United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 10, 2006 Decided February 24, 2006

No. 04-1432

PDK LABORATORIES INC.,
PETITIONER

v.

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

On Petition for Review of an Order of the
United States Drug Enforcement Agency

Saul Pilchen argued the cause for petitioner. With him on the briefs were *Joseph L. Barloon* and *David E. Carney*.

Teresa A. Wallbaum, Appellate Counsel, U.S. Department of Justice, argued the cause for respondent. With her on the brief were *Kenneth L. Wainstein*, U.S. Attorney, and *Stephen A. Sola*, Trial Attorney.

Before: TATEL and GARLAND, *Circuit Judges*, and EDWARDS, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* TATEL.

TATEL, *Circuit Judge*: Pursuant to the Chemical Diversion and Trafficking Act of 1988, the Drug Enforcement Agency (DEA) "may order the suspension of any importation or exportation of a listed chemical . . . on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance." Petitioner, a pharmaceutical manufacturer, does not dispute that some of its products contain ephedrine and pseudoephedrine, both "listed chemicals" and both critical in the manufacture of methamphetamine, a "controlled substance." Nor does petitioner dispute that its ephedrine- and pseudoephedrine-containing products have been and will continue to be "diverted" to illicit methamphetamine labs. Instead, petitioner argues that when DEA suspends shipments of listed chemicals—in this case, the agency suspended two such shipments—it may act only on the basis of evidence that the raw listed chemical, not the finished product containing the listed chemical, "may be diverted." Alternatively, petitioner argues that even if DEA may act on the basis of evidence that the finished product may be diverted, the suspension orders in this case were unsupported by substantial evidence. We disagree on both counts and deny the petition for review. DEA, acting on the basis of its law enforcement experience and expertise, reasonably interpreted the phrase "listed chemical" to include ephedrine and pseudoephedrine contained in finished drug products. Moreover, a series of letters from DEA warning petitioner that thousands of bottles of its products had been found in some 140 methamphetamine labs in at least eighteen states provides more than enough evidence to support the suspension orders.

I.

A powerful and highly addictive synthetic stimulant, methamphetamine is a growing problem for law-enforcement and public-health officials across the country, particularly in western states. "Chronic methamphetamine abuse can lead to

psychotic behavior including intense paranoia, visual and auditory hallucinations, and out-of-control rages that can result in violent episodes." Office of Nat'l Drug Control Policy, Methamphetamine Fact Sheet 1 (2003). Rooting out the illegal manufacture and distribution of the drug has proven especially difficult because it "can be made in a portable cooler with ingredients bought at the corner drugstore." Timothy Egan, *Meth Building Its Hell's Kitchen in Rural America*, N.Y. Times, Feb. 6, 2002, at A14.

Congress's first major effort to arm the federal government with adequate authority to stamp out homemade methamphetamine production came in the Chemical Diversion and Trafficking Act of 1988 (CDTA), Pub. L. No. 100-690, tit. VI, subtit. A, 102 Stat. 4312. To discourage the diversion of "listed chemicals"—including two critical methamphetamine ingredients, ephedrine and pseudoephedrine, *id*. § 6054(3) (codified as amended at 21 U.S.C. § 802(34)(C), (K))—the CDTA requires companies to report transactions in such chemicals to DEA, *see id.* § 6052(a) (codified at 21 U.S.C. § 830(b)), and imposes criminal liability on individuals who import a listed chemical "knowing, or having reasonable cause to believe, that [it] will be used to manufacture a controlled substance," *see id*. § 6053(c) (codified as amended at 21 U.S.C. § 960(d)(2)). Using language central to the issue before us, one section of the Act, now codified at 21 U.S.C. section 971(c)(1), also provides that DEA "may order the suspension of any importation or exportation of a listed chemical . . . on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance." *Id*. § 6053(a) (codified as amended at 21 U.S.C. § 971(c)(1)).

As the CDTA tightened the screws on access to raw listed chemicals, illicit methamphetamine manufacturers shifted to extracting ephedrine and pseudoephedrine from common over-

the-counter medications, including Sudafed and some types of Primatene. Since the two listed chemicals are present in such medications in a chemically unchanged form, the extraction process is relatively simple. Congress sought to counter this trend with the Domestic Chemical Diversion Control Act of 1993, which (for the first time) required companies to report all transactions in FDA-approved drug products containing listed chemicals. Pub. L. No. 103-200 § 2(a)(6)(C), 107 Stat. 2333, 2333-34 (codified as amended at 21 U.S.C. § 802(39)(A)(iv)). Still dissatisfied, Congress enacted the Methamphetamine Anti-Proliferation Act of 2000, Pub. L. No. 106-310, tit. XXXVI, 114 Stat. 1227, which allocated significant funding to combating methamphetamine production, *id*. §§ 3623(c), 3624(b)(1), 3625(c), and imposed stiffer penalties on the operators of methamphetamine laboratories, *id*. § 3612.

Petitioner PDK Laboratories, Inc., a large manufacturer of generic drugs containing ephedrine and pseudoephedrine, has long known that its products have been diverted to clandestine methamphetamine labs. In March 1998, DEA sent PDK a "warning letter" documenting the appearance of the company's products at fifty-one methamphetamine labs in various states over an eight-month period. Two years later, another DEA warning letter informed PDK that its products had been found at forty-nine additional methamphetamine labs. And over the subsequent eleven months, DEA sent twenty-one additional warning letters informing the company that its ephedrine- and pseudoephedrine-containing products were still showing up at illicit drug labs across the country. In total, DEA alerted PDK to the diversion of "thousands of bottles of its previously imported [listed] chemicals to approximately 140 illicit methamphetamine laboratory-related sites located in at least 18 states." *See Indace, Inc., Suspension of Shipments*, 69 Fed. Reg. 67,951, 67,959 (Nov. 22, 2004).

By January 2001, DEA had had enough. Relying on the string of warning letters, as well as on PDK's failure to report several "regulated transactions," DEA flexed its section 971(c)(1) authority and issued suspension orders to two foreign manufacturers preparing to ship 6,000 kilograms of raw ephedrine to PDK. PDK challenged the suspension orders, and an administrative law judge (ALJ), siding with the company, concluded that the orders lacked adequate legal and factual support. In her analysis, the ALJ construed DEA's authority to suspend importations of "listed chemicals" to extend only to cases in which the agency has evidence that bulk listed chemicals like raw ephedrine—and not finished over-the-counter drug products that contain listed chemicals—may be diverted to clandestine drug manufacturers.

On appeal, DEA's Deputy Administrator disagreed with the ALJ. *Indace, Inc., Suspension of Shipments*, 67 Fed. Reg. 77,805 (Dec. 19, 2002). Reading section 971(c)(1) to permit suspension if DEA finds that finished drug products containing listed chemicals "may be diverted," the Deputy Administrator held that DEA could properly rely on the diversion of PDK products to justify suspending the ephedrine shipments. *Id*. at 77,806. Considering the "totality of the circumstances," including both the warning letters and the reporting violations, the Deputy Administrator concluded that substantial evidence supported the suspension orders. *Id*. at 77,807.

PDK filed a petition for review in this court. In considering this first appeal, we saw ambiguity as to "whether, as the suspension orders assume, [the phrase] 'the chemical may be diverted' [from section 971(c)(1)] includes the prospect that PDK's ephedrine-containing pills in retail stores will be sold to, or shoplifted by, people who then use the pills to produce methamphetamine." *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 794 (D.C. Cir. 2004) ("*PDK I*"). Reasoning that the Deputy

Administrator had therefore improperly concluded that section 971(c)(1) compelled a result that it did not in fact compel, we vacated and remanded to DEA to "fill in the gap" by "bring[ing] its experience and expertise to bear in light of competing interests at stake." *Id*. at 797-98. Although then-Judge Roberts disagreed on this point, he joined in the majority's alternative reason for vacating the Deputy Administrator's order, *id*. at 799 (Roberts, J., concurring in part and concurring in the judgment), namely, that it failed to address DEA's own relevant precedent in finding that PDK violated the CDTA's reporting requirements. *See id*. at 798-99 (providing the majority's reasoning).

On remand, a new Deputy Administrator explained that, in her view, "the totality of [Congress's] progressive enactments" reflected its "intent to provide DEA the regulatory means to monitor the domestic production, manufacture and distribution of [listed] chemicals and prevent their illicit use in manufacturing methamphetamine." 69 Fed. Reg. at 67,955. Therefore, while acknowledging that these chemicals are often found in products that have "legitimate therapeutic uses," *id.* at 67,954, the Deputy Administrator held that section 971(c)(1) permits suspension of imports of listed chemicals based on evidence that finished drug products containing such chemicals "may be diverted," *id*. at 67,957. Because "[s]ection 971(c)(1) is considered by DEA to be a significant component of the regulatory arsenal given it by Congress to combat this immense and growing problem," and because "using precursor chemicals[] obtained by theft or purchase of listed chemical products" poses an acute law-enforcement challenge, *id.* at 67,956, the Deputy Administrator concluded that a narrow interpretation of the statute would unnecessarily hamper the agency's efforts to prevent the diversion of listed chemicals. *Id*. at 67,595-96.

Defending her interpretation of section 971(c)(1), the Deputy Administrator asserted that her approach comported with the statute's text, reasoning that "[i]f Congress wanted to make an express distinction between a bulk listed chemical and a finished product . . . it could have done so." *Id*. at 67,955. She further explained that "listed chemical . . . should be construed broadly in light of that term's use in other parts of the same statute . . . enacted by Congress in 1988," *id*. at 67,954, and pointed out that the Ninth Circuit had already interpreted "listed chemical" as used in one of the CDTA's criminal provisions to cover the ephedrine and pseudoephedrine in finished drug products, *id*. (citing *United States v. Daas*, 198 F.3d 1167, 1175 (9th Cir. 1999)). The Deputy Administrator also believed that a narrow interpretation would "create an arbitrary dual standard," for if DEA could suspend shipments only if raw ephedrine were at risk of diversion, then even when DEA "had facts to show that an importer had reasonable cause to believe that a listed chemical was to be imported, tableted, and distributed to a clandestine laboratory," it could do nothing to suspend the shipment. *Id*. at 67,955. Such a result, she concluded, "is certainly inconsistent with the criminal penalty provisions of the law involving imports," which would allow for the imposition of lengthy prison terms on the importer. *Id*.

Turning to the second issue—whether substantial evidence supported the suspension orders—the Deputy Administrator again looked to the totality of the circumstances. Examining three categories of evidence—the warning letters and two types of reporting violations—she concluded that the orders were adequately supported, emphasizing that "the evidence of diversion reflected in the series of Warning Letters provides a sufficient independent basis" for sustaining the suspension orders. *Id*. at 67,961 n.9. In reaching this conclusion, the Deputy Administrator rejected PDK's argument that DEA's failure to compare the rate of diversion of other companies'

products to PDK's diversion rate rendered the suspension orders invalid. She explained:

> DEA recognizes that it and other law enforcement agencies are aware of and able to take action against only a small number of the total clandestine methamphetamine laboratories and dump sites in this country. Accordingly, the specific universe of PDK product diverted, *vis a vis*, all other manufacturers' products, is a number which cannot be established with any specificity. . . .
>
> Given the quantities and diverse locations of PDK listed chemical products discovered at illicit sites reflected in the Warning Letters, DEA is able to draw a reasonable inference regarding the likelihood that the instant shipments may be diverted and to exercise its discretion as to the need to prohibit their import.

Id. at 67,959. The Deputy Administrator also pointed out that she had considered warning letters to be adequate grounds for taking adverse action against other drug manufacturers, and that in one case she had sustained a suspension order based on fewer warning letters than DEA had sent to PDK. *Id*.

Before addressing the two types of reporting violations (neither of which is relevant to our disposition of this case), the Deputy Administrator noted "[a]s a collateral matter" that Michael Lulkin, PDK's former in-house counsel "responsible for implementing PDK's operating procedures for responding to DEA Warning Letters," had been convicted of four counts of felony fraud, one of which involved PDK. *Id*. Yet after his conviction, Lulkin remained at PDK, "where his duties include overseeing the company's regulatory compliance." *Id*. The Deputy Administrator also observed that PDK's former

president, Michael Krasnoff, had been convicted of similar charges, yet "continued to serve as a consultant to the company," *id*.—despite his statement that "it's none of my business if someone gets high off of this stuff," *id*. at 67,960 n.7. "Neither of these personnel decisions," she concluded, "but particularly the retention of Mr. Lulkin as a key overseer of regulatory matters . . . , generates confidence on the part of the Deputy Administrator that PDK is sufficiently committed to complying with the myriad of regulatory requirements designed to prevent diversion of listed chemicals." *Id*. at 67,959.

PDK again petitions for review, challenging the Deputy Administrator's interpretation of section 971(c)(1) and arguing that insufficient evidence supports the suspension orders. We address each contention in turn.

II.

When considering the legitimacy of an agency's interpretation of a statute it is charged with enforcing, we first ask "whether Congress has directly spoken to the precise question at issue." *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984). In this case, *PDK I* has already answered this question in the negative: it concluded that section 971(c)(1) is ambiguous as to whether DEA can issue suspension orders based on the diversion of finished drug products that contain listed chemicals. *See PDK I*, 362 F.3d at 797 ("we do not agree that the meaning of § 971(c)(1) is as plain as DEA says it is"). This leaves us with the task of resolving at *Chevron*'s second step whether the Deputy Administrator's resolution of that ambiguity "is based on a permissible construction of the statute," *Chevron*, 467 U.S. at 843, keeping in mind that "[a] court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency," *id*. at 844.

Even at *Chevron*'s second step, we begin with the statute's language. *Abbott Labs. v. Young*, 920 F.2d 984, 988 (D.C. Cir. 1990) ("The 'reasonableness' of an agency's construction depends on the construction's 'fit' with the statutory language as well as its conformity to statutory purposes."). Recall that section 971(c)(1) provides that DEA "may order the suspension of any importation or exportation of a listed chemical . . . on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance." 21 U.S.C. § 971(c)(1). According to PDK, section 971(c)(1) does not "vest DEA with the authority to suspend an import based on misuse of a finished product." Pet'r's Br. 23. But nothing in the statute's spare language supports that contention. Section 971(c)(1) simply authorizes DEA to suspend an importation when it finds that a "listed chemical" may be diverted. While it's true that under the Deputy Administrator's interpretation, the listed chemical subject to diversion may be part of a finished drug, section 971(c)(1) in no way precludes her view that a listed chemical remains a listed chemical when, without any change in its chemical structure, it is incorporated into pills or tablets. As then-Judge Roberts explained in his *PDK I* separate opinion, the Deputy Administrator's

> interpretation comports with common sense. If a methamphetamine manufacturer steals, for the purpose of making methamphetamine, a bottle containing pure ephedrine, or pure ephedrine dissolved in water, or a bottle containing 50 ephedrine pills and 50 guaifenesin pills [guaifenesin is another compound present in some of PDK's products], we would not hear an argument that he did not divert a listed chemical because he also diverted a bottle, some water, or some guaifenesin. The presence of packaging materials or other extraneous items does not vitiate the existence of the listed chemical. Here, a bottle of PDK Mini Two-Way Action

> contains pills each consisting of 25 mg of ephedrine and 200 mg of guaifenesin and binders. For purposes of Section 971(c), the decongestant and the binders are extraneous materials, no more relevant to the analysis than the bottles and boxes in which the pills are packaged.

PDK I, 362 F.3d at 801 (Roberts, J., concurring in part and concurring in the judgment).

Absent anything in section 971(c)(1)'s language suggesting that the Deputy Administrator's interpretation is impermissible, PDK resorts to the assertion that Congress, committed to ensuring that popular cold medications remain readily available, could never have intended to give DEA authority to "shutter the industry." Although citing nothing in the CDTA's legislative history to support this contention, PDK explains that:

> Given that some misuse [of ephedrine drug products] concededly is endemic to the industry, the Deputy Administrator's interpretation . . . would allow DEA to shutter the entire [listed chemicals] industry by using Section 971 to suspend imports to any and every manufacturer whose finished goods are misused in some amount—that is, every manufacturer in the United States.

Pet'r's Br. 24-25. Invoking *PDK I*'s statement that "no one doubts that Congress did not intend to ban, *or to give DEA the authority to ban*, all sales of ephedrine-containing drugs in retail stores," *PDK I*, 362 F.3d at 797 (emphasis added), PDK contends that the Deputy Administrator's interpretation must therefore be unreasonable. We disagree.

For starters, the Deputy Administrator has never suggested that section 971(c)(1) permits DEA to ban drug sales in retail stores. Nor has she claimed authority "to suspend imports to any and every manufacturer . . . in the United States." She has concluded only that in deciding whether to suspend a particular shipment of raw ephedrine, DEA may consider evidence that ephedrine-containing drug products are being diverted. If, as PDK asserts, DEA can readily amass evidence of diversion sufficient to warrant suspending any ephedrine shipment, that attests to the rampant nature of the diversion problem and—critically for our purposes—to section 971(c)(1)'s breadth, not to whether the Deputy Administrator's interpretation is unreasonable. As we have explained, "the Supreme Court has consistently instructed that statutes written in broad, sweeping language should be given broad, sweeping application." *Consumer Elecs. Ass'n v. FCC*, 347 F.3d 291, 298 (D.C. Cir. 2003).

Even under PDK's narrow interpretation, moreover, DEA would still have authority, at least in principle, to "shutter the industry." After all, there is a risk that every shipment of raw ephedrine could be diverted before delivery, just as there is a risk that finished drug products containing ephedrine could be diverted after delivery. If DEA could amass substantial evidence to support the inference that all raw ephedrine shipments "may be diverted"—a big if, of course—then no one doubts it would have the authority to suspend those shipments, thus "shuttering the industry." When even a narrow interpretation of section 971(c)(1) would authorize DEA to "shutter the industry," a more expansive interpretation could hardly be considered unreasonable on that basis. The relative ease with which DEA can document diversion of ephedrine- and pseudoephedrine-containing drugs goes to the quantum of evidence necessary to justify the inference that a shipment "may

be diverted" (a question we shall turn to shortly), but it has little relevance to the interpretation of "listed chemical."

Nor do we see any merit to PDK's charge that the Deputy Administrator failed to consider the "competing interests at stake," as *PDK I* instructs. *PDK I*, 362 F.3d at 797-78. Contrary to PDK's insistence, nothing in *PDK I* requires the Deputy Administrator to weigh the risk that her interpretation could potentially "shutter the industry" against DEA's statutory charge to prevent ephedrine diversion. *PDK I* merely gives the boilerplate instruction that the Deputy Administrator, when interpreting section 971(c)(1), must "bring [her] experience and expertise to bear in light of competing interests at stake." *Id*.

Moreover, as *PDK I* directs, the Deputy Administrator *did* interpret section 971(c)(1) in light of her experience and expertise. *See Cont'l Air Lines, Inc. v. DOT*, 843 F.2d 1450, 1452 (D.C. Cir. 1988) (an agency must provide "a reasonable explanation for its conclusion that the interpretation serves the statutory objectives" (internal quotation marks and alterations omitted)). She emphasized not only that DEA considers the suspension provision a critical weapon in its anti-methamphetamine arsenal, but also that PDK's narrow reading would severely hamper the provision's usefulness. 69 Fed. Reg. at 67,956. She reasoned that PDK's interpretation would lead to an "arbitrary dual standard," i.e., an importer who delivered ephedrine knowing that it would be diverted after being processed into finished products could be held criminally liable, yet DEA would lack authority to suspend the shipment itself. *Id*. at 67,955. And drawing on DEA's experience with the growing problem of homemade methamphetamine, she concluded that the statute "should be construed broadly to effectuate its purpose" of protecting the public. *Id*. at 67,956. Far from being a case in which an agency has failed to explain its interpretive decision, *see Republican Nat'l Comm. v. FEC*, 76

F.3d 400, 407 (D.C. Cir. 1996) ("[W]e might determine that although not barred by statute, an agency's action is arbitrary and capricious because the agency has not considered certain relevant factors or articulated any rationale for its choice."), the Deputy Administrator's reasoning provides a more-than-adequate justification for her resolution of section 971(c)(1)'s ambiguity, *see Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1287 (D.C. Cir. 2000) ("As long as the agency stays within Congress' delegation, it is free to make policy choices in interpreting the statute, and such interpretations are entitled to deference." (internal quotation marks and alterations omitted)).

In reaching this conclusion, we acknowledge that DEA could someday abuse its broad section 971(c)(1) authority to reach an outcome Congress would not have approved. Yet all congressional delegations of discretionary authority—particularly broad delegations like this one—carry such a risk. Without more, the theoretical possibility that an agency might someday abuse its authority is of limited relevance in determining whether the agency's interpretation of a congressional delegation is reasonable. Should DEA one day opt to "shutter the industry," as PDK fears, the courts remain open to consider a challenge to that action pursuant to the Administrative Procedure Act.

PDK's remaining arguments likewise lack merit. The company rightly points out that *PDK I* criticizes the Deputy Administrator for relying on post-CDTA legislative enactments to explicate what the CDTA plainly meant, reasoning that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *PDK I*, 362 F.3d at 794 (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). But here, the Deputy Administrator used post-enactment legislative action for a very different purpose, namely, to help her choose among several plausible constructions of a statute Congress

charged her agency with administering. We see nothing inappropriate about this. In exercising delegated authority to resolve statutory ambiguities, agencies can and should consider policy input from a wide variety of sources, including the views of private citizens, industry groups, non-governmental organizations, legal commentators, and, most certainly, Congress. Our case law supports this. For example, while we cautioned in *Southern California Edison Co. v. FERC*, 116 F.3d 507 (D.C. Cir. 1997), against relying on subsequent legislative history to divine an earlier Congress's intent, *id*. at 514, we nonetheless observed that "[w]ith respect to Congress's current policy goals, as distinguished from retrospective legislative history, we find the [subsequent] committee reports . . . quite illuminating," *id*. at 516; *cf. McCreary v. Offner*, 172 F.3d 76, 82 (D.C. Cir. 1999) ("[T]o determine whether [a statute] is reasonably susceptible to more than one meaning . . . post-enactment legislative commentary offering a plausible interpretation is certainly relevant, much like plausible interpretations from litigants, other courts, law review articles, or any other source would be."). Indeed, it would be quite peculiar to bar an agency seeking to fill a statutory gap from considering strong indications of Congress's developing preferences. Here, for example, subsequent congressional action reflects the severity of the diversion problem, as well as Congress's commitment to addressing it aggressively, both of which clearly support the Deputy Administrator's broad interpretation of her statutory authority.

PDK next points to our observation in *PDK I* that the 1993 Domestic Chemical Diversion Control Act (DCDCA) "drew a distinction between, on the one hand, the finished product and, on the other hand, the listed chemical." *PDK I*, 362 F.3d at 795. According to PDK, this "tends to indicate that Congress intended Section 971 to address diversion of raw, bulk listed chemicals from their intended destination." Pet'r's Br. 28.

Even setting aside the hypocrisy of this claim when juxtaposed with PDK's previous one—either later congressional enactments are relevant to interpreting section 971(c)(1) or they're not—the argument is without merit. True, the DCDCA does speak of "drugs" and "drug products" as distinct from "listed chemicals," *see* DCDCA § 2(b)(1) (codified at 21 U.S.C. § 814(a), (e)), leading us to have reasoned in *PDK I* that "[o]ne *might* say . . . that in the view of a later Congress it is PDK's 'drug' or 'drug product,' not the 'listed chemical' mentioned in § 971(c)(1), that is being diverted," *PDK I*, 362 F.3d at 795 (emphasis added). But the DCDCA's distinction could just as easily demonstrate that when Congress wishes to distinguish between "drugs" and "listed chemicals," it does so. Indeed, the Deputy Administrator took just this position, 69 Fed. Reg. at 67,955 ("If Congress wanted to make an express distinction between a bulk listed chemical and a finished product in section 971(c), it could have done so."), and we have no license to substitute PDK's preferred interpretation for the agency's reasonable one, *see Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1321 (D.C. Cir. 1998) ("[U]nder *Chevron*, courts are bound to uphold an agency interpretation as long as it is reasonable—regardless whether there may be other reasonable, or even more reasonable, views.").

Finally, PDK argues that the Deputy Administrator inappropriately relied on the Ninth Circuit's decision in *United States v. Daas*, 198 F.3d at 1175, which held that the phrase "listed chemical" in one of the CDTA's criminal provisions encompasses listed chemicals found in drug products. Disinclined to read the same phrase in the same act to mean different things, the Deputy Administrator explained that she would resolve section 971(c)(1)'s ambiguity to comport with the Ninth Circuit's broad interpretation. *See* 69 Fed. Reg. at 67,954. Given this explanation, we see no basis for PDK's assertion that the "Deputy Administrator did not explain [*Daas*'s] application . . . to Section 971," Pet'r's Br. 28-29. Nor do we see anything

unreasonable about the Deputy Administrator's adoption of an approach that we previously found to have "logic" to it. *PDK I*, 362 F.3d at 796.

In short, as directed in *PDK I*, the Deputy Administrator brought her "expertise and experience" to bear in filling the gap left by Congress when it drafted section 971(c)(1). Finding her interpretation consistent with the provision's text, as well as with its manifest purpose of preventing the diversion of chemicals used in the illegal manufacture of a controlled substance, we shall defer to her reasonable, well-considered interpretation. *See Chevron*, 467 U.S. at 843.

III.

This leaves us with the question whether substantial evidence supports the suspension orders. Although the parties lock horns over all three categories of evidence upon which DEA rested its suspension orders—the warning letters and the two types of reporting violations—the Deputy Administrator made clear that "the evidence of diversion reflected in the series of Warning Letters provides a sufficient independent basis" for sustaining the suspension orders. 69 Fed. Reg. at 67,961 n.9. We agree and shall affirm on that basis. But before explaining why the warning letters suffice, we must address PDK's contention that the Deputy Administrator's use of a totality-of-the-circumstances test to decide whether substantial evidence exists to suspend a shipment is so formless that her conclusion is "purely results-driven." Pet'r's Br. 31.

The Totality-of-the-Circumstances Test

Although we take PDK's point that, "[i]n the absence of an explanation, the 'totality of the circumstances' can become simply a cloak for agency whim—or worse," *LeMoyne-Owen Coll. v. NLRB*, 357 F.3d 55, 61 (D.C. Cir. 2004), we disagree

that an agency's use of the test is necessarily arbitrary and capricious. Agencies routinely employ multi-factor standards when discharging their statutory duties, and we have never hesitated to uphold their decisions when adequately explained. *See, e.g.*, *Ark Las Vegas Rest. Corp. v. NLRB*, 334 F.3d 99, 105-106 (D.C. Cir. 2003); *ExxonMobil Gas Mktg. Co. v. FERC*, 297 F.3d 1071, 1081, 1084-88 (D.C. Cir. 2002). Indeed, we ourselves use a totality test to make a variety of fact-intensive determinations. *See, e.g.*, *United States v. Moore*, 394 F.3d 925, 930 (D.C. Cir. 2005) (whether reasonable suspicion exists for making a *Terry* stop); *Kingman Park Civic Ass'n v. Williams*, 348 F.3d 1033, 1040 (D.C. Cir. 2003) (whether state political processes "are not equally open to participation by members of a class of [protected] citizens" under the Voting Right Act). Nor is this a case, as PDK alleges, where the agency has failed to explain the basis for its decision or the relative significance of the evidence before it. *See LeMoyne-Owen*, 357 F.3d at 61 ("[A] thorough, careful, and consistent application of a multi-factor test is important to allow relevant distinctions between different factual configurations to emerge, and . . . appellate courts depend on it for the performance of their assigned task of review." (internal citations, quotation marks, and alterations omitted)). Quite to the contrary, the Deputy Administrator explained that the warning-letter evidence was by itself sufficient to justify suspending the shipments. What better way for the Deputy Administrator to have acknowledged the warning letters' relative importance to her decision?

To support its challenge to the Deputy Administrator's application of a totality test, PDK relies on *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), and *Chippewa & Flambeau Improvement Co. v. FERC*, 325 F.3d 353 (D.C. Cir. 2003). According to PDK, *Pearson* stands for the proposition that "an unarticulated standard does not comport with . . . the APA." Pet'r's Br. 33. But that case holds only that an agency

proceeding on a case-by-case basis must pour "some definitional content" into a vague statutory term by "defining the criteria it is applying." *See Pearson*, 164 F.3d at 660. In upholding the suspension orders on the strength of the warning-letter evidence, the Deputy Administrator did just that, giving "some definitional content" to the phrase "may be diverted": in her view, a string of warning letters documenting the diversion of thousands of pills to dozens of illicit methamphetamine labs is sufficient to warrant a finding that a drug "may be diverted." Although PDK is correct that this falls short of an exhaustive definition, *Pearson* itself acknowledges that an agency is not "necessarily required to define [an open-ended] term in its initial general regulation—or indeed . . . obliged to issue a comprehensive definition all at once." *Id*. at 661. Rather, in fleshing out the contours of vague statutory terms, agencies are "entitled to proceed case by case," *id*., precisely as DEA did here, *see* 69 Fed. Reg. at 67,597 ("DEA need not issue an array of regulations to anticipate every situation where a [listed] chemical may be diverted. . . . The statute clearly envisions permitting the agency to proceed by adjudication.").

Worse still for PDK, *Chippewa* actually supports the Deputy Administrator's decision. That case touched on the Federal Energy Regulatory Commission's (FERC) statutory authorization to require a reservoir operator to procure a license whenever "necessary or appropriate in the maintenance and operation" of downstream power plants. 16 U.S.C. § 796(11). Although FERC considers the totality of the circumstances when deciding whether a license is "necessary or appropriate," over time the agency has identified "a series of relevant factors" that it "balanc[es] . . . in light of the facts of the [particular] case," the most important of which is the percentage by which the reservoir increases the power generation of downstream plants. *Chippewa*, 325 F.3d at 358. Rejecting a reservoir operator's claim that this standard's flexibility doomed a FERC order

requiring the operator to obtain a license, we observed that the reservoir at issue increased downstream power generation more than other reservoirs FERC had also required to have licenses. *Id*. Because "the increase was clearly above the line of demarcation [at which FERC requires a reservoir to get a license], wherever it may lie," *id*. at 359, we upheld the order—even though FERC had never articulated the threshold above which licensing would be required.

Like FERC, DEA applied an all-things-considered standard to implement a statute that confers broad discretionary authority. Also like FERC, in applying that standard, DEA relied on its precedent, namely, *Mediplas Innovations*, 67 Fed. Reg. 41,256 (June 17, 2002), which upheld a suspension order based on less evidence of product diversion than DEA amassed against PDK. *See* 69 Fed. Reg. at 67,959. And also like FERC, DEA provided no clear "line of demarcation" to define an open-ended term, *Chippewa*, 325 F.3d at 359, instead choosing to establish the term's contours through a series of adjudications. Just as we upheld FERC's reasonable exercise of its discretion in *Chippewa*, so too must we uphold the Deputy Administrator's here.

The Warning Letters

This brings us to the question whether the warning-letter evidence supports DEA's inference that the ephedrine shipments "may be diverted." PDK argues that before suspending the two ephedrine shipments, the Deputy Administrator should have compared the percentage of PDK products documented in the warning letters with the percentage of other companies' products that had been diverted. Although never contesting that its products have been diverted to many illicit methamphetamine labs, PDK argues that "[t]he Deputy Administrator's failure to compare PDK to other companies in the industry . . . prevents this Court from . . . assess[ing] . . . whether DEA is treating

similarly situated parties similarly." Pet'r's Br. 35. In other words, PDK seems to think that DEA may not suspend its shipments unless the agency also suspends shipments to other companies whose products are diverted in equal or greater rates.

PDK's argument lacks merit. Section 971(c)(1) offers no hint that DEA must undertake a comparative analysis before issuing a suspension order. Instead, it says that DEA may suspend "any importation . . . of a listed chemical" based on a finding that "the chemical may be diverted." 21 U.S.C. § 971(c)(1). The rate at which other companies' products are diverted has no bearing on whether PDK's products "may be diverted." As the government nicely puts it, moreover, "[a] law enforcement agency is not limited to investigating only those companies or persons who have committed comparatively more crimes than others. In the law enforcement context, absolute amounts matter." Resp't's Br. 42. And the "absolute amounts" of diverted PDK products—thousands of bottles to roughly 140 illicit labs in at least eighteen states, *see* 69 Fed. Reg. at 67,959—serve as a more-than-adequate foundation for the Deputy Administrator's inference that PDK's two ephedrine shipments "may be diverted" somewhere down the line. "[A]n agency's predictive judgments about areas that are within the agency's field of discretion and expertise," we have held, "are entitled to particularly deferential review, so long as they are reasonable." *Milk Indus. Found. v. Glickman*, 132 F.3d 1467, 1478 (D.C. Cir. 1998) (internal quotation marks omitted).

PDK challenges the Deputy Administrator's finding that "substantial amounts" of PDK products have been diverted. 69 Fed. Reg. at 67,959. According to PDK, the warning letters document only a "minuscule percentage" of its total distributed products. Pet'r's Br. 34. That may be so, but PDK is a large company, and a minuscule percentage of its products is a large

amount—thousands of bottles, according to the warning letters—and absolute amounts matter.

Moreover, we think that PDK's dubious personnel decisions reinforce the Deputy Administrator's conclusion that the warning letters support DEA's finding that the two ephedrine shipments "may be diverted." 69 Fed. Reg. at 67,959. Hiring Krasnoff, a convicted felon who believes "it's none of my business if someone gets high off of this stuff," surely demonstrates "a cavalier approach toward complying with DEA regulations." *Id*. at 67,960 n.7. And retaining Lulkin, who had been convicted for fraud against PDK itself, as "a key overseer of regulatory matters," hardly demonstrates PDK's "commit[ment] to complying with the myriad of regulatory requirements designed to prevent diversion of listed chemicals." *Id*. at 67,959.

PDK objects to the Deputy Administrator's consideration of a DEA employee's statement that "PDK products were number one in terms of being seized at methamphetamine labs." *Id*. Although PDK did refer to the employee's statement as "hearsay" in the fact section of its opening brief, it waited until its reply to argue that the Deputy Administrator should have disregarded it. This is too late, of course, and we will not consider the claim. *See City of Nephi, Utah v. FERC*, 147 F.3d 929, 933 n.9 (D.C. Cir. 1998) ("By merely informing the court in the statement of facts in its opening brief [of the factual basis for a claim] . . . [petitioner] failed properly to raise this argument."); *Rollins Envtl. Servs. v. EPA*, 937 F.2d 649, 653 n.2 (D.C. Cir. 1991) ("Issues may not be raised for the first time in a reply brief.").

In a footnote, PDK argues that the Deputy Administrator improperly ignored factual inaccuracies that the ALJ identified in the warning letters. In support, however, PDK cites a portion

of the ALJ's opinion that has nothing to do with factual errors. To be sure, elsewhere the opinion does contain a vague reference to some errors in a small number of warning letters. *See In re Indace, Inc.*, Nos. 01-12, 01-13, slip op. at 38-39 (Apr. 5, 2002) (included at J.A. 59-60). But judging from the citations, at most six (and probably only four) letters contained any such errors. We agree with the government that "[a]ny factual inaccuracies identified by the ALJ, even if true, are *de minimis*." Resp't's Br. 41 n.11; *see Braniff Airways, Inc. v. Civil Aeronautics Bd.*, 379 F.2d 453, 466 (D.C. Cir. 1967) ("A court will not reject an agency finding that is supported by substantial evidence merely because the agency also incidentally mentions incompetent or irrelevant material."). The Deputy Administrator's lapse, if any, thus provides no basis for setting aside the suspension orders. *See* 5 U.S.C. § 706 (instructing courts to take "due account . . . of the rule of prejudicial error"); *Mass. Trs. v. United States*, 377 U.S. 235, 248 (1964) (finding reversal unwarranted "when a mistake of the administrative body is one that clearly had no bearing on . . . the substance of decision reached"); *Fed. Express Corp. v. Mineta*, 373 F.3d 112, 118 (D.C. Cir. 2004) ("No principle of administrative law or common sense requires us to remand a case in quest of a perfect opinion unless there is reason to think that the remand might lead to a different result.").

In a similar vein, PDK argues that the Deputy Administrator "failed to address the numerous infirmities in the warning letters that led the ALJ to conclude 'it is difficult to determine what, if any, inference can be drawn from these warning-letter figures.'" Pet'r's Br. 32. Viewed in context, however, the ALJ's statement makes clear that the only infirmity she had in mind was DEA's failure to undertake a comparative analysis, and we have already explained why we think the Deputy Administrator's articulated position that DEA has no obligation to do so is perfectly reasonable.

Finally, PDK alleges that, factual inaccuracies aside, the Deputy Administrator's reliance on the warning letters was itself arbitrary because, according to the company, in deciding whether to send the letters, DEA "followed no rules, regulations, or even the most basic informal internal guidelines." *Id*. at 37. PDK explains that

> [t]he pertinent point here is not that it was unfair of DEA to document discoveries of PDK products in warning letters while ignoring discoveries of competitors' products. The point is that the inconsistent treatment regarding the preparation of warning letters shows that the Deputy Administrator's reliance on them . . . is arbitrary and capricious—largely because the record demonstrates that the decision to document a discovery of misused product, in a warning letter, is *itself* arbitrary and capricious.

Id. at 38. We disagree. Even assuming the standards for issuing warning letters are arbitrary, that does not automatically invalidate the suspension orders. To succeed on such a claim, PDK must identify exactly how defects in the standards for issuing warning letters tainted the suspension orders. *See* 5 U.S.C. § 706. A hypothetical shows why. Suppose it were DEA's policy, upon discovering a company's drug product at a methamphetamine lab, to send warning letters only if a coin toss came up heads. The arbitrariness of that policy would do nothing to undermine the evidence that the company's product had been diverted to clandestine methamphetamine labs. Likewise, because PDK nowhere argues that DEA's allegedly arbitrary issuance of warning letters impeaches the evidence of rampant product diversion—indeed, PDK acknowledges the diversion—any possible arbitrariness in the process for sending warning letters is of no moment.

IV.

In sum, we find the Deputy Administrator's construction of "listed chemical" reasonable and her conclusion that the two ephedrine shipments "may be diverted" supported by substantial evidence. We realize the interpretation of section 971(c)(1) we validate gives DEA significant authority over shipments of listed chemicals, but the provision's undemanding language invites such a result. Facing a persistent threat to public health and a challenging law-enforcement problem, Congress armed DEA with broad suspension authority, and only Congress, not this court, can take it away. We deny the petition for review.

So ordered.