoking or refusing to grant registrations for independent distributors (Independents) that sell ephedrine and pseudoephedrine cough and cold remedies to retail stores in direct competition with the distributors of Wyeth's Primatene and Primatene Mist and Pfizer's Sudafed. Every company the DA charged she condemned, revoking or denying 54 out of the 54 registrations she called into question.[1] She has done so even in instances where there is no reliable evidence of diversion to the illicit methamphetamine trade, as in Novelty's case. Despite state criminal actions against over 20 distributors of the Wyeth and Pfizer brands to pharmacies, the DA has not brought

[1] Since the Novelty case was decided below, the DA granted a single renewal of application on July 24, 2009. *See CBS Wholesale Distributors,* 74 FR 36746 (2009).

any action against them.[2] Hers has been a biased, anticompetitive campaign where in the case of Independents a record void of criminal conduct is treated equally with one replete with it and where a charge from the DA leads to her ultimate decision to revoke regardless of the evidence adduced at hearing – with the rights of the accused suspended throughout. That biased, anticompetitive campaign the majority D.C. Circuit decision condones in perpetuity unless and until this Court intervenes to restore the rule of law.

By resolving the issues presented here, this Court will decide whether the DA may wield her power arbitrarily and capriciously beyond statutory limits by revoking the DEA registration of a company that directs its products to those with legitimate

[2] In an illegitimate line of cases preceding Novelty's, the DA, in reliance on the very "expert" rejected in the Novelty case, Jonathan E. Robbin, proclaimed there to be two markets for ephedrine and pseudoephedrine. One, said to be legitimate, was the "traditional market" served by the distributors of the Pfizer and Wyeth brands that Robbin presumed, despite contrary evidence, free from diversion risk (the pharmacies). Another was termed the "nontraditional market" served by independent distributors and competitors to the Pfizer and Wyeth brands that Robbin presumed inherently at risk of diversion (convenience stores). There is no sound evidence to support this distinction, yet, the DA has credited it since 2004 and has revoked or denied at least 54 DEA registrations in reliance upon it. *See, e.g., Sunny Wholesale, Inc.,* 73 FR 57655, 57666-67 (2008); *Wholesale, Inc.*, 72 FR 71956 (2007); *Tri-County Bait Distributors*, 71 FR 52160, 52161-62 (2006); *Joy's Ideas*, 70 FR 33195, 33199 (2005); *Branex, Inc*., 69 FR 8682, 8690-92 (2004).

medical need without requisite proof that the company's principals engaged in any unlawful activity or created any provable risk of diversion to the illicit methamphetamine trade.

This case proved to the ALJ's (and to Circuit Judge Janice Brown's) satisfaction, based on Emory University expert statistician Joanna M. Shepherd, Ph.D.'s rebuttal testimony, that the DEA's sole "expert" on diversion risk was inexpert in statistics (had no Ph.D. in that or any other subject) and was biased. That same person, Jonathan E. Robbin, the DA used in at least 26 cases to justify revocation, often on the basis of Robbin's contrived (and patently absurd) representation (also made in Novelty's case) that the sale of any SLC cough and cold products by a single convenience store over $14.39 per month was proof of sales beyond legitimate demand. On a complete record, the ALJ concluded that Robbin lacked credibility, relied on an impeached methodology (one that violated basic principles of statistics), and employed biased data.[3] Novelty not only refuted Robbin, it proved to the DEA ALJ's satisfaction that Novelty posed no unreasonable risk of diversion; had a long history of compliance with the

[3] Even after accepting the ALJ's findings on Robbin's incompetence and bias in the Order, the DA continues to rely on Robbin's figures as the basis for the national ephedrine and pseudoephedrine quota. *See Established Assessment of Annual Needs for the List I Chemicals Ephedrine*, *Pseudoephedrine, and Phenylpropanolamine for 2009,* 74 FR 32954.

law (indeed, no executive of the company had ever been accused of a criminal offense); had developed a sophisticated anti-diversion program exceeding federal regulatory requirements; had never been complicit in drug diversion; and had proven itself a reliable partner for DEA.

Despite that proof, the DA reversed the ALJ's well-reasoned decision and condemned Novelty anew on grounds not recited in her charges against the company and not the subject of the evidentiary hearing before the DEA – grounds two D.C. Circuit Judges rejected. Nevertheless, relying on different (and contradictory) *post hoc* rationales, two of the D.C. Circuit Judges upheld the DA's decision, ending the employment of 26 Novelty employees and forcing an $8,000 per year reduction in income for 100 more, not to mention the loss of major contracts with Novelty's primary customers.

In her dissent from the decision, Judge Brown lamented:

> It does not matter that no Novelty executive has ever been convicted of a crime. It does not matter that notwithstanding Novelty's millions of sales, the best evidence the DA can point to of diversion is one – *one!* – instance from over six years ago. It does not matter that the DEA inspected Novelty's records for years and never peeped about a problem before deciding to bring down the full weight of the Executive Branch on Novelty's head. It also is irrelevant that

> Novelty has credibly offered to overhaul its internal processes to comply with the DA's whims.

D.C. Circuit Decision at 1199 (Brown, J., dissenting); App. 57-58.

Judges Henderson and Tatel offered separate and conflicting bases for the decision. There is no majority basis for violation. Judge Henderson found Novelty violated the CSA, 21 U.S.C. § 822(e), presuming each in-transit cross-docking station used by Novelty truck transport to be a "principal place of business" that had to be DEA-registered under Section 822(e). She then justified revocation because of isolated single instances of alleged violation of Novelty's own corporate policy,[4] not required by federal law, that distributors limit sale of 24 count SLC packages to two per transaction[5] and because of record-keeping errors that amounted to less than 0.00012% out of millions of properly recorded transactions.[6] Judge

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[4] The dissent correctly explained an error rate of no more than 0.2%. *See D.C. Circuit Decision* at 1197 (Brown, J., dissenting).

[5] Faulting Novelty for its convenience store customers' rare violation of Novelty's 24 count SLC package sales limit makes little sense for a second reason. Under federal law, Novelty is forbidden to review the content of those customers' sales logs. Only DEA may examine the logs. *See D.C. Circuit Decision* at 1195 n.6 (Brown, J., dissenting) (citing Order at 52699 n.43); App. 48. Consequently, the isolated instances of violation found by DEA could not have been discovered by Novelty.

[6] *See* ALJ Decision at 78; App. 259 (discussing very low error rate of 60,000 out of 300-500 million units).

Tatel rejected Judge Henderson's grounds, finding no DEA registration required under Section 822(e) for in-transit cross-docking stations, interpreting "principal place of business" within the CSA not to reach every point in-transit between a company's headquarters and the ultimate delivery point. Rather, Judge Tatel upheld the DA because by concluding (on a record void of evidence) that security at the cross-docking stations (the very ones he said were not required to be registered and thus not required to have the security of a registered facility) was "unlikely" to meet the security requirements of registered facilities. Thus, Judge Tatel's position contradicts itself while also contradicting Henderson. He also concluded that the few instances of convenience store violation of Novelty's 24 count package sales limit (a limit not required by federal law) justified the sanction of revocation. Accordingly, the D.C. Circuit decision is incompetent because the basis articulated by one judge in the majority contradicts the basis articulated by the other.

The D.C. Circuit's decision conflicts with precedent from this Court, the D.C. Circuit, and the sister circuits. It substitutes the panel's own *post hoc* rationale for decision for the DA's articulated basis. Had the case been evaluated on the DA's basis, two of the three panel judges by their own statements would have reversed. Instead, upon a new rationale for revocation, two of the three upheld registration revocation. The decision tells the DA that the D.C. Circuit will uphold her decisions even when the

rationale she articulates fails to support the decision she reaches. To arrest and reverse the lawless actions, Novelty respectfully requests grant of this Petition.

A. Novelty, Inc.

Under the Controlled Substances Act ("CSA"), "[e]very person who . . . distributes any . . . list I chemical shall obtain annually a registration issued by the Attorney General." 21 U.S.C. § 822(a)(1). The Attorney General must register all applicants unless he determines registration to be "inconsistent with the public interest." 21 U.S.C. § 823(h). He must evaluate five factors in determining whether the public interest would be disserved by registration:

> (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
>
> (2) compliance by the applicant with applicable Federal, State, and local law;
>
> (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
>
> (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
>
> (5) such other factors as are relevant to and consistent with the public health and safety.

21 U.S.C. § 823(h).

Between 1998 and 2007, DEA never issued Novelty a warning letter, never accused Novelty of committing any rule violation, never informed Novelty that its product was illegally diverted,[7] and never told Novelty that it acted in any way inconsistent with the public interest. DEA conducted 3 investigations of Novelty, informing Novelty after each that it was in full compliance with DEA requirements and issuing Novelty registration renewals.[8] The record abundantly supports the DEA ALJ's conclusion that Novelty's executives were law-abiding, credible, dedicated to the institution and maintenance of diversion controls, and deserved the agency's trust.[9]

Novelty expended millions on diversion risk reduction training, education, security, and monitoring. Novelty distributed its products through a

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[7] *See D.C. Circuit Decision*, at 1195 (Brown, J., dissenting) ("The best the DA can muster is an event from 2002 when 'twenty-two' [bottles of ephedrine based product] were found at an illicit methamphetamine laboratory . . . and it is uncertain whether [Novelty] even distributed them"); App. 47.

[8] *See Novelty, Inc. v. Tandy et al.*, No. 1:04-cv-01502 (S.D. Ind. 2008) (Hamilton, C.J.) ("The DEA conducted investigations of Novelty in 2002-2003 and in 2007 . . . , and the DEA continued to be aware of Novelty's distribution practices. At no time during the pre-registration or subsequent investigations did the DEA inform Novelty that its practices violated . . . federal regulations regarding distribution of List I chemicals"), *available at*, 2008 WL 3835655 ("Hamilton Opinion"); App. 373-374.

[9] *See, e.g.,* ALJ Decision, at 98-99 (summarizing Novelty's compliance with the CSA); App. 279-281.

costly closed system of distribution employing Novelty manned trucks, manned by Novelty anti-diversion trained drivers. Novelty products were shipped from its headquarters over great distances for temporary placement in padlocked cross-dock storage units where they were transferred, usually within hours, to regional Novelty route sales persons' ("RSPs") trucks for convenience store delivery. These RSPs then directly stocked the SLCs in Novelty-supplied, locked plexiglass cabinets serviced by Novelty employees. Novelty did not employ middle-men.

Novelty employed multiple, complimentary, and effective means to identify and eliminate diversion risk, resulting in no documented instance of diversion despite over 300-500 million transactions of SLCs. *See* ALJ Decision at 78; App. 250. Novelty imposed limits on customer purchases not required by law, such as its 24 count package sales limit.[10] Novelty sold only to DEA self-certified customers whose employees completed Novelty's anti-diversion course and agreed to abide by Novelty's sales limits. Novelty voluntarily reduced ephedrine content in its private label 24 count product from 25 mg to 12.5 mg to help

[10] Novelty's case limit on sale of 24 count ephedrine packets was honored by almost all of its distributors; the evidentiary record reveals that only a fraction of one percent were shown by the government not to have abided by the limit and even then no diversion was found. *See D.C. Circuit Decision* at 1197 (Brown, J., dissenting) ("the error rate thus may have been less than .2%"); App. 52.

reduce diversion risk. *See* ALJ Decision at 60; App. 225. In addition, Novelty packed its SLCs in sealed, tamper resistant containers. Novelty employed a state of the art, handheld computer system for every Novelty driver to log and communicate to Novelty headquarters up to date SLC inventory and sales data.

In May 2004, DEA Diversion Group Supervisor Dan Raber sent an advisory letter to all independent distributors of ephedrine and pseudoephedrine SLCs ("Raber letter").[11] There is no evidence that the letter was sent to Pfizer or Wyeth brand distributors. The Raber letter stated a position at odds with prior DEA policy: that overnight List I chemical storage in delivery trucks on long routes would be permissible only if the products had been preordered; the sales representative was a company employee; the delivery vehicle was company owned; and that representative stayed overnight at a hotel. *See Raber Letter* at 1; App. 413-415.[12] Alternatively, the Raber letter stated that registrants could use overnight mail carriers (FedEx, UPS, and USPS). Novelty believed its system more secure than those stated in the Raber letter. Moreover, the letter appeared to impose an unlawful

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[11] *See* Raber Letter at 1; App. 413-415.

[12] In her dissent Judge Brown found the Raber letter distinctions mind-boggling: "I am confused, however, about the logic in the Raber Letter . . . [W]hy does it matter if the drugs are for 'pre-placed customer specific orders' or for on-site orders?" *D.C. Circuit Decision* at 1196 n.7 (Brown, J., dissenting); App. 48.

agency rule adopted without requisite notice and comment rulemaking. Novelty filed suit seeking declaratory and injunctive relief in *Novelty, Inc. v. Tandy et al.*, No. 1:04-cv-01502 (S.D. Ind. 2008) (Hamilton, C.J.) *available at*, 2008 WL 3835655 ("Hamilton Opinion"); App. 369. During the pendency of its suit, Novelty pledged to change its shipping model if the DA, upon a review of the facts, adopted the Raber letter or another requirement.[13] Thus, Novelty did not evince an intent to violate the law. Rather, it sought clear judicial or administrative guidance as to the legality of the Raber letter and whether its content constituted a binding rule. The DA never revealed whether she endorsed the Raber letter until her final decision against Novelty, over four years after the letter's date. District Court Judge Hamilton determined that the letter was not an agency rule (a decision he described as a close call) and, thus, dismissed Novelty's suit. *See Hamilton Opinion* at 35-36; App. 388-389. Although Novelty's suit concerning the legality of the Raber letter and pledge to the DA to follow any requirement she wished to impose were proof of Novelty's good faith, the DA construed Novelty's suit as evidence of Novelty's non-compliance with the law. She did so

[13] *See* ALJ Decision at 19 ("Mr. Bledsoe credibly testified that, should the DEA's final order instruct the Respondent to change its shipping methods or DEA registrations, the Respondent would comply with such directions"); App. 165; *see also D.C. Circuit Decision* at 1196 (Brown, J., dissenting) ("Novelty credibly offered to modify its distribution network to address safety concerns"); App. 49.

disingenuously because DEA represented to the federal district court in Indiana that the Raber letter was not a binding agency rule. Thus, the DA avoided Judge Hamilton's review on the basis that the letter was not binding yet thereafter declared the letter binding in her Order (and Novelty a law violator for not following it). That legerdemain reinforces the conclusion that the DA wields unbridled discretion beyond statutory limits.

In 2007, Novelty filed comments challenging a DEA decision to set quota limits on ephedrine, pseudoephedrine, and phenylpropanolamine below legitimate demand in the market.[14] In those comments and in a suit it brought after adoption of the below market demand limits, Novelty filed suit in federal court challenging the biased statistics generated by none other than Jonathan E. Robbin, the same "expert" held incompetent and biased by the DEA ALJ in Novelty's case.[15] Shortly after Novelty's

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[14] *See Established Assessment of Annual Needs for the List I Chemicals Ephedrine*, *Pseudoephedrine, and Phenylpropanolamine for 2008,* 72 FR 73361.

[15] *See, e.g., Novelty v. DEA*, No. 08-1026 (D.C. Cir.) (Petition for review of DEA's Annual Assessment of Needs ("AAN") for ephedrine, pseudoephedrine, and phenylpropanolamine). DEA calculated its Annual Assessment of Needs for ephedrine products using, in part, the statistical analysis of Jonathan E. Robbin. In *Novelty v. DEA*, No. 08-1026, Novelty sought to challenge Robbin's opinion and his concept of a "traditional market." Following the ALJ hearing in the instant action, the ALJ determined that Robbin's statistical analysis was not credible. *See* ALJ Decision at 94-98; *see also Novelty, Inc.,* 571

(Continued on following page)

suit, DEA issued its Order to Show Cause (OSC) against Novelty.

B. DEA

On January 17, 2008, DEA issued an OSC to Novelty, soliciting Novelty's response as to why DEA ought not summarily revoke Novelty's registration.[16] In anticipation of the OSC, the DA dispatched agents to investigate Novelty. The ALJ and Judge Brown admonished DEA for investigative irregularities, including imposition of a prior restraint on Novelty's right to record investigative irregularities taking place at Novelty's headquarters.[17] *See D.C. Circuit Decision,* at 1192 n.3 (Brown, J., dissenting) ("such tactics do not reflect well on the United States"); App. 38. The OSC included six allegations – the DA's foundation for presuming Novelty's continued registration an imminent threat to the public under

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F.3d at 1192 n.3 (Brown, J., dissenting) ("[o]ne wonders if the DEA feels remorse for preying on companies that lack the wherewithal or sophistication to fight back against sloppy statistics"); App. 41.

[16] *See* OSC at 1; App. 417-421.

[17] *See D.C. Circuit Decision,* at 1192 n.3 (Brown, J., dissenting) (stating "Agents interfered with Novelty's understandable efforts to document in real time the search of the company's own facility by forbidding the use of and disabling video and audio recorders." These agents also "requested 12,000 additional pages of documents," giving only "three hours to produce them," and threatened an executive with arrest [a threat the agents had no lawful authority to make or effectuate]); App. 38.

the factors in 21 U.S.C. § 823(h).[18] Following an exhaustive two week hearing, each was held unsupported, demonstrably without merit, or insufficient to support revocation by the ALJ.[19] In her Order, the DA acknowledged a total lack of evidentiary support for all but one of her charges. The DA relied instead on new, alternative bases for revocation not the subject of the hearing.[20] *D.C. Circuit Decision,* at 1192 (Brown, J., dissenting); App. 40-41.

The ALJ found the charge of diversion of Novelty-distributed product unproved because the product in question was never shown to have actually been distributed by Novelty. Repeatedly DEA agents told Novelty that its product had never been found in the illicit trade. *See* ALJ Decision at 13-14, 74; App. 157-159, 245-246; *see also* OSC Hearing Transcript at 1099-1102 (DEA Diversion Investigator Madeline Kuzma testifying that DEA never gave Novelty a notice of diversion); App. 429-431. The ALJ

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[18] *See id*. at 1191; App. 37-38.

[19] *See* ALJ Decision at 37-39 (Novelty did not distribute products in forms or packages that violated law); App. 190-193; *id*. at 87-88 (60,000 dosage units were not unaccounted for; the DEA audit was insufficient); App. 263-266; *id*. at 91 (Novelty did not distribute to stores that were not self-certified); App. 269-270; *id*. at 96-97 (DEA "expert" witness Robbin was inaccurate and unreliable, and DEA failed to prove excessive sales); App. 276-279.

[20] *See D.C. Circuit Decision,* at 1192 (Brown, J., dissenting) (citing Order at 52695-97 (finding unsubstantiated several allegations in the OSC); App. 40-41.

additionally found DEA's audit of Novelty inventory[21] incompetent and that DEA lacked a reasonable basis to estimate legitimate SLC demand.[22] The ALJ found Novelty officials honest and credible in their willingness to ensure that Novelty's system met DEA requirements.[23] The ALJ credited Novelty with a "history of compliance." ALJ Decision at 100-101; App. 281-283. She held the public interest best served by continuing Novelty's DEA registration with conditions. *See id.* ("I conclude that this is a case where teamwork between the DEA and this major distributor would further . . . the public interest . . . I recommend that the [DA] not revoke this . . . registration").

In her Order rejecting the ALJ's recommendation, the DA ruled that (1) Novelty did not maintain effective controls against diversion as a result of inadequate recordkeeping and distribution to some stores in excess of Novelty's average customer purchase amounts and (2) Novelty violated 21 U.S.C. § 822(e) by not registering each in-transit cross-dock.[24] Her decision rests on no proof of actual diversion to the illicit methamphetamine trade. It rests on the assumption that Novelty's system of distribution, the very same DEA upheld without

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[21] *See* ALJ Decision at 87-88; App. 190-193.

[22] *Id*. at 96-97; App. 276-279.

[23] *Id*. at 98-99; App. 279-281.

[24] *See* Order at 52691 (summarizing reasons for revocation); App. 66-71.

question in every annual registration renewal since 1998, created an unacceptable diversion risk.

The DA determined that in-transit locations where SLCs are temporarily stored must be registered as "principal places of business" under 21 U.S.C. § 822(e) and held Novelty violated that "rule," the legally binding status of that rule she first announced in her Order. She construed three of four Section 823(h) factors as favoring revocation based entirely on that single legal statutory interpretation, an interpretation rejected by two D.C. Circuit judges.[25] *See* Order at 52702; App. 125-126.

Section 822(e) provides that a distributor of List I chemicals must obtain "a separate registration . . . at each principal place of business . . . where the applicant . . . distributes . . . list I chemicals." 21 U.S.C. § 822(e). In her Order the DA found each of Novelty's over 100 in-transit cross-docks "principal places of business." *See* Order at 52700-52702; App. 116-125.

The DA also construed Novelty's correspondence concerning possible reliance on a statutory exception

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[25] *See* Order at 52698-52702 (citing use of the unregistered cross-dock storage sheds in her analysis under 21 U.S.C. § 823(h)(1), (2), and (4)); App. 104-127; *but see D.C. Circuit Decision* at 1187-1188 (Tatel, D., concurring in part) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 27-31; *id.* at 1193-1195 (Brown, J., dissenting) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 42-47.

for SLC sales agents under 21 U.S.C. § 822(c)(1) proof that Novelty could not be trusted to distribute SLCs. The record revealed that Novelty never effectuated any plan to become a sales agent and merely broached the subject via the letter. *See D.C. Circuit Decision* at 1197-1198; App. 53-55.

C. The D.C. Circuit Decision and Issues Presented

Novelty challenged the DA's Order as a violation of the Administrative Procedure Act, 21 U.S.C. § 822(e); 21 U.S.C. § 823(h). The D.C. Circuit's per curiam decision upheld revocation with two "splintered-on-seemingly-all-points-but-outcome" concurring statements from Judges Henderson and Tatel and a vigorous dissent from Judge Brown. *D.C. Circuit Decision* at 1199; App. 56.

In her dissent, Judge Brown found six fatal errors in the Order requiring reversal and remand. She found almost every original DA allegation against Novelty without merit. *Id*. at 1192-1193; App. 40-42. She condemned the DA's interpretation of Section 822(e), it having written the word "principal" out of the statute. *Id*. at 1193-1195 (labeling the DA's interpretation "Hogwash"); App. 42-47; *see also id.* ("[t]he heart of the DA's analysis – that unregistered storage units *always* violate federal law – contradicts the statute"); App. 42-43. She found the DA's "expert" incompetent and the DA to have proceeded without evidence, logic, or statistics when she declared

Novelty's national average sales figure for SLCs to be the divining point of "legitimate demand." *See id.* Judge Brown found that the DA had erected a "zero-tolerance standard" in violation of the statute by not allowing the slightest mistake in business operations. *Id*. at 1197 (" . . . no complex system can be 100% foolproof " and "the DA applied an unreasonable zero-tolerance standard that Congress . . . did not intend"); App. 52. The DA had rejected the ALJ's credibility findings summarily jumping to revocation without seriously considering whether registration conditions would suffice. *See id*. at 1196 ("DA wrongfully rejected the ALJ's credibility findings based on her erroneous belief that the storage units were illegal"); App. 49.

Although Judge Tatel was "troubled by several aspects" of the DA's decision, he upheld it based on the DA's non-specific reference in dicta to security issues at certain of Novelty's cross-docks. *See D.C. Circuit Decision* at 1188-1190 (Tatel, D., concurring) (citing Order at 52698); App. 28-30. Judge Tatel credited the DA with making a finding of fact concerning the security of the cross-docks when she wrote in passim (absent specific evidence) that it was "unlikely" the units would meet DEA security requirements. *Id*. at 1188; App. 31. The security of Novelty's cross-dock storage units was not in issue in the OSC or at hearing. As a result, Judge Tatel's transformation of this dicta into a decisional reliance was a *post hoc* rationalization in conflict with this Court's, the sister circuits', and the D.C. Circuit's precedent.

Judge Henderson chose to uphold the DA's Order on grounds different from Judge Tatel. Henderson upheld the DA's erroneous interpretation of 21 U.S.C. § 822(e). *Id*. at 1184 (Henderson, K., concurring); App. 21; *but see id.* at 1187-1188 (Tatel, D., concurring) (holding the DA's interpretation of Section 822(e) invalid under *Chevron U.S.A., Inc. v. Natural Resources Defense Council,* 467 U.S. 837 (1984)); App. 27-31; *id.* at 1193-1195 (Brown, J., dissenting) (holding the DA's interpretation of Section 822(e) invalid under *Chevron*); App. 42-47.

REASONS FOR GRANTING THE PETITION

A. THE DA VIOLATED CSA LIMITS, 21 U.S.C. § 823(h), REVOKING A REGISTRATION ON A PRETEXT NOT COGNIZABLE UNDER THE STATUTE, WITHOUT EFFECTIVE FEDERAL JUDICIAL REVIEW UNDER THE CSA OR THE APA, 5 U.S.C. § 706(2)(b), IN CONTRAVENTION OF THE DECISIONS OF THIS COURT, THE SISTER CIRCUITS, AND THE D.C. CIRCUIT

The decision below condones the exercise of DA discretion beyond CSA limits, 21 U.S.C. § 823(h), upholding revocation on a pretext, without subjecting the DA's decision to effective federal judicial review under the CSA or the APA, 5 U.S.C. § 706(2)(b), in violation of this Court's, the sister circuits', and the D.C. Circuit's precedent.

This Court has required agencies to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 2866 (1983) (quoting *Burlington Truck Lines, Inc. v. U.S.*, 371 U.S. 156, 168, 83 S.Ct. 239 (1962)); *see also FCC v. Fox TV Stations, Inc.*, 129 S.Ct. 1800, 1810 (2009) (" . . . we insist that an agency examine the relevant data and articulate a satisfactory explanation for its action") (internal citations omitted). An agency action is

> 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.

State Farm, 463 U.S. at 43. Judicial review of an agency action is not just a formal process to "rubber-stamp [an] agency decision." *American Radio Relay League, Inc. v. FCC,* 617 F.2d 875, 879 (D.C. Cir. 1979); *see also Nat'l Wildlife Fedn. v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 924 (9th Cir. 2008) (requiring a court to engage in a careful, searching review to ensure that the agency has made a rational analysis and decision on the record before it). The

court must determine whether the decision was "based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Oreg. Natural Res. Council*, 490 U.S. 360, 378, 109 S.Ct. 1851 (1989) (internal quotation marks omitted).

In its decision the D.C. Circuit sanctioned the DEA's arbitrary and capricious decision by upholding revocation. The DA erroneously interpreted the controlling statute (which calls for reduction but not elimination of diversion risk, the latter possible only through a total ban on SLCs that Congress rejected). She imposed zero risk tolerance in violation of the CSA's plain and intended meaning. She invented an unreasonable litmus test (average Novelty sales) to adduce illegitimate market demand. She arbitrarily shifted the burden of proof to Novelty in violation of 21 C.F.R. 1309.54(b). Those actions violate the APA yet were condoned by the Circuit decision. As Judge Brown stated in dissent, the rule of law demands consistency, evenhandedness and predictability from an impartial adjudicator. Containing none of those requisites, the DA's decision is an abuse of power.

1. The DA's Zero Risk Standard Violates the CSA and the APA

Congress could have banned ephedrine and pseudoephedrine containing cough and cold remedies, thus creating a zero risk tolerance; instead, Congress

chose to protect the availability of ephedrine and pseudoephedrine for legitimate "medical, scientific, and industrial" uses. 21 U.S.C. § 823(b)(1). In condemning Novelty, the DA possessed neither evidence proving Novelty complicit in diversion nor evidence that Novelty executives were law violators. Each of her OSC charges were disproven. Presented with a record that did not support revocation, she nonetheless ordered it by relying not on her original charges but by reaching anew beyond those charges and the limits in 21 U.S.C. § 823(h).

The zero-risk standard she employed is precisely that kind of action inconsistent with statutory mandate that cries out for effective federal judicial review. When the DA revokes a registration under Section 823 based on any perceived transgression (such as those present here that have no meaningful link to diversion or other illegality), the system designed by Congress to provide for legitimate demand becomes rent, providing no meaningful weighing of factors and making revocation an ineluctable conclusion for every party the DA charges. Such a system is a sham and is tyrannical. Because the DA can revoke based on any error (even on one error out of millions of correct records maintained) without proof of a nexus to diversion, a registrant remains so at the DA's whim and caprice. If she brings charges, then it is a fait accompli that the registrant will lose its registration. The ALJ well understood the DA's

unlawful strategy bravely faulting her boss as follows:

> The DEA . . . seems to be trying to remedy [the meth] problem by restricting or eliminating the availability of such over-the-counter products by removing the distributors of SLC products to convenience stores from the market place. This action is based upon the premise that distributors are placing excessive amounts of SLC products into the market place by selling such products to their convenience store customers. Further, the DEA's premise also seems to be that these excessive amounts are being diverted to the illicit manufacture of methamphetamine. This record, however, calls such an analysis into question.

See ALJ Decision at 93; App. 273.

Judge Brown likewise appreciated that far from weighing statutory factors judiciously, the DA concluded her case at the time she brought her charges (her combined status as law maker, prosecutor, and judge thus destroys the separation of functions and gives her tyrannical power). *D.C. Circuit Decision* at 1199 (Brown, J., dissenting); App. 57-58.[26] DEA

[26] Judge Brown cited various abuses in this case, including the refusal to allow Novelty to make a contemporaneous record of DEA's execution of a warrant on Novelty's premises. None was substantively addressed by the concurring Panel members. *See D.C. Circuit Decision* at 1191 n.2 (Brown, J., dissenting) (stating

(Continued on following page)

admits Congress did not intend to ban OTC ephedrine in retail stores,[27] the only way to achieve zero risk.[28] Demanding zero risk, the DA looks (and inevitably finds) some infraction, regardless of how innocuous and unconnected with diversion, and then deems that alleged infraction enough to support revocation without requisite proof of gravity. As Judge Brown explained, "[j]ust as 'safe' does not mean 'risk-free' 'maintenance by the applicant of effective controls against diversion' as used in 21 U.S.C. § 823(h) cannot mean perfect controls, an impossible standard." *See D.C. Circuit Decision* at 1197 n.9 *(*Brown, J., dissenting) (quoting *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 642, 100 S.Ct. 2844 (1980) (Stevens, J., plurality)); App. 52. With perfect compliance her required standard, the DA may scour Novelty's decade of compliance for an apparent blemish and then lay waste to Novelty's

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that "[s]uch tactics do not reflect well on the United States"); App. 38.

[27] *See, e.g., Implementation of the Comprehensive Methamphetamine Control Act of 1996*, 62 FR 52253 (Oct. 7, 1997) ("Congress [intended] that public access to the products at the retail level be protected . . . "); *see also PDK Laboratories, Inc. v. DEA*, 362 F.3d 786, 797 (D.C. Cir. 2004) ("no one doubts that Congress did not intend to ban, or give the DEA authority to ban, all sales of ephedrine-containing drugs in retail stores").

[28] *See D.C. Circuit Decision* at 1197 (Brown, J., dissenting) ("[i]gnoring that no complex system can be 100% foolproof, the DA applied an unreasonable zero-tolerance standard that Congress surely did not intend"); App. 52.

business on the basis of that de minimis imperfection without proof of any nexus to diversion.

Section 823(h) may not be construed to defeat satisfaction of legitimate demand. The statute contemplates an evaluative process (a weighing of Section 823 factors under the public interest, a flexible approach, not an inflexible one that compels revocation on the finding of any perceived error no matter how slight). That type of limitless power to condemn cannot be allowed to stand in any country that respects the rule of law. *See* BLACK'S LAW DICTIONARY 100 (7th ed. 1999) (defining "arbitrary" as "founded on prejudice or preference rather than on reason or fact").

2. The DA Invented an Unreasonable Test Based on Unreliable Data to Determine Market Demand for SLCs

Agency decisions based on data that is "unreliable or inadequately explained" are arbitrary and capricious and must be overturned. *Friends of the Boundary Waters Wilderness v. Bosworth*, 437 F.3d 815, 824 (8th Cir. 2006); *see also State Farm*, 463 U.S. at 43. Under 21 U.S.C. § 823(h), the DA found that Novelty sales amounted to a risk of diversion based not on any proof of diversion or of sales exceeding the legal limit, but on Novelty selling amounts above its own national sales average to some of its retail customers. *See* Order at 52699; App. 112-115. Without any empirical basis to conclude that a particular

quantitative amount sold necessarily leads to diversion (a grossly illogical assumption), the DA held Novelty's national sales average the arbitrary point above which illegitimate demand existed. The DA provided no reasoned analysis for that determination,[29] no market data, no multivariate statistical study. *See D.C.* Circuit Decision at 1196 (Brown, J., dissenting); App. 50. On that flawed assumption, she found the first factor of Section 823(h) "*strongly supports* the conclusion that [Novelty's] registration 'is inconsistent with the public interest.'" Order at 52700 (emphasis added); App. 115-116.

To a mind possessed of a modicum of mathematical sensibility, a national sales average says nothing about legitimate demand, "after all, 50% of all convenience stores should be expected to have sales greater than the average." *D.C. Circuit Decision* at 1196 (Brown, J., dissenting); App. 50-51. The DA's reliance illogically assumes similarity across the

[29] The DEA originally relied upon the supposed expert Jonathan Robbin to determine legitimate market demand for ephedrine/pseudoephedrine products supplied to convenience stores. His analysis was debunked by Novelty and found unsupported by the ALJ, and not defended by the DA in her Order. *See D.C. Circuit Decision* at 1192 (Brown, J., dissenting) (citing Order at 52693-94); App. 40-41; *see also id.* at n.3 (Brown, J., dissenting) (commenting on the DEA's reliance on Robbin in more than twenty previous cases Judge Brown questioned, "How many jobs have been lost and reputations ruined because of this dubious analysis? One wonders if the DEA feels remorse for preying on companies that lack the wherewithal or sophistication to fight back against sloppy statistics."); App. 41.

nation in demand despite differences in demographics, weather, proximity to airborne pollutants, respiratory disease frequencies, store operating hours, and store proximity to other retail outlets and pharmacies. That reliance is not based on substantial evidence and should have been checked by effective federal judicial review.

3. The DA Shifted the Burden of Proof to Novelty to Explain Why Some Stores Sold More Than Others in Violation of 21 C.F.R. 1309.54(b)

In DEA registration revocation hearings, DEA has the burden of proving the requirements for revocation. 21 C.F.R. 1309.54(b). After using Novelty's average sales data to condemn it, the DA stated, "[Novelty] offered no explanation that was specific to any store for why it was selling in such quantities." Order at 52700; App. 114-115. Here, the DA holds Novelty to DEA's burden. Judge Brown condemned the burden shifting:

> But the burden of proof is on the government before it can take away someone's livelihood . . . and even if it were otherwise, this is an unfair obligation to spring on Novelty as the company was responding to the statistics of DEA's so-called expert – statistics that even the DA does not defend.

D.C. Circuit Decision at 1196-1197 (Brown, J., dissenting); App. 51. "This statistical inevitability is not something that a company should have to

explain, nor should the DEA be able to escape its burden . . . effortlessly." *Id*. The DA's unlawful burden shifting is now the rule of law because the D.C. Circuit condoned the practice. In her dissenting opinion, Judge Brown concluded, "If arbitrary and capricious is to mean anything . . . this decision cannot be allowed to stand." *Id.* at 1193; App. 42.

B. THE MAJORITY OPINIONS ARE CONTRADICTORY AND SHOULD NOT HAVE RESULTED IN AN ORDER UPHOLDING THE DA'S DECISION

The decisions of Judges Tatel and Henderson conflict. Judge Henderson finds that Novelty had to register every in-transit cross-dock as a "principal place of business" under 21 U.S.C. § 822(e). *See D.C. Circuit Decision* at 1184 (Henderson, K., concurring); App. 21. Judges Tatel and Brown reject that conclusion as contrary to the statute's plain meaning. *See id.* at 1187-1188 (Tatel, D., concurring) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 27-31; *id.* at 1193-1195 (Brown, J., dissenting) (holding the DA's interpretation of 822(e) invalid under *Chevron*); App. 42-47. Judge Tatel illogically finds that although the cross-docks need not be registered, they must nonetheless meet security requirements applicable to registered locations (and, without facts of record to support, concludes they did not). *See id.* at 1188-1189; App. 28-33. The majority opinions of Judges Henderson and Tatel thus conflict. Violation of the CSA and revocation of

Novelty's registration should not be permitted to stand in such a circumstance.

Judges Brown and Tatel held the DA's interpretation patently unreasonable and, thus, unlawful, under step two of *Chevron U.S.A., Inc. v. Natural Resources Defense Council,* 467 U.S. 837 (1984). *See D.C. Circuit Decision* at 1187, 1193-1194; App. 27, 42-47. Following the canons of statutory interpretation, courts require agencies to give effect to every word in an enabling statute. *See Sierra Club v. EPA*, 536 F.3d 673, 680 (D.C. Cir. 2008) (citing *U.S. v. Menasche,* 348 U.S. 528, 538-539, 75 S.Ct. 513 (1955)) ("It is [a court's] duty to give effect, if possible, to every clause and word of a statute"). In the DA's Order she errs by making "surplusage of the word 'principal.'" *D.C. Circuit Decision* at 1187 (Tatel, D., concurring); App. 29; *see also id*. at 1193 (Brown, J., dissenting) (calling DA's interpretation "[H]ogwash" stating, "[e]ven with the winds of deference at its back, this interpretation of § 822(e) is a nonstarter. It reads the word "principal" out of a statute whose plain language requires . . . : (1) "distribut[ion]" from (2) a "principal place of business"); App. 43-44. The DA chose to expand the statute beyond its plain limits. As the "heart of the DA's analysis" this unreasonable reading creates agency precedent contrary to law and must be overturned. *Id.* at 1193; App. 42-43.

According to Judges Tatel and Henderson, however, if DEA's erroneous ruling on 21 U.S.C. § 822(e) were corrected, that would not affect the

ultimate outcome. *See PDK*, 362 F.3d 786 (administrative error deemed insufficient to justify remand unless rectification of it altered outcome).[30] Judge Brown disagreed, finding the DA's reliance on her erroneous statutory interpretation the "heart of" the DA's Order. *D.C. Circuit Decision* at 1193 (Brown, J. dissenting); App. 42-43. Judges Tatel and Henderson erred by invoking the harmless error rule on an issue of dispositive significance.

Under the multi-factor totality of the circumstances test prescribed by 21 U.S.C. § 823(h), the DA relied on Novelty's supposed violation of Section 822(e) to implicate three of four statutory public interest factors.[31] The DA predicated almost her entire decision on her erroneous construction of that section, *see* Order at 52698; App. 106-107, but the majority of the D.C. Circuit's panel held the DA's statutory construction in violation of 21 U.S.C. § 822(e). The DA's interpretation of that section was the only basis in her decision sufficient to support revocation. Thus, the DA's decision hinges on the weakest of reeds. Despite the DA's heavy reliance on

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[30] This Court has repeatedly recognized *PDK* as correct in *Shinseki v. Sanders*, 129 S.Ct. 1696, 1704, (2009); *Nat'l Assn. of Home Builders v. Defenders of Wildlife,* 551 U.S. 644, 659, 127 S.Ct. 2518, 2530 (2007); *Morse v. Frederick*, 127 S.Ct. 2618, 2642, 551 U.S. 393, 431 (2007) (Breyer, J., dissenting).

[31] *See* Order at 52698-52702 (citing use of the unregistered cross-dock storage sheds in her analysis under 21 U.S.C. § 823(h)(1), (2), and (4)); App. 104-127.

a violation of law a majority of the Court found not violated, the panel failed to remand the case to DEA.

The Order minus the alleged 21 U.S.C. § 822(e) violation, should equal the ALJ's recommended ruling (wherein the ALJ refused to address that alleged violation and held that Novelty should retain its registration).[32] The decision in *PDK* obligated the panel to remand with instructions not to consider Novelty's unregistered locations as law violations and, on that basis, to reconsider the prudence of the ALJ's recommended continued registration. *See PDK,* 362 F.3d at 794; *see also Fed. Express Corp. v. Mineta,* 373 F.3d 112, 118 (D.C. Cir. 2004) (remand is appropriate where "there is reason to think that the remand might lead to a different result"); *Mass. Trs. v. U.S.,* 377 U.S. 235, 248, 84 S.Ct. 1236 (1964) (upholding agency decision "when a mistake of the administrative body is one that *clearly had no bearing on* . . . the substance of decision reached") (emphasis added). Here, the DA deemed Novelty a blatant law breaker. That conclusion permeates her analysis. By contrast, the ALJ found Novelty to have demonstrated a history of compliance with the law. The statutory violation clearly impacted the totality of the circumstances test applied by the DA. A majority of the panel having found the interpretation incorrect should have reversed and remanded the decision to DEA.

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[32] *See* ALJ Decision at 91 n.38; App. 269.

The conflicted panel provides no guidance for the regulated industry, or constraints to prevent the DEA's continued unlawful enforcement. The legal issues on appeal remain unsettled. Although flawed, the majority opinion somehow binds the parties despite the absence of a consensus. Allowing the conflicted decision to stand is contrary to this Court's precedent and that of the D.C. Circuit. *See, e.g.,* Note, *Plurality Decisions and Judicial Decisionmaking*, 94 HARV. L. REV. 1127, 1130-1132 (1981) (explaining that fractured opinion relying on two distinct rationales results in a "false plurality decision" which "is completely useless as guides to lower courts . . . in resolving future cases, and to legislatures trying to cope with incomprehensible pronouncements" of law); *Neil v. Biggers*, 409 U.S. 188, 192, 93 S.Ct. 375 (1972) (explaining that an equally divided affirmance was not an actual adjudication barring subsequent consideration of the same issues and stating that, "[i]f the judges are divided, the reversal cannot be had, for no order can be made"); *Macklin v. Spector Freight Systems, Inc.*, 478 F.2d 979, 990 (D.C. Cir. 1973), *overruled on other grounds*, 421 U.S. 454; *U.S. v. Pink*, 315 U.S. 203, 216, 62 S.Ct. 552 (1942) ("the lack of an agreement by a majority of the Court on the principles of law prevents it from being an authoritative determination for other cases").

C. THE COURT CANNOT SUBSTITUTE ITS OWN REASONING *POST HOC* WHEN NO MAJORITY SUPPORTS THE DA'S REASONING

Judge Tatel's basis for revocation is not the DA's. Judge Tatel's is a *post hoc* rationalization, upholding the DA's revocation on two grounds: the security at Novelty's in-transit cross-docking stations and the precious few instances when Novelty customers sold in excess of Novelty's self-imposed (and not legally required) two 24 count package per transaction limit. The DA did not base her decision on those two factors. *See D.C. Circuit Decision* at 1188 (Tatel, D., concurring); App. 31-32.[33]

In her brief discussion of security at certain of Novelty's cross-dock storage units, the DA stated, "putting aside momentarily the issue of whether these storage units must be registered, it is *unlikely* that they could meet the security requirements of this Agency." Order at 52698 (emphasis added); App. 106-107. Thus the DA did not make a specific finding that the cross-docks did not, in fact, meet the security requirements of registered locations (there was no such issue in the OSC or adduction of requisite evidence at hearing). The DA speculated that lack of

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[33] *See* Order at 52703 (DA acknowledges the totality of circumstances test and states that "the Agency considers all of the facts and circumstances in determining the appropriate sanction"); App. 131; *see also* Order at 52691 (summarizing reasons for revocation); App. 68-69.

security at the storage units, if supported by DEA's burden of proof (which it was not), would "provide reason alone to support the finding that its continued registration is 'inconsistent with the public interest.'" *Id*. Judge Tatel reinterpreted that speculation as evidence supporting his *post hoc* rationalization. He did so inconsistently. He held the cross-docks were not legally required to be registered but upheld the DA's decision on the basis that the cross-docks had to meet the security requirements for registered locations (and he did so without requisite evidence to conclude that the cross-docks were inadequately secured).

The record shows that the cross-docks were secured with Novelty's own padlocks accessible only by keys issued to Novelty's truckers and their Novelty supervisors. *See* ALJ Decision at 16-17, 84; App. 161-162, 259. The cross-docks were ordinarily used to hold product for a matter of hours to permit transfer of goods from Novelty's long-distance trucks to Novelty's direct delivery trucks. *See id*. The security of the cross-docks was never a material issue in this case. DEA failed to raise the issue in the OSC; its investigators never investigated a single cross-dock to evaluate security. The DEA failed to present evidence that Novelty's cross-docks had ever been compromised or their goods stolen. The DA was thus unable to conclude them insecure, but Judge Tatel did so conclude.

Judge Tatel's reliance on this factor as a violation of the CSA is not supported by precedent. In two

previous applications submitted to the DEA (cited by the DA in her opinion) use of unsecured storage units was a factor among many in finding against registration of those applicants, but in neither case was it dispositive. *See* Order at 52698 (citing *Stephen J. Heldman*, 72 FR 4032, 4034 (2007) and *Sujak Distributors*, 71 FR 50102, 50104 (2006)); App. 106-107.[34] When stating her grounds, the DA included none that were later recited by Judge Tatel.[35]

The DA's Order must stand on its own; the D.C. Circuit is not empowered to uphold the decision on a rationale not appearing in the DA's Order. *See Clark County, Nev. v. FAA*, 522 F.3d 437, 441 (D.C. Cir. 2008) ("a court is not to substitute its judgment for that of the agency"); *see also Federal Power Commission v. Texaco, Inc.*, 417 U.S. 380, 397, 94 S.Ct. 2315 (1974) (court cannot accept *post hoc* rationalizations of appellate counsel). This Court, the D.C. Circuit, and the sister circuits have consistently

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[34] In *Sujak*, the DA's findings were part of a totality of the circumstances balancing wherein the respondent's lack of security was among other factors militating against registration. *See Sujak Distributors*, 71 FR at 50104 (2006).

[35] *See* Order at 52691 (DA summarizing her reasons for revoking Novelty's registration citing; first, Novelty did not maintain effective controls against diversion as a result of inadequate recordkeeping and distribution to some stores in excess of Novelty's average customer purchases; and second, Novelty violated 21 U.S.C. § 822(e) by not registering each cross-dock storage unit used in its distribution method) (all constituting grounds soundly refuted by Novelty); App. 68-69.

rejected *post hoc* rationalizations.[36] When the court creates justifications for agency action as a substitute for the agency's own, it transgresses the line between judicial review and executive action, involving the court in the business of agency policy and rule creation. That separation of powers is violated by the D.C. Circuit's reliance on the *post hoc* rationale in this case. *See Burlington Truck Lines v. U.S.*, 371 U.S. 156, 168, 83 S.Ct. 239 (1962); *Martin v. Occupational Safety and Health Review Comm'n*, 499 U.S. 144, 157 (1991); *see also AT&T Corp. v. FCC*, 220 F.3d 607, 631 (D.C. Cir. 2000) (decision on how to promote competition in local and long distance telephone markets was a policy judgment, therefore "it is for the agency – not this court – to make"); *Nat'l Treasury Emples. Union v. Chertoff*, 452 F.3d 839, 867 (D.C. Cir. 2006) (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 494 (D.C. Cir. 1989). The Court was "obliged to respect 'the fundamental principle that agency

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[36] *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 2866 (1983); *SEC v. Chenery Corp.,* 318 U.S. 80, 87, 63 S.Ct. 454 (1943); *Wedgewood Village Pharmacy v. DEA*, 50 F.3d 541, 550 n.13 (D.C. Cir. 2007); *U.S. v. Garner*, 767 F.2d 104, 116-117 (5th Cir. 1985); *UHFC Co. v. U.S.*, 916 F.2d 689, 699 (Fed. Cir. 1990); *Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service*, 378 F.3d 1059, 1071 n.7 (9th Cir. 2004); *Marshall v. Lansing*, 839 F.2d 933, 943-944 (3d Cir. 1988); *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 79-80 (2d Cir. 2006); *W. Va. v. Thompson*, 475 F.3d 204, 212 (4th Cir. 2007); *Sierra Club v. Flowers*, 526 F.3d 1353, 1360 (11th Cir. 2008); *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1580 (10th Cir. 1994).

policy is to be made, in the first instance, by the agency itself – not by courts, and not by agency counsel'").

By adopting a *post hoc* rationalization, the D.C. Circuit stepped outside its judicial role and assumed a legislative role. *NLRB v. Metro. Life Ins.* Co., 380 U.S. 438, 444, 85 S.Ct. 1061 (1965) ("[*post hoc* rationales] are incompatible with the orderly function of the process of judicial review").

CONCLUSION

For the forgoing reasons, this Court should grant this Petition.

Respectfully submitted,

JONATHAN W. EMORD*
ANDREA G. FERRENZ
PETER A. ARHANGELSKY
CHRISTOPHER K. NIEDERHAUSER
EMORD & ASSOCIATES, P.C.
11808 Wolf Run Lane
Clifton, VA 20124
Ph: (202) 466-6937
Fx: (202) 466-6938
jemord@emord.com
**Counsel of Record*