

**United States Court of Appeals**  
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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Argued January 14, 2009

Decided June 22, 2009

Unsealed July 7, 2009

No. 08-1296

NOVELTY, INC.,  
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION *ET AL.*,  
RESPONDENTS

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On Petition for Review of an Order  
of the Drug Enforcement Administration

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*Jonathan W. Emord* argued the cause for the petitioner.

*Teresa A. Wallbaum*, Acting Deputy Chief for Policy and Appeals, United States Department of Justice, argued the cause for the respondent. *Anita Gay*, Attorney, entered an appearance.

Before: HENDERSON, TATEL and BROWN, *Circuit Judges*.

Separate statements filed by Circuit Judge KAREN LECRAFT HENDERSON, Circuit Judge DAVID S. TATEL and Circuit Judge JANICE ROGERS BROWN.

**ORDER**

Novelty, Inc. petitions for review of the order of the United States Drug Enforcement Administration in *Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689 (Sept. 10, 2008).

IT IS ORDERED that the petition for review be denied. Judge Henderson sets forth her reasons for denying the petition in her separate concurring statement, as does Judge Tatel in his separate concurring statement. Judge Brown dissents from the denial for the reasons stated in her dissent.

*Per Curiam*

KAREN LECRAFT HENDERSON, *Circuit Judge*, concurring:

Novelty, Inc. (Novelty) petitions for review of the order of the United States Drug Enforcement Administration (DEA), *Novelty Distributors, Inc.*, 73 Fed. Reg. 52,689 (Sept. 10, 2008) (Final Order), which revoked its registration to distribute list I chemical products pursuant to the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* (CSA or Act). For the reasons set out below, I conclude that Novelty's petition for review should be denied.

### I.

The CSA requires “[e]very person who . . . distributes any . . . list I chemical [to] obtain annually a registration issued by the Attorney General.” 21 U.S.C. § 822(a)(1). Section 823(h) requires the Attorney General to “register an applicant to distribute a list I chemical unless [he] determines that registration of the applicant is inconsistent with the public interest.” *Id.* § 823(h). The Attorney General considers five factors in determining whether registration is inconsistent with the public interest:

- (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.

*Id.* § 823(h). The Attorney General may suspend or revoke a registration if the registrant “has committed such acts as would render his registration . . . inconsistent with the public interest as determined under [21 U.S.C. § 823].” *Id.* § 824(a)(4). A list I chemical distributor must obtain a “[s]eparate registration . . . at each principal place of business or professional practice where [it] . . . distributes . . . list I chemicals.” *Id.* § 822(e). The Attorney General has delegated the authority to deny, revoke or suspend registration to the DEA Administrator, 28 C.F.R. § 0.100(b), who has redelegated to the Deputy Administrator (DA). *Id.* § 0.104.

Novelty is an Indiana-based wholesale distributor of retail products to approximately 10,000 convenience stores in the United States, including over-the-counter pharmaceutical products containing ephedrine and pseudoephedrine. The CSA defines ephedrine and pseudoephedrine as “list I chemicals.” 21 U.S.C. § 802(34)(C) & (K). Ephedrine and pseudoephedrine have legitimate uses<sup>1</sup> but they can also be diverted for use in the

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<sup>1</sup>“Pseudoephedrine is a decongestant used for the temporary relief of nasal congestion due to the common cold, hay fever, or other upper respiratory allergies. Ephedrine is used for the temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.” DEA, Security Requirements for Handlers of Pseudoephedrine, Ephedrine, and Phenylpropanolamine, 69 Fed. Reg.

manufacture of methamphetamine, a schedule II controlled substance. *Id.* § 812(c); 21 C.F.R. § 1308.12(d). In 1998, the DEA granted Novelty a certificate of registration authorizing it to distribute list I chemical products from its Greenfield, Indiana facility. The DEA renewed Novelty's registration annually until 2008.

According to Novelty's president,<sup>2</sup> Novelty stores its list I chemical products in a secure area in its registered Greenfield, Indiana warehouse. Administrative Hearing Transcript at 131-32, *Novelty Distributors*, Docket No. 08-33 (DEA Mar. 24-Apr. 1, 2008) (Hearing Tr.). Only employees who pass a background check and receive training are authorized to enter the secure area. Each Novelty sales representative services approximately 80 convenience store customers and makes deliveries to each customer approximately every two weeks. According to Novelty's vice president of product, the customer tells the sales representative how many list I chemical products it needs and the sales representative orders them from Novelty's Greenfield facility. Novelty drivers transport the list I chemical products weekly in company trucks to approximately 150 self-storage units that Novelty rents from independent self-storage facilities throughout the country. Novelty informs its sales representative of the time of delivery to the self-storage unit. The list I chemical products typically remain in the self-storage unit anywhere from a few hours to two days until the sales representative transfers them to his vehicle for delivery to the customer. Each self-storage unit is locked and has varying degrees of additional security as provided by the individual

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45,616, 45,616 (July 30, 2004).

<sup>2</sup>Novelty's president as well as other Novelty officials and various DEA personnel testified at the administrative hearing held to decide whether Novelty's registration should be revoked. *See infra* at 9.

storage facilities. According to Novelty's president, "there are cameras around . . . a lot of [the storage facilities]," "[t]hey have access points" and "[t]hey have codes to get into places." *Id.* at 131. One Novelty sales representative testified that the self-storage unit he used had only a padlocked door for security. *Id.* at 538. None of Novelty's approximately 150 self-storage units is registered with the DEA.

Novelty sells combination ephedrine and pseudoephedrine products of different strengths and in varying quantities per package and it carries more than ten product lines containing list I chemicals. Novelty's vice president of product testified that Novelty limits each convenience store customer to one case of each product type per the sales representative's bi-weekly delivery to reduce the risk of diversion. According to Novelty's director of category management, Novelty enforces its one case per product type limit by issuing a warning to a noncompliant sales representative for a first infraction and terminating him for a second infraction. In addition, Novelty ceases selling list I chemical products to any customer purchasing in excess of one case per product type. Novelty's director of category management testified that between January 2007 and January 2008, there were approximately 35 to 45 violations of the one case limit of an estimated 100,000 to 120,000 total transactions. According to one of the DEA investigators who testified, however, Novelty violated its one case limit 85 times between January and July 2007. According to another DEA investigator, during a November 2002 raid on an illegal methamphetamine lab in Connecticut, the DEA discovered ephedrine product manufactured by DMD Pharmaceuticals (DMD). DMD informed the DEA that in September 2002 it had shipped the product to Novelty for distribution. When the DEA contacted Novelty, Novelty was unable to identify the convenience stores that had purchased the ephedrine product later diverted.

On May 5, 2004, Dan Raber, Diversion Group Supervisor in the DEA's Indianapolis District Office, sent Novelty and other Indiana registrants a letter regarding the transportation and delivery of list I chemical products to retailers. Letter from Dan E. Raber, Diversion Group Supervisor, to Novelty Distributors, *Novelty Distributors*, Docket No. 08-33 (May 5, 2004) (Raber Letter). The Raber Letter specifically addressed the practice of "storing List I chemical products (including over-the-counter ephedrine and pseudoephedrine items) and distributing them from satellite locations, such as commercial storage units, personal residences and or delivery vehicles." *Id.* at 1. It "remind[ed] all registrants that 'any . . . distribution from[] a location other than the registered location (including the use of delivery vehicles for overnight storage) is a violation of federal law.'" *Id.* According to Novelty's vice president of product, Novelty concluded that it had to register all 150 self-storage units or stop using the units for list I chemical products, which it declined to do. In September 2004, it filed suit in the Southern District of Indiana seeking a declaratory judgment that the Raber Letter constituted a rule making conducted without the requisite notice and comment. *Novelty, Inc. v. Tandy*, No. 04-cv-1502, 2006 WL 2375485, at \*1 (S.D. Ind. Aug. 15, 2006). Almost four years later, on August 7, 2008, the district court granted the DEA's motion for summary judgment, concluding that the Raber Letter was an interpretive rule that did not require notice and comment.<sup>3</sup> *Novelty, Inc. v. Tandy*, No. 05-cv-1502, 2008 WL 3835655, at \*16 (S.D. Ind. Aug. 7, 2008).

On January 17, 2008, the DA suspended Novelty's registration and issued an order to show cause why the DEA

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<sup>3</sup>From the Raber Letter's issuance in May 2004 until the Suspension Order issued in January 2008, Novelty continued using the self-storage units for distribution of list I chemical products. *See infra* at 19-20.

should not revoke Novelty's registration, setting forth several grounds therefor. Order to Show Cause and Immediate Suspension of Registration, *Novelty Distributors*, Docket No. 08-33 (DEA Jan. 17, 2008) (Suspension Order). First, Novelty used unregistered self-storage units to distribute list I chemical products, a factor weighing against Novelty's continued registration under 21 U.S.C. §§ 823(h)(2) (noncompliance with applicable laws) and 824(a)(4) (acts inconsistent with public interest). *Id.* at 1. Second, Novelty distributed list I chemical products to its customers in quantities greater than could be used for legitimate purposes, a factor weighing against Novelty's continued registration under 21 U.S.C. § 823(h)(1) (ineffective controls against diversion). *Id.* at 2. Third, Novelty maintained inaccurate records in violation of 21 U.S.C. § 830(a) (record keeping requirements for list I chemical transactions) and 21 C.F.R. § 1310.04.<sup>4</sup> *Id.* Fourth, Novelty distributed ephedrine and pseudoephedrine products to retailers that were not self-certified as required by 21 U.S.C. § 830(e)(1)(B)(i).<sup>5</sup> *Id.* Fifth,

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<sup>4</sup>A distributor must keep records of "regulated transaction[s] involving a listed chemical . . . for two years after the date of the transaction." 21 U.S.C. § 830(a). The records must be "retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer." 21 U.S.C. § 830(a)(2); *see also* 21 C.F.R. § 1310.04 (tracking 21 U.S.C. § 830(a)).

<sup>5</sup>"A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii)." 21 U.S.C. § 830(e)(1)(B)(i). Subparagraph (A)(vii) requires a seller to "submit[] to the Attorney General a self-certification that all [employees of the seller who deliver list I chemical products to the consumer's custody] have . . . undergone training provided by the

Novelty distributed list I chemical products packaged in a form that did not comply with 21 U.S.C. § 830(d)(2).<sup>6</sup> *Id.* at 2-3. Sixth, Novelty distributed list I chemical products in Kentucky and North Carolina in a form (tablets instead of gel-caps) prohibited by their respective state laws. *Id.* at 3. Based on the above-cited grounds, the DA found that “the scheduled listed chemical products distributed by Novelty have been, and are likely to continue to be, diverted into the illicit manufacture of methamphetamine” and that “Novelty has failed to maintain effective controls against such diversion as required by 21 U.S.C. § 823(h)(1).” *Id.* Accordingly, the DA concluded that “Novelty’s continued registration . . . would constitute an imminent danger to the public health and safety.” *Id.*

Shortly after the Suspension Order issued, Novelty approached an ephedrine product manufacturer proposing that Novelty act as its sales agent. Novelty offered to receive retailers’ orders for ephedrine products and then transmit the orders to the manufacturer. The manufacturer would then use a third-party shipper to “distribute” the ephedrine products directly to the retailers. Under Novelty’s proposal, the retailer itself could either prepare<sup>7</sup> the ephedrine product for sale or the

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seller.” *Id.* § 830(e)(1)(A)(vii).

<sup>6</sup>“With respect to ephedrine base [or] pseudoephedrine base . . . in a scheduled listed chemical product . . . a seller or distributor may not sell such a product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches.” 21 U.S.C. § 830(d)(2).

<sup>7</sup>Preparation for sale involves removing the ephedrine product from the box in which it is shipped and placing the product in the retailer’s secure display cabinet.



Novelty sales representative could do so when he next called on the retailer. The manufacturer rejected the proposal.

Novelty requested a hearing before an administrative law judge (ALJ) as allowed by the Suspension Order. The hearing was held from March 24 to April 2, 2008. The ALJ then issued her decision, rejecting the charges that Novelty had (1) distributed list I chemical products to retailers that were not self-certified, (2) distributed ephedrine products packaged in a non-conforming way and (3) distributed ephedrine products in Kentucky and North Carolina in violation of state law. Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the ALJ, *Novelty Distributors*, Docket No. 08-33, at 37-40, 71-72, 78-79 (DEA May 21, 2008) (ALJ Decision). The ALJ found, however, that Novelty did not maintain effective controls against diversion under 21 U.S.C. § 823(h)(1) based both on its record-keeping errors and on multiple violations of its one case per product type limit.<sup>8</sup> The ALJ declined to decide whether 21 U.S.C. § 822(e) (requiring “separate registration at each principal place of business” where list I chemicals are distributed) required Novelty to register its self-storage units because of the then-pending litigation regarding the Raber Letter in the Southern District of Indiana. *Id.* at 91 n.38. Nevertheless, the ALJ did find that Novelty had a duty to comply with the Raber Letter until the litigation challenging Raber’s interpretation of the statute was resolved, which duty Novelty failed to meet and, as a consequence thereof, Novelty’s failure weighed in favor of revocation under 21 U.S.C. § 823(h)(2). *Id.* at 91. While the ALJ found that the first two factors listed in section 823(h) supported the conclusion that Novelty’s continued registration was inconsistent with the public interest, she found that the third

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<sup>8</sup> The DA cited the DMD Pharmaceuticals diversion, *supra* at 5, as evidence thereof. Final Order at 52,694.

factor (prior convictions), fourth factor (past distribution experience) and fifth factor (other considerations) weighed in Novelty's favor and thus were consistent with the public interest under 21 U.S.C. § 823(h)(3), (4) and (5), respectively. The ALJ recommended that the DA "levy compliance requirements upon [Novelty]."<sup>9</sup> *Id.* at 101. On review, the DA instead revoked Novelty's registration. Final Order at 52,704. Novelty timely petitioned for review under the Administrative Procedure Act, 5 U.S.C. § 702, and the CSA, 21 U.S.C. § 877.

## II.

Under the APA, we must "set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "Findings of fact by the Attorney General [are conclusive] if supported by substantial evidence." 21 U.S.C. § 877. We "may not find substantial evidence merely on the basis of evidence which in and of itself justified [the agency's decision], without taking into account contradictory evidence or evidence from which conflicting inferences could be drawn." *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (quoting *Lakeland Bus Lines, Inc. v. NLRB*, 347 F.3d 955, 962 (D.C. Cir. 2003) (internal quotations omitted)) (alteration in *Morall*). The DEA is the ultimate fact finder but "[t]he agency's departures from the [ALJ's] findings are vulnerable if they fail to reflect attentive consideration to the [ALJ's] decision." *Id.* (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 853 (D.C. Cir. 1970)) (first alteration added). To uphold agency action, we must determine "that the agency examine[d] the relevant data and articulate[d] a satisfactory explanation for its

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<sup>9</sup>The ALJ recommended that the DA "use her discretion to levy compliance requirements upon [Novelty] to a degree that would satisfy the DEA that [Novelty] is operating [sic] with the DEA to protect the public interest." ALJ Decision at 101.

action including a rational connection between the facts found and the choice made.” *Id.* (quoting *El Rio Santa Cruz Neighborhood Health Ctr. v. U.S. Dep’t of Health & Human Servs.*, 396 F.3d 1265, 1276 (D.C. Cir. 2005) (internal quotations omitted)) (alteration in original). In determining the public interest under the factors set forth in 21 U.S.C. § 823(h), the DA need not “make findings as to all of the factors enumerated. . . . Rather, he may give each factor the weight he deems appropriate.” *Id.* at 173-74 (internal quotations omitted) (ellipsis in original). We “review the DA’s decision[], insofar as [it] interpret[s] statutes, under the standard articulated by the Supreme Court in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).” *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007). Under *Chevron* step 1, if a statute is unambiguous, then we “must give effect to the unambiguously expressed intent of Congress.” *Chevron*, 467 U.S. at 843. If the statute is ambiguous, we move to *Chevron* step 2 and “must defer to the agency’s interpretation as long as it is ‘based on a permissible construction of the statute.’” *Creekstone Farms Premium Beef, L.L.C. v. Dep’t of Agric.*, 539 F.3d 492, 498 (D.C. Cir. 2008) (quoting *Chevron*, 467 U.S. at 843). Although Novelty raised a host of objections both to the DA’s investigation and to the Final Order, I conclude that only the following merit discussion.<sup>10</sup>

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<sup>10</sup>Novelty made the following additional objections: (1) the DA imposed a no-risk standard on distributors of list I chemical products to convenience stores and small retailers contrary to “congressional intent,” Pet’r Br. at 31; (2) the DA did not articulate a discernible standard of acceptable risk of diversion, *id.* at 32; (3) the DA’s revocation of Novelty’s registration was part of a biased enforcement campaign against distributors of list I chemical products to convenience stores and small retailers, *id.* at 33-35; (4) the DA exhibited prejudgment bias, *id.* at 38-43; *see generally Withrow v. Larkin*, 421 U.S. 35, 47 (1975); and (5) DEA agents imposed a prior restraint—in violation of the First Amendment to the United States

## A.

Novelty argues that the DA failed to consider contradictory evidence and failed to explain her departure from the ALJ's recommended sanction. Novelty lists numerous facts favorable to it that the ALJ relied upon but that the DA allegedly disregarded. Pet'r Br. at 23-30. Contrary to Novelty's assertion, the DA referenced most of the listed facts in her Final Order. Those facts not explicitly mentioned—such as areas of Novelty's distribution system free of the risks she identified in other areas—are either irrelevant to the DA's reasoning or of little weight, such as the fact that many of Novelty's packages were secured with plastic zip-ties. I can “reasonably discern,” *ACS of Anchorage, Inc. v. FCC*, 290 F.3d 403, 408 (D.C. Cir. 2002), that the DA considered the holes she identified in Novelty's distribution system to be serious notwithstanding an otherwise compliant background; that is, to find Novelty's distribution system flawed, she was hardly required to identify every non-flawed aspect of it.

The DA also adequately explained why she revoked Novelty's registration despite the ALJ's recommendation to impose compliance conditions. The DA acknowledged that “the evidence points to some measures which [Novelty] voluntarily undertook” to prevent diversion. Final Order at 52,703. But the DA found that “these measures do not address the serious problems with its distribution practices that are established by the record, and which were either ignored, or discounted by the ALJ.” *Id.* The ALJ found that Novelty's “10 year history of compliance, as evidenced by the DEA's continued registration,” weighed against revocation. ALJ Decision at 100-01. The DA did not regard Novelty's registration renewals as “probative of

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Constitution—on Novelty's video and audio recording of DEA investigators while they conducted their investigation of Novelty, Pet'r Br. at 43-47. I reject these objections as meritless.

a registrant's record of compliance," stating that "[t]here are a variety of reasons why the Agency may not be prepared to go forward with a Show Cause Proceeding at a particular time including, *inter alia*, a lack of resources, the complexity of the matters under investigation, and the need to pursue other enforcement priorities." Final Order at 52,702 n.53. The ALJ viewed favorably Novelty's "willingness to comply with the laws and regulations," ALJ Decision at 98, but the DA was not persuaded by Novelty's willingness to change because of the "sustained nature of the violations and [its] failure to voluntarily cease its misconduct."<sup>11</sup> Final Order at 52,703. I conclude that the Final Order "reflect[s] attentive consideration to the [ALJ's] decision," *Morall*, 412 F.3d at 177 (internal quotations omitted) (alteration in original), and took into account contradictory evidence.

## B.

Novelty argues that the CSA does not require it to register its rented self-storage units. The CSA requires "[a] separate registration . . . at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals." 21 U.S.C. § 822(e); *see also* 21 C.F.R. § 1309.23(a) ("A separate registration is required for each principal place of business at one general physical location where List I chemicals are distributed . . ."). "[D]istribute" means "to deliver (other than by administering or dispensing) a controlled substance or

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<sup>11</sup>As noted earlier, after the Suspension Order issued, Novelty approached an ephedrine manufacturer about acting as the latter's sales agent, *see supra* at 8, rather than either registering each of the self-storage units or discontinuing their use. At the time of the hearing, moreover, a Novelty executive testified that the sales agent proposal was "[s]omething that we're still continuing to explore." Hearing Tr. at 2403.

a listed chemical.” 21 U.S.C. § 802(11). “Deliver” means “the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.” *Id.* § 802(8).

Novelty makes two arguments to support its reading of section 822(e) not to require the registration of each of the self-storage units. First, it asserts that each self-storage unit is not a “place of business . . . where [it] . . . *distributes* . . . list I chemicals.” *Id.* § 822(e) (emphasis added). I disagree. A Novelty truck driver transports the ephedrine products from the Greenfield, Indiana facility to the self-storage unit, where the ephedrine products remain for several hours or days. The sales representative then transfers the products to his vehicle for delivery to Novelty’s convenience store customers. The unit is therefore a “place of business” because it is a “general physical location” whence Novelty distributes ephedrine products. 21 C.F.R. § 1309.23(a). In other words, the Novelty sales representative distributes the ephedrine products from the self-storage units to retailers.<sup>12</sup>

Second, Novelty argues that each self-storage unit is not a “*principal* place of business.” 21 U.S.C. § 822(e) (emphasis added). The CSA does not define “principal place of business.” The word “principal” means “most important, consequential, or influential.” Merriam-Webster’s Third New Int’l Dictionary Unabridged 1802 (1993); *see also United States v. Clinical*

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<sup>12</sup>Both parties note that the DEA exempts from registration “[a] warehouse where List I chemicals are stored by or on behalf of a registered person, *unless such chemicals are distributed directly* from such warehouse *to locations other than the registered location* from which the chemicals were originally delivered.” 21 C.F.R. § 1309.23(b)(1) (emphases added). Because Novelty’s list I chemical products *are* distributed directly from the self-storage units to customers, the units do not come within the warehouse exception.

*Leasing Serv., Inc.*, 925 F.2d 120, 123 (5th Cir. 1991) (defining “principal” in 21 U.S.C. § 822(e) as “important [or] consequential” (quoting Webster’s New Collegiate Dictionary 908 (1979)) (alteration in original)). While the statute does not require registration of every place of business whether or not it is a “principal” one, as the DA correctly noted, the statute plainly contemplates the existence of more than one “principal place of business” as manifested by the use of “each” in requiring “each principal place of business” to be registered. See Final Order at 52,701. Nevertheless, in my view, “principal”—as used in section 822(e)—is ambiguous because the Congress has not supplied criteria, e.g., a minimum percentage of total products distributed from a location, to guide the DEA. I am therefore required to reach *Chevron* step 2. See *Pub. Serv. Co. of Colo. v. FERC*, 91 F.3d 1478, 1482 (D.C. Cir. 1996). The DEA must decide which “place[s] of business” are “principal” in each registrant’s distribution system. I must examine whether its reading—requiring Novelty to register the self-storage units—is “based on a permissible construction” of 21 U.S.C. § 822(e). *Chevron*, 467 U.S. at 843.

Notwithstanding Novelty’s assertion that each self-storage unit “processes a small fraction of Novelty’s total [list I chemical] product[s] shipped nationwide,” Pet’r Br. at 49, *all* of the list I chemical products it distributes passes through a self-storage unit. Moreover, as noted earlier, the DA permissibly found that the products remain at the units for up to several days at a time. Each storage unit is therefore “important” and “consequential” to Novelty’s distribution system. The DA’s interpretation of “principal” also correctly relied on the statutory context.<sup>13</sup> See *Pharm. Research & Mfrs. of Am. v. Thompson*,

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<sup>13</sup>The DA noted:

Congress imposed on a registrant the obligation to obtain a

251 F.3d 219, 224-25 (D.C. Cir. 2001) (examining context, including statutory purpose, in interpreting statute’s wording). The DA also rejected Novelty’s interpretation because it “would clearly frustrate the Congressional purpose.” Final Order at 52,701.

In enacting the CSA’s registration provisions, Congress’ purpose was to protect against diversion by requiring that those persons who propose to engage in the legitimate distribution of controlled substances and listed chemicals apply for a registration, notify this Agency of the proposed location of their activity, and submit the facility for inspection by the Agency to ensure that it has adequate security controls and procedures. *See, e.g.*, 21 U.S.C. 822(f) (authorizing the Attorney General “to inspect the establishment of a registrant or applicant for registration”). Indeed, inspection by the Agency of a proposed facility is fundamental to the CSA’s mandate to protect the public interest. *Id.* 823(h); *see also* 21 CFR 1309.41.

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separate registration at “*each* principal place of business \* \* \* where the applicant \* \* \* distributes \* \* \* List I chemicals.” 21 U.S.C. 822(e) (emphasis added). . . . In determining whether a facility is a principal place of business within the meaning of the CSA, the Act looks to the nature of the activity that occurs at the particular location and not at the dollar volume of business that is transacted out of the facility. *See* 21 CFR 1309.23(b)(2) (exempting from registration “[a]n office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals . . . nor serves as a distribution point for filling sales orders”).

Final Order at 52,701 (alteration of statute and regulation in original).



*Id.*; *see also* 21 C.F.R. § 1309.71 (listing factors DA must consider in evaluating effectiveness of security controls and procedures). The DEA cannot inspect a facility it either does not know exists or the location of which it does not know.

The DA also noted the “perverse incentive” created by interpreting “principal” based on the volume of business at a particular location instead of the nature of that business. Final Order at 52,701. An interpretation “which determines whether a facility must be registered by looking to the amount of business activity that occurs out of a facility rather than the nature of the activity that occurs therein, would encourage an entity to keep adding warehouses or storage facilities so that it could eventually claim that its warehouses were no longer principal places of business and were thus not subject to the registration requirement.” *Id.*

I conclude that the DA reasonably construed 21 U.S.C. § 822(e) to require that each of Novelty’s self-storage units is a “principal place[s] of business” subject to the registration requirement.<sup>14</sup>

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<sup>14</sup>As my dissenting colleague points out, *Dissenting Opinion* at 7, the DA concluded that section 822(b) “requires that *a separate registration be obtained at each location at which List I chemicals are distributed.*” Final Order at 52,700 (emphasis in original). Because, as the DA found, Novelty’s self-storage units fit within the statutory language of a “principal place of business . . . where [Novelty] . . . distributes . . . list I chemicals,” *id.* § 822(e), I do not reach her more general pronouncement that *every* place of business where list I chemicals are distributed must be registered.

**C.**

Finally, Novelty challenges the DA's reliance on several facts in support of revocation.<sup>15</sup> First, Novelty argues that its failure to enforce its one case of each ephedrine product per sales visit limit did not violate any statute or regulation but instead its self-imposed limit. But the DA did not conclude that Novelty violated any law by not enforcing its limit. Novelty asserted that its one case limit constituted an effective control against diversion and the DA rejected the one case limit as an

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<sup>15</sup>Novelty also challenges the sufficiency of the evidence to support the DA's finding that Novelty distributed list I chemical products in excess of legitimate demand to some convenience stores. Final Order at 52,699-700. At the hearing, the DEA's expert witness testified that the average monthly expected retail value of list I chemical products to satisfy legitimate demand is \$14.39 per convenience store. Both the ALJ and the DA rejected the DEA expert's legitimate demand analysis and his conclusion that any ephedrine product sale above \$14.39 per month was presumably diverted to methamphetamine manufacturing. Final Order at 52,694. The DA used a different method to determine excessive distribution. She compared the average monthly retail value of list I chemical products distributed to each Novelty customer during the three months before the Suspension Order issued with the average monthly retail value of list I chemical products distributed by Novelty to all of its customers. A Novelty executive testified that, on average, Novelty distributed list I chemical products with a retail value of approximately \$640 to each customer per month. But the DA found that within three months of the Suspension Order's issuance, Novelty distributed list I chemical products with an average monthly retail value in excess of \$2,000 to approximately 120 customers, in excess of \$4,000 to 9 customers and in excess of \$7,000 to one customer. *Id.* at 52,699. While I question the probative value of looking at sales that "greatly exceed[]" the average without statistical analysis, *id.* at 52,700, I need not reach the issue because I conclude that the Final Order is supported on other grounds, *see infra* note 17.

effective control because Novelty did not enforce it, a finding the evidence supports. *See* Final Order at 52,693 (Novelty sales representatives violated one case limit 85 times between January and July 2007).

Second, Novelty argues that it should not be penalized for continuing to use self-storage units while its challenge to the Raber Letter was pending in the Southern District of Indiana. *See id.* at 52,703 (“[Novelty]’s disregard of the letter and continuation of its practices for some forty-four months makes its conduct especially egregious.”). Novelty stopped distributing list I chemical products—and thus stopped using the self-storage units for the products—once the Suspension Order issued on January 17, 2008. The Indiana district court rejected Novelty’s challenge to the Raber Letter on August 7, 2008. In revoking Novelty’s registration, the DA relied on Novelty’s failure to register the self-storage units following the Raber Letter and its failure to enforce its one case limit as evidence that compliance conditions alone would not protect the public interest. *Id.* Novelty argues that its failure to register the self-storage units does not demonstrate its unwillingness to comply because its non-compliance was based on its good faith belief that the Raber Letter was invalid, as evidenced by its legal action challenging the letter.<sup>16</sup> Who was responsible for Novelty’s continued use of self-storage units *pendente lite*—whether Novelty because it did not seek to stay the Raber Letter or the DEA because it did not attempt to enforce the Raber Letter until some forty months after issuance—we do not decide inasmuch as the DA found that

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<sup>16</sup>Novelty also asserted that its legal challenge to the Raber Letter was motivated by its belief that using the common carrier alternative to deliver list I chemical products to its customers created a higher risk of diversion than its distribution system. Pet’r Br. at 55; Final Order at 52,701. The DA rejected Novelty’s assertion, concluding that Novelty produced no evidence of diversion when products were shipped by common carrier. Final Order at 52,701-02.

Novelty's "failure to enforce its own policies [i.e., the one-case limit] provides reason alone to conclude it cannot be trusted to adhere to compliance conditions." Final Order at 52,704. As the DA's sanction would have been the same even absent this factor, I need not review her analysis of it. *See PDK Labs. Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration."). For similar reasons, I need not reach the question whether the DA erred in finding that Novelty "attempt[ed] to circumvent the suspension order," Final Order at 52,703, by proposing acting as a sales agent.<sup>17</sup>

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<sup>17</sup>As noted earlier, between the Suspension Order and the ALJ's decision, Novelty proposed to an ephedrine products manufacturer that Novelty act as its sales agent. The CSA exempts from registration "[a]n agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment," 21 U.S.C. § 822(c)(1), and thus, according to Novelty, had the manufacturer agreed, Novelty would have been exempt from registration.

My dissenting colleague believes that I must decide the circumvention issue and remand if I disagree with the DA, relying on *PDK Laboratories Inc. Dissenting Opinion* at 16. Assuming without concluding that I did in fact disagree with the DA on this point, *PDK Laboratories Inc.* would not support remand here. In *PDK Laboratories Inc.*, we vacated the DA's decision and remanded for the DA to reconsider his interpretation of a statute. 362 F.3d at 797-99. We then noted that even if we had upheld the DA's statutory interpretation, we "would still have to vacate the [DA's] decision and remand the case" because the DA had failed to distinguish DEA precedent in finding certain regulatory violations. *Id.* at 798-99. The DA made his decision based on "the totality of the circumstances" and "four of the 'circumstances' prominently mentioned were [the regulatory] . . . violations." *Id.* at 799. We found it "impossible to discern" the "weight he gave to those circumstances" and noted that,

Third, Novelty argues that substantial evidence does not support the finding that Novelty had “serious recordkeeping deficiencies.” Final Order at 52,698. A registrant must “provide effective controls and procedures to guard against theft and diversion of List I chemicals,” 21 C.F.R. § 1309.71(a), which includes maintaining “systems for monitoring the receipt, distribution, and disposition of List I chemicals.” *Id.* § 1309.71(b)(8); *see also id.* § 1310.03 (list I chemical products distributors must keep record of all regulated transactions and file reports with DEA). The records must be “readily retrievable and available for inspection.” *Id.* § 1310.04(d). Novelty does

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if the DA concluded on remand that the petitioner’s actions were not regulatory violations, the outcome could change. *Id.* In contrast, the DA’s conclusion that Novelty attempted to circumvent the Suspension Order is not a “prominent” reason for the Final Order revoking Novelty’s registration. The DA concluded that the first (maintenance of effective controls against diversion) and second (statutory compliance) factors under 21 U.S.C. § 823(h) “*strongly* support[]” revocation. Final Order at 52,700, 52,702 (emphasis added). She found that the fourth factor (past distribution experience) and fifth factor (other considerations) “*also* support[]” revocation. *Id.* at 52,702-03 (emphasis added). The sole consideration under the fifth factor was Novelty’s “attempt to circumvent the suspension order.” *Id.* at 52,703. In selecting a sanction, the DA cited, first, Novelty’s failure to register the self-storage units and, second, Novelty’s failure to enforce its one case limit, *id.*, concluding, as noted above, “[Novelty’s] failure to enforce its own policies provides reason alone to conclude that it cannot be trusted to adhere to compliance conditions.” *Id.* at 52,704. She found “further support[]” for revocation—as opposed to imposing compliance conditions—in Novelty’s “sustained and flagrant violations of Federal law, as well as its attempt to circumvent the suspension order.” *Id.* Accordingly, Novelty’s alleged attempt to circumvent the Suspension Order was merely an additional factor supporting revocation and, if incorrect, would not have altered the outcome. Remand is therefore unnecessary.

not dispute the fact of the record keeping deficiencies the DA cited in support of her finding, *see* Final Order at 52,698-99, but instead asserts they do not add up to inadequate records. Pet'r Br. at 57-58. The DA cited the fact that Novelty was missing invoices for sales of list I chemical products and that its records contained inadequate and inaccurate information regarding shipment dates and delivery locations. Final Order at 52,698-99. I conclude that these deficiencies support the finding that Novelty's "failure to maintain adequate records . . . constitutes . . . a violation of Federal law." *Id.* at 52,699; *see* 21 U.S.C. § 830(a) (record keeping requirements for list I chemical transactions). I also reject Novelty's assertion that the DA did not adequately explain her disagreement with the ALJ's description of Novelty's records as "thorough." ALJ Decision at 84. But the ALJ also found several errors in Novelty's records, concluding that they were "not adequate to conduct an effective audit of [Novelty's list I chemical] products." *Id.* at 86, 88. The DA as the ultimate fact-finder is entitled to ascribe different significance to the deficiencies of Novelty's records. *Cf. Reckitt & Coleman, Ltd. v. Adm'r*, 788 F.2d 22, 26-27 (D.C. Cir. 1986). Accordingly, I reject Novelty's sufficiency challenge to the evidence supporting the DA's deficient record keeping finding.

For the foregoing reasons, I conclude that Novelty's petition for review should be denied.

TATEL, *Circuit Judge*, concurring in the judgment: Although troubled by several aspects of the Deputy Administrator's decision, I concur in the denial of the petition for review because substantial evidence supports two of her findings, which together constitute sufficient and independent grounds for the sanction of revocation.

Unlike Judge Henderson, I believe that the Deputy Administrator unreasonably construed section 822(e). That section requires a separate registration for "each principal place of business . . . where the applicant . . . distributes . . . list I chemicals." 21 U.S.C. § 822(e). This provision is hardly unambiguous as to the "precise question at issue," *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842 (1984), i.e., whether the word "principal" can apply to places such as Novelty's self-storage units. The word "each" prevents "principal" from taking its ordinary meaning of "most important, consequential, or influential: relegating comparable matters, items, or individuals to secondary rank," WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1802 (1993) (emphasis added). Given this ambiguity, we must accept the Deputy Administrator's construction if reasonable. *See Chevron*, 467 U.S. at 843.

Judge Henderson reads the Deputy Administrator as finding that certain characteristics of Novelty's self-storage units made them sufficiently "consequential" to the company's operations for the units to constitute principal places of business under section 822(e). *Op.* at 15–17. Although I think it quite counterintuitive that anyone would ever describe a self-storage unit as a "principal place of business" for a corporation with hundreds of employees and a nationwide client base, that interpretation might well be defensible as a reasonable exercise of the Deputy Administrator's authority to interpret an ambiguous provision of the Act. *See id.* But because it isn't the interpretation on which the Deputy Administrator actually relied, we may not

use it to sustain her action. *See, e.g., PDK Labs. Inc. v. DEA*, 362 F.3d 786, 798 (D.C. Cir. 2004) (“[I]f we find that an agency’s stated rationale for its decision is erroneous, we cannot sustain its action on some other basis the agency did not mention.” (citing *SEC v. Chenery Corp.*, 332 U.S. 194, 200 (1947))).

Instead of determining that the self-storage units were “consequential” due to their particular status in Novelty’s business structure, *see Op.* at 15–16, the Deputy Administrator determined they were “consequential” (and thus “principal”) simply because they were locations from which Novelty distributed list I chemicals, *Novelty Distributors, Inc. (“Final Order”)*, 73 Fed. Reg. 52,689, 52,700 (Sept. 10, 2008). Making this interpretation quite clear, she stated that section 822(e) “requires that a separate registration be obtained at *each* location at which List I chemicals are *distributed*.” *Id.* at 52,700 (internal quotation marks and some emphasis omitted); *see also id.* (explaining DEA’s position that “[t]he person who distributes List I chemicals from independently owned warehouses *must register at each location*” (internal quotation marks omitted, alteration in original)).

The Deputy Administrator’s interpretation suffers from a fatal flaw—it makes surplusage of the word “principal.” If all locations where an applicant distributes list I chemicals must be registered, then the phrase “each principal place of business . . . where the applicant . . . distributes . . . list I chemicals” would mean exactly the same thing if the word “principal” disappeared. Although “principal” as used in section 822(e) could have several permissible readings, any reasonable interpretation must impose some limitation not already captured by the term “distributes.” *See Dissenting Op.* at 7–8; *see also, e.g., Sierra Club v. EPA*, 536 F.3d 673,



680 (D.C. Cir. 2008) (“It is a court’s duty to give effect, if possible, to every clause and word of a statute.” (internal quotation marks, brackets and ellipsis omitted)).

To be sure, in the course of explaining her interpretation the Deputy Administrator did say at one point that “[a] location where List I chemicals are stored and distributed from, is a principal place of business because it plays a ‘consequential’ part in the registrant’s activity of distributing.” *Final Order*, 73 Fed. Reg. at 52,701. Although a requirement that list I chemicals be “stored” at a location could supplement the requirement that they be distributed, the word “stored” instead seems little more than a verbal flourish. After all, it’s mentioned only in passing during the Deputy Administrator’s argument for her expansive interpretation and never makes its way into any narrowing formulation. Clearly, then, as the Deputy Administrator sees it, “*each* location at which List I chemicals are distributed,” *id.* at 52,700 (some emphasis omitted), must be registered, not just those locations at which the chemicals are also stored. Given that the word “stored” fails to avoid surplusage, the Deputy Administrator’s interpretation is thus unreasonable under *Chevron* and cannot support her conclusion that Novelty failed to comply with applicable law.

But this does not end the matter, for the Deputy Administrator placed independent reliance on two findings unrelated to her flawed statutory interpretation. Each finds support in the record, and together they form a sufficient basis for the sanction imposed.

First, the Deputy Administrator found that whether or not section 822(e) required their registration, the self-storage units posed a serious risk of diversion. *See* 21 U.S.C. § 823(h)(1) (requiring consideration of the registrant’s maintenance of

effective controls against diversion). She stated that it was “unlikely” that the units would meet DEA’s security requirements, citing agency precedent finding that the use of similar units posed “an unacceptable risk of diversion.” *Final Order*, 73 Fed. Reg. at 52,698. She also pointed to several flaws in Novelty’s storage units, such as the fact that the door of one unit was accessible to the public. *Id.* Finally, she noted that even by the time of her decision Novelty had failed to provide DEA with accurate locations for thirty-four of its storage units. *Id.* For all of these reasons, the Deputy Administrator concluded that Novelty’s “use of these storage facilities . . . does not provide adequate controls against diversion and provides *reason alone* to support the finding that its continued registration is inconsistent with the public interest.” *Id.* (emphasis added, internal quotation marks omitted). Read in context as part of a discussion of the adequacy of Novelty’s controls against diversion, this statement amounts to a finding that the company’s use of the self-storage facilities posed risks of diversion sufficient to show that Novelty failed to maintain effective diversion controls. *See id.* at 52,700 (finding that this factor supports revocation). And as Judge Henderson explains, the Deputy Administrator adequately addressed contrary evidence in making this finding. *See Op.* at 12.

Second, and just as important, when turning to the choice of sanction, the Deputy Administrator stated that Novelty’s failure to enforce its own diversion control policies “provides *reason alone* to conclude that it cannot be trusted to adhere to compliance conditions,” *Final Order*, 73 Fed. Reg. at 52,704 (emphasis added)—the only lesser sanction under consideration. Substantial evidence supports this conclusion. The Deputy Administrator found that on 85 occasions during a six-month period, Novelty violated its policy limiting customers to one case per sales cycle. *Id.* at 52,703. Novelty

insists the policy applied only to certain packages and was thus violated just 35 to 45 times in a one-year period. Petr.'s Reply Br. 19. But the Deputy Administrator credited testimony establishing that the policy applied to a wider range of packages and thus that Novelty in fact committed 85 violations, Hr'g Tr. at 624. Contrary to the dissent, the Deputy Administrator had no obligation to consider how many completed transactions were made during that six-month period, *see* Dissenting Op. at 14, because many of the completed transactions may have been ones in which the customer only demanded one case, and thus would hardly count as instances of successful enforcement of the one-case limit. The Deputy Administrator was also skeptical of Novelty's failure to issue warnings to its sales force until after DEA's administrative inspection warrant, permissibly discrediting testimony that this delay stemmed from a computer glitch. *Final Order*, 73 Fed. Reg. at 52,703; *see also* Hr'g Tr. at 1435.

The Deputy Administrator made several additional points that support her finding that Novelty failed to enforce its own policies. She observed that the record contained no evidence that Novelty ever completely cut off any of the stores that violated the one-case policy (as the company's CEO promised he would). *Final Order*, 73 Fed. Reg. at 52,703; *see also* Hr'g Tr. at 159. She also pointed out that Novelty sold extremely high quantities of list I products to one store even after the company itself became concerned that the store was making excessive purchases, inferring from this that Novelty's "policy of monitoring unusual sales activity and cutting off sales if such purchases continue is a sham and not a legitimate effort to control diversion." *Final Order*, 73 Fed. Reg. at 52,703–04 (internal quotation marks and citation omitted). This inference is perfectly rational, though I hasten to add that I wouldn't necessarily agree with the Deputy

Administrator's more general treatment of high sales volumes as prima facie evidence of diversion. It's one thing to infer, as the Deputy Administrator did here, *id.*, that Novelty's high volume of sales to a store that it had previously found made excessive purchases indicates that Novelty isn't serious about its policy of monitoring suspicious transactions. It's quite another to infer, as the Deputy Administrator did elsewhere, *id.* at 52,700, that similarly high volumes of sales made to stores never suspected of suspicious activity signal a high risk of diversion. But only the former, more sensible inference is necessary to the sanction imposed.

According to the Deputy Administrator, her finding that Novelty failed to enforce its own policies provided "reason alone" to reject sanctions short of revocation. *Id.* at 52,704. The dissent believes that the Deputy Administrator couldn't have meant what she said given that she spent much of her opinion enumerating additional factors favoring revocation. Dissenting Op. at 16 n.10. But agencies often enumerate multiple grounds for their actions, even when one or more of the grounds would be adequate standing alone. By referring to this finding as "reason alone" to reject lesser sanctions, the Deputy Administrator clearly did so here.

Together, these two findings—that Novelty's use of self-storage units rendered its delivery system unsecure and that its disregard of its own policies required revocation—provided an independent basis for the Deputy Administrator's action. I thus have no need to address Novelty's objections to (1) the Deputy Administrator's treatment of high sales volumes as prima facie evidence of diversion, (2) its finding that Novelty attempted to circumvent the order suspending it from distributing list I chemicals, or (3) its condemnation of Novelty's use of the self-storage units while challenging the Raber letter. Although I am somewhat troubled by the first

two, none of these challenges could possibly affect the outcome of this petition for review given the Deputy Administrator's reliance on independent and sufficient grounds for revocation. *See PDK Labs.*, 362 F.3d at 799 ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration.").

I agree with Judge Henderson that Novelty's other objections to the Deputy Administrator's decision are without merit. The Deputy Administrator correctly concluded that even if DEA agents violated the First Amendment during their inspection of Novelty's warehouse, the exclusionary rule is inapplicable to administrative proceedings of the kind at issue here. *See Pa. Bd. of Prob. & Parole v. Scott*, 524 U.S. 357, 363 (1998) ("[W]e have repeatedly declined to extend the exclusionary rule to proceedings other than criminal trials."). Novelty complains that the Deputy Administrator failed to articulate the level of tolerable risk, but the Raber letter gave perfectly adequate guidance. Finally, neither Novelty's complaint that the Deputy Administrator conducted a biased campaign of enforcement against independent distributors of list I chemicals nor its complaint of unconstitutional prejudgment bias finds support in the record. Especially given the Deputy Administrator's rejection of much of the government's evidence, my concerns with her reasoning fall short of the level at which "a disinterested observer may conclude that [the Deputy Administrator] has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it," *Cinderella Career & Finishing Sch., Inc. v. FTC*, 425 F.2d 583, 591 (D.C. Cir. 1970) (internal quotation marks omitted).

BROWN, *Circuit Judge*, dissenting: Tellingly called poor man's crack (especially telling, as crack is already poor man's cocaine), methamphetamine—meth—is a national scourge. Behind only “alcohol and marijuana as the drug used most frequently in many Western and Midwestern states,” Methamphetamine, <http://www.usdoj.gov/dea/concern/meth.html> (last visited May 19, 2009), meth addiction can cause “paranoia, auditory hallucinations, mood disturbances,” and even “homicidal or suicidal thoughts,” Meth Awareness, <http://www.usdoj.gov/methawareness/> (last visited May 19, 2009). “A fairly common hallucination experienced by meth users is the so-called crank bug” where a “user gets the sensation that there are insects creeping on top of, or underneath, her skin,” causing her to “pick at or scratch her skin trying to get rid of the imaginary bugs,” “open[ing] sores that may become infected.” *Id.* Meth also “reduces the amount of protective saliva around the teeth,” which, along with the fact that “users also consume excess sugared, carbonated soft drinks, tend to neglect personal hygiene, grind their teeth and clench their jaws,” causes “what is commonly called ‘meth mouth,’” as addicts’ teeth “fall out” “even as they do simple things like eating a sandwich.” *Id.* Meth is a very bad thing. A monster.

But we don't toss the law aside in our zeal to eradicate even an obvious menace. The Deputy Administrator (DA) here has done just that,<sup>1</sup> in the process crippling a successful

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<sup>1</sup> As the Administrative Law Judge (ALJ) perceptively observed, no party “dispute[s] that illegal methamphetamine is a major drug problem in the United States,” but the agency “seems to be trying to remedy this problem by restricting or eliminating the availability of such over-the-counter products by removing the distributors of [these] products to convenience stores from the market place” altogether, despite lacking sufficient record evidence. *In re Novelty Distrib.*, No. 08-33, slip op. at 93 (May 21, 2008) (Recommended Ruling of the Administrative Law Judge) (“*ALJ Ruling*”).

enterprise and costing many employees their jobs. In rejecting the ALJ's recommendation that Novelty be allowed to retain its registration, the DA transforms a trivial violation of Novelty's own rules into an imminent danger to the public health and shifts the burden to Novelty to explain why some of the thousands of convenience stores it services are busier than others. Subject to this perverse alchemy, ordinary business practices somehow provide proof of rampant lawlessness. Thus, the DA (1) misreads a statute so any place used for distribution is a "principal place of business," even a padlocked storage shed; (2) uses the average sales of every convenience store serviced by Novelty as a proxy for legitimate demand at each location without regard to any individual characteristics; and (3) finds Novelty's efforts to stay in business after its registration was suspended to be proof of villainy.<sup>2</sup> Because "[t]he war on drugs is not an excuse to violate the norms of fair play and evenhandedness," *United States v. Cuellar*, 478 F.3d 282, 307 (5th Cir. 2007) (en banc) (Smith, J., dissenting), *rev'd* 128 S. Ct. 1994 (2008), I respectfully dissent.

## I.

To appreciate how poorly supported the DA's decision really is, a little history is helpful. This case first came before us when Novelty challenged the DA's suspension order, but the DA mooted that initial challenge by revoking Novelty's

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<sup>2</sup> Alas, these are not the only things the Drug Enforcement Administration (DEA) did wrong. 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 an executive believed he would be arrested because he could not do the impossible. *ALJ Ruling*, slip op. at 62–65. Such tactics do not reflect well on the United States.

registration before oral argument. To justify that initial suspension, the DA gave five reasons why Novelty's continued operations endangered the public. First, Novelty violated 21 U.S.C. § 822(e) by distributing from unregistered locations. *In re Novelty Distrib.*, Order to Show Cause & Immediate Suspension of Registration, slip op. at 1 (Jan. 17, 2008). Second, Novelty sold products to stores in amounts that "far exceeded what those retail outlets could be expected to sell for legitimate, therapeutic purposes," and some drugs were diverted to a Connecticut meth lab in 2002. *Id.* at 2. Third, Novelty "could not account for more than 60,000 dosage units of two ephedrine products," and there were other gaps in the company's records. *Id.* Fourth, "[f]rom January 1, 2007, through July 9, 2007, Novelty distributed scheduled listed chemical products on at least 284 occasions to 35 retail outlets that were not self-certified under" federal law. *Id.* Finally, Novelty distributed products in unlawful containers and in forms that violated state laws. *Id.* at 2–3.

The case went before an ALJ, who rejected most of these allegations as factually unsupportable. For instance, it's just not true that Novelty distributed drugs to stores that were not self-certified. *ALJ Ruling*, slip op. at 91. Nor did Novelty sell drugs in forms or packages that violated any law. *See id.* at 37–39. And the DEA's audit failed to consider all the data it received from Novelty: "Specifically, the DEA had failed to take into account dosage units returned to vendors, data that had been removed from the inventory because of expired or obsolete inventory, and other unspecified documents reflecting miscellaneous transfers or adjustments." *Id.* at 87–88. Based on the evidence, the most that could be said about those "60,000 dosage units" was that Novelty's recordkeeping was inadequate. *Id.* at 88. In her revocation decision, the DA conceded the ALJ was correct on these points. *See Novelty Distrib., Inc.*, 73 Fed. Reg. 52689, 52695 (Sept. 10, 2008)



(Revocation of Registration) (“At most, the evidence suggests that [Novelty] made a single distribution to a single store before it obtained its certification.”); *id.* at 52695–96 (form and packaging); *id.* at 52696–97 (audit).

The ALJ also debunked the DEA’s argument that Novelty was selling over-the-counter drugs in amounts that exceeded legitimate demand. Jonathan Robbin, the DEA’s expert, concluded “a convenience store is expected to sell no more than \$14.39 worth of . . . products per month,” even though one 24-count package could cost up to \$14.99. *ALJ Ruling*, slip op. at 96 & n.40. In other words, selling even one package per month would be suspicious. The ALJ set forth the flaws in this analysis. Robbin, for example, used the wrong denominator, thereby “forcing a lower expected sales value.” *Id.* at 55. He did “not provide a detailed breakdown” of how he determined important inputs in his formula, “other than providing a narrative of his approach,” and he offered data about the entire retail industry and just not convenience stores. *Id.* He ignored that much of his data relied on self-reporting, and instead of reporting sales as “cold and cough products,” some stores used the “general merchandise” category. *Id.* at 56–57 n.28. He also did not do a multivariate analysis to consider “[f]actors such as store hours, store location, store size, advertising expenditures, and management practices,” or other “seasonal and environmental variables.” *Id.* at 58. Unsurprisingly, the DA did not defend Robbin’s analysis. 73 Fed. Reg. at 52693–94.<sup>3</sup>

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<sup>3</sup> Though the DA did not uphold Robbin in this case, he has been relied upon in more than twenty other cases, even though his approach—aside from being internally defective—does not appear even to yield consistent results. *Compare Sunny Wholesale, Inc.*, 73 Fed. Reg. 57655, 57658 (Oct. 3, 2008) (“Mr. Robbin explained . . . that during 2005, [t]he expected average monthly convenience store sales of nonprescription drug products containing

Thus, all that lingered of the DA's aggressive allegations was that Novelty broke the law by using unregistered storage units; that Novelty's records were deficient in certain respects; and that a small amount of product had been diverted. In revoking Novelty's registration, the DA also emphasized Novelty's letter to one of its suppliers that supposedly manifested an intent to circumvent the suspension order, and that Novelty did not comply consistently with its own anti-diversion rules. Finally, because Robbin's statistics were useless, the DA invented, seemingly *sua sponte*, a new statistical analysis, placing the burden on Novelty to rebut it. These grounds, though much less compelling than the grand claims made in the suspension order, were enough for the DA to shut down Novelty's list I chemicals operations for good.

To say the case for revocation is razor thin greatly exaggerates its sufficiency. As the statute is written, the storage units are not illegal. The DA's newly-concocted

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pseudoephedrine (hcl) in Georgia were \* \* \* \$82.00.”) *with Holloway Distrib.*, 72 Fed. Reg. 42118, 42119 (Aug. 1, 2007) (“Mr. Robbin explained that a monthly retail sale of \$60 of pseudoephedrine (Hcl) \* \* \* would be expected to occur less than one in 1,000 times in random sampling, and a monthly retail sale of . . . \$100 in pseudoephedrine (Hcl) . . . would occur about once in a million times in random sampling.”) *with H&R Corp.*, 71 Fed. Reg. 30168, 30169 (May 25, 2006) (“Mr. Robbin . . . . determined that the normal expected retail sales of pseudoephedrine tablets in a convenience store would . . . average . . . about \$20.00 and the sales of more than \$100.00 in a month would be expected to occur in a random sampling about once in one million to the tenth power, a number he characterized as nearly equivalent to the number of atoms in the universe.”). 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.

statistics are just as bad as Robbin's, and the "smoking gun" letter is anything but. Moreover, though Novelty did not always live up to its own policies, mistakes were rare, and the DA failed to even consider the relevant denominator. True, company records were somewhat deficient, but no DEA agent had ever before complained of Novelty's "thorough" records, despite multiple inspections, *ALJ Ruling*, slip op. at 84, 93, and, in any event, the DA said if the only problem were recordkeeping, "imposing compliance conditions might well protect the public interest." 73 Fed. Reg. at 52703. If "arbitrary and capricious" is to mean anything in the DEA context, this decision cannot be allowed to stand.

## II.

The heart of the DA's analysis—that unregistered storage units *always* violate federal law—contradicts the statute, *Chevron* notwithstanding. Under no reasonable reading does 21 U.S.C. § 822(e) require each link in the distribution chain to be registered. Nonetheless, in revoking its registration, the DA gave top billing to Novelty's supposed lawbreaking: "First, for more than three and a half years, Respondent disregarded a DEA letter specifically warning it that its use of 150–180 self-storage units . . . violated Federal law." 73 Fed. Reg. at 52703. In fact, not only did the DA lean on this finding for purposes of 21 U.S.C. § 823(h)(2) (compliance with law), she double-dipped and used again it for § 823(h)(4) (past experience). *See id.* at 52702. But she was wrong; it was not Novelty that bent the law.

Section 822(e) says a "separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals." 21 U.S.C. § 822(e). Novelty argued its scores of run-of-the-mill self-storage units were not "principal places of business," and

thus did not need to be registered. The DA rejected this position, determining that federal law “requires that *a separate registration be obtained at each location at which List I chemicals are distributed.*” 73 Fed. Reg. at 52700.

Hogwash. Even 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 two things: (1) “distribut[ion]” from (2) a “principal place of business.” The question is simple: if *all* locations where distribution occurs must be registered, why would Congress specifically refer to “each *principal* place of business”? To make the word “principal” disappear, the DA resorted to magic tricks. She determined each “location” where “List I chemicals are . . . distributed from” is a “principal” one because it “plays a ‘consequential’ part in the registrant’s activity of distributing.” *Id.* at 52701 (quoting WEBSTER’S THIRD NEW INT’L DICTIONARY 1802 (1976)).<sup>4</sup> Hence “principal place of business where a registrant distributes list I chemicals” = “consequential” place of business = “each location where list I chemicals are distributed.” (abracadabra omitted). But after the smoke fades away, the DA’s approach to the word “principal” causes § 822(e) to read like this: “A separate registration shall be required at each location where list I chemicals are distributed where the applicant distributes list I chemicals.” That is a silly way to read a statute. *E.g., Reiter v. Sonotone Corp.*, 442

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<sup>4</sup> The relevant definition of “principal” is: “1: *most* important, consequential, or influential: relegating comparable matters, items, or individuals to secondary rank.” WEBSTER’S THIRD NEW INT’L DICTIONARY 1802 (1976) (emphasis added). Though the DA elected to not even quote it, much less consider it, 73 Fed. Reg. at 52701, the word “most” is particularly meaningful.

U.S. 330, 339 (1979) (“In construing a statute we are obliged to give effect, if possible, to every word Congress used.”).

To be sure, § 822(e) contains ambiguity, as it invokes a common term of art in a way that is not consistent with its ordinary usage. “Principal place of business” is most prominently used in 28 U.S.C. § 1332(c), relating to corporate diversity, and it is settled that for diversity jurisdiction there can only be one “principal place of business.” *E.g.*, *Capitol Indem. Corp. v. Russellville Steel Co.*, 367 F.3d 831, 835 (8th Cir. 2004). Section 822(e), by use of the word “each”, contemplates multiple such places. But just because a statute is ambiguous does not mean any interpretation of it is reasonable. *See, e.g.*, *Int’l Alliance of Theatrical and Stage Employees v. NLRB*, 334 F.3d 27, 34–35 (D.C. Cir. 2003). Though the language here cannot mean the exact same thing as in § 1332(c), it is unreasonable to find that any place where distribution occurs is per se “principal.” No matter how defined, “principal place of business” surely means more than *that*. If every place is “principal,” no place is.

The DA mused, however, that any other reading than hers “would clearly frustrate the Congressional purpose,” which was to prevent “diversion by requiring that those persons who propose to engage in the legitimate distribution of . . . listed chemicals apply for a registration, notify this Agency of the proposed location of their activity, and submit the facility for inspection . . . to ensure that it has adequate security controls and procedures.” 73 Fed. Reg. at 52701. For this proposition, she cited 21 U.S.C. 822(f), which reads: “The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.” This is not at all sufficient to support her construction of § 822(e) as “establishment”—used in § 822(f)—is not the same as

“principal place of business.” The surest Rosetta Stone into “Congressional purpose” is the language Congress actually uses, but the DA’s construction of § 822(e) effectively deletes Congress’s word “principal” from the U.S. Code.

The DA then explained that accepting Novelty’s view “would also create a perverse incentive” for registrants to “keep adding warehouses or storage facilities so that it could eventually claim that its warehouses were no longer principal places of business and thus were not subject to the registration requirement.” 73 Fed. Reg. at 52701. Perhaps, but if records are kept at these hypothetical warehouses, if employees work there full-time, if they are listed in the phone book, if drugs are kept there for an indefinite duration, and so on, then there may be an argument that these warehouses are “principal places of business.” The DA did not even attempt to offer such a nuanced test. Instead, she found all storage units must, as a matter of law, be registered. How is a shed, locked with a padlock, a “principal place of business” for a company like Novelty with hundreds of employees and thousands of customers across the nation?<sup>5</sup>

What is most aggravating is that reading the statute correctly would not create the dire dichotomy painted by the DA, one in which any other view but hers would “render the Act a nullity.” *Id.* The DEA still has recourse to the first factor under 21 U.S.C. § 823(h), relating to the risk of diversion. If a registrant’s distribution practices are not safe, that problem can be addressed by the statutory scheme *as written*. There is no need to mangle the text to make unsafe

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<sup>5</sup> As the ALJ found, nearly all Novelty’s sales were to “major retail convenience store chain customers”—“billion dollar companies” with “full-time staff” and “legal counsel, to ensure compliance with state and federal regulations.” *ALJ Ruling*, slip op at 6.

distribution an independent violation of federal law. However, instead of simply relying on that first § 823(h) factor (perhaps because there is almost zero evidence of actual diversion), the DA adopted an atextual claim of lawbreaking to bolster the argument in favor of revocation.

### III.

The DA also botched her diversion analysis. Let's be clear: there is remarkably little evidence of actual diversion in this record. The best the DA can muster is an event from 2002 when "twenty-two [sixty-count bottles of an ephedrine-based product] were found at an illicit methamphetamine laboratory in Thompson, Connecticut." 73 Fed. Reg. at 52694. Novelty, however, did not produce those bottles, and it is uncertain whether the company even distributed them. *See ALJ Ruling*, slip op. at 74. The DEA, it seems, also never formally warned Novelty about the diversion until it took action against the company in 2008. 73 Fed. Reg. at 52702. But even given the benefit of the doubt, the DA can only point to one instance of diversion, despite Novelty's *hundreds of millions* of doses sold.<sup>6</sup> *See, e.g., Pet'r's Br.* at 15 (Novelty has sold between three and five hundred million doses).

Because proof of actual diversion was paltry, revocation rested on Novelty's theoretically ineffective controls against diversion. There is much in the DA's reasoning that I sympathize with; I too wonder whether it is prudent to keep

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<sup>6</sup> DEA investigators also "visited a number of [Novelty's] customers," and, after looking at the "logbooks" used to record drug sales, found five stores with questionable patterns (though not all sales were illegal, they nonetheless were "suspicio[us]"). 73 Fed. Reg. at 52694–95. Novelty, however, "cannot review the logbooks." *Id.* at 52699 n.43. The DEA, it seems, did not investigate further to see if these drugs were being illicitly used.

drugs in storage sheds or on trucks for over a week.<sup>7</sup> Likewise, though her concern about Novelty's recordkeeping was overstated, I agree it is important to keep complete records, and if Novelty had concerns about a particular store, it should have been especially vigilant. At the same time, as the ALJ found, Novelty took "a proactive role in ensuring its customers are self-certified," made sure its customers used "lockable, plexiglass display cases for the display and sale of" drugs, and "when the DEA brought the recordkeeping errors" to Novelty's attention, Novelty "identified a reasonable reason for the errors, and acted to correct those errors by upgrading its computer system." *ALJ Ruling*, slip op. at 98–99. Novelty also credibly offered to modify its distribution network to address safety concerns. *Id.* at 100–01. (The DA wrongfully rejected the ALJ's credibility finding based on her erroneous belief that the storage units were illegal, 73 Fed. Reg. at 52703). Given the large number of transactions, moreover, some mistakes will happen; what human endeavor is done perfectly millions of times in a row? Nonetheless, there is some reason to conclude Novelty's protections against diversion—even if factually "effective," as the statute requires, 21 U.S.C. § 823(h)(1)—were imperfect, though such oversights should be addressed by compliance conditions far short of the corporate death penalty that is revocation.

But instead of just relying on this theoretical diversion, the DA went further and reasoned Novelty's own statistics "showing its sale of [drugs] in the three months prior to the

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<sup>7</sup> I am confused, however, about the logic in the Raber Letter. Registrants are allowed to keep drugs in the truck "overnight" for "long delivery route[s]," provided the delivery is for "pre-placed customer specific orders for List I chemical products." Raber Letter. But if the concern is "a thief can steal the vehicle's cargo," 73 Fed. Reg. at 52698, then why does it matter if the drugs are for "pre-placed customer specific orders" or for on-site orders?



issuance of the suspension order” demonstrated that Novelty did not maintain effective controls against diversion. 73 Fed. Reg. at 52699. The support for that claim is embarrassingly weak. Despite the almost self-evident fact that not all convenience stores are created equal (for instance, the AM/PM next to a major freeway may be a lot busier than Ma’s Gas-N-Go in Middle-of-Nowhere Alabama), the DA conjured a very blunt instrument to derive legitimate market demand: Novelty’s average sales data. Instead of relying on a multivariate statistical study that could have accounted for factors affecting sales at individual stores, she operated on an unstated assumption that every store in the country should request an amount close to the average, meaning any request above the average suggests a likelihood of diversion. But what a store should request is based on legitimate, non-diversionary demand for the product *at its location*. Just as a store selling below the national average might still show a risk of diversion if it requests many more drugs than non-diversionary demand would warrant at its location, a store selling above the average does not show a diversion risk if it requests the amount which would be expected at its location. The DA’s approach ignored this basic and obvious point.

Similarly, as Novelty’s expert observed, “if an average legitimate sales figure was derived from data from both high-sales revenues stores and low-sales revenues stores, but then that average legitimate sales figure was used to predict sales in only the high-sales revenues stores, the prediction would suffer from aggregation bias.” Instead of accepting this unassailable logic, the DA said “proof that a distributor is selling quantities in excess of the national monthly average of sales of [drugs] by convenience stores would be highly probative of the distributor’s lack of effective controls against diversion.” 73 Fed. Reg. at 52700. This tells us very little

about anything; after all, 50% of all convenience stores should be expected to have sales greater than the average.

The DA then said “[m]ore specifically, a registrant cannot ignore evidence that some of its customers are purchasing quantities that greatly exceed what its typical customer buys from it.” *Id.* This statement, of course, seems a little more persuasive (but only a little); if one assumes all convenience stores are similar, and if a store is receiving many more drugs than others, that should raise a red flag—but, of course, not all stores are similar. The DA concluded by stating Novelty “offered no explanation that was specific to any store for why it was selling in such quantities.” *Id.* But the burden of proof is on the government before it can take away someone’s livelihood, *see* 21 C.F.R. § 1309.54(b), 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, 73 Fed. Reg. at 52693–94. In any event, there is no basis to shift the burden to Novelty because we should expect statistical outliers. *See id.* at 52700 n.45. Of the thousands of stores serviced by Novelty across the country in countless different climes and circumstances, is it really unthinkable that a small subset of them will be much busier than the others? This statistical inevitability is not something that a company should have to explain, nor should the DEA be able to escape its burden of proof so effortlessly.<sup>8</sup>

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<sup>8</sup> Novelty, moreover, showed no reluctance to police its own operations. When Store # BPM55, its largest customer, purchased noticeably large quantities—*although not more than federal law allowed*—Novelty prohibited the sale of 100-count ephedrine to that store. Perhaps Novelty could have done more, but if a single debatable judgment call about what extralegal steps must be taken to avoid diversion can cost a company its registration, then all the world’s a cage, with every registrant just waiting to be culled.

The DA's problems with large numbers do not end there. Ignoring that no complex system can be 100% foolproof, the DA applied an unreasonable zero-tolerance standard that Congress surely did not intend.<sup>9</sup> She found, for example, that Novelty "violated its case limit policy [i.e., its *own* policy that it would only sell one 24-count package to a store per visit] some 85 times" during a six-month period, 73 Fed. Reg. at 52699. That sounds pretty bad, but the DA omitted the denominator; according to the record, the number of transactions during that year was "approximately 100,000 to 120,000." The error rate thus may have been less than .2% (no one knows for sure the exact rate because the DA did not even attempt to discern it using any methodology whatsoever, Judge Tatel's or otherwise, *see* Tatel Op. at 4–5). Despite the burden resting with the government, the DA did not explain how much risk is too much, nor did she give any context to those "85" violations (a number, by the way, that Novelty says is at least forty too high). All we know is sales staff may have mistakenly sold extra packages of product to convenience stores—not to meth makers, mind you—less than two times per thousand transactions. Yet somehow Novelty's "failure to enforce its own policies provides reason alone to conclude that it cannot be trusted to adhere to compliance conditions"? 73 Fed. Reg. at 52704.

#### IV.

In revoking the registration, the DA also stressed Novelty's attempt to find a new way of doing business once its registration was suspended. Though conceding Novelty

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<sup>9</sup> Just as "safe" does not mean "risk-free," *Industrial Union Dep't v. American Petroleum Inst.*, 448 U.S. 607, 642 (1980) (Stevens, J., plurality), "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.

did nothing illegal, she nonetheless found Novelty did more than “merely think[] about a legal option or seek[] legal advice about the scheme,” but also “affirmatively sought out one of its suppliers and attempted to induce it to enter the scheme only to be rebuffed by the supplier.” 73 Fed. Reg. at 52703. The DA concluded “[i]t would fundamentally undermine the [Controlled Substance Act’s] purpose of protecting against diversion to allow an entity whose registration has been revoked to subsequently engage in the same or related activities as an agent.” *Id.*

Here are the real facts. In January 2008, the DEA suspended Novelty’s registration. After receiving the suspension order, Novelty sent a letter, which I quote, explaining its “plan to get back in the ephedrine business” to one of its suppliers. Letter from Novelty, Inc. (under seal). Under the “plan”—which was “still [being] finaliz[ed] . . . with the DEA to insure everything can work smoothly and we do not have any issues” and was awaiting “approval” before any sales would occur—Novelty’s sales force would “tak[e] orders” which would be sent “to a third party logistics company for shipping and handling” to “fill the order . . . via UPS or similar carrier.” *Id.* The “costs [to the owner of the store would] remain the same,” and “[a]ll invoices [would be] from Novelty.” *Id.* The owner of the store would “have the choice of stocking the [drug] cabinet or holding it for [Novelty’s] sales person.” *Id.* The effect would be to “basically keep[] the business the same,” except with “a UPS box.” *Id.* The supplier declined to participate, but a Novelty executive testified during the administrative process that Novelty was “still continuing to explore” this idea.

The DA’s reading of the letter is unfair. Making tentative plans—plans contingent upon DEA authorization no less—suggests nothing nefarious. Novelty, moreover, planned on

substantially changing its business, including no longer using its own distribution network (i.e., the very network at issue in this case). Under 21 U.S.C. § 822(c)(1), a sales agent need not be registered if he “is acting in the usual course of his business or employment,” which, under this completely new business model, seemingly would include Novelty. Granted, Novelty said its plan would “basically keep[] the business the same,” but, in context, the only plausible reading of the sentence is the business would remain the same for Novelty’s customers, not for Novelty itself. How could the business be unchanged for Novelty which would not longer do the shipping and handling of these drugs?

Neither of my colleagues reaches this issue (though both hint they might agree with my analysis). This is a mistake. The DA employed a totality of the circumstances test, but the only evidence she relied upon in assessing 21 U.S.C. § 823(h)(5)—the statute’s catch-all category—was Novelty’s letter. *See* 73 Fed. Reg. at 52702–03. Because the DA erred as to this factor, and because we do not know how much weight she gave it in her analysis,<sup>10</sup> at a minimum this court should remand for her to reweigh the evidence. *See, e.g., PDK Labs., Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) (“If the agency’s mistake did not affect the outcome, if it did

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<sup>10</sup> In context, I charitably assume the DA’s otherwise staggering suggestion that Novelty’s “failure to enforce its own policies provides reason alone to conclude that it cannot be trusted to adhere to compliance conditions” was not intended to be taken literally, particularly as it was not the first reason given for revocation, 73 Fed. Reg. at 52703–04, and if Novelty’s failure to self-police were intended to be sufficient on its own, then there was no reason for the rest of the DA’s lengthy opinion. But if the statement was not hyperbole, then we obviously should vacate this decision because, as explained, the DA entirely failed to consider the relevant denominator. What can be more arbitrary and capricious than that?

not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration. But in this case we cannot say that the Deputy Administrator's error was of that sort . . . . [as he] stated that it was 'the totality of circumstances' that led him to sustain the suspension orders.').

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I close with a few words on how easily the administrative state can slip its leash. A familiar argument for enhanced administrative authority (and hence diminished judicial review) is the need for "flexibility," as old-fashioned courts are ill-suited to deal with the complexities of the modern world. *E.g.*, Cass R. Sunstein, *Law and Administration After Chevron*, 90 COLUM. L. REV. 2071, 2079 (1990) (citing, *inter alia*, J. LANDIS, *THE ADMINISTRATIVE PROCESS* 6–12 (1938)). That may be true. But the flipside of flexibility is certainty, consistency, evenhandedness, and predictability—those Rule of Law values that mark a free society. *E.g.*, THOMAS PAINE, *COMMON SENSE* 31–32 (Dover Thrift ed., 1997) (1776) (“[L]et a crown be placed thereon, by which the world may know, that so far as we approve of monarchy, that in America THE LAW IS KING. For as in absolute governments the king is law, so in free countries the law *ought* to be king; and there ought to be no other.”). If my splintered-on-seemingly-all-points-but-outcome colleagues are right that despite her many errors, the DA's decision to revoke Novelty's registration still must be upheld, then I fear we have traded away far too much law in our bargain for elasticity.

But in the end, because of this “flexibility,” it is probably for the best that the DA's decision is upheld today. If the registration was not revoked this time, it surely would have happened next time. On this record, I have no confidence that Novelty would ever receive a fair shake from the DEA. Indeed, if we were reviewing a district court that acted like

this, I would not remand to that court. But the DEA is the only game in town for drug registrants, and in deciding whether to revoke a registration the DA balances a number of open-ended factors with no requirement “to make findings as to all of the factors,” and with power to “give each factor the weight [s]he deems appropriate.” *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005). Add *Chevron* deference to that mush and we have a very powerful Deputy Administrator. In other words, if in the future the DA were to find any errors in Novelty’s records or operations (and, given that Novelty sells millions of doses a year, it is inevitable that she would), then she could revoke the registration by claiming a pattern of dangerous recordkeeping and distribution errors, knowing full well that Novelty would face an uphill scramble to persuade a court that she has abused her overflowing discretion. Given the law of large numbers, such a pattern could be found in *any* registrant’s records, meaning *all* registrants live by the grace of the Deputy Administrator.

No, old-fashioned law will not save Novelty and the jobs of its employees. 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. When an agency has gone rogue, and when judicial review is gutted, the only thing left is the Law of the Jungle, the weak versus the strong. And in this war of all against all, who can withstand the might of the federal government?