United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 17, 2007 Decided June 26, 2007

No. 06-1105

PENICK CORPORATION, INC.,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

CHATTEM CHEMICALS, INC. AND
MALLINCKRODT, INC.,
INTERVENORS

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

Wayne H. Matelski argued the cause for the petitioner. *Julia C. Tierney* was on brief.

Steven J. Poplawski and *Scott M. Badami* were on brief for intervenor Mallinckrodt, Inc. in support of the petitioner.

Brian M. Tomney, Attorney, United States Department of Justice, argued the cause for the respondent. *Teresa A. Wallbaum*, Attorney, was on brief.

Douglas J. Behr was on brief for intervenor Chattem Chemicals, Inc. in support of the respondent.

Before: SENTELLE, HENDERSON and RANDOLPH, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* HENDERSON.

KAREN LECRAFT HENDERSON, *Circuit Judge*: Chattem Chemicals, Inc. (Chattem) applied to the Drug Enforcement Administration (DEA) for registration as an importer of narcotic raw materials (NRMs) pursuant to the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq*., and the Controlled Substances Import and Export Act, 21 U.S.C. §§ 952 and 958 (collectively referred to as CSA). Penick Corp. (Penick) opposed the application and requested a hearing before the DEA, arguing that Chattem's registration as a NRM importer would increase the danger of NRM diversion to illicit use and thereby undermine the public interest. The Deputy Administrator of the DEA granted the application, concluding that Chattem "met its burden of proof to show that it is in the public interest . . . to grant its application to be registered as an importer of NRMs." Chattem Chems., Inc., 71 Fed. Reg. 9834, 9839 (Feb. 27, 2006). Penick petitions for review of the Deputy Administrator's decision and, as detailed below, we deny the petition.

I.

The CSA requires that the importation of NRMs and the manufacture of their alkaloids—the most prominent of which are morphine and codeine—remain tightly controlled in order to prevent their diversion to illicit use. Accordingly, the CSA prohibits the importation of NRMs into the United States unless the importing company is registered by the DEA, 21 U.S.C. §§ 952(a), 958(a), and importation is limited to "such amounts of [NRMs] . . . as the Attorney General finds to be necessary to provide for medical, scientific, or other legitimate purposes," *id*.

§ 952(a)(1).[1] The Attorney General "register[s] an applicant to import or export [NRMs] if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols." *Id.* § 958(a). In determining whether registration is consistent with the public interest, the Attorney General must consider the factors enumerated in section 823(a) of Title 21, *see id.*, which include:

> **(1)** maintenance of effective controls against diversion of particular controlled substances . . . into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate . . . purposes;
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> **(2)** compliance with applicable State and local law;
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> **(3)** promotion of technical advances in the art of manufacturing these substances and the development of new substances;
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> **(4)** prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

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[1]The Attorney General has delegated this function under the CSA to the Administrator of the DEA, *see* 28 C.F.R. § 0.100(b), who, in turn, delegated it to the DEA Deputy Administrator, *see* 28 C.F.R. § 0.104, App. § 7(j).

> **(5)** past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
>
> **(6)** such other factors as may be relevant to and consistent with the public health and safety.

Id. § 823(a). Pursuant to these provisions, on February 9, 2001, Chattem applied to the DEA for registration as an importer of NRMs and bulk manufacturer of their alkaloids.

On December 18, 2001, the DEA approved Chattem's application for registration as a bulk manufacturer. Its concurrent application to import NRMs was opposed, however, by Penick, Noramco of Delaware, Inc. (Noramco) and Mallinckrodt, Inc. (Mallinckrodt), all of which requested a hearing on Chattem's application under 21 C.F.R. § 1301.34(a).[2] At the time of Chattem's application, Noramco and Mallinckrodt were the only registered importers of NRMs, a group that Penick joined in 2004.[3] Because of these potential competitors' opposition, then, the administrative law judge (ALJ) conducted hearings on Chattem's application in September and October 2002 at which all parties—as well as the government—"called witnesses to testify and introduced

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[2]Section 1301.34(a) permits a bulk manufacturer of the controlled substance an applicant seeks to import to "file a written request for a hearing on the application" and "[i]f a hearing is requested, the Administrator shall hold a hearing on the application." 21 C.F.R. § 1301.34(a); *see also infra* note 9.

[3]Penick was registered after we rejected Noramco's challenge to the DEA's interpretation and application of 21 U.S.C. § 823(a) in granting Penick's registration. *See Noramco of Del., Inc. v. DEA*, 375 F.3d 1148 (D.C. Cir. 2004).

documentary evidence" relating to the impact on the public interest of Chattem's registration. Chattem Chems., Inc., 71 Fed. Reg. at 9835. The ALJ ultimately recommended that Chattem's application be granted. *See id*.

On February 17, 2006, the Deputy Administrator heeded that recommendation and decided "to grant [Chattem's] application to be registered as an importer of NRMs." *Id*. at 9839. The Deputy Administrator, applying 21 U.S.C. § 958(a), first determined that Chattem's registration would not violate any international obligations of the United States because the registration "would not likely cause significant increased diversion" and thus it was not " 'essential' to deny Chattem's application" in order to prevent global diversion of NRMs. *Id*. at 9836. The Deputy Administrator then moved on to consider the public interest factors outlined in 21 U.S.C. § 823(a). Regarding Chattem's potential impact on diversion, the Deputy Administrator recognized that diversion "at the retail level has greatly increased in recent years, and is an extremely serious problem," *id*. at 9836, but nonetheless concluded that "Chattem ha[d] met its burden of proof in showing that its registration as an importer of NRMs will not significantly interfere with the maintenance of effective controls against diversion," *id*. at 9838. The Deputy Administrator noted the unchallenged adequacy of Chattem's internal security measures to prevent diversion of narcotics to illicit use, the complete lack of "documented cases of diversion of NRMs imported into the United States," the "DEA['s] continued . . . regist[ration of] bulk manufacturers" during the pendency of Chattem's application and the fact that the DEA already conducts regular inspections of Chattem as a registered bulk manufacturer of alkaloids. *Id*. at 9836–37. Accordingly, the Deputy Administrator found that the first factor under 21 U.S.C. § 823(a) supported Chattem's registration. *See id*. at 9838.

The Deputy Administrator further determined that all but one of the remaining public interest factors weighed in favor of registration. She found that "[t]here is no significant evidence that Chattem has failed to comply with applicable State and local law" or violated state or federal narcotics regulations. *Id*. She also determined that "the evidence showed that Chattem possesses sufficient technology to process NRMs with efficiency" because "Chattem introduced credible evidence . . . that the processing of NRMs is not complicated, and that Chattem has sufficient facilities to carry out the process," facilities already approved by the DEA for bulk manufacture of NRM alkaloids. *Id*. at 9838–39.[4] In light of these considerations, the Deputy Administrator concluded that "Chattem . . . met its burden of proof to show that it is in the public interest . . . to grant its application to be registered as an importer of NRMs." *Id*. at 9839. Penick now petitions for review.[5]

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[4]The only factor weighing against Chattem's registration was the applicant's likelihood to "promot[e] . . . technical advances," 21 U.S.C. § 823(a)(3), because "[t]here was little evidence . . . that Chattem ha[d] achieved any noteworthy success in technical advances in the manufacturing of controlled substances, or in the development of new substances or patents," Chattem Chems., Inc., 71 Fed. Reg. at 9838.

[5]Because Chattem applied for both a registration and permission to import NRMs, the Deputy Administrator noted that the proceeding was a combined adjudication (the registration) and rulemaking (the permission). Regarding the rulemaking, the Deputy Administrator determined that (1) Chattem intended to import NRMs only for legitimate use; (2) "there is nothing in the legislative history of the [CSA] that supports any intention to limit the number of importers" and; (3) the precise quantity of NRMs necessary for legitimate use is

II.

The Deputy Administrator's findings of fact are conclusive "if supported by substantial evidence," 21 U.S.C. § 877, viewing "the record in its entirety," *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951). And although the DEA's reasoning, as distinguished from its factfinding, may be set aside if the action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," *Tourus Records, Inc. v. DEA*, 259 F.3d 731, 736 (D.C. Cir. 2001) (quoting 5 U.S.C. § 706(2)(A)), that review is narrow and "we will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974). "At a minimum," however, the arbitrary or capricious "standard requires the agency to 'examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.' " *Tourus Records*, 259 F.3d at 736 (quoting *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation omitted)). Our statutory interpretation is governed by the deferential two-step analysis of *Chevron U.S.A. Inc. v. Natural Resources Defense*

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determined in separate proceedings. Chattem Chems., Inc., 71 Fed. Reg. at 9835. Consequently, the Deputy Administrator concluded that "Chattem's proposed importation of [NRMs] is 'necessary to provide for medical, scientific, or other legitimate purposes,' " thereby meeting the rulemaking requirements pursuant to 21 U.S.C. § 952(a). *Id*. On appeal, neither Penick nor intervenor Mallinckrodt challenges the rulemaking decision, focusing entirely on Chattem's registration (the adjudication) under 21 U.S.C. § 958(a). *See* Pet'r's Br. at iii; Br. of Intervenor Mallinckrodt at iii.

Council, Inc., 467 U.S. 837, 842–43 (1984). *See Noramco of Del., Inc. v. DEA*, 375 F.3d 1148, 1152 (D.C. Cir. 2004).

Penick raises two primary challenges to the DEA's approval of Chattem's registration application: (1) the DEA misconstrued its obligations under 21 U.S.C. § 823(a)(1) by ignoring "the systemic impact of [Chattem's] registration" on diversion "throughout the chain of distribution," Pet'r's Br. at 12; and (2) the DEA acted arbitrarily and capriciously by "improperly shifting the burden of proof from Chattem to the objectors," *id.* at 15. We find neither ground meritorious.

A.

Section 823(a)(1) requires the Deputy Administrator to consider "maintenance of effective controls against diversion of particular controlled substances . . . into other than legitimate medical, scientific, research, or industrial channels" in determining whether registration is consistent with the public interest. 21 U.S.C. § 823(a)(1). Penick argues that, in section 823(a)(1), the Congress has "directly spoken"[6] and "requires the applicant to establish the systemic impact of its registration throughout the chain of distribution, including the registration's

[6]In reviewing an agency's interpretation of a statute it is charged with implementing, "under the *Chevron* two-step, we stop the music at step one if the Congress 'has directly spoken to the precise question at issue' because we—and the agency—'must give effect to [its] unambiguously expressed intent.' " *Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 151 (D.C. Cir. 2005) (quoting *Chevron*, 467 U.S. at 842–43) (alteration in original). "But if the statute is silent or ambiguous, we dance on and, at step two, defer to the [agency's] interpretation if it is 'based on a permissible construction of the statute.' " *Id.* (quoting *Chevron*, 467 U.S. at 843).

impact on" diversion at the retail level.[7] Pet'r's Br. at 11–12. Instead, Penick claims, the Deputy Administrator misinterpreted this requirement and rendered the factor superfluous by focusing her diversion discussion solely on Chattem's internal security measures, a factor properly covered by section 823(a)(5)'s mandate to consider "the existence in the establishment of effective control against diversion." *Id*. at 12 (citing 21 U.S.C. § 823(a)(5)). Yet this claim fails for a simple reason: the Deputy Administrator plainly considered and rejected the contention that Chattem's registration would increase retail-level diversion.

Before the Deputy Administrator, "[t]he Government argued that registering another importer could lead to increase[d] diversion at the retail level because of the potential of increased importation, increased manufacturing . . . and greater availability of narcotic medication." Chattem Chems., Inc., 71 Fed. Reg. at 9836. Indeed, the Deputy Administrator found "that the diversion of . . . narcotics at the retail level has greatly increased in recent years, and is an extremely serious problem." *Id*. She nonetheless concluded that Chattem's registration would not increase retail-level diversion because "there [was] little evidence in the record that Chattem's registration as an importer would have any greater effect on diversion downstream than DEA's continued registration of bulk manufacturers." *Id*. Moreover, the Deputy Administrator noted the DEA's ability to control the level of NRM importation and diversion through quotas and inspections, both of which already included Chattem in its capacity as a registered bulk manufacturer of controlled substances. *Id*. at 9836–37; *cf*. *Noramco*, 375 F.3d at 1155

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[7]Diversion at the retail level is also referred to as "downstream" diversion. *See* Chattem Chems., Inc., 71 Fed. Reg. at 9836.

(rejecting, in part, claim that DEA misinterpreted CSA as not requiring consideration of foreign diversion because "the DEA in fact considered and rejected the contention that Penick's registration would increase diversion in India"). Accordingly, we reject Penick's challenge to the DEA's interpretation of section 823(a)(1).[8]

B.

Still, an agency's action will be overturned if its findings are not "supported by substantial evidence," *see, e.g.*, 21 U.S.C. § 877, or its reasoning is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A). Penick asserts that the DEA's registration of Chattem fails both of these standards because the Deputy Administrator arbitrarily and "improperly shift[ed] the burden of proof from Chattem to the objectors." Pet'r's Br. at 15. In light of this alleged shift in the burden of proof—requiring the

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[8]In any event, the Deputy Administrator's decision to supplement her discussion of diversion under section 823(a)(1) with evidence of Chattem's internal security measures was reasonable. The overall goal of section 823(a)(1) "is to effectively control against diversion," *Noramco*, 375 F.3d at 1153, and evidence that the applicant's facilities include adequate controls against diversion logically connects to that goal. Moreover, both the DEA and this court have previously upheld importation registrations that relied on evidence of the applicant's internal controls as "consistent" with the consideration of section 823(a)(1), particularly where, as here, the adequacy of those controls is not disputed. *See* Penick Corp., 68 Fed. Reg. 6947, 6949 (Feb. 11, 2003) (relying on Penick's internal security measures to find that section 823(a)(1) weighed in favor of its registration); *cf. Noramco*, 375 F.3d at 1153 (describing DEA's section 823(a)(1) findings, based solely on the applicant's internal diversion controls, and noting that DEA "was required to approve [applicant's] registration").

objectors to establish that Chattem's registration does not satisfy the public interest standards of 21 U.S.C. § 823(a) rather than requiring Chattem to establish that its registration is in the public interest—Penick claims that the Deputy Administrator's registration of Chattem was not supported by substantial public interest evidence supplied by Chattem. *See id*. at 16–18. We disagree.

It is true that an applicant for registration as an NRM importer has "the burden of proving that the requirements for such registration pursuant to [21 U.S.C. § 958(a) and (d)] are satisfied," while "[a]ny other person participating in the [registration] hearing . . . ha[s] the burden of proving any propositions of fact or law asserted by him/her." 21 C.F.R. § 1301.44(c). Yet 21 C.F.R. § 1301.44(c) and 21 U.S.C. § 958(a) together simply require that the applicant prove by a preponderance of the evidence that its registration is consistent with the "public interest" as defined by 21 U.S.C. § 823(a). Indeed, section 823(a)'s enumerated factors represent components of the public interest rather than independent requirements for registration and thus, the Deputy Administrator may find a given registration consistent with the public interest even if one (or possibly more) of the public interest factors is not satisfied. *See* Johnson Matthey, Inc., 60 Fed. Reg. 26,050, 26,052 (May 16, 1995) ("It is well established that the Deputy Administrator is not required to make findings with respect to each of the [section 823(a)] factors, but has discretion to give each factor the weight he deems appropriate, depending upon the facts and circumstances in each case."); *cf. Air Line Pilots Ass'n v. Dep't of Transp.*, 791 F.2d 172, 177–78 (D.C. Cir. 1986) (although statute requires agency to "*consider* all these factors, the weight to be given to any particular factor lies largely within its discretion" because "[t]he Act itself does not dictate that the Board give priority to" any one factor); *MD*

Pharm., Inc. v. DEA, 72 F.3d 920 (unpublished judgment) (relying on *Air Line Pilots* to reject claim that DEA gave "too little weight" to section 823(a) factor).

Here, the Deputy Administrator recognized that the ultimate burden of proof rested with Chattem, *see* Chattem Chems., Inc., 71 Fed. Reg. at 9835, 9839, and relied on Chattem's evidence with respect to each of the enumerated public interest factors. For instance, in deciding that section 823(a)(1) weighed in favor of Chattem's registration, the Deputy Administrator noted the undisputed evidence "that Chattem maintains adequate security at its manufacturing plant." *Id*. at 9836. In addition, the Deputy Administrator concluded that the risk of diversion at the retail level would not be significantly increased by Chattem's registration in light of Chattem's evidence that the DEA continued to register additional bulk manufacturers of opium alkaloids even though those manufacturers present comparable diversion dangers. *See id*. at 9837.[9] Finally, the Deputy

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[9]Penick contends that the Deputy Administrator arbitrarily departed from DEA policy—which Penick claims treats an importer's registration more strictly than a bulk manufacturer's—in basing her no diversion finding in part, "on the presumption that applicants for registration as *importers* are subject to the same standards, and the same level of scrutiny, as applicants for registration as *manufacturers* of controlled substances." Pet'r's Br. at 21 (emphasis in original). "An agency may of course alter its positions over time, but the agency acts arbitrarily when it departs from its precedent without giving any reason." *PDK Labs. v. DEA*, 362 F.3d 786, 798–99 (D.C. Cir. 2004). Yet Penick ignores the context of the Deputy Administrator's comparison of importers and manufacturers. The Deputy Administrator did not suggest that importers and manufacturers be registered under identical standards but rather that—according to evidence offered by the government—"*both* bulk manufacturers of . . . controlled substances and importers of NRMs [are] a potential *source*

Administrator relied on the existence of DEA quotas and inspections to control diversion, *see id*., as well as testimony that "there were no documented cases of diversion of NRMs imported into the United States, and no significant diversion at the bulk manufacturing level," *id*. at 9836.[10] Given all of this evidence, the Deputy Administrator concluded that "Chattem . . . met its burden of proof in showing that its registration as an importer of NRMs will not significantly interfere with the

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of increased diversion." Chattem Chems., Inc., 71 Fed. Reg. at 9836–37 (second emphasis added). In the absence of evidence that "Chattem's registration as an importer would have any greater effect on diversion downstream than DEA's continued registration of bulk manufacturers," the Deputy Administrator declined to credit the objectors' claim that registration of an additional importer would increase diversion beyond the DEA's capacity to control. *Id*. Thus, the Deputy Administrator recognized that, whatever differences exist between the procedures for registering importers and manufacturers, they possess a similar capacity to increase diversion—highlighting an inconsistency in the objectors' arguments rather than announcing any shift in DEA policy. Indeed, the CSA commands the DEA to maintain control over diversion "by limiting the importation *and* bulk manufacture" of controlled substances. 21 U.S.C. § 823(a)(1) (emphasis added). While Mallinckrodt notes that, unlike an objector to an importer applicant, an objector to a manufacturer has no right to a hearing, *see* Br. for Mallinckrodt at 4–5, the DEA eliminated manufacturer hearings only "to discourage potential future abuse of the hearing process" in the interest of "judicial economy." Registration of Mfrs. and Importers of Controlled Substances, 60 Fed. Reg. 32,099, 32,100–01 (June 20, 1995) (final rule).

[10]Although the Deputy Administrator expressly cited an objector witness's statement on cross-examination, *see* Chattem Chems., Inc., 71 Fed. Reg. at 9836, the identical statement was made by one of Chattem's witnesses.

maintenance of effective controls against diversion." *Id*. at 9838.[11]

The Deputy Administrator similarly relied on Chattem's evidence regarding the remaining public interest factors. Specifically, Chattem's vice president provided evidence that Chattem has complied with state and local narcotics laws, *see id*. at 9838 (section 823(a)(2)), and it was "undisputed" that Chattem has never violated state or federal laws relating to narcotic production and distribution, *see id*. (section 823(a)(4)). With respect to Chattem's past experience in the manufacture of controlled substances (section 823(a)(5)), the Deputy Administrator recognized that "Chattem ha[d] experience in manufacturing [non-NRM] controlled substances" and noted that "Chattem introduced credible evidence . . . that the processing of NRMs is not complicated, and that Chattem has sufficient facilities to carry out the process." *Id*. Thus, the Deputy Administrator affirmatively kept the burden of proving the public interest on Chattem and relied on Chattem's evidence in concluding that each statutory public interest factor supported its registration.[12]

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[11]While the Deputy Administrator did not consider the second part of section 823(a)(1)—the adequacy of competition in the existing market—we have previously sustained the DEA's interpretation of the CSA that where, as here, "[the Deputy Administrator] determines that there would be no increased difficulty in controlling diversion, the requirements of [section 823(a)(1)] are satisfied, and an analysis of adequate competition is not required." *Noramco*, 375 F.3d at 1153 (alteration original) (internal quotation omitted).

[12]She did find that Chattem proffered "little evidence" it would promote technical advances in manufacturing or the development of new substances. Chattem Chems., Inc., 71 Fed. Reg. at 9838 (section

The objectors primarily contended that Chattem's registration would increase diversion both at the retail, *see id*. at 9836–37, and international levels, *see id*. at 9837. As noted earlier, however, the Deputy Administrator cited significant evidence of diversion controls in rejecting the claim that Chattem's registration would increase retail diversion. With respect to international diversion, the Deputy Administrator correctly noted that we have held that the DEA need not consider foreign diversion under section 823(a)(1), *see* Chattem Chems., Inc., 71 Fed. Reg. at 9837 (citing *Noramco*, 375 F.3d at 1156 ("[T]he Congress was concerned with preventing diversion in this country rather than abroad.")), and concluded, at any rate, that the objectors "adduced insufficient evidence that foreign diversion was likely to occur . . . and no evidence of the effect of such diversion . . . on the diversion of narcotics in the United States," *id*.

Given the significant evidence Chattem supplied, the Deputy Administrator's decision was neither based on insubstantial evidence nor arbitrary or capricious. We "will not disturb the decision of an agency that has 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.' " *MD Pharm., Inc. v. DEA*, 133 F.3d 8, 16 (D.C. Cir. 1998) (quoting *State Farm*, 463 U.S. at 43). This is all that is required in our limited review of the DEA's decision.

III.

Penick raises an additional challenge to Chattem's registration which we also reject. The DEA may register an importer only if "it determines that such registration is

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823(a)(3)); *see also supra* note 4.

consistent . . . with United States obligations under international treaties, conventions, or protocols." 21 U.S.C. § 958(a). Penick asserts that Chattem's registration is inconsistent with the United Nations Single Convention on Narcotic Drugs of 1961 (Single Convention), 18 U.S.T. 1407, which obligates the United States "to take all necessary measures to ensure that the international movement of narcotics is limited to legitimate medical and scientific needs," Chattem Chems., Inc., 71 Fed. Reg. at 9836. The Single Convention's commentary, *see Nat'l Org. for Reform of Marijuana Laws v. DEA*, 559 F.2d 735, 751 (D.C. Cir. 1977), notes that "it may be advisable or even essential to keep to a minimum the number of . . . manufacturers and international traders (importers as well as exporters) . . . engaged in these activities." *Commentary on the Single Convention on Narcotic Drugs*, 1961 (Commentary), United Nations, New York, 1973, p. 264. Although the Deputy Administrator found Chattem's registration consistent with the Single Convention, Penick argues that (1) the Single Convention requires the DEA to control diversion by "*first* . . . restricting the registration of importers." Pet'r's Br. at 20 (emphasis in original) and (2) the Deputy Administrator improperly ignored the danger of increased foreign diversion from Chattem's registration. Penick's contentions ignore the requirements of the Single Convention, the Deputy Administrator's opinion and our precedent.

First, the Single Convention does not, as Penick asserts, require that the number of importers be limited as the first step in preventing diversion. Instead, the commentary merely suggests "it *may* be advisable or even essential to keep to a *minimum* the number of . . . importers" without defining the "minimum" that would be "advisable," Commentary at 264 (emphasis added), and the Deputy Administrator found "that the evidence did not show that it would be 'advisable' or 'essential'

to deny Chattem's application for registration," Chattem Chems., Inc., 71 Fed. Reg. at 9836 (quoting Commentary at 264). Indeed, the Deputy Administrator considered Chattem's registration's potential effect on downstream diversion and the potential "contribution of foreign diversion to diversion in the United States," Chattem Chems., Inc., 71 Fed. Reg. at 9837, specifically referencing this diversion discussion in finding that Chattem's registration would not circumvent the Single Convention, *see id*. at 9836 (Single Convention not violated because "registration of Chattem would not likely cause significant increased diversion"); *id*. at 9836–38 (considering retail and foreign diversion in concluding that Chattem's registration did not carry increased risk of diversion).

Moreover, while the Deputy Administrator considered evidence of foreign diversion only to the extent such diversion might "contribut[e] . . . to diversion in the United States," *id*. at 9838, her decision is consistent with our holding that, in enacting the CSA, "the Congress was concerned with preventing diversion in this country rather than abroad," *Noramco*, 375 F.3d at 1156. In light of the speculative nature of any increased foreign diversion stemming from Chattem's registration and the existence of alternative means of controlling diversion, such as quotas, "the Deputy Administrator f[ound] no substantial evidence in the record that Chattem's registration as an importer would result in a significant increase in foreign diversion of NRMs, or that such diversion, if it were to occur, would significantly increase diversion of controlled substances in this country." Chattem Chems., Inc., 71 Fed. Reg. at 9838. Because the Deputy Administrator's conclusion under 21 U.S.C. § 958(a)

is consistent with the Single Convention, the evidence and our precedent, we reject Penick's challenge.[13]

For the foregoing reasons, Penick's petition for review is denied.

So ordered.

[13]Although we decline Chattem's invitation to impose sanctions on Penick, *see* Br. for Chattem at 28 ("This petition for review is frivolous and damages and double costs should be awarded under Fed. R. App. P. 38 . . . ."), we note, as evidenced above, the similarity between Penick's challenges to Chattem's registration and Noramco's earlier challenges to Penick's registration, which we rejected in *Noramco of Del., Inc. v. DEA*, 375 F.3d 1148 (D.C. Cir. 2004). The Deputy Administrator expressly relied on *Noramco* to find Chattem's registration consistent with the CSA and our decision today—iterating the deference we owe to the DEA in these circumstances—should curtail this rite of passage for new entrants in the NRM importation market.