FOR PUBLICATION

In the
United States Court of Appeals
For the Eleventh Circuit

No. 23-10340

SUALEH KAMAL ASHRAF,

Petitioner,

versus

UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Review of a Decision of the
Drug Enforcement Agency
Agency No. 4410-09-P

Before ROSENBAUM, ABUDU, and TJOFLAT, Circuit Judges.

ABUDU, Circuit Judge:

Doctor Sualeh Ashraf petitions for review of a Drug Enforcement Administration's ("DEA") final order that revoked his certificate of registration ("COR") to dispense controlled

substances, denied his pending application for a COR, and denied any other pending applications he submitted.[1] The DEA Administrator issued the final order after finding Dr. Ashraf violated several federal and state laws dealing with dispensing, storing, reporting, and labeling controlled substances, and determined that allowing him to retain his registration was inconsistent with the public interest. On appeal, Dr. Ashraf asserts that the DEA violated his procedural due process rights. He also argues that he never authorized or issued the prescriptions which served as the basis for some of the alleged violations of federal and state laws. Finally, he contends that, under *Ruan v. United States*, 597 U.S. 450 (2022), to revoke his COR, the DEA was required, but failed, to find that he knowingly and intentionally issued unauthorized prescriptions for controlled substances.

After carefully reviewing the record and the parties' briefs, and with the benefit of oral argument, we deny Dr. Ashraf's petition for review.

I. FACTUAL BACKGROUND & PROCEDURAL HISTORY

Dr. Ashraf, a physician licensed in Florida, worked at a weight management clinic called "Doctor Drop It Like It's Hot" (the "Clinic"), which was owned and operated by Jesusadelaida Lopez ("J.L."). Dr. Ashraf met J.L. at the Heart of Florida Hospital

[1] We refer to petitioner as "Dr. Ashraf" throughout this opinion to reflect his professional designation at the time, and we have no information suggesting that he no longer has a valid medical license.

when she was a pharmacy technician, and in late 2016 or early 2017, the two opened a weight-loss clinic together. J.L. managed the Clinic's day-to-day operations, and Dr. Ashraf worked with and supervised her daily. However, about a year later, Dr. Ashraf claims their relationship became strained after J.L. informed the police that some controlled substances were missing from the Clinic, which triggered an investigation by local police and the DEA. Soon after the DEA began its inquiries, Dr. Ashraf gave J.L. notice that he no longer wanted to work for the Clinic.

While he was at the Clinic, Dr. Ashraf's responsibilities included maintaining a COR under the Controlled Substances Act ("CSA"), 21 C.F.R. § 1301.11, in order to dispense controlled substances from the Clinic. The CSA establishes "a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005) (citing 21 U.S.C. §§ 841(a)(1), 844(a)). It gives the Attorney General the authority to deny, revoke, or suspend CORs, and the Attorney General has delegated that authority to the DEA. *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 827 (11th Cir. 2018); 21 U.S.C. §§ 823(f), 824(a). The DEA may deny, revoke, or suspend a COR for several reasons, including if it finds the registrant has acted "inconsistent with the public interest." 21 U.S.C. §§ 823(f), 824(a)(4).

Before taking such action, the DEA must serve the registrant an "order to show cause" that gives a registrant an opportunity to

contest the proposed DEA action. *Id.* § 824(c). The order must (1) contain the basis for the DEA action, including specific citations to law and regulations that the registrant allegedly violated; (2) provide the registrant an opportunity for a hearing before an administrative law judge; and (3) notify the registrant of the opportunity to submit a corrective action plan. *Id.* An administrative law judge must then prepare a report and certify the record to the DEA Administrator. 21 C.F.R. §§ 1316.65. If the registrant does not request a hearing within 30 days of the publication of the order to show cause, he waives his right to a hearing. *Id.* § 1301.43. After that, and "[a]s soon as practicable," the Administrator must publish a final order with findings of fact and conclusions of law. *Id.* § 1316.67.

Here, the DEA had issued Dr. Ashraf a COR to possess and dispense controlled substances from the Clinic, which was set to expire on June 30, 2024. On January 6, 2021, he filed an application for an additional COR for a different location in Florida. The DEA became concerned that Dr. Ashraf was potentially violating the CSA after local police informed them that controlled substances had been stolen from the Clinic. Subsequently, Diversion Investigator Peter Flagg launched an investigation into Dr. Ashraf and the Clinic, which encompassed site inspections, audits, document requests, interviews with local police, and enlisting an expert, Mark Rubenstein, M.D., to review prescriptions Dr. Ashraf issued. Flagg then signed a declaration which memorialized his findings and the evidence that supported those findings.

First, Flagg concluded that Dr. Ashraf issued over 30 prescriptions for controlled substances without a valid doctor-patient relationship. The DEA informally requested, and later issued, a subpoena for specific patient files, but Dr. Ashraf failed to turn over any documentation justifying any of these prescriptions. After reviewing the relevant files, Dr. Rubenstein noted that there were no records in the files showing that Dr. Ashraf had a physician-patient relationship with those who received prescriptions. However, as Dr. Rubenstein determined, the types and quantities of prescriptions he was prescribing would have required such a relationship. Dr. Rubenstein also found that Dr. Ashraf's pattern or practice of prescribing drugs "demonstrated a lack of reasonable skill or safety to [the] patients," his method of prescribing controlled substances "was not within the usual scope of professional practice," and his deviation from standard practice lacked any "legitimate medical purpose."

Second, Flagg concluded Dr. Ashraf did not maintain proper records regarding how he dispensed controlled substances based on site inspections at the Clinic, he failed to produce such records when specifically requested, and he never produced an inventory of controlled substances as required by 21 C.F.R. § 1304.11(b), stating instead that J.L. possessed the inventory. Based on an audit of the Clinic's invoices and inventory, Dr. Ashraf did not have the proper reporting records for a purchase of the controlled substance phentermine, and he could not account for 25,000 dosage units that were missing. Dr. Ashraf also neglected to report the dispensing of phentermine to the Florida Prescription Drug Monitoring Program

based on a review of an online reporting site. Although Dr. Ashraf reported the theft of phentermine to the local police after the incident, there was no evidence showing he reported the theft to the DEA. Finally, based on a site inspection, Dr. Ashraf was dispensing phentermine in containers without the proper warning label and failed to store phentermine in a securely locked cabinet as required.

Based on Flagg's investigation and the evidence he collected, the DEA served Dr. Ashraf an Order to Show Cause (the "Order") that notified him that the DEA intended to revoke his COR and deny his current and any other pending COR applications, finding "such registrations are inconsistent with the public interest." The Order included the laws and regulations that Dr. Ashraf allegedly violated and the facts to support those allegations and informed him of his opportunity to challenge the proposed DEA actions. Specifically, the Order notified Dr. Ashraf that his improper issuance of at least 35 prescriptions violated 21 C.F.R. § 1306.04(a) and Fla. Stat. §§ 456.072(gg), 456.44(3)(a), (b), (c), & (f), and 458.331(1)(m) & (q), and that his inadequate inventory system, record-keeping, reporting, labeling, storage, and dispensing practices violated 21 C.F.R. §§ 1304.03(b), 1304.22(c), 1304.11(b), 1301.76(a) & (b), and 290.5, as well as Fla. Stat. § 893.055(3)(a). The Order also informed Dr. Ashraf of his right to request a hearing in front of an administrative law judge and his right to submit a Corrective Action Plan, and it included all the procedures and deadlines to do both.

Dr. Ashraf later submitted a Corrective Action Plan in which he denied any wrongdoing on his part and accused J.L. of having "most likely forged [his] signature" on the prescriptions at issue. He then described three remedial measures that he would take to address the DEA's findings and CSA violations: (1) he would not leave his prescription pads outside of his briefcase or allow anyone other than himself to handle his prescriptions, (2) he would not allow anyone other than himself to call prescriptions to pharmacies, and (3) he would better monitor the prescription activity occurring under his name. Dr. Ashraf did not request a hearing, but he did ask permission to implement his proposed Corrective Action Plan in lieu of having his COR revoked and his pending application denied. The DEA rejected his request and sought a final order from the Administrator revoking his COR and denying his current and any other pending COR applications.

On January 6, 2023, the Administrator issued a Final Order granting the DEA's revocation request. The Administrator concluded that the "Government's evidence satisfie[d] its prima facia burden of showing that [Dr. Ashraf's] continued registration would be 'inconsistent with the public interest.'" Although the Administrator considered all five factors used to determine the public interest, it confined its decision to factor two—"compliance with applicable State and local law," 21 U.S.C. § 823(f)(2)—and factor four—"past experience in the distribution of controlled substances," *id.* § 823(f)(4). The Administrator accepted and adopted most of the factual findings set forth in the Order to Show Cause and agreed that Dr. Ashraf had violated the statutory provisions the DEA

identified. The Administrator also highlighted Dr. Ashraf's failure to accept responsibility for his own actions which led to the CSA violations by blaming J.L. for the malfeasances and referring to her as the "criminal mind and the criminal muscle." Overall, the Administrator concluded that Dr. Ashraf's proposed Corrective Action Plan did not adequately resolve his numerous violations and did not ensure he would comply with federal and state laws moving forward. Instead, it found there was "simply no evidence that Registrant's behavior is unlikely to recur in the future such that the Agency can entrust him with a CSA registration, and when considered with the scope of Registrant's misconduct as well as considerations of deterrence," the factors weighed in favor of revoking Dr. Ashraf's COR and denying his current and any other pending applications. Dr. Ashraf timely petitioned for review of the DEA's final decision.

II. STANDARD OF REVIEW

We review an agency's final decision to revoke or deny a registrant's COR for abuse of discretion, and therefore only set aside such decision if it is "arbitrary, capricious . . . or otherwise not in accordance with the law." *Jones*, 881 F.3d at 829 (quoting 5 U.S.C. § 706(2)(A)). We give the agency making the final decision deference when we apply the arbitrary and capricious standard. *Id.* We cannot substitute the agency's decision with our own when the agency's conclusions are rational and based on the evidence available. *Id.* However, we may set aside an agency decision as "arbitrary and capricious" if, among other issues, the agency relied on factors not intended by Congress, ignored an important aspect of

the issue, or offered an explanation for its decision that contradicts the evidence before it. *Id*.

That said, we accept the DEA Administrator's findings of fact as conclusive if they are supported by substantial evidence. *Id.*; 21 U.S.C. § 877. The substantial evidence standard is lower than the preponderance of the evidence standard and is met when a reasonable person would consider the relevant evidence adequate to support, in this particular case, the DEA Administrator's factual findings. *Jones*, 881 F.3d at 829. Thus, even if a reasonable person could reach an opposite conclusion, we will still affirm the Administrator's findings if there is nevertheless substantial evidence to support it. *Id.*

III. DISCUSSION

Dr. Ashraf contends the Administrator's final order must be set aside because the DEA violated his procedural due process rights in revoking his COR. Additionally, he argues he never authorized or issued the prescriptions at issue that served as the basis for some of the alleged violations of federal and state laws. Finally, he asserts that, pursuant to *Ruan v. United States*, 597 U.S. 450 (2022), to revoke his COR, the DEA was required, but failed, to find that he knowingly and intentionally issued unauthorized controlled substances prescriptions. We take each argument in turn.

A. Due Process Challenge to the DEA's Actions

Dr. Ashraf maintains he was not given adequate notice because he was not informed of what he was "truly accused of" and was not given a copy of some of the evidence used by the DEA in

its decision to revoke his COR. Although Dr. Ashraf's argument is unclear as to what procedural due process rights he thinks were violated, his concerns can be addressed by applying an account of the facts to general due process principles.

To succeed on a procedural due process claim, an appellant must prove: "(1) a deprivation of a constitutionally-protected liberty or property interest; (2) state action; and (3) constitutionally-inadequate process." *Grayden v. Rhodes*, 345 F.3d 1225, 1232 (11th Cir. 2003). Procedural due process requires adequate notice and a meaningful opportunity to be heard. *Mathews v. Eldridge*, 424 U.S. 319, 333, 348–49 (1976). "Due process 'is not a technical conception with a fixed content unrelated to time, place and circumstances,' but rather is 'flexible' and 'requires analysis of the governmental and private interests that are affected.'" *Schultz v. Alabama*, 42 F.4th 1298, 1332 (11th Cir. 2022) (quoting *Mathews*, 424 U.S. at 334). In determining whether there has been constitutionally inadequate process, we apply the balancing test from *Mathews* and "look to the nature of the private interest affected, the risk of erroneous deprivation, the value of additional safeguards, and the government's interest, including any burdens." *Id.* Where the government has provided the opportunity for a remedy to address the deprivation of the constitutionally protected interest, but the appellant "failed to take advantage of" it, the appellant cannot rely on that failure to prove that he was deprived of procedural due process. *Cotton v. Jackson*, 216 F.3d 1328, 1331 (11th Cir. 2000).

In *Jones*, a procedural due process case in the context of DEA COR revocations, the appellant argued the administrative law judge's denial of discovery of a report the government's expert prepared violated its due process rights. 881 F.3d at 823, 834–35. We explained that "discovery must be granted if in the particular situation a refusal to do so would so prejudice a party as to deny him due process." *Id.* (quoting *McClelland v. Andrus*, 606 F.2d 1278, 1285 (D.C. Cir. 1979)). We then held that the appellant was not prejudiced by the administrative law judge's denial of discovery because the "Petitioners were fully informed of the government's theory of the case and the evidence that it intended to rely on. Any suggestion that they were unable to dispute the government expert's findings or her credibility is purely speculative." *Id.* at 835.

Here, Dr. Ashraf was given adequate notice that the DEA sought to revoke his COR in the Order to Show Cause, which expressly warned Dr. Ashraf that he was being given "notice . . . to afford [him] an opportunity to Show Cause . . . as to why the DEA should not revoke [his] DEA Certificate of Registration (COR) . . . ." That document included a "*non-exhaustive summary* of facts and law at issue as well as citations to law and regulations that [Dr. Ashraf had] violated or attempted to violate . . . ." Additionally, the Order informed Dr. Ashraf of his right to request a hearing and his right to submit a corrective action plan (including all the procedures to do both). Further, under 21 C.F.R. § 1316.46, had Dr. Ashraf requested a hearing, he would have had the right to inspect and copy the record bearing on the hearing. Thus, Dr. Ashraf was given an opportunity to be heard and to review the record evidence

that supported the Order, but he did not request a hearing. Dr. Ashraf, therefore, cannot claim he was prejudiced when an adequate remedy was available, but he failed to take advantage of it. *Cotton*, 216 F.3d at 1331. Like the petitioner in *Jones,* Dr. Ashraf was fully informed of the government's basis for revocation and denial and informed of the evidence on which it intended to rely. 881 F.3d at 835.

Accordingly, the DEA did not violate Dr. Ashraf's procedural due process rights when it fully informed him of the law and facts at issue, gave him notice of the revocation proceedings, and afforded him an opportunity for a hearing, which he declined.

B. Evidentiary Challenge to the DEA's Actions

Dr. Ashraf also contends he never authorized or issued the 35 prescriptions the DEA concluded were improper, but rather J.L. forged his signature on those prescriptions.

In a dispute over the denial, revocation, or suspension of a COR, "[t]he government bears the initial burden of proving that registration is inconsistent with the public interest," and, "[i]f the government proves its *prima facie* case, the burden of proof shifts to the registrant to show why it can be trusted with a registration." *Id.* at 830. The DEA Administrator must consider each of the following factors in determining the public interest: (1) maintenance of effective controls to prevent diversion of particular controlled substances into non-legitimate channels; (2) compliance with applicable state and local law; (3) prior convictions under federal or state laws relating to the manufacture, distribution, or dispensing of

controlled substances; (4) past experience in the distribution of controlled substances; and (5) any other factors bearing on public health and safety. 21 U.S.C. § 823(f). Additionally, the DEA can weigh a registrant's acceptance of responsibility in determining if registration should be revoked because, if a registrant has previously failed to meet its responsibilities, it is reasonable for the agency to assess whether the registrant will change its behavior in the future. *Jones*, 881 F.3d. at 830–31. Although the DEA must consider each factor, it does not need to make an explicit finding on each and maintains discretion to weigh the factors as it deems appropriate. *Id.* at 829–30; *see also* Robert A. Leslie, M.D., 68 Fed. Reg. 15227, 15230 (Drug Enf't Admin. Mar. 28, 2003) (revocation of registration) ((DEA considers public interest factors in the disjunctive); *Morall v. Drug Enf't Admin.*, 412 F.3d 165, 173-74 (D.C. Cir. 2005) (DEA weighs each factor on a case-by-case basis); David H. Gillis, M.D., 58 Fed. Reg. 37507, 37508 (Drug Enf't Admin. July 12, 1993) (granting of registration) (any one factor, or combination of factors, may be decisive).

Here, the Administrator considered each factor, but focused on factor 2 ("compliance with applicable State and local laws" 21 U.S.C. § 823(f)(2)) and factor 4 ("past experience in the distribution of controlled substances," *id.* § 823(f)(4)), in reaching its conclusion that Dr. Ashraf's pharmaceutical practices were inconsistent with the public interest. As to the issuance of the 35 prescriptions in violation of federal and state law, the DEA submitted copies of those prescriptions, pointed to Dr. Ashraf's failure to provide the necessary medical records to justify their issuance, and

relied on Dr. Rubenstein's expert conclusions to support its finding that they were issued without a legitimate medical purpose and without the appropriate physician-patient relationship. Beyond his own self-serving statements, there is no evidence to support his contention that J.L. forged his signature on those prescriptions and, therefore, he has not met his burden to overcome the government's ample evidence to the contrary. *See Jones*, 881 F.3d at 829–30 ("If the government proves its *prima facie* case, the burden of proof shifts to the registrant to show why it can be trusted with a registration.").

Regardless, Dr. Ashraf admitted to the Polk County Sheriff's Office that he left "pre-signed prescription pads with J.L. for her to use his registration" and trusted her to use them. So, the DEA found, "even if . . . J.L. was the one who misused [Dr. Ashraf's] registration, [he] bears responsibility for her misuse because he entrusted her with his registration."

Additionally, putting those prescriptions aside, the DEA cited to ample unrefuted evidence that Dr. Ashraf violated several other federal and state laws in his handling, dispensing, record keeping, reporting, labeling, and storage of phentermine. Accordingly, we accept as conclusive the DEA Administrator's factual findings, as they are supported by substantial evidence, on which the Administrator based its decision that Dr. Ashraf's continued registration is inconsistent with the public interest. *Id.* at 829; 21 U.S.C. § 877. Thus, the DEA's decision to revoke and deny Dr.

Ashraf's CORs was not arbitrary and capricious. *Jones*, 881 F.3d at 829 (citing 5 U.S.C. § 706(2)(A)).

C. *Application of* Ruan *to 21 U.S.C. Section 824*

Lastly, Dr. Ashraf contends the DEA was required to show that he "knowingly or intentionally acted in an unauthorized manner" before revoking and denying his CORs. Dr. Ashraf bases his argument on *Ruan v. United States*, in which the Supreme Court held that "in a § 841 prosecution in which a defendant meets his burden of production under § 885, the Government must prove beyond a reasonable doubt that the defendant knowingly or intentionally acted in an unauthorized manner." 597 U.S. at 468. Dr. Ashraf maintains he did not have the "necessary *mens rea*" established in *Ruan* because he did not issue the 35 improper prescriptions, but rather J.L. forged his signature.

In *Ruan*, the Court considered *criminal appeals* from two defendants convicted of unlawfully dispensing and distributing drugs in violation of 21 U.S.C. § 841. *Id.* at 454. *Ruan's* holding about the *mens rea* required for a criminal conviction under Section 841 has no bearing on the current non-criminal, regulatory matter of certificate revocations under Section 824. Dr. Ashraf was not criminally charged under Section 841, and neither the DEA final decision nor the Order to Show Cause mention Section 841.

Rather, Dr. Ashraf's license was revoked under the regulatory provisions of Section 824 after a finding that his acts were "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). Section 824 authorizes the Attorney General to suspend or revoke a

registrant's COR upon a finding that he: (1) "has materially falsified any [relevant] application;" (2) "has been convicted of a felony" relating to a controlled substance; (3) "has had his State license or registration suspended, revoked, or denied," by the State authority or it has recommended that such action occur; (4) "has committed such acts as would render his registration . . . inconsistent with the public interest;" or (5) "has been excluded . . . from participation in a program pursuant to section 1320a-7(a) of Title 42." 21 U.S.C. § 824(a). The plain text of Section 824 does not include the words "knowingly" or "intentionally" and, as this is not a criminal statute, does not establish that a registrant have a specific *mens rea* for the Attorney General to suspend or revoke a COR.

In construing a statute, we of course look to the plain meaning of the text, and we are not permitted to add words to the statute that are not in that text. *Romag Fasteners, Inc. v. Fossil, Inc.*, 590 U.S. 212, 215 (2020); *Fernandez v. Seaboard Marine LTD.*, 135 F.4th 939, 949 (11th Cir. 2025). Courts should be "doubly careful to avoid" adding words "when Congress has . . . included the term in question elsewhere in the very same statutory provision." *Romag Fasteners*, 590 U.S. at 215. Other sections of the CSA distinguish between criminal and civil or administrative proceedings. For example, Section 842(a) requires a "knowing" *mens rea* for criminal liability but, under the same provision, does not require it for civil liability. *See* 21 U.S.C. § 842(c), (c)(2)(A). That makes sense. After all, when it comes to determining whether a person's registration is in the public interest, the DEA has long held that "unintentional" or "innocent" misconduct "does not preclude revocation or

denial." Bobby D. Reynolds, N.P., Tina L. Kellebrew, N.P., & David R. Stout, N.P., 80 Fed. Reg. 28,643, 28,662 (Drug Enf't Admin. May 19, 2015) (decision) (quoting Paul J. Caragine, Jr., 63 Fed. Reg. 51,592, 51,601 (Drug Enf't Admin. Sept. 28, 1998) (grant of restricted registration)). Nothing in *Ruan* intimates that the Supreme Court meant for its holding to extend beyond criminal proceedings under Section 841 to administrative certificate revocation proceedings under Section 824, and no outside authority supports such an extension. Accordingly, Section 824 does not require a finding that the registrant "knowingly or intentionally acted in an unauthorized manner." Thus, the Administrator's decision was not contrary to law in this respect.

For the reasons explained above, all of Dr. Ashraf's arguments on appeal fail.

PETITION DENIED.

TJOFLAT, Circuit Judge, concurring:

I write separately to emphasize one point. The Order to Show Cause informed Dr. Ashraf of the facts against him and of his right to request a hearing before an administrative law judge. The purpose of such a hearing is for the Administrator to "receiv[e] factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration." 21 C.F.R. § 1301.42. In other words, the hearing is the proper place for Dr. Ashraf to first challenge the facts against him, not here. When Dr. Ashraf did not request that hearing, he waived the opportunity. Had he requested a hearing and made these challenges there, there might be something for us to discuss now. But this Court is not the place for parties to redo what they've come to regret.[1] Dr. Ashraf had notice of his right to appear and dispute the facts against him. When he rejected that opportunity, he left the facts in the Order to Show Cause undisputed, and the Agency rightly acted on them. There was no denial of due process, and no evidentiary challenges should be entertained at this point.

[1] Dr. Ashraf's Corrective Action Plan did seemingly "respond" to the allegations in the Order to Show Cause, but that is irrelevant here. The plan, like this Court, is not a place to challenge factual allegations, and Dr. Ashraf was informed as such. He was "advised that the submission of a corrective action plan shall not constitute a request for a hearing . . . or a written statement regarding [his] position on the matters of fact and law involved" and that he "must separately submit a request for a hearing . . . or a written statement."