

[DO NOT PUBLISH]

In the  
United States Court of Appeals  
For the Eleventh Circuit

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No. 20-14626

Non-Argument Calendar

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SUNTREE PHARMACY AND  
SUNTREE MEDICAL EQUIPMENT, LLC,

Petitioners,

*versus*

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

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Petition for Review of a Decision of the  
Drug Enforcement Administration  
Administration No. 17-09 / 17-10

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Before NEWSOM, LUCK, and ANDERSON, Circuit Judges.

PER CURIAM:

Suntree Pharmacy and Suntree Medical Equipment, LLC petition for review of the Acting Administrator of the Drug Enforcement Administration’s decision to revoke their registrations to dispense controlled substances and to deny their pending renewal applications. *See Suntree Pharmacy & Suntree Med. Equip., LLC*, 85 Fed. Reg. 73753 (Nov. 19, 2020). The Acting Administrator revoked and denied Suntree Pharmacy’s and Suntree Medical’s registrations and pending renewal applications after an administrative hearing revealed that Suntree Pharmacy had filled prescriptions for controlled substances outside of the usual course of practice and in violation of federal and state law.<sup>1</sup> Suntree argues that the Acting Administrator’s revocation of its registrations was arbitrary and capricious and that the length of the administrative proceedings violated its procedural due process rights. We deny the petition for review.

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<sup>1</sup> Suntree Pharmacy and Suntree Medical consented to a consolidated hearing. The administrative law judge concluded that it was appropriate to treat Suntree Pharmacy and Suntree Medical “as one integrated enterprise” because of “the obvious commonality of ownership, management, and operations.” The Acting Administrator agreed and concluded that Suntree Pharmacy and Suntree Medical “are essentially one and the same.” Suntree Pharmacy and Suntree Medical do not challenge this part of the Acting Administrator’s order on appeal. So we refer to them together as “Suntree.”

**FACTUAL BACKGROUND AND PROCEDURAL HISTORY***The Controlled Substances Act*

We briefly summarize the relevant statutory framework before turning to the facts of this case. The Controlled Substances Act “creates ‘a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the [Act].’” *Jones Total Health Care Pharmacy, LLC v. Drug Enf’t Admin.*, 881 F.3d 823, 827 (11th Cir. 2018) (quoting *Gonzales v. Raich*, 545 U.S. 1, 13 (2005)). The Act requires pharmacies that dispense prescriptions for controlled substances to obtain proper registration from the Attorney General. *Id.*

The Act places “the responsibility for the proper prescribing and dispensing of controlled substances, which must be for ‘a legitimate medical purpose,’ . . . on the prescribing practitioner, ‘but a corresponding responsibility rests with the pharmacist who fills the prescription.’” *Id.* (quoting 21 C.F.R. § 1306.04(a)). Pharmacists therefore “have a ‘corresponding responsibility’ to refuse to fill prescriptions that are not issued for a legitimate medical purpose.” *Id.*; see *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979) (“The pharmacist is not required to have a ‘corresponding responsibility’ to practice medicine. What is required of him is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.”).

The Attorney General has delegated his authority to deny, revoke, or suspend pharmacy registrations to the Drug Enforcement Administration. *Jones*, 881 F.3d at 827. The Administration may revoke an existing registration or deny an application for registration if the registration is or would be “inconsistent with the public interest.” *Id.* at 829 (quoting 21 U.S.C. §§ 824(a)(4), 823(f)). When the Administration proposes to revoke an existing registration, it must serve an “order to show cause” on the registrant and provide the registrant an opportunity for a hearing before an administrative law judge in order to contest the proposed action. *Id.* at 827 (citing 21 U.S.C. § 824(c)). After the administrative law judge certifies the record to the Administrator, he or she must publish a final order with findings of fact and conclusions of law. *See* 21 C.F.R. §§ 1316.65, .67. The final order must be published “[a]s soon as practicable after the [administrative law judge] has certified the record to the Administrator.” *Id.* § 1316.67.

#### *Suntree and the Order to Show Cause*

Suntree Pharmacy and Suntree Medical were registered retail pharmacies in Florida. On October 5, 2016, the Administration issued an order to show cause why Suntree’s registrations shouldn’t be rescinded and its pending renewal applications shouldn’t be denied because Suntree’s “continued registrations are inconsistent with the public interest.” The Administration alleged that, from October 2013 to March 2015, Suntree filled more than two hundred controlled substances prescriptions “outside the usual course of pharmacy practice” and “in contravention of [its]

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‘corresponding responsibility.’” Specifically, the order to show cause alleged that Suntree violated its corresponding responsibility by: (1) filling prescriptions for patients without resolving red flags that the prescriptions were not for a legitimate medical purpose; (2) filling prescriptions for a doctor that he wrote for himself in violation of state law; and (3) filling prescriptions for “office use” in violation of federal law.

As to the prescriptions for patients, the order to show cause alleged that Suntree “repeatedly filled controlled substances prescriptions that contained multiple red flags of diversion and/or abuse without addressing or resolving those red flags, and under circumstances indicating that [Suntree was] willfully blind or deliberately ignorant of the prescriptions’ legitimacy.” As to the prescriptions written by the doctor for himself, the order to show cause alleged that the prescriptions “were written in violation of Florida law . . . which prohibits a physician from ‘prescribing, dispensing, or administering any’ drug in Schedule II-VI ‘by the physician to himself.’” And as to the prescriptions for “office use,” the order to show cause alleged that Suntree “dispensed testosterone on at least fourteen different occasions pursuant to invalid prescriptions which indicated the ultimate user was an ‘office,’ in violation of 21 C.F.R. [section] 1306.04(b).”

#### *The Administrative Law Judge’s Decision*

An administrative law judge held a hearing on the order to show cause in April 2017. At the hearing, the Administration presented the testimony of its expert witness, Dr. Tracey Gordon,

Pharm.D., its diversion investigator, James Graumlich, an employee of Suntree Medical, Michael Peterson, and the owner of Suntree, Dr. Diahn Clark, Pharm.D. Suntree presented the testimony of its expert witness, Dr. Wayne Grant, Pharm.D., Suntree Pharmacy's regulatory attorney, Darren Meacham, and Dr. Clark.

On August 15, 2017, the administrative law judge issued his findings of fact and conclusions of law, recommending that the Acting Administrator revoke Suntree's registrations and deny its pending renewal applications. The administrative law judge credited Dr. Gordon's testimony that Suntree filled multiple prescriptions for controlled substances to twenty-two patients that had one or more "red flags"—indicia that the prescriptions were not issued for a legitimate medical purpose—and should not have been filled without first investigating and resolving the red flags.

Dr. Gordon testified that the usual course of professional practice in Florida required a pharmacist to investigate and resolve red flags before dispensing a controlled substance. Dr. Gordon identified more than a dozen red flags that Suntree ignored in filling prescriptions, including: (1) patients traveling long distances—some as far as 170 miles—to obtain prescriptions; (2) "groups" of patients traveling to the same physicians on the same days to obtain similar prescriptions which Suntree frequently filled at the same time; (3) patients making cash payments; (4) patients obtaining prescriptions for well-known, highly diverted and abused controlled substances; (5) patients obtaining prescriptions for the highest dosages; (6) patients obtaining repeated prescriptions for highly

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abused drug “cocktails”; (7) patients obtaining early refills of prescriptions; (8) patients obtaining prescriptions for two immediate release opioids that do the same thing; and (9) physicians prescribing outside the scope of their usual practice.

The administrative law judge credited Dr. Gordon’s testimony and found that “[w]hen a red flag is resolved, it must be documented before the prescription is dispensed” and that “[i]f a red flag cannot be resolved, under the standard practice [of] a pharmacy in Florida, the medication should not be dispensed.” The administrative law judge also credited Dr. Gordon’s testimony and found that “nothing in the record resolves the red flags raised by prescriptions dispensed” by Suntree. The administrative law judge found that the “blatant” unresolved red flags were “sufficient circumstantial evidence” to establish that the prescriptions were not written for a legitimate medical purpose. And the administrative law judge reasoned that, “while nothing in the [Administration’s] regulations specifically requires a pharmacist to document the resolution of a red flag, Florida laws specifically require that a pharmacist maintain records that include discussions with licensed health care practitioners and information about a patient’s drug therapy and information peculiar to a specific patient,” and that, “[i]n light of these requirements, the absence of such documentation is circumstantial evidence that those requirements were not met.” Based on these factual findings, the administrative law judge sustained the Administration’s allegations that Suntree violated its corresponding responsibility in dispensing prescriptions written for

patients because it “dispensed highly abused controlled substances to many of its customers without resolving numerous red flags raised by the prescriptions.”

The administrative law judge also sustained the Administration’s allegations that Suntree violated its corresponding responsibility by filling prescriptions that a prescribing physician wrote for himself because: (1) the prescribing physician violated Florida law by prescribing a controlled substance to himself; and (2) “filling such a prescription would not be in the usual course of the professional practice of a pharmacy.” But the administrative law judge didn’t sustain the Administration’s allegation that Suntree violated its corresponding responsibility by filling prescriptions for “office use” because “these ‘prescriptions’ were issued to physicians” and the Administration didn’t prove that the physicians “were going to be dispensing the controlled substances to patients.”

Having sustained the Administration’s allegations that Suntree violated its corresponding responsibility by filling red-flagged prescriptions for patients and by filling prescriptions that the prescribing physician wrote for himself, the administrative law judge found that that the government had met its burden to establish a prima facie case that revocation of Suntree’s registrations was in the public interest. The administrative law judge then addressed whether Suntree had put forward sufficient evidence to show that it could be trusted not to engage in future misconduct. The administrative law judge concluded that Suntree hadn’t done so because it hadn’t accepted responsibility for its violations. The



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administrative law judge therefore recommended the revocation of Suntree's registrations and the denial of its pending renewal applications.

*The Acting Administrator's Final Order*

In September 2017, Suntree filed exceptions to the administrative law judge's recommendation and the administrative law judge certified the record to the Acting Administrator. Three years later, the Acting Administrator issued an eighty-five-page final order concluding that there was substantial evidence that Suntree's continued registrations would be inconsistent with the public interest.

Relying on Dr. Gordon's testimony, the Acting Administrator determined that Suntree had a corresponding responsibility to resolve red flags before filling prescriptions for controlled substances. The Acting Administrator agreed with the administrative law judge and found that Suntree failed to exercise its corresponding responsibility by filling hundreds of prescriptions for patients without resolving red flags.

The Acting Administrator did "not find it necessary to find" whether Suntree violated Florida law by failing to document the resolution of red flags because Dr. Gordon's "testimony [was] independently credible that documentation of the resolution of red flags [was] a requirement of the practice of pharmacy in the State of Florida." The Acting Administrator also agreed with the administrative law judge that Suntree violated its corresponding

responsibility by filling prescriptions that a prescribing physician had written for himself because, even if the prescribing physician hadn't violated Florida law in writing the prescriptions, "the fact that there was even a question about whether the prescriptions violated Florida law presented . . . a red flag" that Suntree didn't resolve. And the Acting Administrator did "not consider the allegation related to the prescriptions issued for 'office use'" because the Administration had "not adequately established a legal basis for . . . finding . . . a violation."

Based on his findings, the Acting Administrator determined that "it would be inconsistent with the public interest to permit [Suntree] to maintain its registration[s]." And Suntree couldn't be entrusted with a registration, the Acting Administrator concluded, because it had neither accepted responsibility for its violations nor offered any remedial measures. The Acting Administrator therefore revoked Suntree's registrations and denied its pending renewal applications.

### STANDARD OF REVIEW

We may set aside an agency's final decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Jones*, 881 F.3d at 829 (quoting 5 U.S.C. § 706(2)(A)). "The arbitrary and capricious standard is exceedingly deferential." *Id.* (citation omitted). We "may not substitute our judgment for that of the agency so long as its conclusions are rational and based on the evidence before it." *Id.* We may, however, "set aside a decision as 'arbitrary and capricious when, among other flaws, the

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agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency.” *Id.* (citation omitted).

The Acting Administrator’s factual findings “are conclusive if supported by substantial evidence.” *Id.* (citing 21 U.S.C. § 877). “Substantial evidence is less than a preponderance of the evidence, but rather such relevant evidence as a reasonable person would accept as adequate to support a conclusion.” *Id.* The Acting Administrator’s factual findings are supported by substantial evidence even if “two inconsistent conclusions [could be drawn] from the evidence.” *Id.* (citation omitted).

## DISCUSSION

Suntree contends that the Acting Administrator’s final order must be set aside for two reasons. First, it argues that the Acting Administrator’s decision was arbitrary and capricious because the government failed to prove that the red-flagged prescriptions were not issued for a legitimate medical purpose. Second, it contends that the four years between the order to show cause and the final order, and the three years between the administrative law judge’s certification of the record and the Acting Administrator’s entry of the final order, violated its procedural due process rights. Neither argument has merit.

*Revocation and Denial*

Suntree does not challenge the Acting Administrator’s factual finding that Suntree failed to resolve red flags raised by prescriptions for controlled substances before it dispensed them. It argues instead that the Acting Administrator erroneously determined that this failure amounted to a violation of Suntree’s corresponding responsibility because there was “no evidence that the prescriptions in question lacked a legitimate medical purpose” and the illegitimacy of a prescription must be established before finding that Suntree was willfully blind to the prescription’s validity. According to Suntree, “[t]he mere showing of dispensing prescriptions in the face of ‘red flags’” is insufficient to demonstrate a violation of a pharmacist’s corresponding responsibility because the corresponding responsibility is not “triggered” unless a prescription lacked a legitimate medical purpose.

Suntree’s argument is based almost entirely on a footnote in the Acting Administrator’s decision in *Hills Pharmacy, LLC*, 81 Fed. Reg. 49816 (July 28, 2016). That footnote reads,

Respondent argues that the Government cannot establish that a pharmacist has violated his corresponding responsibility unless it first establishes that the prescription lacked a legitimate medical purpose and that the issuing physician acted outside of the usual course of professional practice. It argues that “neither the fact of this corresponding responsibility nor the pharmacist’s performance of his corresponding

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responsibility affects whether the prescription was, in the first place, issued to the patient for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” And it further argues that “the test for the proper dispensing of a controlled substances remains at its foundation a medical question” and that “the Government provided not one scintilla of evidence to prove that the prescriptions at issue were issued for other than a legitimate medical purpose.”

Respondent is mistaken. *While it is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose, Respondent ignores that the invalidity of a prescription can be proved by circumstantial evidence.* I find that to be the case here. For similar reason, I reject Respondent’s contention that the Government failed to meet its burden because Mr. Parrado is a pharmacist with “no medical training or experience that would have allowed him to evaluate the legitimacy of a physician's prescribing.”

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Here . . . the Government relied on the circumstantial evidence that the prescriptions lacked a legitimate medical purpose. Accordingly, I reject Respondent’s contention that “the Government provided not one

scintilla of evidence to prove that the prescriptions . . . were issued for other than a legitimate medical purpose.”

*Id.* at 49836 n.33 (citations omitted and emphasis added).

Suntree repeatedly quotes the portion of the sentence in italics that “it is true that a pharmacist cannot violate his corresponding responsibility if a prescription was nonetheless issued for a legitimate medical purpose.” But, like the respondent in *Hills Pharmacy*, Suntree ignores “that the validity of a prescription can be proved by circumstantial evidence.”<sup>2</sup>

Contrary to Suntree’s assertion, the Administration “has long interpreted [21 C.F.R. section 1306.04(a)] as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ‘knows *or has reason to know* that the prescription was not written for a legitimate medical purpose.’” *JM Pharmacy Grp., Inc., d/b/a Farmacia Nueva & Best Pharma Corp.*, 80 Fed. Reg. 28667, 28670 (May 19, 2015) (citation omitted and emphasis added); *see also Hayes*, 595 F.2d at 261 n.6 (“[A] pharmacist can

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<sup>2</sup> This sentence from *Hills Pharmacy* was quoted in *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, 83 Fed. Reg. 10876 (Mar. 13, 2018). As in *Hills Pharmacy*, the Acting Administrator in *Pharmacy Doctors Enterprises* rejected the respondent’s argument “that the Government’s case must fail because the [diversion investigator] did not meet with any prescriber or speak with any customer” to establish that the prescriptions were not issued for a legitimate medical purpose because “Agency precedent has made clear that [the respondent’s] argument is mistaken.” 83 Fed. Reg. at 10899 & n.36 (citing *Hills Pharmacy*, 81 Fed. Reg. at 49836 n.33).

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know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science.”). When confronted with red flags, “a pharmacist may not intentionally close his eyes and thereby avoid positive knowledge of the real purpose of the prescription, and thereafter fill the prescription ‘with impunity.’” *JM Pharmacy Grp.*, 80 Fed. Reg. at 28670 (citation omitted).

Here, the Acting Administrator found that circumstantial evidence—the “blatant” red flags identified by Dr. Gordon and ignored by Suntree—showed that the prescriptions were not issued for a legitimate medical purpose. And the Acting Administrator found that Suntree violated its corresponding responsibility by filling the prescriptions even though it knew—or was willfully blind to—the prescriptions’ illegitimacy. The Acting Administrator’s finding that Suntree violated its corresponding responsibility is supported by substantial evidence, and it is therefore conclusive. *See* 21 U.S.C. § 877; *Jones*, 881 F.3d at 830 (finding that “[t]he record supports the [Administration’s] determination that [the pharmacy] unlawfully filled numerous controlled substance prescriptions that were not issued for a legitimate medical purpose” where “the evidence showed that [the pharmacy] . . . filled over one-hundred prescriptions that had at least one red flag that [the pharmacy] did not attempt to resolve and that could not have been resolved” and “[t]he government also put forward other substantial evidence indicating that the controlled substances dispensed by [the pharmacy] were being diverted for improper use”).

Based on his finding that Suntree violated its corresponding responsibility by filling prescriptions for controlled substances without resolving obvious red flags that the prescriptions lacked a legitimate medical purpose, the Acting Administrator’s decision to revoke Suntree’s registrations and to deny its pending renewal applications was not “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.”<sup>3</sup> See 5 U.S.C. § 706(2)(A).

#### *Administrative Delay*

Suntree also argues that the four years between the order to show cause and the final order, and the three years between the administrative law judge’s certification of the record and the Acting Administrator’s entry of the final order, violated its procedural due process rights. But Suntree had the opportunity to object to the Administration’s delay, see, e.g., 5 U.S.C. § 706(1); 21 C.F.R. § 1316.67, and it didn’t take it.

Despite having the opportunity, Suntree never raised the delay issue before petitioning for review of the Acting Administrator’s decision. Because Suntree raises the delay issue for the first time here, the issue is waived. See *United States v. L.A. Trucker Truck Lines, Inc.*, 344 U.S. 33, 36–37 (1952) (“We have recognized

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<sup>3</sup> Because we conclude that substantial evidence supported the Acting Administrator’s finding that Suntree violated its corresponding responsibility by filling prescriptions for patients without first resolving red flags, we do not need to reach the issue of whether Suntree violated Florida law by dispensing prescriptions from a prescribing physician to himself or by failing to document the resolution of red flags.



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in more than a few decisions, and Congress has recognized in more than a few statutes, that orderly procedure and good administration require that objections to the proceedings of an administrative agency be made while it has opportunity for correction in order to raise issues reviewable by the courts.” (footnotes omitted)); *Polypore Int’l, Inc. v. Fed. Trade Comm’n*, 686 F.3d 1208, 1219 n.13 (11th Cir. 2012) (“Polypore [didn’t] raise[] this issue before the Commission . . . so the issue is waived.”); *Nuclear Energy Inst., Inc. v. Env’t Prot. Agency*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) (“It is a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review.”).

**PETITION DENIED.**