

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 16-17346
Non-Argument Calendar

Agency No. 15-2

JONES TOTAL HEALTH CARE PHARMACY, LLC,
SND HEALTHCARE, LLC,

Petitioners,

versus

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Review of a Decision of the
Drug Enforcement Agency

(January 29, 2018)

Before MARTIN, ROSENBAUM, and ANDERSON, Circuit Judges.

PER CURIAM:

Before this Court is a petition for review of a final order of the United States Drug Enforcement Administration (“DEA”) revoking Jones Total Health Care

Pharmacy, LLC's ("Jones Pharmacy") certificate of registration under the Controlled Substances Act ("CSA") to dispense controlled substances and denying SND Healthcare, LLC's ("SND Healthcare") application for a certificate of registration to dispense controlled substances. The DEA Acting Administrator revoked Jones Pharmacy's registration after determining that it unlawfully dispensed controlled substances and that Cherese Jones, the pharmacy's owner and operator, failed to accept full responsibility for the misconduct. Because Jones also owned and operated SND Healthcare, the Acting Administrator denied SND Healthcare's pending application for the same reasons. Jones Pharmacy and SND Healthcare ("Petitioners") then filed this petition for review, arguing that the DEA's decision is arbitrary and capricious. We disagree, so we deny the petition for review.

I.

Jones Pharmacy is a community pharmacy started by Jones in Fort Lauderdale. Jones graduated from Texas A&M University with a Doctor of Pharmacy degree in 2000 and worked in clinical and retail pharmacy positions before opening Jones Pharmacy in February 2010.

Jones Pharmacy was registered with the DEA to dispense substances controlled by the CSA, 21 U.S.C. § 801, *et seq.* In 2013, Jones sought to open

SND Healthcare and submitted an application for registration to dispense controlled substances through that entity.

The CSA creates “a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *See Gonzales v. Raich*, 545 U.S. 1, 13 (2005). Pharmacies that dispense prescription medications that are controlled substances are required to obtain proper registration from the Attorney General. *See* 21 U.S.C. §§ 822(a), 823(f); *Gonzales v. Oregon*, 546 U.S. 243, 250–51 (2006). Under the CSA, the responsibility for the proper prescribing and dispensing of controlled substances, which must be for “a legitimate medical purpose,” is on the prescribing practitioner, “but a corresponding responsibility rests with the pharmacist who fills the prescription.” 21 C.F.R. § 1306.04(a). Thus, pharmacists have a “corresponding responsibility” to refuse to fill prescriptions that are not issued for a legitimate medical purpose. *See id.*

The Attorney General has the authority to deny, revoke, or suspend registrations. *See* 21 U.S.C. §§ 823(f), 824(a). The Attorney General has delegated this authority to the DEA. *See United States v. Lippner*, 676 F.2d 456, 460 (11th Cir. 1982) (holding that the functions vested in the Attorney General by the Comprehensive Drug Abuse Prevention Act were properly delegated to the DEA). When an existing registration is proposed for revocation, the DEA must

serve an “order to show cause” on the registrant and give the registrant an opportunity for a hearing before an Administrative Law Judge (“ALJ”) in order to contest the proposed action. *See* 21 U.S.C. § 824(c).

On October 6, 2014, the DEA issued an order to show cause proposing to revoke Jones Pharmacy’s existing registration and to deny SND Healthcare’s application for registration. In the order, the DEA alleged that, from February 2010 to July 2012, Jones Pharmacy “repeatedly failed to ensure that it filled only prescriptions issued for legitimate medical purposes within the usual course of professional practice.” Jones Pharmacy, according to the order, repeatedly ignored “obvious and unresolvable red flags of diversion.” The order also alleged record-keeping violations. According to the order, Jones Pharmacy’s practices warranted denial of SND Healthcare’s application because Jones was the owner and operator of both entities and they were one integrated enterprise.

Petitioners requested a hearing, which was held before an ALJ in March 2015. At the hearing, the ALJ heard testimony from several persons, including Domingo Gonzales (a DEA diversion investigator), Mary Crane (a Pharmacy Inspector for the Florida Department of Health), Dr. Tracy Gordon (the government’s expert), Donna Horn (Jones Pharmacy’s expert), and Jones.

After the hearing, the ALJ issued her findings of fact, conclusions of law, and recommendations that the DEA Acting Administrator revoke Jones

Pharmacy's registration and deny SND Healthcare's application for registration. The ALJ credited the testimony of Gordon, who reviewed over one-hundred prescriptions filled by Jones Pharmacy between February 2010 and July 2012 and found that they had one or more "red flags"—indicia that the prescriptions were not issued for a legitimate medical purpose—and should not have been filled. According to Gordon, these red flags included the following: (1) individuals traveling long distances to fill prescriptions; (2) prescriptions for drug "cocktails," known for their abuse potential, such as oxycodone and Xanax; (3) individuals who arrived together with identical or nearly identical prescriptions; (4) purported pain patients with prescriptions for immediate-release rather than long-acting narcotics; (5) cash purchases; and (6) doctors prescribing outside the scope of their usual practice. The ALJ credited Gordon's testimony that many of these red flags could not have been resolved by the pharmacists. Accordingly, the ALJ determined that Jones Pharmacy violated its "corresponding responsibility" by filling controlled-substances prescriptions with unresolved red flags.

Crediting Gonzales's testimony and other evidence submitted by the government, the ALJ also found additional indicators that Jones Pharmacy dispensed controlled substances unlawfully. The ALJ cited statistics showing that, from February 2010 to July 2012, Jones Pharmacy's business was based primarily on sales of controlled substances. In addition, of the more than 3,000 controlled-

substance prescriptions filled, 99% were for immediate-release drugs, 89% were for “cocktail” drugs, and 93% were paid for in cash. The ALJ noted that these statistics were “unusually high compared to national averages.” For instance, according to a report from the IMS Institute of Healthcare Informatics, the national average for cash sales between 2007 and 2011 was 6%. The ALJ also found that Jones Pharmacy’s high markup on the price per pill—including 415 instances where the markup on the price per pill was over 1,000%—combined with the high rate of cash-based customers indicated diversion because “it elucidates a customer base willing to pay exorbitant prices for a drug the customer could otherwise purchase at a nearby pharmacy for much less.”

The ALJ rejected Petitioners’ contentions that Jones was unaware of the concept of “red flags” and that she did not know or have reason to know that the prescriptions filled by Jones Pharmacy were not written for a legitimate medical purpose. The ALJ was unpersuaded by testimony offered by Jones Pharmacy’s expert Horn, who stated that pharmacists were generally unaware of the concept of red flags during the relevant time period. Instead, the ALJ credited the contrary testimony of the government’s expert, Gordon, and concluded that “the concept of red flags has long been recognized as a reflection of the norms of the pharmacy profession,” so Jones Pharmacy’s purported ignorance was not a credible defense.

Having found that the government met its burden of establishing a *prima facie* case that revocation of Jones Pharmacy's registration was in the public interest, the ALJ then addressed whether Jones Pharmacy put forward sufficient evidence to show that it could be trusted with a registration going forward. The ALJ explained that a registrant must establish two things to rebut the government's *prima facie* case: (1) full acceptance of responsibility and (2) remedial measures so that such violations will not happen in the future. Based on Jones's testimony at the hearing, the ALJ determined that she had not fully accepted responsibility for Jones Pharmacy's unlawful dispensing of controlled substances. Citing agency precedent holding that acceptance of responsibility is an independent and essential requirement for rebutting the government's *prima facie* case, the ALJ declined to address Jones Pharmacy's remedial efforts. *See, e.g., Holiday CVS, L.L.C.*, 77 Fed. Reg. 62316, 62323, 2012 WL 4832770 (Oct. 12, 2012).

Petitioners filed exceptions in May 2015, which the Acting Administrator overruled in a 54-page final order issued on October 31, 2016. Addressing and rejecting many of the arguments we are faced with here, and which we address in more detail below, the Acting Administrator adopted the ALJ's recommendations. This petition for review followed. *See* 21 U.S.C. § 877.

II.

We may set aside the Acting Administrator’s final decision if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.” 5 U.S.C. § 706(2)(A). “The arbitrary and capricious standard is exceedingly deferential.” *Def. of Wildlife v. U.S. Dep’t of Navy*, 733 F.3d 1106, 1115 (11th Cir. 2013) (internal quotation marks 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. *Miccosukee Tribe of Indians of Fla. v. United States*, 566 F.3d 1257, 1264 (11th Cir. 2009). Nevertheless, we may set aside a decision as “arbitrary and capricious when, among other flaws, the 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.” *High Point, LLLP v. Nat’l Park Serv.*, 850 F.3d 1185, 1193–94 (11th Cir. 2017) (internal quotation marks omitted).

The Acting Administrator’s factual findings are conclusive if supported by substantial evidence. 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. *Consolo v. Fed. Mar. Comm’n*, 383 U.S. 607, 619–90 (1966). An administrative agency’s finding is supported by substantial evidence even if “two inconsistent conclusions [could be drawn] from the evidence.” *Id.*

III.

The DEA may revoke registration to dispense controlled substances upon a finding that the registrant “has committed such acts as would render his registration . . . inconsistent with the public interest.” 21 U.S.C. § 824(a)(4). Likewise, the DEA may deny registration to dispense controlled substances if such registration is “inconsistent with the public interest.” 21 U.S.C. § 823(f).

Section 823 lists five factors that “shall be considered” in determining the public interest. 21 U.S.C. § 823(f). These factors include “[t]he applicant’s experience in dispensing, or conducting research with respect to controlled substances,” as well as “[c]ompliance with applicable State, Federal, or local laws relating to controlled substances.” *Id.* § 823(f)(2), (4).¹ The Acting “Administrator must consider each factor, though he need not make explicit findings as to each one and can give each factor the weight [he] determines is

¹ In full, the statute directs that the following five factors shall be considered in determining the public interest:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing, or conducting research with respect to controlled substances.
- (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).

appropriate.” *Akhtar-Zaidi v. Drug Enf’t Admin.*, 841 F.3d 707, 711 (6th Cir. 2016).

The government bears the initial burden of proving that registration is inconsistent with the public interest. 21 C.F.R. § 1301.44(d), (e). 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. *Morall v. Drug Enf’t Admin.*, 412 F.3d 165, 174 (D.C. Cir. 2005).

Here, Petitioners do not dispute that the government met its initial burden of proving that Jones Pharmacy’s registration was inconsistent with the public interest. The record supports the agency’s determination that Jones Pharmacy unlawfully filled numerous controlled substance prescriptions that were not issued for a legitimate medical purpose. *See* 21 C.F.R. § 1306.04(a). As discussed above, the evidence showed that Jones Pharmacy from February 2010 through July 2012 filled over one-hundred prescriptions that had at least one red flag that Jones Pharmacy did not attempt to resolve and that could not have been resolved. The government also put forward other substantial evidence indicating that the controlled substances dispensed by Jones Pharmacy were being diverted for improper use. Accordingly, the agency reasonably determined that revocation of Jones Pharmacy’s registration was in the public interest because of Jones

Pharmacy's failure to comply with federal laws relating to controlled substances. *See* 21 U.S.C. § 823(f)(4).

Petitioners instead challenge as arbitrary and capricious the DEA's determination that Jones Pharmacy did not prove that it could be trusted with a registration notwithstanding the prior misconduct. In particular, Petitioners argue that the agency's finding that Jones, the owner and operator of Jones Pharmacy, did not credibly accept full responsibility is fatally flawed for a number of reasons. The agency, according to Petitioners, misconstrued Jones's testimony, relied too heavily on the severity of the misconduct, and unreasonably refused to consider the remedial measures Jones Pharmacy put in place after the time period at issue. Petitioners also contend that the agency's choice of the most severe sanction—revocation—was inconsistent with prior agency decisions that either suspended or continued registrations despite more egregious misconduct.

We address Petitioners' arguments in three parts. First, we conclude that substantial evidence supports the agency's determination that Jones did not credibly accept full responsibility. Second, we hold that the agency's refusal to consider Jones Pharmacy's remedial measures does not render its decision arbitrary or capricious in the circumstances of this case. Finally, we find that the chosen sanction was not arbitrary or capricious.

A. Acceptance of Responsibility

At the outset, we agree with the other circuits that have addressed this issue that the DEA may properly consider a registrant's acceptance of responsibility in determining if registration should be revoked. *See MacKay v. Drug Enf't Admin.*, 664 F.3d 808, 820 (10th Cir. 2011) ("The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked."); *Hoxie v. Drug Enf't Admin.*, 419 F.3d 477, 483 (6th Cir. 2005) ("The DEA properly considers the candor of the physician and his forthrightness in assisting in the investigation and admitting fault important factors in determining whether the physician's registration should be revoked."). If a pharmacy has failed to comply with its responsibilities in the past, it makes sense for the agency to consider whether the pharmacy will change its behavior in the future. *MacKay*, 664 F.3d at 820; *Alfa Labs., Inc. v. Drug Enf't Admin.*, 54 F.3d 450, 452 (7th Cir. 1995) ("An agency rationally may conclude that past performance is the best predictor of future performance."). "[T]hat consideration is vital to whether continued registration is in the public interest." *MacKay*, 664 F.3d at 820.

Turning to the facts at hand, substantial evidence supports the DEA's determination that Jones did not fully accept responsibility for Jones Pharmacy's unlawful dispensing practices. The ALJ, who heard Jones testify in person and was therefore in the best position to assess Jones's credibility, extensively

reviewed Jones's testimony and found her admission of fault to be equivocal at best. In relevant part, the ALJ summarized Jones's testimony as follows:

Ms. Jones claimed that she was following her corresponding responsibility [to fill only legitimate prescriptions] as she understood it from 2010–2012 when over a hundred prescriptions that were presented with multiple unresolved red flags were dispensed at Jones Pharmacy. Ms. Jones purported to accept responsibility for Jones Pharmacy's dispensing practices by repeatedly asserting that she did what she knew at the time, but now she knows she could have done more.

The ALJ found, however, that Jones made other statements that demonstrated she “does not fully understand her corresponding responsibility even yet today.” For example, Jones indicated on cross-examination that she did not understand that the law required her to make sure that prescriptions were issued for legitimate medical purposes before filling them. And, significantly, she did not admit that Jones Pharmacy's past dispensing practices failed to comply with its legal obligations. Thus, the ALJ concluded that Jones did not accept responsibility and that her claimed ignorance about her legal responsibilities, particularly her continued lack of understanding of those responsibilities, was no excuse. The Acting Administrator agreed with the ALJ's findings after conducting his own review of Jones's testimony.

Petitioners maintain that the agency's assessment of whether Jones accepted responsibility is fatally flawed for a number of reasons. They insist that Jones accepted responsibility by acknowledging and correcting her mistakes, and that the

ALJ's interpretation of her testimony was strained and unreasonable. The ALJ, according to Petitioners, failed to properly consider Jones's explanation that her misunderstanding of her responsibilities was based in part on what she learned while working at other pharmacies earlier in her career. Petitioners also contend that the ALJ, by drawing a negative inference from Jones's attempt to explain why she failed to comply with her corresponding responsibility in the past, imposed a test for acceptance of responsibility "that can only be met by the most blatant offenders" who knowingly violate their responsibilities.

Petitioners' arguments are unpersuasive. To begin with, both the ALJ and the Acting Administrator considered Jones's explanation of her conduct and reasonably concluded that her purported confusion or ignorance was not a valid excuse. Jones believed that it was the prescribing physician's responsibility to issue medically legitimate prescriptions. That may be true, but as a pharmacist registered with the DEA, Jones had a "corresponding responsibility" not to fill prescriptions that were not issued for a medically legitimate purpose. 21 C.F.R. § 1306.04(a). The "corresponding responsibility" rule is not new, *see United States v. Hayes*, 595 F.2d 258, 261 & n.6 (5th Cir. 1979) (holding that pharmacists have an obligation "not to fill an order that purports to be a prescription but is not a

prescription within the meaning of the statute”),² nor is it unreasonable for the DEA to expect a pharmacist entrusted with dispensing highly regulated, addictive, and potentially destructive substances to fully understand her obligations under the law, regardless of prior work experience.

Moreover, the ALJ credited the government’s evidence that a pharmacist who exercised her corresponding responsibility would not have filled the prescriptions that Jones Pharmacy did from February 2010 to July 2012. The government’s evidence reflected that Jones Pharmacy from February 2010 to July 2012 filled at least one-hundred prescriptions with one or more unresolved red flags. In addition, Jones Pharmacy’s business during that time was based substantially on immediate-release “cocktail” pain medications purchased with cash at a high markup on the price per pill.

As the Acting Administrator stated, however, “notwithstanding the obvious and compelling evidence that the prescriptions lacked a legitimate medical purpose, [Jones] continued to deny that the prescriptions were unlawfully dispensed.” To be sure, Jones indicated in her testimony that she was naïve, made mistakes, and could and should have done “more digging” to verify prescriptions. But Petitioners have not identified any clear admission by Jones—regardless of whether she acted knowingly or not—that she understood Jones Pharmacy violated

² This Court adopted as binding precedent all Fifth Circuit decisions prior to October 1, 1981. *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (*en banc*).

its obligations under the CSA. Instead, Jones reiterated her belief that Jones Pharmacy was fulfilling its responsibilities as she understood them at the time.

Jones's refusal to admit that Jones Pharmacy's dispensing practices violated its obligations under federal law reflects that she did not "recognize[] the extent of [the] misconduct." *MacKay*, 664 F.3d at 820. It also supports the factual finding, critical to both the ALJ's and the Acting Administrator's decisions, that Jones did not fully understand her legal obligations as a pharmacist.

Nor was the finding that Jones did not fully understand her obligations under 21 C.F.R. § 1306.04(a) based on some strained interpretation of her testimony. Jones's statements at the hearing show that she continued to struggle with the idea that pharmacists have an independent duty, apart from the prescribing physician, to ensure that prescriptions are issued for medically legitimate purposes before filling them. For instance, when asked on cross-examination whether she knew "one way or another" if she had a corresponding responsibility, Jones answered, "I did not know that the law said that I had to make sure that prescriptions said it was legitimate, medically legitimate[,] even "sitting here today." And despite Jones's assertions to the contrary, pharmacists do not need to practice medicine or independently examine a patient in order to determine in certain cases that a prescription was not issued for a legitimate medical purpose. *See Hayes*, 595 F.2d at 261 & n.6 ("[A] pharmacist can know that prescriptions are issued for no

legitimate medical purpose without his needing to know anything about medical science.”).

Finally, we reject Petitioners’ argument that the ALJ impermissibly required Jones to admit to knowing misconduct in order to accept responsibility. For starters, the record supports an inference of knowing misconduct, even though Jones maintained that the misconduct was not intentional.³ More significantly, however, Jones could have maintained that the misconduct was not intentional while, at the same time, recognizing at the hearing that it nonetheless violated the pharmacy’s obligations under the CSA. We do not know whether the agency would have credited that testimony, of course, but it was reasonable for the agency to conclude that her failure to clearly acknowledge even unintentional misconduct demonstrated a lack of understanding of her legal obligations.

Because the record supports the Acting Administrator’s findings that Jones did not acknowledge the prior misconduct and still did not understand the scope of her responsibilities under the CSA, we conclude that the determination that Jones did not fully accept responsibility for Jones Pharmacy’s misconduct was rational and supported by substantial evidence. *See Miccosukee Tribe*, 566 F.3d at 1264; *Consolo*, 383 U.S. at 619–90.

³ Indeed, the Acting Administrator determined that Jones Pharmacy’s “pharmacists either knew or were willfully blind to the fact that the prescriptions were issued in violation of 21 C.F.R. § 1306.04(a).”

B. Remedial Measures

We acknowledge that Jones Pharmacy appears to have implemented policies to address the misconduct at issue here. According to Petitioners, these remedial efforts are evidence that they can be trusted with registrations going forward, so it was unreasonable for the DEA to ignore that evidence even if Jones did not unequivocally admit fault.

Of course, corrective measures undertaken by a pharmacy are certainly relevant to whether it can be trusted with a registration to dispense controlled substances. At the same time, though, the DEA must have confidence that, if the registration is continued, the pharmacy will faithfully comply with its obligations under the CSA. *See* 21 U.S.C. § 823(f)(4); *Holiday CVS*, 77 Fed. Reg. at 62345–46. If a pharmacy shows that it does not understand the extent of the past misconduct or its current responsibilities under the law, the DEA rationally could doubt that the pharmacy would faithfully comply in the future with its obligations under the CSA.

Here, the DEA's refusal to consider Jones Pharmacy's remedial measures does not render the decision to revoke its registration arbitrary and capricious. The Acting Administrator explained that, based on the scope and duration of misconduct, Jones's failure to acknowledge that misconduct, and her testimony that she still does not understand the scope of a pharmacist's obligations under the

CSA, he had no confidence that either entity owned or operated by Jones (Jones Pharmacy and SND Healthcare) would faithfully comply with the CSA.⁴ We conclude that the Acting Administrator's determination was rational and supported by substantial evidence in the record. *See Miccosukee Tribe*, 566 F.3d at 1264. Accordingly, the Acting Administrator's decision to revoke Jones Pharmacy's registration as inconsistent with the public interest was not arbitrary, capricious, or an abuse of discretion.

C. Choice of Sanction

Petitioners contend that the Acting Administrator unreasonably recommended the severe sanction of revocation when the DEA has imposed lesser sanctions under equal or more egregious circumstances. We disagree.

Under the APA, the agency's "choice of sanction is entitled to substantial deference." *MacKay*, 664 F.3d at 820. It is not to be overturned unless it is "unwarranted in law or without justification in fact." *Butz v. Glover Livestock Comm'n Co., Inc.*, 411 U.S. 182, 186 (1973) (internal quotation marks omitted); *MacKay*, 664 F.3d at 820; *Morall*, 412 F.3d at 181. Where, as here, Congress intended to grant the agency significant discretion, "mere unevenness in the application of the sanction does not render its application in a particular case

⁴ We also note that the Acting Administrator found that, even if Jones had credibly accepted full responsibility, he still would have revoked Jones Pharmacy's registration because the "proven misconduct [was] so extensive and egregious."

‘unwarranted in law.’” *Butz*, 411 U.S. at 186; *see* 21 U.S.C. § 823(f) (directing the DEA to make registration decisions based on the “public interest”). The agency’s sanction may be set aside, however, if it represents a “flagrant departure” from agency policy and practice. *See Chein v. Drug Enf’t. Admin.*, 533 F.3d 828, 835 (D.C. Cir. 2008).

Here, Petitioners have not shown that the agency’s choice of sanction was unwarranted in law or without justification in fact. The DEA decisions Petitioners rely on are distinguishable because, in each of the decisions, the agency found that the registrant had rebutted the government’s case by, among other things, admitting fault or expressing remorse. The general pattern of the cited decisions is that a physician engaged in misconduct attributable in part to alcoholism or drug abuse, sought treatment, did not engage in other misconduct since obtaining treatment, and expressed remorse or otherwise accepted responsibility for the misconduct. *See Karen A. Kruger, M.D.*, 69 Fed. Reg. 7016, 7017–18, 2004 WL 250335 (Feb. 12, 2004); *Theodore Neujahr, D.V.M.*, 65 Fed. Reg. 5680, 5682, 2000 WL 126521 (Feb. 4, 2000); *Jimmy H. Conway, Jr., M.D.*, 64 Fed. Reg. 32271, 32274, 1999 WL 389996 (June 16, 1999); *Robert G. Hallermeier, M.D.*, 62 Fed. Reg. 26818, 26821, 1997 WL 249912 (May 15, 1997).

Petitioners focus on the past misconduct in these cases, but they do not cite any decision in which the DEA has continued a registration despite finding that the

registrant did not fully accept responsibility. Because substantial evidence supports the DEA's finding that Jones did not accept responsibility for the misconduct in this case, Petitioners have not shown that the agency's choice of sanction represented a flagrant departure from prior practice. *See Chein*, 533 F.3d at 835. Therefore, the agency's decision to revoke Jones Pharmacy's registration was not arbitrary or capricious.

IV.

Finally, Petitioners argue that the ALJ violated their due-process rights by denying discovery of a report prepared by the government's expert, Tracy Gordon. Petitioners contend that, without the report, they were unable to challenge the expert's credibility and the basis of her opinions.

As a general matter, a party's entitlement to discovery in an administrative proceeding is governed by the agency's own rules. *See, e.g., McClelland v. Andrus*, 606 F.2d 1278, 1285 (D.C. Cir. 1979). Nevertheless, the agency is bound to ensure that its procedures meet basic due process requirements. *Id.* at 1285–86. “Therefore, 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.* at 1286.

The Acting Administrator found that Petitioners were not prejudiced because they were “fully apprised of the Government's theory of the case and the evidence it intended to rely on and [they] had ample opportunity to prepare a defense.” The

Acting Administrator further noted that the report was not offered as evidence and that Petitioners were able to fully cross-examine the expert about her testimony and the basis of her opinions at the hearing. Finding Petitioners' claim of prejudice purely speculative, the Acting Administrator concluded that the ALJ properly denied discovery of the expert's report.

Here, we agree with the Acting Administrator that Petitioners have not shown prejudice flowing from the denial of discovery of the expert report. Petitioners claim that they needed the report because it "formed the basis of the DEA's case," but as the Acting Administrator found, 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. Accordingly, the agency did not violate Petitioners' due-process rights by denying discovery of the expert's report.

V.

For the reasons stated, the DEA Acting Administrator's decision to revoke Jones Pharmacy's registration to dispense controlled substance was not "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *See* 5 U.S.C. § 706(2)(A). The factual findings underlying that decision were supported by substantial evidence, and Petitioners have demonstrated no fatal flaw

in the proceedings or reasoning leading to the revocation decision. *See High Point*, 850 F.3d at 1193–94. Finally, Petitioners do not challenge the DEA’s determination that Jones Pharmacy’s practices are an appropriate basis to deny SND Healthcare’s application for registration. Accordingly, we deny Petitioners’ petition for review.

PETITION DENIED.