United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 10, 2007 Decided December 11, 2007

No. 06-1156

WEDGEWOOD VILLAGE PHARMACY,
PETITIONER

v.

DRUG ENFORCEMENT ADMINISTRATION,
RESPONDENT

Consolidated with
06-1196

On Petitions for Review of Orders of the
United States Drug Enforcement Agency

Derek L. Shaffer argued the cause for the petitioner. *Michael W. Kirk* and *Charles J. Cooper* were on brief.

Lena D. Watkins, Attorney, United States Department of Justice, argued the cause for the respondent. *Teresa A. Wallbaum* and *Stephen A. Sola*, Attorneys, United States Department of Justice, were on brief.

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

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

KAREN LECRAFT HENDERSON, *Circuit Judge:* Wedgewood Village Pharmacy (Wedgewood) challenges the decision of the United States Drug Enforcement Administration (DEA) to revoke its registration as a "practitioner" within the meaning of 21 U.S.C. § 823(f). Before the revocation of its registration, Wedgewood's business focused primarily on supplying equine veterinarians with specially formulated medications. Following an investigation of Wedgewood's Sewell, New Jersey facility, DEA determined that Wedgewood was operating outside the scope of its registration. Specifically, DEA objected to Wedgewood's practice of preparing large amounts of "compounded" controlled substances and then delivering the medications to veterinarians and physicians instead of directly to their patients. DEA viewed these practices as "manufacturing" and "distributing" controlled substances as defined by the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. § 801 *et seq.*) (CSA or Act). Under Wedgewood's DEA registration as a "practitioner," however, it is authorized only to "compound" and "dispense" controlled substances. For the reasons that follow, we vacate the revocation of Wedgewood's registration and remand to the agency for further proceedings.

I.

A. Statutory/Regulatory Background

The Congress enacted the CSA in 1970 to reduce drug abuse by preventing the diversion of controlled substances. *See Gonzales v. Oregon*, 546 U.S. 243, 250 (2006) (discussing legislative history of CSA). A central feature of the CSA is its "closed system" of distribution in which all persons in the "legitimate distribution chain" of controlled substances must

register with DEA.[1] H.R. Rep. No. 91-1444 (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4572. In its closed distribution system, the CSA created three categories of registrants: "manufacturer," "distributor" and "practitioner"—each with distinct requirements for registration. *See* 21 U.S.C. § 823(a) (criteria for "manufacturer" registration), 823(b) (criteria for "distributor" registration), 823(f) (criteria for "practitioner" registration). A "manufacturer" is authorized to engage in "[t]he production, preparation, propagation, *compounding*, or processing of a drug." *Id.* § 802(15) (emphasis added). A "distributor" is authorized to "deliver (*other than by administering or dispensing*) a controlled substance." *Id.* § 802(11) (emphasis added). The CSA describes a "practitioner" as a "physician, dentist, veterinarian, . . . [or] pharmacy" registered to "distribute, *dispense*, . . . [or] administer . . . a controlled substance in the course of professional practice." *Id.* § 802(21) (emphasis added). The CSA explains that "dispens[ing]," as used in the definition of "practitioner," is the "*deliver*[*y* of] a controlled substance to an ultimate user . . . , including . . . *compounding* necessary to prepare the substance for such delivery." *Id.* § 802(10) (emphases added). "Delivery" includes "the actual, *constructive*, or attempted transfer of a controlled substance." *Id.* § 802(8) (emphasis added). In addition, the CSA specifies that "the preparation [or] *compounding* . . . of a drug . . . *by a practitioner* as an incident to his administration or dispensing of [the] drug" does not

[1]The CSA requires manufacturers, distributors and dispensers to register with the Attorney General, 21 U.S.C. § 822(b); the Attorney General, in turn, has delegated the registration authority to DEA. *See* 28 C.F.R. § 0.100(b).

constitute "manufacturing."[2] *Id.* § 802(15) (emphases added). The CSA does not define "compounding."

The scope of the terms "manufacture," "compound," "distribute" and "dispense" as used in the CSA remains unsettled. Beginning in the 1990s, the United States Food and Drug Administration (FDA), along with other government agencies, grew concerned that some pharmacies were using their compounding authorization under 21 U.S.C. § 801(10) and (21) to, in effect, manufacture controlled substances without FDA approval. In response to their concern, the Congress enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2296. According to the legislative history of the FDAMA, its "intent [was] to ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding." H.R. Conf. Rep. No. 105-399, at 94, *as reprinted in* 1997 U.S.C.C.A.N. 2880, 2884.

The FDAMA contained a definition of "compounding" that required a prescription therefor to be unsolicited by a retail pharmacy and prohibited the pharmacy from advertising the

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[2]DEA regulations governing each category of registrant vary accordingly. For example, a manufacturer has strict storage and security requirements. *Compare* 21 C.F.R. § 1301.72 (storage and security requirements for "non-practitioner") *with* 21 C.F.R. § 1301.75 (security requirements for practitioner). Similarly, both a manufacturer and a distributor have more stringent record-keeping requirements than a practitioner, *compare id.* § 1304.22(a) (record-keeping requirements for manufacturer), *and id.* § 1304.22(b) (record-keeping requirements for distributor) *with id.* § 1304.22(c) (record-keeping requirements for "dispenser," i.e., practitioner), and must renew their registrations more often. *Compare* 21 U.S.C. § 822(a)(1) (annual registration for manufacturer and distributor) *with* 21 U.S.C. § 822(a)(2) (registration for practitioner every one to three years).

compounding of a particular drug. Pub. L. No. 105-115 § 127 (codified at 21 U.S.C. § 353a(a), (c)). Several pharmacies with large compounding practices, including Wedgewood, challenged these provisions as violative of the First Amendment. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360 (2002). The Supreme Court agreed, holding that the FDAMA improperly restricted solicitation and advertising, both legitimate forms of commercial speech. *Id.* Accordingly, its holding invalidating the language left DEA—and pharmacies—without a statutory definition of compounding.[3]

B. Agency Proceedings Against Wedgewood

In early 2003, DEA began investigating Wedgewood after receiving reports that Wedgewood was ordering controlled substances in unusually large quantities. *See* In re Wedgewood Vill. Pharmacy, Docket No. 04-08, at 4–5 (Mar. 4, 2005) (JA 935–36) (ALJ Dec.) (describing reports). DEA obtained an administrative inspection warrant to search Wedgewood's Sewell, New Jersey facility. DEA executed the warrant between March 12–14, 2003 and collected evidence that it believed demonstrated that Wedgewood was both "manufacturing" and "distributing" controlled substances. *See* Order to Show Cause 1–5 (JA 67–71) (describing evidence). For example, according to DEA and FDA investigators, Wedgewood had "large quantities of bulk drug substances to manufacture large quantities of unapproved drug products" as well as large scale equipment, neither of which, they concluded, was "consistent

[3]In *Thompson*, the Court described "compounding" as "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available." *Thompson*, 535 U.S. at 361.

with traditional retail pharmacy activities."[4] Report of Investigation 2, 7 (JA 757, 762). The inspectors also examined Wedgewood's "Log of Scripts." The Log, which contained a record of all controlled substances sold by Wedgewood between January 1, 2002 and December 31, 2002, indicated that Wedgewood routinely delivered controlled substances to another practitioner rather than directly to the ultimate user, using "prescriptions" that listed the same person as both prescribing "doctor" and "patient."[5] *See* Log of Scripts (JA 349–446); *see also* Wedgewood Vill. Pharmacy; Revocation of Registration, 71 Fed. Reg. 16,593, 16,594 (DEA Apr. 3, 2006) (JA 976) ("Over 95% of [Wedgewood's] sales were to physicians or

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[4]For example, the investigation revealed that Wedgewood received 131 kilograms of phenylpropanolamine (PPA) between November 27, 2000 and October 29, 2002. *See* Report of Investigation 13 (JA 768). DEA claimed that during this time Wedgewood manufactured over 750,000 PPA tablets. Order to Show Cause 3 (JA 69). PPA is often diverted to the illicit manufacture of amphetamines. *Id.* According to DEA, "true compounding pharmacies . . . received PPA in minimal quantities." *Id*; *see also* ALJ Dec. 37 (JA 968) (explaining that typical retail pharmacy is expected to handle between 25 and 1,000 grams of PPA during same time period). DEA charged that Wedgewood's handling this volume of PPA violated 21 C.F.R. § 1310.04 and other regulations. *See* Order to Show Cause 3 (JA 69) (citing, e.g., 21 C.F.R. § 1310.04 (imposing stricter record-keeping requirements on registrant with sales of more than 2.5 kilograms of PPA per month)).

[5]Wedgewood's Log of Scripts referred to all entries as "prescriptions" even though those listing the "doctor" and the "patient" as the same person did not comply with DEA regulations governing prescriptions. *See* 21 C.F.R. § 1306.05(a) ("All prescriptions for controlled substances . . . shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner.").

veterinarians documented by what the pharmacy called prescriptions which contained the name of the physician or veterinarian as the patient."). Under DEA's reading of the CSA, a retail pharmacy may dispense controlled substances only to the ultimate user and not to another practitioner. *See id.* at 16,596 (JA 979); *see also* 21 U.S.C. § 802(10) ("[D]ispense means to deliver a controlled substance to an ultimate user . . . ."); *id.* § 802(27) ("[U]ltimate user means a person who has lawfully obtained . . . a controlled substance for his own use . . . or for an animal owned by him . . . .").

Following the inspection, DEA informed Wedgewood by letter that Wedgewood was "not configured as a typical retail pharmacy, but [rather] as a drug manufacturing and distribution facility," and that Wedgewood was "operating in a manner . . . outside the scope of [its] registration as a [practitioner]." DEA Letter, Aug. 21, 2003, at 1 (JA 79). DEA ordered Wedgewood to "immediately cease and desist manufacturing and distributing activities outside the scope of its registration" or risk revocation of its registration pursuant to 21 U.S.C. § 824.[6] *Id.* Despite the cease and desist order, Wedgewood continued to compound controlled substances for approximately two months as Wedgewood challenged DEA's decision. Wedgewood Vill. Pharmacy, 71 Fed. Reg. at 16,594 (JA 975). It eventually ceased operation after it moved to a new facility in Swedesboro, New Jersey and DEA declined to allow it to modify its registration to reflect its new address pursuant to 21 C.F.R. § 1301.51. *See* ALJ Hr'g Tr. 35–41 (JA 12–18) (discussing Wedgewood's inability to handle controlled substances

[6]21 U.S.C. § 824(a)(4) authorizes DEA to revoke a registration if the registrant "has committed such acts as would render his registration . . . inconsistent with the public interest."

following DEA's denial of Wedgewood's requested modification). *Id.*[7]

On September 8, 2003, DEA began proceedings to revoke Wedgewood's registration as a retail pharmacy by issuing an order to show cause (Order). *See* Order to Show Cause 1 (JA 67). The Order charged, *inter alia*, that Wedgewood was "manufacturing" controlled substances in violation of Wedgewood's registration as a "retail pharmacy." *See id.* at 1–2 (JA 67–68). The Order explained that "[a]ll compounding of drugs must be *patient specific*, and dispensed only by the compounder to that patient identified in the order." *Id.* at 1 (emphasis added). By "compounding" multi-dosage batches of controlled substances pursuant to orders which did not identify a specific patient, Wedgewood exceeded its registration. *See id.* at 4 (JA 70) (noting most of Wedgewood's sales were made pursuant to orders listing prescribing veterinarian or physician as patient). The Order also explained that "[a] drug compound prepared . . . for distribution to practitioners . . . is considered to be a manufacturing activity under . . . the Controlled Substances Act." *Id.* at 1 (JA 67). Because Wedgewood delivered controlled substances to other practitioners (i.e., veterinarians and physicians), the controlled substances were "manufactured" and not "compounded." *See id.* at 4 (JA 70) (noting that Wedgewood routinely distributed "office stock" to other practitioners). Accordingly, DEA informed Wedgewood that it intended to revoke Wedgewood's registration if Wedgewood did not request a hearing within thirty days. *See id.* at 1, 6 (JA 67, 72).

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[7]Wedgewood unsuccessfully sought a temporary restraining order and a preliminary injunction to require DEA to approve the modification. *Wedgewood Vill. Pharmacy, Inc. v. Ashcroft*, 293 F. Supp. 2d 462, 477 (D. N.J. 2003).

Wedgewood timely requested a hearing which was held before a DEA Administrative Law Judge (ALJ) on January 26–28, 2004. Approximately one year after the hearing, the ALJ issued her decision, concluding that Wedgewood had "manufactured and distributed controlled substances . . . without a valid DEA registration authorizing such activities." ALJ Dec. 39 (JA 970). The ALJ further determined that Wedgewood's continued registration "would not be in the public's interest." *Id*. As a framework for her analysis, the ALJ used the five-factor "public interest" test set forth in 21 U.S.C. § 823(f). *Id*. at 24–25 (JA 955–56).[8] She determined that three of the five factors weighed in favor of revoking Wedgewood's registration.[9]

First, regarding factor two—Wedgewood's experience dispensing controlled substances—the ALJ found that

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[8]The five factors are:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
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> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
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> (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
>
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f).

[9]The ALJ acknowledged that factors (1) and (3) did not support revocation. *See* ALJ Dec. 25–26, 30 (JA 956–57, 961).

Wedgewood had violated two DEA regulations. Under 21 C.F.R. § 1306.04(b), "[a] prescription may not be issued in order for [an] individual practitioner to obtain controlled substances for supplying the individual practitioner [i.e., a veterinarian or physician] for the purpose of general dispensing to patients." The ALJ noted the testimony of Wedgewood's owner, George Malmberg, before the New Jersey Pharmacy Board, to the effect that the majority of the controlled substances dispensed by Wedgewood " 'would be used by physicians and veterinarians for office use in their practice, rather than by an individual patient seeking medications . . . for [his] own ingestion.' "[10] *Id.* at 21 (JA 952). The ALJ also focused on the so-called "5% Rule." *Id.* at 28–29 (JA 959–60). Under 21 C.F.R. § 1307.11, a practitioner "may dispense controlled substances to another registered entity, provided the total number of dosage units thus dispensed does not exceed 5% of the total number of controlled substances dispensed by that registrant [during the calendar year]." ALJ Dec. 28 (JA 959) (citing 21 C.F.R. § 1307.11(a)(4)). Relying on the entries in Wedgewood's Log of Scripts, the ALJ determined that during the calendar year 2002, Wedgewood "dispensed 7,445 prescriptions which accounted for a total of 1,083,154 dosage units of controlled substances. Of this number 1,017,392 dosage units were distributed pursuant to prescriptions written by a physician, with the named patient also being the physician." ALJ Dec. 29 (JA 960). Based on the Log, the ALJ concluded that Wedgewood had plainly violated the 5% Rule. *Id.* at 29 (JA 960).

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[10]A physician or a veterinarian who uses a prescription to obtain controlled substances "for the purpose of general dispensing . . . to . . . patients" violates DEA regulations. *See* 21 C.F.R. § 1307.11(a) (2005); *see also* DEA Pharmacist's Manual 41 (JA 250) (use of "a prescription written for office stock or 'medical bag' use" is prohibited).

Regarding factor four—compliance with state and federal law—the ALJ considered, *inter alia*, whether Wedgewood was "manufacturing" or "compounding" controlled substances. The ALJ noted that, although the CSA defines "manufacturing," it does not define "compounding." *Id.* at 31 (JA 962). Consequently, the ALJ "look[ed] to" the FDA's regulations for guidance in defining "compounding." *Id.* According to FDA guidelines, "compounding" is the preparation of "a *customized* medication for an *individual* patient in response to a licensed practitioner's *prescription*." *Id.* (quoting FDA's Compliance Policy Guide) (emphases added). The ALJ concluded that Wedgewood was routinely filling orders for veterinary medicines in bulk rather than "pursuant to a prescription from a licensed physician for a specifically identified patient's use" and therefore Wedgewood was manufacturing, not compounding, controlled substances. *Id.* at 32 (JA 963).

Finally, with regard to factor five—other conduct that may threaten the public health and safety—the ALJ noted that Wedgewood "did not keep records of regulated transactions," it "had overages and shortages" of controlled substances, it had been "untruthful" during the DEA investigation and that it had "challenged the DEA's authority to regulate [its] activities." *Id.* at 37–38 (JA 968–69). The ALJ concluded that "the Government ha[d] clearly met its burden of proof" and recommended revocation of Wedgewood's registration as a practitioner. *Id.* at 39 (JA 970).

On April 3, 2006, over one year after the ALJ's decision, DEA's Deputy Administrator (DA) issued the agency's final decision, which adopted in full the ALJ's findings and recommendations. Wedgewood Vill. Pharmacy, 71 Fed. Reg. at 16,593 (JA 975). The DA's decision characterized the central issue as whether Wedgewood "was compounding as an adjunct to dispensing controlled substances in the course of retail pharmacy practice or manufacturing and distributing controlled

substances as those terms are defined in the Controlled Substances Act." *Id.* at 16,594–95 (JA 976–77). The DA concluded that Wedgewood's actions constituted "manufacturing" and "distributing" for two reasons. First, Wedgewood's practice of "not preparing or compounding medications . . . on an individualized patient basis" was inconsistent with the traditional view of "compounding." *Id.* at 16,955 (JA 978). Using the Supreme Court's description of "compounding" in *Thompson v. Western States Medical Center*, *see supra* note 3, the DA explained that

> to be exempt from the definition of manufacturer under the CSA a DEA practitioner registrant must be engaged in compounding controlled substances on an *individual patient basis*. That is, a pharmacy must receive a prescription for a specific patient from a physician or other individual practitioner . . . . Since the evidence in this case clearly demonstrates that [Wedgewood] is not preparing or compounding medications containing controlled substances on an *individualized patient basis*, [Wedgewood's] activities constitute manufacturing under the CSA and it must be registered as a manufacturer to conduct such activity.

Id. (emphases added). Second, the DA reasoned that under the CSA definition of "dispensing," a practitioner may deliver controlled substances only to an "ultimate user." Because "[a] physician or [a veterinarian] who receives controlled substances . . . is not the ultimate user, but another DEA practitioner registrant," Wedgewood's practice of delivering controlled substances to other practitioners for the latter's administering to their respective patients constituted "distribution" and not "dispensing." *Id.* Accordingly, the DA

adopted the ALJ's recommendation to revoke Wedgewood's registration.[11]

Wedgewood timely petitioned for reconsideration. Recons. Letter, Apr. 18, 2006, at 1 (JA 989). In its request, Wedgewood advanced the new argument that "standard procedures for veterinary medicine practice (which is approximately 95% of Wedgewood's controlled substance sales) are different than the protocol for human health care." *Id.* Wedgewood explained that "[u]nlike human health care physicians, equine veterinarians usually do not treat animals on an individual basis." *Id.* at 3 (JA 991). Instead, "[v]eterinarians, particularly those with an equine practice, travel to their patients, examine and diagnose them, and administer the appropriate medicines on site, a procedure that requires them to have a variety of medicines at their immediate disposal." *Id.* According to Wedgewood, DEA's interpretation of dispensing threatened to "severely handicap[]" the practice of equine veterinary medicine by making it difficult for a veterinarian to administer controlled substances to horses at the stables. *Id.* at 2 (JA 990). Furthermore, the requirement that a "practitioner" must dispense controlled substances directly to the "ultimate user" (i.e., the animal's owner) runs counter to the goal of the CSA because "it is a considerably more secure

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[11]In revoking Wedgewood's registration, the DA specifically referenced Wedgewood's decision to continue operations "even when advised by the agency in writing that its activities were in violation of the [CSA]." Wedgewood Vill. Pharmacy, 71 Fed. Reg. at 16,597 (JA 980). The DA's annoyance with Wedgewood's decision to challenge DEA's interpretation of the CSA rings throughout the decision. *See id.* at 16,596 (JA 978–980) (Wedgewood "appears to dispute [DEA's] reading of the CSA and has refused to comply with the August 21, 2003, letter from DEA advising that it is in violation of the statute."); *id.* (Wedgewood "has been on notice by both the FDA and DEA that their [sic] activities were manufacturing and distribution, but has chosen to contest the position of the agencies.").

procedure and provides better protection against drug diversion for a licensed veterinarian to possess and be responsible for the controlled substances rather than to send medications for each animal to the farm or stable where any worker has access to them."[12] *Id.* at 3 (JA 991).

On June 7, 2006 the DA denied Wedgewood's request for reconsideration, giving two reasons therefor. Recons. Letter Jun. 7, 2006, at 1 (JA 994). The DA first noted that section 802(21) of the CSA makes no distinction among physicians, veterinarians, dentists and researchers as practitioners. *Id.* Second, the DA concluded that, in any event, a veterinary exception was unnecessary because "the law and regulations provide an adequate mechanism for any practitioner, including a veterinarian, to obtain controlled substances for general office use . . . [e.g.] obtaining controlled substances to be dispensed to a herd or a large group of animals as opposed to a specific animal." *Id.* A practitioner, "including a veterinarian, may

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[12]In its request for reconsideration Wedgewood also argued that DEA's interpretation of the CSA was inconsistent with the Supreme Court's holding in *Gonzales v. Oregon*, 546 U.S. 243 (2006). In *Gonzales* the Court considered a challenge to the Attorney General's interpretation of the CSA to prohibit the use of controlled substances in physician-assisted suicide—a practice legal in Oregon under the Oregon Death With Dignity Act. *Id.* at 249. The Court held that the Attorney General's reliance on the CSA was mistaken because the CSA "manifests no intent to regulate the practice of medicine generally." *Id.* at 270. The DA distinguished *Gonzales*, concluding that "DEA registration of Wedgewood Pharmacy does not involve the regulation of the practice of medicine, veterinary or otherwise, but the regulation of the manufacture, distribution and dispensing of controlled substances. These matters are clearly within the purview of the DEA and do not require deference to state law." Recons. Letter Jun. 7, 2006, at 2 (JA 995).

obtain controlled substances for general dispensing from any properly registered manufacturer, distributor or pharmacy [subject to the 5% Rule]." *Id.* Therefore, the DA concluded, no exception was necessary to accommodate the needs of veterinary practice.

Wedgewood timely petitioned this court for review of the DA's revocation decision (06-1156) as well as the denial of Wedgewood's petition for reconsideration (06-1196). We consolidated the two petitions for briefing and argument. Order Granting Mot. to Consolidate, June 13, 2006.

II.

We review the DA's decisions, insofar as they interpret 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). Under *Chevron*, we do not set aside an agency's statutory interpretation unless the interpretation is "arbitrary, capricious, or manifestly contrary to the statute." *Id.* at 844. " '[A]n agency [decision is] arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.' " *Morall v. DEA*, 412 F.3d 165, 177 (D.C. Cir. 2005) (interpreting Administrative Procedure Act, 5 U.S.C. § 706(2)(A) and quoting *Motor Vehicle Mfrs. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (alterations in original). Having reviewed the DA's decisions, we cannot help but conclude that the DA's decision "entirely failed to consider an important aspect of the problem" before her. *Id.*

Wedgewood argues before us, as it did during the administrative proceedings, that the CSA does not limit dispensing to a "direct" transfer of controlled substances to a

patient. Rather, Wedgewood argues, the CSA permits a pharmacy to "constructively" dispense controlled substances to a patient by delivering the controlled substances to an intermediary such as a veterinarian. Wedgewood relies on the express language of section 802 of the CSA. As noted earlier, the CSA authorizes a practitioner like Wedgewood to "distribute, *dispense* [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. § 802(21) (emphasis added). The CSA defines "dispensing" as the "*deliver*[*y* of] a controlled substance to an *ultimate user* . . . *including* . . . *[any] compounding* necessary to prepare the substance for such delivery." *Id.* § 802(10) (emphases added). And "delivery" expressly includes "the actual, *constructive*, or attempted transfer of a controlled substance." *Id.* § 802(8) (emphasis added).

According to Wedgewood, "constructive" in the definition of "delivery" is critical. By allowing a "constructive" transfer, the CSA recognizes that a pharmacy is not limited to dispensing controlled substances *directly* to the ultimate user. Instead, Wedgewood argues, dispensing controlled substances to a veterinarian for later administration to his animal patients is a "paradigmatic" example of a constructive transfer. *See* Petitioner's Reply Br. 5. Therefore, Wedgewood argues, DEA's conclusion that Wedgewood distributed controlled substances because Wedgewood did not deliver them " '*directly* to specific patients' " is incorrect because DEA failed to consider delivery by "constructive" transfer. *See* Petitioner's Br. 32 (quoting Recons. Letter Jun. 7, 2006, at 2 (JA 995)) (emphasis in original).

Although neither the ALJ nor the DA addressed Wedgewood's "constructive transfer" argument, DEA now posits that Wedgewood's view of "constructive transfer" is too broad. According to DEA, "constructive" must be defined narrowly to maintain a meaningful distinction among the three

classes of registrants recognized by the CSA. Wedgewood's interpretation of constructive transfer, DEA claims, would "eviscerate[] the distinction between a distributor and a dispenser [by] allow[ing] any practitioner to become a distributor of controlled substances, under the guise that the drugs were delivered 'constructively' to the ultimate user." Respondent's Br. 30–31.

In addition—and despite its silence during its own proceedings—DEA now offers its interpretation of this language.[13] According to DEA, a constructive transfer is limited to circumstances in which no "actual" transfer of controlled substances takes place. *See id.* at 31. Specifically, DEA claims that other courts have

> limited [constructive transfers] to situations in which controlled substances were not actually delivered, but rather were constructively delivered by virtue of a person illegally distributing prescriptions, which in turn could be used by the recipient to obtain the controlled drugs from a pharmacy.

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[13]Of course, its argument comes too late. "[A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency. If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." *SEC v. Chenery Corp*., 332 U.S. 194, 196 (1947); *see also Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188, 204 n.4 (D.C. Cir. 2007) ("[W]e cannot affirm [the agency decision] on the basis of a post-hoc explanation by agency counsel.").

Id. at 31–32 (citing *United States v. Roya*, 574 F.2d 386, 393 (7th Cir. 1978); *United States v. Tighe*, 551 F.2d 18, 20 (3d Cir. 1977)).[14] DEA argues that its interpretation is reasonable because it maintains a meaningful distinction among the three categories of DEA registrants. *See id.* at 30. Nevertheless, the definition of "constructive transfer" DEA now offers—namely, the fact that at least one "actual" transfer of controlled substances to another person or entity (be it a postal carrier, authorized agent or other intermediary) has occurred necessarily means there can be no "constructive" transfer—fails for at least three reasons.

First, DEA's interpretation does not tally with the ordinary meaning of "constructive transfer." Black's Law Dictionary defines "constructive transfer" as "[a] delivery of an item—esp. a controlled substance—by someone other than the owner but at the owner's direction." Black's Law Dictionary 1503 (7th ed. 1999). Nothing in the definition precludes a "constructive" transfer simply because an "actual" transfer has taken place.

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[14]*United States v. Roya*, 574 F.2d 386 (7th Cir. 1978), involved a physician, Roya, who wrote prescriptions at the request of his "patients" without asking any questions about the patients' medical histories or conducting any type of physical examination. The government charged the physician with dispensing and attempted dispensing of a Schedule II controlled substance in violation of 21 U.S.C. §§ 841(a)(1) and 846. *Id.* at 388–89. Roya argued that he did not in fact dispense controlled substances. The court rejected this argument, holding that " 'dispens[ing]' includes constructive transfers which encompass . . . issuing written prescriptions to patients entitling them to purchase the substances from a pharmacist." *Id.* at 393. *United States v. Tighe*, 551 F.2d 18 (3d Cir. 1977), involved a physician, Tighe, who gave an undercover DEA agent 18 prescriptions for a Schedule II controlled substance. The government charged Tighe with violating 21 U.S.C. § 841(a)(1). The court affirmed Tighe's conviction, holding that his transfer of invalid prescriptions constituted "constructive" dispensing. *Id.* at 20.

Second, DEA's view is not supported by the statutory definition. To repeat, the CSA defines "delivery" as the "actual, constructive, or *attempted* transfer of a controlled substance or a listed chemical, *whether or not there exists an agency relationship*." 21 U.S.C. § 802(8) (emphases added). The definition of "delivery" includes an "attempted" transfer as a distinct term, presumably to cover circumstances in which there is no "actual" transfer. Moreover, the definition of "delivery" expressly provides that delivery may, in some circumstances, occur constructively through an agent. The CSA definition thus appears to conflict with DEA's assertion that "dispensing" includes only the direct transfer of a controlled substance to the ultimate user.

Finally, DEA's narrow interpretation of "constructive transfer" also appears to conflict with at least one of DEA's regulations interpreting the CSA. DEA's regulation defining "prescription" provides that a prescription is "an order for medication which is dispensed to *or for* an ultimate user." 21 C.F.R. § 1300.01(b)(35) (emphasis added). That a prescription may be dispensed "for" the ultimate user suggests a definition of "constructive" transfer broader than DEA set forth in its brief.

At oral argument, DEA retreated from the definition set out in its brief. When asked to clarify her understanding of the term, DEA counsel offered a new explanation—one in which an "actual" transfer does not preclude a "constructive" transfer. She explained that under the CSA's constructive transfer language, "*the patient or even the ultimate user does not have to be the person that actually picks up the prescription, but the transfer requires that the pharmacy identify who that patient is*." Recording of 9/10/07 Oral Argument at 30:50 (emphasis added). DEA counsel's amended definition of "constructive transfer" suggests that DEA's primary concern may not be with the practice of dispensing controlled substances through an intermediary but instead with the practice of "compounding"

medications without an *individualized* prescription.[15] This statement may accurately reflect the DA's concerns about general dispensing. *See, e.g.*, Wedgewood Vill. Pharmacy, 71 Fed. Reg. at 16,595 ("[A] pharmacy must receive a prescription for a specific patient . . . ."); *id.* at 16,596 ("[Wedgewood] is rarely dispensing controlled substances to specific patients . . ., and, in the majority of cases, has no documentation of the identity of the patients to whom the controlled substances will ultimately be dispensed or administered."). It does not, however, explain why the DA prohibited practitioners from acting as intermediaries on behalf of "ultimate user[s]." *See, e.g.*, *id.* at 16,595 ("Sending controlled substances to another DEA practitioner for dispensing is distribution, not dispensing."). We note that requiring the identification of a specific patient for delivery comports with the statutory scheme. *See, e.g.*, 21 C.F.R. § 1306.04(b) (prohibiting using prescriptions "for the purpose of general dispensing"); 21 C.F.R. § 1306.05 ("All prescriptions . . . shall bear the full name . . . of the patient . . ."); 21 C.F.R. § 1307.11 (permitting practitioners to "distribute (without being registered to distribute)" 5% of total dosage units "for the purpose of general dispensing"). Moreover, requiring individualized dispensing maintains the distinction between "dispens[ing]" and "distribut[ing]" by preserving the "ultimate user" requirement. *See* 21 U.S.C. § 802(10); § 802(27). When

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[15]In its January 3, 2006 settlement offer, Wedgewood proposed to "dispense compounded medication pursuant to an individualized lawful order issued by a licensed practitioner or veterinarian for a clearly identified patient." *See* Wedgewood Letter Jan. 3, 2005, at 2 (JA 982) (emphasis omitted). In her reconsideration denial letter, the DA made note of the settlement offer but concluded that the matter was better left to the Department of Justice lawyers representing DEA in court. *See* Recons. Letter June 7, 2006, at 2 (JA 995) ("I have reviewed your settlement proposal. Because a Notice of Appeal has been filed, the matter is best left to the Department of Justice attorneys who will be representing DEA on the petition for review.").

a pharmacy dispenses controlled substances without identifying a specific patient, as Wedgewood apparently did here, it is unclear who the "ultimate user" is. Nonetheless, this requirement still fails to explain why the DA prohibited *any* registrant-to-registrant transfer, even one pursuant to an individualized prescription.

DEA also ignored an important aspect of Wedgewood's practice. In its request for reconsideration, Wedgewood argued that DEA's ruling that " '[a] pharmacy must receive a prescription for a *specific patient* . . . and must deliver or dispense that medication to the patient' " was "unworkable for veterinary practice." Recons. Letter Apr. 19, 2006, at 3 (JA 991) (quoting Wedgewood Vill. Pharmacy, 71 Fed. Reg. at 16,595 (emphasis and ellipsis in original)). Wedgewood explained that

> [v]eterinarians, particularly those with an equine practice, travel to their patients, examine and diagnose them, and administer the appropriate medicines on site, a procedure that requires them to have a variety of medicines at their immediate disposal. The veterinarian will not know the name or names of an animal to be treated until she examines the animal and makes a diagnosis whether and which treatment is required.

Id. DEA knew from the beginning of its investigation that the bulk of Wedgewood's business was with veterinarians. In addition, it had information before it indicating that animal medicine operates differently from human medicine. *See, e.g.*, ALJ Op. ¶ 59 (JA 948–49) (discussing FDA Compliance Policy Guide No. 7125.40—Compounding of Drugs for Use in Animals). DEA did not consider this difference in its original decision and it failed to address the difference again when it denied reconsideration. The DA explained that "[t]he CSA itself makes no distinction between physicians, dentists, researchers,

and veterinarians." Recons. Letter Jun. 7, 2006, at 1 (JA 994). Furthermore, the DA said that no distinction between veterinary medicine and human medicine is required because, under the existing law and regulations, a veterinarian has a means of obtaining controlled substances to treat animals on-site by ordering the controlled substances for "general office use" through a manufacturer or distributor—or a pharmacy pursuant to the 5% rule. *Id.*

We believe DEA's analysis is inadequate. The scope of activities allowed under "general office use" is unclear from the DA's letter. Apparently DEA believes that a veterinarian can adequately treat animals on-site by ordering controlled substances for "general office use" but it reached that conclusion without defining what "general office use" encompasses. Further, it appears that the term is not defined anywhere in DEA regulations. DEA also failed to explain how a veterinarian would be able to obtain enough compounded medicine for general office use, using only the 5% a pharmacy can lawfully provide.

For the foregoing reasons, we vacate DEA's revocation of Wedgewood's registration and remand the case for further proceedings consistent with this opinion. On remand, DEA should address the scope of "constructive transfer" as that term is used in 21 U.S.C. § 802(8). DEA should also clarify its interpretation of "general office use," "order" and "prescription" as used in the CSA, the FDAMA and relevant regulations. Finally, in reexamining these issues, DEA should explain how

the difference, if any, between the practices of human and veterinary medicine might affect its analysis.[16]

So ordered.

[16]Because of our remand, we do not reach Wedgewood claims that DEA's interpretation of relevant CSA provisions intrudes on state regulation of veterinary medicine, that DEA's findings are not supported by substantial evidence and that revocation constitutes excessive punishment.