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No. 08-3079

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

MEDICINE SHOPPE - JONESBOROUGH,	)	
	)	
Petitioner,	)	
	)	
v.	)	ON PETITION FOR REVIEW OF AN
	)	ORDER OF THE DRUG
DRUG ENFORCEMENT	)	ENFORCEMENT ADMINISTRATION
ADMINISTRATION,	)	
	)	
Respondent.	)	

Before: KENNEDY, SUTTON and McKEAGUE, Circuit Judges.

SUTTON, Circuit Judge. Medicine Shoppe seeks review of an order of the Drug Enforcement Administration (DEA) revoking its registration to dispense controlled substances. Because substantial evidence supports the DEA's determination, we affirm.

I.

Jeffrey Street, a state-licensed pharmacist, opened a Medicine Shoppe pharmacy in Jonesborough, Tennessee in 1994. The pharmacy obtained its federally required certificate of registration from the DEA to dispense controlled substances that same year, and Street has owned and operated the pharmacy ever since.

In 1995, the DEA investigated a physician in the area, Dr. Royce Blackmon, who appeared to be issuing improper prescriptions on a large scale. DEA investigators discovered that Medicine Shoppe had filled an "abnormal" number of Blackmon's prescriptions, JA 213, which Blackmon often issued "without even seeing the patient" and which he told his patients to fill at Medicine Shoppe, JA 11 (internal quotation marks omitted). Two years later, investigators found that Medicine Shoppe, unlike most pharmacies in the area, continued to fill many of Blackmon's prescriptions.

All of this prompted the DEA to investigate Medicine Shoppe. The agency audited the pharmacy in 1999, 2001 and 2002, and in each year it found serious discrepancies between the pharmacy's records and its on-hand inventory. Medicine Shoppe dispensed controlled substances under suspicious circumstances hundreds of times: It filled prescriptions that exceeded safe limits for specific drugs or combinations, that duplicated or conflicted with other prescriptions the pharmacy had filled for the patient (often issued by other physicians) or that were inconsistent with the issuing doctor's area of practice. In most of these cases, the pharmacy did not verify the prescription with the issuing doctor first.

Based on these findings, the DEA ordered Medicine Shoppe to show cause why its registration to dispense controlled substances should not be revoked. In a 96-page order, the Deputy Administrator concluded that Medicine Shoppe's poor record-keeping, its questionable dispensing practices and its failure to acknowledge its errors or reform its ways warranted revoking its registration (and denying its pending application for renewal). *Medicine Shoppe–Jonesborough;*

Revocation of Registration, 73 Fed. Reg. 364 (DEA Jan. 2, 2008). Medicine Shoppe petitioned us to review and overturn the DEA's order. *See* 21 U.S.C. § 877.

II.

We review the Deputy Administrator's factual findings for substantial evidence, *id.*, but we cannot reject his reasoning or discretionary determinations unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005).

Under the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, a pharmacy may dispense controlled substances only after it has obtained a valid federal registration, *id.* § 822(a)(2). The Deputy Administrator may revoke a registration if it determines that the pharmacy "has committed such acts as would render [its] registration . . . inconsistent with the public interest." *Id.* § 824(a)(4); 28 C.F.R. §§ 0.100, 0.104. The statute identifies five factors the agency must consider "[i]n determining the public interest":

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
>
> (2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The [registrant'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). Although the Deputy Administrator must consider each factor, he need not make findings as to each one and can "give each factor the weight [he] determines is appropriate." *Hoxie*, 419 F.3d at 482.

In this case, the Deputy Administrator determined that Medicine Shoppe's failure to maintain adequate required records, its alarming (and unlawful) drug-dispensing practices and its refusal even to acknowledge its poor performance demonstrated that its continued registration was at odds with the public interest. Substantial evidence, we conclude, supports this conclusion.

First, Medicine Shoppe fell short of meeting its duty to maintain accurate records of the controlled substances it dispensed. The CSA requires all prescription-dispensing entities to conduct a biennial inventory of all of the controlled substances it has on-hand and to "maintain, on a current basis, a complete and accurate record of each [controlled] substance" that it has "received, sold, delivered, or otherwise disposed of." 21 U.S.C. § 827(a)(1), (3); *see also* 21 C.F.R. § 1304.21. These records must "includ[e] the name and address of the person to whom [a drug] was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser." 21 C.F.R. § 1304.22(c). Records relating to Schedule I and II drugs must be separated from the pharmacy's other files, while records for other controlled substances must remain "readily retrievable" from the pharmacy's regular records. *Id.* § 1304.04(h).

Substantial evidence supports the agency's conclusion that Medicine Shoppe's record-keeping did not satisfy these standards. The 1999, 2001 and 2002 audits all showed substantial shortages and overages in various prescription drugs. The pharmacy disputed the findings of each of the agency's audits, identifying errors and omissions in each one, but each time its own independent audits confirmed discrepancies involving thousands of dosage units. Small discrepancies, to be sure—in the neighborhood of 50 dosage units—are not uncommon. But many of Medicine Shoppe's tallies missed the mark by a wide margin: Its records for more than half of the drugs examined in its own 1999 audit were off by more than 50 units, in some cases misstating the inventory on hand by more than 100%.

The Deputy Administrator also found unpersuasive Medicine Shoppe's "human error" defense. JA 18 (internal quotation marks omitted). In his testimony, Street chalked up most of the missing and extra drugs to run-of-the-mine mistakes: He or his staff may have mixed up pills containing the same drug in different concentrations or confused a name-brand drug with its generic equivalent, simply "pull[ing] the wrong one off the shelf." JA 18. But as the Deputy Administrator noted, proof to corroborate Street's account should have been easy to produce—as Medicine Shoppe could have tested this hypothesis in its own independent audits—and yet the pharmacy declined to do so. Even if these recurring mistakes reflected no more than human error, the Deputy Administrator explained, they nonetheless posed "alarming" risks; dispensing the right drug in the wrong strength "can have serious consequences for the health of patients." JA 19.

That leaves Medicine Shoppe's fall-back assertion that, whatever caused the discrepancies, they did not reflect any "deliberate diversion" of controlled substances. Br. at 18. But this too, the Deputy Administrator correctly concluded, adds nothing to the equation. In imposing the record-keeping requirements, the statute and regulations say nothing about deliberate diversion, much less about making it a prerequisite for finding a pharmacy failed to meet its obligations. Medicine Shoppe's only evidence on this point, at any rate, was meager at best. *See* JA 19, 95 n.57 (attributing no weight to Street's testimony that neither he nor his employees deliberately diverted drugs, noting that Street never bothered to investigate his employees' behavior); JA 20, 21 & n.16, 95 (discounting testimony of Medicine Shoppe's putative expert concerning the deliberate-diversion issue as he failed to account for several shortages shown in the pharmacy's independent audits).

Second, the pharmacy frequently doled out drugs in an irresponsible and unlawful manner. The CSA forbids a pharmacy to dispense a Schedule II, III or IV controlled substance without a prescription, 21 U.S.C. § 829(a)–(b), which "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice," 21 C.F.R. § 1306.04(a). Although the main "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," DEA regulations place a "corresponding responsibility" on the "pharmacist who fills the prescription." *Id.*

The DEA's interpretation of its own regulation is "controlling unless plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (internal quotation marks omitted). The agency has long interpreted this "corresponding responsibility" to

"mean[] . . . that a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose." *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043, 30,044 (DEA July 24, 1990) (internal quotation marks omitted). The regulation thus requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse. *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed. Reg. 4,729, 4,730 (DEA Feb. 9, 1990). "When [pharmacists'] suspicions are aroused as reasonable professionals," they must at least verify the prescription's propriety, and if not satisfied by the answer they must "refuse to dispense." *Id.*; *see also United States v. Henry*, 727 F.2d 1373, 1378–79 (5th Cir. 1984).

Tennessee law also places a responsibility on pharmacists to prevent improper prescriptions from being filled. In accordance with the State's regulations, a pharmacist must undertake a "reasonable review of a patient's record prior to dispensing each medical or prescription order" by examining several enumerated aspects of the patient's profile before releasing the drugs. Tenn. Comp. R. & Regs. 1140-3-.01(3)(a).

The record is replete with evidence that Medicine Shoppe fell asleep at the wheel in honoring prescriptions no reasonable pharmacist would fill without further inquiry. For starters, the pharmacy at one stage processed more than one hundred prescriptions every other day written by a veterinarian whose state license and DEA registration were expired, that were issued in the names of several

different patients and that were brought to the pharmacy by the veterinarian's brother. (The patients, it turned out, were all alter-egos of the veterinarian who was abusing the drugs himself.) As the ALJ and the Deputy Administrator recognized, this pattern "easily could have indicated diversion of controlled substances," and "[y]et Mr. Street filled these prescriptions without further investigation." JA 73 (internal quotation marks omitted).

The Deputy Administrator also identified a dozen patients to whom Medicine Shoppe dispensed drugs despite obvious warning signs of "doctor shopping" and other dangers. JA 81 n.52. Though the details differ, all of these transactions were variations on a common theme: Street or a substitute pharmacist filled prescriptions that were issued to the same patient by numerous prescribers (sometimes as many as two dozen) or that involved excessive (and potentially toxic) quantities of drugs, two or more conflicting drugs or remedies outside the prescriber's ordinary area of practice. The pharmacy, for example, filled prescriptions for one patient issued by 21 different prescribers for an array of identical, overlapping or incompatible drugs, resulting in quantities and combinations that the government's experts concluded would be "toxic" and potentially "devastating for the patient," JA 34 (internal quotation marks omitted). It filled prescriptions for a different patient for hydrocodone and acetaminophen at "twice the acceptable limits," JA 30 (internal quotation marks omitted), and for a third patient it dispensed a drug despite written warnings on the package of harmful interactions with another drug the same patient was taking. And for two other patients, it repeatedly filled prescriptions issued by a dentist for large quantities of high-strength cough syrup.

Street, it is true, offered at least partial explanations for all but one of these patients. But as the Deputy Administrator explained, even accepting Street's testimony as credible, his accounts were inadequate. His explanations as to ten patients were incomplete because they addressed some but not all of the suspicious transactions. As for the other two, Street's explanations were unpersuasive: One instance involved a patient receiving such a large, unsafe amount of drugs that not even verifying the prescriptions with the issuing practitioner (as Street said he did) could justify filling them, and in the other case Street apparently ignored a drug's written warnings—inexcusable under any standard.

Each case, in short, should have raised red flags at Medicine Shoppe. By filling these prescriptions anyway, the Deputy Administrator reasonably concluded, the pharmacy not only violated its duties under federal (and state) law to ensure that only proper prescriptions were filled but also put public health and safety at risk.

Third, instead of owning up to its mistakes and making amends, Medicine Shoppe remained largely in denial. As the Deputy Administrator concluded, the pharmacy refused "even [to] acknowledge[] that it ha[d] serious recordkeeping problems, let alone that it committed numerous violations of federal law in dispensing controlled substances." JA 98. Nor did it provide evidence of meaningful remedial measures it had taken to prevent similar problems in the future. Street, it is true, offered abstract assurances that, since the audits, the staff has been "a lot more careful" and is in "general just trying to . . . practice by a higher standard." ALJ Hr'g Tr. 152, May 24, 2005. But the only specific corrective steps he described—fixing data-entry errors in its database and being

"more careful on [its] counting"—relate only to its record-keeping failures and do nothing to redress its irresponsible dispensing practices. Whether willfully or naively blind to its blunders, in short, Medicine Shoppe failed to "present[] sufficient mitigating evidence to assure the [Deputy] Administrator that [it] can be entrusted with the responsibility carried by [its] registration." JA 97 (internal quotation marks omitted, first and third alterations in original).

In resisting the Deputy Administrator's assessment as both unsupported by substantial evidence and arbitrary and capricious, Medicine Shoppe points out that he did not respect the findings made by the ALJ who heard and saw the witnesses testify. Giving much greater weight to the mitigating evidence—including Street's efforts to assist the DEA during audits, his (partial) attempts to verify prescriptions, the knowledge he demonstrated at the hearing of specific patients' circumstances and his other "affirmative action[s] to preclude the diversion of controlled substances," such as reporting forged prescriptions to authorities, JA 286—the ALJ determined that allowing Medicine Shoppe to continue dispensing drugs would not pose unacceptable risks to the public interest. The answer, the ALJ believed, was more monitoring, not revoking Medicine Shoppe's registration. Because the Deputy Administrator did not accept all of the ALJ's findings and the ALJ's ultimate conclusion, the pharmacy argues that we must reject the agency's decision for want of substantial evidence.

But disagreement between an agency and an ALJ does not rewrite the rules of substantial-evidence review. *See Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951); *NLRB v. Local 334, Laborers Int'l Union*, 481 F.3d 875, 879 (6th Cir. 2007). So long as the Deputy Administrator

does not "ignore[]" the ALJ's decision but instead "take[s] the ALJ's findings into consideration," no stricter standard applies, and we simply must examine those findings with the rest of the record. *Morall v. DEA*, 412 F.3d 165, 179 (D.C. Cir. 2005). A conflict between the two decisions, to be sure, may render the evidence underlying the Deputy Administrator's decision "less substantial," *Universal Camera*, 340 U.S. at 496, but only to the extent the case turns on questions of credibility that make the ALJ's face-to-face assessment of relevant testimony material. Yet, as explained above, many of the Deputy Administrator's conclusions depended not on what witnesses said but what they did *not* say and the dispensings they failed to explain.

Although the Deputy Administrator took issue with some of the ALJ's findings, he explained why, noting in most instances the ALJ's failure to consider contrary evidence. Medicine Shoppe in the end has not met its burden of showing either that the Deputy Administrator failed to "examine the relevant data" or that his decision does not "reflect a rational connection between the facts found and the choice made." *Hoxie*, 419 F.3d at 482 (internal quotation marks omitted).

III.

For these reasons, we deny the petition for review.