NO. 22-_____

In the Supreme Court of the United States

SUNTREE PHARMACY AND
SUNTREE MEDICAL EQUIPMENT, LLC,

Petitioners,

v.

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

On February 14, 2022, a three-judge panel of the Eleventh Circuit upheld the DEA Administrator's decision to revoke Suntree Pharmacy's DEA registration interpreting 21 C.F.R. § 1306.04(a) to not require evidence of a prescription's illegitimacy before deciding it was dispensed in violation of the regulation.

This vague regulation is fraught with misconceptions. In *Gonzales,* the Attorney General thought he could interpret "legitimate medical purpose" under § 1306.04(a). *Gonzales v. Oregon*, 546 U.S. 243 (2006). The Court explained, however, he exceeded his limited authority under the Act. *Id*. More recently, a circuit split as to whether "knowingly" applied to "except as authorized" under the CSA brought the regulation back before the Court. *Ruan v. United States*, 597 U.S. ___ (2022) (slip op.).

This Petition raises a third misconception. In ignoring *Gonzales*, the DEA has interpreted "legitimate medical purpose" so that a pharmacy violates its corresponding responsibility whether or not there is evidence of a prescription's illegitimacy. *Holiday CVS,* Fed. Reg. 62316 (2012). This *ultra vires* authority has allowed the DEA to discipline pharmacists for failing to resolve "red flags" before filling a prescription. *See Id*. Sadly, when challenged in court, the DEA hides behind the great deference awarded to administrative agencies. This Petition seeks to fight this harmful deference and asks the Court:

Whether a pharmacy violates its corresponding responsibility under 21 C.F.R. § 1306.04(a) and knowingly fills a prescription for a controlled substance not issued for a legitimate medical purpose where the prescription's legitimacy remains undetermined?

PARTIES TO THE PROCEEDINGS

Petitioners

- Suntree Pharmacy
- Suntree Medical Equipment, LLC

Hereinafter, collectively "Suntree Pharmacy"

Respondent

- Drug Enforcement Administration

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, neither Suntree Pharmacy nor Suntree Medical Equipment, LLC is a publicly held company, has a parent corporation, or has a publicly held company which owns 10 percent or more of its stock.

LIST OF PROCEEDINGS

Administrative Law Judge

Department of Justice,
Drug Enforcement Administration

85 Fed. Reg. 73753

Suntree Pharmacy & Suntree Med. Equip., LLC,
Plaintiff, v. *Drug Enforcement Administration,*
Defendant

Date Decision Issued: Nov. 19, 2020

Date Decision Effective: December 21, 2020

Direct Appeal

United States Court of Appeals for the Eleventh Circuit

Case No.: 20-14626

Suntree Pharmacy & Suntree Med. Equip., LLC,
Plaintiff, v. *Drug Enforcement Administration,*
Defendant

Date of Judgment: February 14, 2022

Date of Rehearing Denial: May 5, 2022

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

Page

APPENDIX TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

Page

STATUTES

TABLE OF AUTHORITIES – Continued

Page

REGULATIONS

LEGISLATIVE MATERIALS

TABLE OF AUTHORITIES – Continued

Page

OTHER AUTHORITIES

TABLE OF AUTHORITIES – Continued

Page

OPINIONS BELOW

The opinion of the U.S. Court of Appeals for the Eleventh Circuit appears in the Appendix at App.1a and can be found at *Suntree Pharmacy and Suntree Medical Equip, LLC v. DEA*, No. 20-14626, 2022 U.S. App. (11th Cir. Feb. 14, 2022). (App.1a). This opinion was not designated for publication. The decision and order of the Department of Drug Administration appears in the appendix at App.17a and can be found in the Federal Register at Fed. Reg. 73753.

JURISDICTION

On February 14, 2022, a three-judge panel of the Eleventh Circuit Court of Appeals entered its opinion in *Suntree Pharmacy and Suntree Medical Equip, LLC v. DEA*, No. 20-14626, 2022 U.S. App. (11th Cir. Feb. 14, 2022). (App.1a). Plaintiff, Suntree Pharmacy filed a Petition for Panel Rehearing, or alternatively, En Banc Rehearing, which the Court denied on May 5, 2022 (App.281a). This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

REGULATIONS AND STATUTES INVOLVED

21 C.F.R. § 1306.04(a)

> A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 U.S.C. § 824
Denial, revocation, or suspension of registration

This statute is included in the appendix at App.283a.

INTRODUCTION

A. An Overview of the Controlled Substances Act and the Authority Granted to the Drug Enforcement Administration.

The Controlled Substances Act (CSA) is a closed regulatory system enacted by Congress, making it unlawful to manufacture, distribute, dispense, or possess any controlled substance, except in a manner authorized by the Act. 21 U.S.C. § 801 et seq.; *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.*, 881 F.3d 823, 827, 830 (11th Cir. 2018) (quoting *Gonzales v. Raich*, 545 U.S. 1, 13 (2005)). The Act entrusts the Attorney General with the authority to develop regulations to monitor and control provider registration for prescribing and dispensing controlled substances. 21 U.S.C. § 823(f); 21 U.S.C. 824(a); *Gonzales*, 546 U.S. at 262 (observing "Sections 823(f) and 824(a) explicitly grant the Attorney General the authority to register and deregister physicians . . . "). The Attorney General has delegated this authority to the Drug Enforcement Administration (DEA) Administrator, under which the Administrator has developed regulations to oversee provider registration. 21 U.S.C. § 871; *Gonzales*, 546 U.S. at 262; *Final Rule: Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official,* 75 Fed. Reg. 4982 (Feb. 1, 2010). One of these regulations includes 21 C.F.R. § 1306.04(a), which places a corresponding responsibility on pharmacies to refuse to fill prescriptions that are not issued for a legitimate medical purpose. 21 C.F.R. § 1306.04(a).

Given that the DEA Administrator draws his authority under the CSA from the Attorney General, the Administrator can have no greater authority than he does. *See Final Rule: Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official,* 75 Fed. Reg. at 4982-83. The Administrator, however, has exceeded his limited authority of overseeing provider registration and has instead created a new category of "unauthorized prescriptions". Without notice, the DEA Administrator has interpreted § 1306.04(a) so that prescriptions filled in the face of unresolved "red flags" are not "issued for a legitimate medical purpose"; whether or not the prescriptions are actually illegitimate. *See Holiday CVS, LLC, d/b/a CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316, 62341 (2012) (declaring the "DEA has interpreted the "legitimate medical purpose" feature of the corresponding responsibility duty "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 . . . "").

There, the DEA Administrator found that Holiday CVS violated its corresponding responsibility under § 1306.04(a) solely on the basis that it filled controlled substance prescriptions without resolving "red flags". *Id*. at 62342-45. Holiday CVS argued that these "red flags" were based on the testimony of one "expert" witness and were not supported by case law, administrative decision, or published DEA guidance. *Id*. at 62317-18. Relying on his—and the DEA's—prior decisions, the Administrator simply responded that DEA precedent dictates the DEA interprets the "legitimate

medical purpose" feature of the corresponding responsibility duty as prohibiting a pharmacist or pharmacy from filling prescriptions with unresolved "red flags". *Id*. at 62341.[1] [2]

The Administrator's decision, however, is indefensible in light of the Court's decision in *Gonzales*, 546 U.S. at 262. There, the Court clarified the Attorney General's —and by extension the DEA Administrator's—authority under the CSA is limited to registering physicians and scheduling drugs:

> It would be anomalous for Congress to have so painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority

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[1] The DEA Administrator cited to the following decisions: *Sun & Lake Pharmacy, Inc.*, 76 Fed. Reg. 24523, 24530 (2011); *Liddy's Pharmacy, LLC,* 76 Fed. Reg. at 48895; *East Main Street Pharmacy,* 75 Fed. Reg. 66149, 66163 (2010); *Lincoln Pharmacy*, 75 Fed. Reg. 65667, 65668 (2010); *Bob's Pharmacy,* 74 Fed. Reg. at 19601; *Carlos Gonzalez*, 76 Fed. Reg. 63118, 63142 (2011) (citing *Holloway Distrib*., 72 Fed. Reg. 42118, 42124 (2007)).

[2] Other decisions include: *Paul J. Volkman,* 73 Fed. Reg. 30,630 (2008) (discussing drug cocktails issued by physician for oxycodone, benzodiazepines and carisoprodol, expert testimony of abuse potential of these drugs, and red flag of patient travelling long distance to fill prescriptions); *George Pharmacy, Inc.; Decision and Order*, 87 Fed. Reg. 211,45 (2022) (finding a pharmacy violated its corresponding responsibility because it filled prescriptions with unresolved "red flags"); *see e.g., Pronto Pharmacy, LLC; Decision and Order,* 86 Fed. Reg. 647,14 (2021); *Superior Pharmacy I and Superior Pharmacy II; Decision and Order*, 81 Fed. Reg. 313,09 (2016); *The Medicine Shoppe; Decision and Order*, 79 Fed. Reg. 595,04 (2014); *Health Fit Pharmacy; Decision and Order*, 83 Fed. Reg. 243,48 (2018).

> to declare an entire class of activity outside "the course of professional practice," and therefore a criminal violation of the CSA. (citation omitted)).

Id.

Clearly, the authority the DEA Administrator lays claim to does not arise out of the CSA or the Court's prior decisions. Instead, the DEA has systematically extended its authority through decisions like *Holiday CVS, LLC*, 77 Fed. Reg. 62316, and this case, and in doing so, has created a new category of "unauthorized prescriptions"—*i.e.*, prescriptions that bear the markers of unenumerated "red flags" that were not developed by notice-and-comment, statute, or medical expertise. In fact, in this case, not only did the DEA Administrator fail to determine the legitimacy of the prescriptions Suntree Pharmacy filled, but he also discouraged such a determination by preventing Suntree Pharmacy from calling the physicians who prescribed the controlled substances it filled to testify and by failing to gather testimony from patients who were prescribed these controlled substances. *See Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. 73753, 73754 (2020) (App.17a). Rather, to streamline revocation, only one "expert", Dr. Gordon, testified, providing a list of DEA-created unresolved "red flags". *Id.* at 73754-55. Indeed, Dr. Gordon even admitted she developed this list of "red flags" based on DEA decisions and that she was unable to cite to medical literature supporting any of the "red flags". Transcript at 21-311; ALJ Recommended Ruling, at 8-11 (App.128a).

Crucially, this overreach by the DEA has resulted in an impossible standard for pharmacists and pharmacies, where they must refuse to fill prescriptions if there are unresolved "red flags" that only the DEA and the DEA's experts can identify with confidence. *See Holiday CVS, LLC*, 77 Fed. Reg. 62317-18 (noting there is no published DEA guidance on "red flags" to refer to). This impossible standard not only affects pharmacists' ability to practice, but it also adversely affects patients because pharmacists increasingly refuse to fill prescriptions out of fear of having their DEA registrations revoked.[3] If the DEA's improper interpretation of § 1306.04(a) continues there is no telling how many more patients will suffer. Unfortunately, the great deference reviewing courts award to the DEA's interpretation has allowed this grave problem to persist.

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[3] Amy Pavuk, *Pain Patients Decry Oxycodone Shortage, But DEA Disagrees,* ORLANDO SENTINEL (Sep. 29, 2012, 6:49 PM), https://www.orlandosentinel.com/news/breaking-news/os-oxycodone-shortage-dea-florida-20120929-story.html; Matt Grant, *New Allegations Made On DEA'S Role In Pain Prescription Denials,* WESH 2 (Jul. 30, 2015, 5:59 PM), https://www.wesh.com/article/new-allegations-made-on-dea-s-role-in-pain-prescription-denials/4443955#; Press Center, *A Misguided Department of Justice Lawsuit Forces Pharmacists Between Patients And Their Doctors* (Dec. 22, 2020), https://corporate.walmart.com/newsroom/2020/12/22/a-misguided-department-of-justice-lawsuit-forces-pharmacists-between-patients-and-their-doctors; Katie Adams, *DEA Takes Hard Stance on Pharmacies Administering Buprenorphine,* BECKER'S HOSPITAL REVIEW (Nov. 8, 2021), https://www.beckershospitalreview.com/opioids/dea-takes-hard-stance-on-pharmacies-administering-buprenorphine.html.

B. The Great Deference Awarded to Administrative Agencies and Whether the Drug Enforcement Administration is Entitled to this Deference.

Administrative agencies are one of the few, perhaps only, governmental bodies that largely act free of the Separation of Powers prescribed by the Framers.[4] A freedom tied to the Court's decision in *Auer*, Justice Scalia deeply regretted the *Auer* decision as he awakened to its pernicious impact. *Id*. (emphasizing the *Auer* decision enables agencies to pass vague regulations and construe them opportunistically while enjoying great [*Auer*] deference from a reviewing court).

In what has come to be known as *Auer* deference, the Court held if an agency's regulation remains genuinely ambiguous after employing all traditional tools of construction, the agency's interpretation of its regulation is entitled to deference from a reviewing court if: 1) the interpretation is reasonable, such that it falls within the zone of ambiguity identified by the reviewing court, and 2) an independent inquiry into the character and context of the agency's interpretation entitles it to controlling weight. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415-16 (2019) (observing " . . . we give *Auer* deference because we presume, for a set of reasons relating to the comparative attributes of courts and agencies, that Congress would have wanted us to." (citation omitted)). While there is no exhaustive test to determine if an agency's interpretation is entitled to controlling weight,

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[4] Evan D. Bernick, *Enough Is Enough: Justice Scalia, Auer Deference, and Judicial Duty,* The Federalist Society (Mar. 3, 2016), available at https://fedsoc.org/commentary/fedsoc-blog/enough-is-enough-justice-scalia-auer-deference-and-judicial-duty.

the Court has identified specific markers to determine when *Auer* deference is and is not appropriate. *Id.*[5]

One important marker focuses on whether the agency's interpretation involves its substantive expertise, like issues involving highly technical and specialized knowledge. *See Id*. at 2417 (noting "[a]dministrative knowledge and experience largely account [for] the presumption that Congress delegates interpretive lawmaking power to the agency." (citation omitted)). For good reason then, when a rule is technical, agencies are believed to possess a nuanced understanding of the regulations they administer and the case for *Auer* deference is strengthened. *See Id*. Conversely, "deference ebbs when [t]he subject matter of the [dispute is] distan[t] from the agency's ordinary duties or fall[s] within the scope of another agency's authority." (citation omitted). *Id*.

At issue in this case is the CSA, which as discussed, entrusts the Attorney General with the authority to develop regulations to monitor and control provider registration for prescribing and dispensing controlled substances; power the Attorney General has delegated to the DEA. 21 U.S.C. § 871; *Gonzales*, 546 U.S. at 262. At first blush, one might think *Auer* deference should apply to this closed system given that § 1306.04(a) is recognized as genuinely ambiguous. *Gonzales*, 546 U.S. at 258 (observing "[a]ll would agree, we should think, that the statutory phrase "legitimate medical

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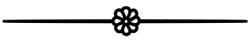
[5] *Kisor,* 139 S. Ct. at 2406 (noting the regulatory interpretation must be the agency's authoritative or official position, rather than any more adhoc statement not reflecting the agency's views, the agency's interpretation in some way must implicate its substantive expertise, and an agency's reading of a rule must reflect its fair and considered judgment (citation omitted)).

purpose" is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense."). However, such an understanding is inapposite given the Court's opinion in *Gonzales*, 546 U.S. at 256-57.

There, the Court held § 1306.04(a) as "nearly equivalent" to the language Congress used in drafting the statutes in the CSA (*i.e.*, 21 U.S.C. § 812(b); § 829(c); § 830(b)(3)(A)(ii); § 802(21)). *Id.* (holding " . . . the near equivalence of the statute and regulation belies the Government's argument for *Auer* deference."). This "near equivalency" lead the Court to conclude that *Auer* deference was inappropriate because, even though the Attorney General claimed he was interpreting § 1306.04(a), he had actually tried to interpret the meaning of the statutes found in the CSA—power that Congress has yet to entrust to the Attorney General. *See Id.* (clarifying "[s]imply put, the existence of a parroting regulation does not change the fact that the question here is not the meaning of the regulation but the meaning of the statute."). But even if the Attorney General were interpreting the regulation, his interpretation would still prove ineffective because as the Court recognized "the structure of the CSA [] convey[s] [Congress'] unwillingness to cede medical judgments to an executive official [Attorney General] who lacks medical expertise." *Gonzales*, 546 U.S. at 266. This unwillingness applies equally to all executive officials who lack medical expertise, whether that be the Attorney General interpreting § 1306.04(a), as in *Gonzales*, or the then-Acting DEA Administrator, Timothy Shea, interpreting the regulation in this case.

Following *Gonzales*, more recent decisions from the Court have further reinforced the Acting DEA

Administrator's interpretation of § 1306.04(a) is not entitled to *Auer* deference. Instead, for the reasons set forth below, the Court should hold that the DEA's interpretation of the regulation is improper and that its revocation of Suntree Pharmacy's registration, based on this improper interpretation, should be reversed.



STATEMENT

On October 5, 2016, the DEA issued an Order to Show Cause ("OSC") to Suntree Pharmacy. R. 1. The OSC alleged that Suntree filled prescriptions in contravention of its corresponding responsibility under 21 C.F.R. § 1306.04(a). R. 1 at 2. Specifically, the OSC claimed that Suntree violated this responsibility by "repeatedly fill[ing] controlled substance prescriptions that contained multiple red flags of diversion and/or abuse without addressing or resolving those red flags and under circumstances indicating that the pharmacists were willfully blind or deliberately ignorant of the prescriptions illegitimacy." R. 1 at 2.

An administrative hearing was held from April 24, 2017, to April 26, 2017, following which, on August 15, 2017, the Administrative Law Judge ("ALJ") filed his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision. (App.128a) R. 5; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73753-54. On September 18, 2017, the ALJ transmitted his recommended decision along with records from the hearing to the then-Acting DEA Administrator, Timothy Shea. *Id.*; *Id.* On November 9, 2020, the Acting Administrator

rendered his decision, finding Suntree Pharmacy had violated its corresponding responsibility under § 1306 .04(a), and issuing an Order revoking Suntree Pharmacy's registration, effective December 21, 2020. *Id.* (App.17a).

In his decision, the Acting Administrator determined that Suntree's actions of filling "hundreds" of prescriptions in the face of "red flags" was egregious conduct that necessitated revocation. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73776-77. The Acting Administrator also found Suntree Medical Equipment, LLC's registration should be revoked because "Respondent LLC could pick up where the Pharmacy left off without missing a beat. Accordingly due to that commonality, it is appropriate to treat the Pharmacy and Suntree Medical as one integrated enterprise." (App.128a).[6]

At no point did the Acting Administrator determine the legitimacy of the underlying controlled substance prescriptions that Suntree Pharmacy filled, nor did any qualified healthcare professional comment on whether the prescriptions were issued for a legitimate medical purpose. *Id.* at 73774-75. The Acting Administrator also never heard testimony from any patients and prevented testimony from the physicians who prescribed the controlled substances Suntree Pharmacy filled. *Id.* at 73754. Instead, the Acting Administrator simply relied on "red flags" identified by Dr. Gordon, a clinical hospice pharmacist for ProCare RX, working from home as a

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[6] Suntree Medical LLC was a separate closed-door pharmacy that did not dispense retail prescriptions. Suntree Medical had a separate DEA registration and was not in any way engaged in the conduct in the Order to Show Cause.

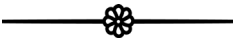
consultant (*i.e.*, not a retail pharmacist), and used these "red flags" as a proxy to conclude the prescriptions were illegitimate. *Id.* at 73754, 73774-75; R. 6 at 21; *See* Br. at 15-20 (describing in detail Dr. Gordon's testimony). To this day, the DEA has never followed-up with or penalized the medical providers who prescribed these "illegitimate" controlled substances that Suntree Pharmacy filled.

Suntree Pharmacy appealed the Acting DEA Administrator's decision to the Eleventh Circuit Court of Appeals. Br. 1. It had jurisdiction to challenge the DEA Administrator's Order in the Eleventh Circuit Court of Appeals pursuant to 21 U.S.C. § 877, which vests jurisdiction for appeal of a DEA Order in either the Court of Appeals for the District of Columbia or the circuit in which Suntree's principal place of business is located. 21 U.S.C. § 877.

On February 14, 2022, the Eleventh Circuit issued its decision upholding the Acting Administrator's revocation of Suntree Pharmacy's registration, finding the Acting Administrator's factual findings were supported by "substantial evidence" and thus conclusive. Op. Issued by Ct. 15-16. In the decision, the Court simply deferred to the Acting Administrator's interpretation of § 1306.04(a), and in doing so, held the Acting DEA Administrator could use "red flags" as a proxy for finding a controlled substance prescription was not issued for a legitimate medical purpose, without actually needing to determine the legitimacy of the underlying prescription. *Id*. at 15 (holding "[h]ere, 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 a14 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.").

In the same way the then-Acting Administrator used "red flags" as a proxy to determine the legitimacy of a controlled substance prescription (without actually making such a determination; either by himself or via a medical expert), the Eleventh Circuit used the length of time the DEA has interpreted § 1306.04(a) as allowing the same as a proxy for whether it should simply defer to the DEA's interpretation. *See Id.* at 14. Unfortunately, the Eleventh Circuit failed to further examine whether the DEA's long-held interpretation of § 1306.04(a) was reasonable and should be upheld. *Id.* at 1-17. Even when the Court was given a second chance, following the filing of Suntree Pharmacy's Petition for Panel Rehearing and En Banc Rehearing, it again simply deferred to the DEA's interpretation and denied the Petition on May 5th, 2022. *See* Order Issued by Ct. (App.281a). This lack of inquiry from the Eleventh Circuit is unsurprising given the great [*Auer*] deference administrative agencies, like the DEA, are awarded when interpreting their regulations.



SUMMARY OF THE ARGUMENT

The DEA has developed a range of regulations to monitor and control provider registration for prescribing

and dispensing controlled substances. One such regulation, 21 C.F.R. § 1306.04(a), places a corresponding responsibility on pharmacists and pharmacies to refuse to fill prescriptions that are not issued for a legitimate medical purpose. The DEA has interpreted § 1306.04(a) so that a pharmacy violates its corresponding responsibility if it fills controlled substance prescriptions without resolving "red flags". Under this interpretation, the DEA Administrator need not determine the underlying legitimacy of the prescriptions a pharmacy filled, but rather, may use "red flags" as a proxy to presume a prescription was illegitimate.

Although § 1306.04(a) has been held genuinely ambiguous, the DEA's interpretation of the regulation is not entitled to the [*Auer*] deference customarily awarded to an agency when it interprets its own regulation. This is because *Auer* deference is only appropriate where an agency's interpretation of its genuinely ambiguous regulation is reasonable and an independent inquiry into the character and context of the agency's interpretation entitles it to controlling weight.

In this case, the DEA's interpretation of § 1306.04(a) is unreasonable given the "near equivalence" of the regulation to the statutes in the CSA. This "near equivalency" means that it is these statutes the DEA has interpreted and not the regulation—power Congress has not entrusted to the DEA. The DEA's interpretation is also unreasonable because it is inapposite given the Court's characterization of willful blindness, which requires the existence of the fact a defendant is found willfully blind of. Here, that fact being whether the prescriptions Suntree Pharmacy filled were not issued for a legitimate medical purpose.

Further, even if the DEA's interpretation of § 1306.04(a) is held reasonable, *Auer* deference is still inappropriate because an independent inquiry into the character and context of the DEA's interpretation reveals it is not entitled to controlling weight. This is because the DEA's interpretation removes § 1306.04(a) from the highly technical and specialized sphere of science and medicine, and instead, places the regulation directly into the purview of the Court.

Auer deference is also inappropriate because the DEA's interpretation does not reflect its fair and considered judgment and "unfairly surprises" pharmacies. Rather than fair and considered judgment, the DEA simply drafted § 1306.04(a) parroting the statutes Congress drafted as part of the CSA. This creates an "unfair surprise" not only because the statutes in the CSA with identical language are enforced disparately, but also because the DEA failed to use notice-and-comment rulemaking in expanding the regulation's reach beyond the statutes of the CSA that it parrots.

Finally, the DEA's interpretation of § 1306.04(a) is not entitled to *Auer* deference because this is an "extraordinary case" and there is no "clear congressional authorization" supporting the authority the DEA has improperly acquired from its interpretation. Specifically, under its interpretation, the DEA has declared an entire class of activity—filling (*i.e.*, dispensing under § 841(a)) a prescription for a controlled substance with unresolved "red flags" whether or not the prescription was issued for a legitimate medical purpose—a criminal violation of the CSA. The Court, however, has recognized that the Attorney General's—who the DEA draws its power from—authority under

the CSA is limited to registering physicians and scheduling drugs. The CSA therefore contains no "clear congressional authorization" supporting the DEA's authority to criminalize an entire class of activity.

Accordingly, the Court should not defer to the DEA's improper interpretation of § 1306.04(a) and instead should enforce the regulation so that it reflects the Court's prior decisions, Congress' intent, and does not "unfairly surprise" pharmacies. The Court should therefore hold that a violation of a pharmacy's corresponding responsibility requires a determination of the legitimacy of the prescriptions it filled, and further, that this determination uncover prescriptions were "not issued for a legitimate medical purpose".

REASONS FOR GRANTING THE PETITION

I. THE REVOCATION OF PETITIONER'S REGISTRATION SHOULD BE REVERSED BECAUSE A VIOLATION OF ITS CORRESPONDING RESPONSIBILITY REQUIRES A DETERMINATION OF THE LEGITIMACY OF THE PRESCRIPTIONS IT FILLED.

The revocation of Suntree Pharmacy's registration should be reversed because it could not have violated its corresponding responsibility under § 1306.04(a) unless it filled controlled substance prescriptions that were not issued for a legitimate medical purpose. 21 C.F.R. § 1306.04(a); *see Ruan*, 597 U.S. ___ (slip op. at 3). (affirming "[w]e assume, as did the courts below and the parties here, that a prescription is "authorized" and therefore lawful if it satisfies this standard [issued for a legitimate medical purpose by an individual

practitioner acting in the usual course of his professional practice].”). Even the plain language of the regulation supports pharmacies do not violate their corresponding responsibility where they fill a prescription issued for a legitimate medical purpose. *Id*. The DEA though is willfully blind of this requirement and has instead interpreted § 1306.04(a) to penalize pharmacies, like Suntree Pharmacy, regardless of the underlying legitimacy of the prescriptions it filled, so long as there are unresolved “red flags”. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73759-60, 73774-75. To make matters worse, when challenged in federal court, as Suntree has done in this case, the reviewing court simply defers to the DEA’s interpretation under the principles of *Auer* deference. Op. Issued by Ct. at 13-16. But should the DEA’s interpretation of § 1306.04(a) be provided *Auer* deference?

Given the Court’s decision in *Gonzales*, where it recognized § 1306.04(a) is genuinely ambiguous, *Auer* deference is appropriate if the DEA’s interpretation of the regulation is reasonable, and an independent inquiry of the character and context of the DEA’s interpretation entitles it to controlling weight. 546 U.S. at 258 (“[a]ll would agree, we should think, that the statutory phrase “legitimate medical purpose” is a generality, susceptible to more precise definition and open to varying constructions, and thus ambiguous in the relevant sense.”); *see Kisor*, 139 S. Ct. at 2415-16. Thoughtful review, however, reveals the DEA’s interpretation is not entitled to deference because it is unreasonable, thereby exceeding the zone of ambiguity identified by this Court’s prior cases. But even if the DEA’s interpretation were reasonable, *Auer* deference is still inappropriate because

its interpretation is not entitled to controlling weight insofar as it exceeds the authority Congress has granted under the CSA and falls short of the agency's "fair and considered judgment", creating an "unfair surprise" to regulated parties.

A. The DEA's Interpretation of § 1306.04(a) Is Unreasonable and Not Entitled to *Auer* Deference Because the Regulation Is "Nearly Equivalent" to the Statutes in the CSA.

As established in *Gonzales*, § 1306.04(a) is "nearly equivalent" to the statutes Congress drafted under the CSA. 546 U.S. at 256-57 (" . . . the near equivalence of the statute and regulation belies the Government's argument for *Auer* deference . . . "). Because these statutes impose criminal liability, every element of each statute [the crime] must be proven beyond a reasonable doubt. *See, e.g.*, *In re Winship*, 397 U.S. 358, 364 (1970) (holding due process requires proof beyond a reasonable doubt of every fact necessary to constitute the crime charged); *Christoffel v. United States*, 338 U.S. 84, 89 (1949). As an example, to convict a defendant under 21 U.S.C. § 841(a), the government must prove beyond a reasonable doubt that a controlled substance was not issued for a legitimate medical purpose. 21 U.S.C. § 841(a) ("[e]xcept as authorized by this subchapter . . . "). Though the burden of proof is not the same for § 1306.04(a) given the regulation does not impose criminal liability, the "near equivalence" of the regulation supports that, like § 841(a), each of the regulation's elements must be proven, including that a pharmacy filled a prescription for a controlled substance that was

not issued for a legitimate medical purpose.[7] 21 C.F.R. § 1306.04(a).

To be sure, in *Gonzales*, the Court observed that though the Attorney General argued he was interpreting "legitimate medical purpose" as it pertained to § 1306.04(a), given the regulation's "near equivalency" to the statutes found in the CSA, he was in fact trying to interpret the statutes—power that Congress has yet to entrust to the Attorney General. 546 U.S. at 257, 262 (acknowledging "[a]n agency does not acquire special authority to interpret its own words when, instead of using its expertise and experience to formulate a regulation, it has elected merely to paraphrase the statutory language."). The Court explained that if the Attorney General could interpret § 1306.04(a) so that he could determine what class of activity was and was not medically legitimate (*i.e.*, outside the course of professional practice), he would have the power to criminalize the actions of DEA registered physicians. *Id.* at 262 ((advising "[i]t would be anomalous for Congress to have so painstakingly described the Attorney General's limited authority to deregister a single physician or schedule a single drug, but to have given him, just by implication, authority to declare an entire class of activity outside "the course of professional practice," and therefore a criminal violation of the CSA." (citation omitted)); *see*

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[7] This means that like 21 U.S.C. § 841(a), the DEA's regulation § 1306.04(a) must also require a healthcare professional with medical expertise to determine the legitimacy of a controlled substance prescription, rather than simply identifying "red flags" from which the then-Acting DEA Administrator may presume a prescription's legitimacy. *See Gonzales,* 546 U.S. at 266 (affirming "[t]he structure of the CSA [] conveys unwillingness to cede medical judgments to an executive official [*i.e.*, the then-Acting DEA Administrator] who lacks medical expertise.").

also H.R. Rep No. R45948, at 17 (2021) (observing "[a] violation of the CSA's registration requirements [] . . . generally does not constitute a criminal offense unless the violation is committed knowingly [*i.e.*, 21 C.F.R. § 1306.04(a)]. However, in the event of a knowing violation, DOJ may bring criminal charges against both individual and corporate registrants."). As a result, the Court held the Attorney General's interpretation of § 1306.04(a) was not entitled to *Auer* deference. *Gonzales*, 546 U.S. at 257-58, 264-66.

In the same way the Attorney General tried to interpret the statutes in the CSA, here too, the Acting DEA Administrator was interpreting these same statutes when he claimed a pharmacy violates its corresponding responsibility under § 1306.04(a) without determining the legitimacy of the controlled substance prescriptions it filled. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; *see also Holiday CVS, LLC*, 77 Fed. Reg. at 62341. In fact, under the DEA's interpretation of § 1306.04(a), the Acting DEA Administrator declared an entire class of activity (*i.e.*, filling (*i.e.*, dispensing under § 841(a)) a prescription for a controlled substance with unresolved "red flags" whether or not the prescription was issued for a legitimate medical purpose) as outside the course of professional practice, and therefore, a criminal violation of the CSA.[8] *See e.g.*, 21 U.S.C. § 841(a); *see* H.R. Rep No. R45948, at 17; *see*

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[8] *See United States v. Binder*, 26 F. Supp. 3d 656, 662-63 (E.D. Mich. 2014) (confirming where no expert determination was made as to the suitability of treatment involved in a case, "red flags" are insufficient); *see also United States v. Tran Trong Cuong*, 18 F.3d 1132, 1141 (4th Cir. 1994); *United States v. Jones*, 570 F.2d 765, 769 (8th Cir. 1978).

Holiday CVS, LLC, 77 Fed. Reg. at 62341 (DEA Administrator declaring the "DEA has interpreted the "legitimate medical purpose" feature of the corresponding responsibility duty "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 . . . ".). However, as discussed, due process requires a prescription to not be issued for a legitimate medical purpose outside the course of professional practice.[9] *See In re Winship*, 397 U.S. at 364; *Christoffel*, 338 U.S. at 89. All this to say, as in *Gonzales*, it was the statutes of the CSA that the Acting DEA Administrator was interpreting rather than § 1306.04(a)—power that Congress has not entrusted to the DEA.

For the foregoing reasons, the Acting DEA Administrator's interpretation of § 1306.04(a) is unreasonable, exceeding the zone of ambiguity identified by the Court's decision in *Gonzales*, and therefore, *Auer* deference is not appropriate. *Kisor*, 139 S. Ct. at 2415-16. Instead, § 1306.04(a) should be enforced consistent with 21 U.S.C. § 801 et seq., as requiring a qualified professional with medical expertise to determine whether a prescription was issued for a legitimate medical purpose. The Acting Administrator's decision that Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should therefore be reversed.

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[9] A determination that must be made by a qualified professional with medical expertise. *See Gonzales*, 546 U.S. at 266.

B. The DEA's Interpretation of § 1306.04(a) Is Unreasonable and Not Entitled to *Auer* Deference Given the Court's Characterization of Willful Blindness.

The Acting DEA Administrator determined that filling controlled substance prescriptions where there are unresolved "red flags" was sufficient to find that Suntree Pharmacy violated its corresponding responsibility under § 1306.04(a). *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75. According to the Administrator, Suntree Pharmacy, by failing to resolve "red flags", was "willfully blind" to the existence of facts that, in the Administrator's view, suggest the prescriptions it was filling were illegitimate. *Id.* at 73772; Op. Issued by Ct. 15. But this is not sufficient for a violation of § 1306.04(a), as discussed above, and it is not sufficient for a finding of "willful blindness" because no evidence was submitted to show that the prescriptions were actually illegitimate. *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73754 (confirming that prescribing physicians and patients did not testify nor did a qualified professional with medical expertise on the legitimacy of the prescriptions Suntree Pharmacy filled); *see also Global-Tech Appliances, Inc.*, 563 U.S. 754 (2011). There, the Court held:

> While the Courts of Appeals articulate the doctrine of willful blindness in slightly different ways, all appear to agree on two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning

> of that fact. We think these requirements give willful blindness an appropriately limited scope that surpasses recklessness and negligence." (citation omitted).

Id. at 769.

Under this definition, the Court found that the Federal Circuit's use of willful blindness exceeded the doctrine's limits by holding there was adequate evidence to support a finding that "Pentalpha deliberately disregarded a known risk that SEB had a protective patent" even though the record contained no direct evidence that Pentalpha knew of SEB's patent prior to the lawsuit. *Global-Tech Appliances, Inc.*, 563 U.S. at 759, 766.

As it relates to § 1306.04(a), the Court has yet to determine whether a defendant acts knowingly under the regulation if he is found willfully blind. Rather, the doctrine of willful blindness is anchored in criminal statutes, where it is used much more often than it is in civil statutes or administrative regulations. *Id.* at 766-67. However, given the doctrine's past use in non-criminal cases and its widespread acceptance across the Federal Judiciary, it is expected the Court agrees with its application under § 1306.04(a). *Id*. at 768.

Returning to this case, the Acting Administrator's failure to determine the underlying legitimacy of the prescriptions Suntree Pharmacy filled stands in opposition of the Court's characterization of willful blindness in *Global-Tech Appliances, Inc.* 563 U.S. at 769 (holding willful blindness requires "the defendant [] take deliberate actions to avoid learning of [] [a] fact."). As the Court explained, though willful blindness surpasses recklessness and negligence, it is limited in

scope, one such limitation being that the fact a defendant is willfully blind of must actually exist so that he could have learned of the fact but for his deliberate actions in avoiding so. *See Id.* (holding "[w]e think th[is] requirements give[s] willful blindness an appropriately limited scope that surpasses recklessness and negligence."). Otherwise, the defendant is not blind by choice, but rather, he is blinded by a reality in which the fact never existed. *See Id.* (confirming that a defendant must take deliberate actions to avoid learning of a fact). Indeed, the Eleventh Circuit's own case law supports this limitation.

In *Obstfeld*, the Eleventh Circuit held that "[u]nder the doctrine of willful blindness or deliberate ignorance, which is used more often in the criminal context than in civil cases, knowledge can be imputed to a party who knows of a high probability of illegal conduct and purposely contrives to avoid learning of it." *Williams v. Obstfeld*, 314 F.3d 1270, 1278 (11th Cir. 2002) (citing *United States v. Perez-Tosta*, 36 F.3d 1552, 1564 (11th Cir. 1994) (holding "[a] 'deliberate ignorance' instruction is appropriate when 'the facts . . . support the inference that the defendant was aware of a high probability of the existence of the fact in question and purposely contrived to avoid learning all of the facts in order to have a defense in the event of a subsequent prosecution." (citation omitted))). This holding confirms the Eleventh Circuit's characterization of willful blindness is consistent with the Court's, and that both require a defendant to have taken deliberate action to avoid learning of a fact. *See Id.*; *see also Global-Tech Appliances, Inc.*, 563 U.S. at 769. Quite significantly, the only way a defendant could have learned of a fact is if

the fact existed at some point in time over the course of the defendant's lifetime.

Given this important limitation, the Acting DEA Administrator's interpretation of § 1306.04(a), finding Suntree Pharmacy knowingly violated the regulation because it filled prescriptions in the face of unresolved "red flags", without actually determining the legitimacy of the prescriptions, was unreasonable. Rephrased, the Acting Administrator never determined whether the fact (*i.e.*, filling prescriptions for controlled substances not issued for a legitimate medical purpose) Suntree Pharmacy was found willfully blind of existed in the first place.

Despite the *Obstfeld* decision, the Eleventh Circuit deferred to the DEA Administrator's interpretation of § 1306.04(a), without examining whether it was entitled to *Auer* deference. See Op. Issued by Ct. at 15. This decision illustrates the significant harm—the pernicious impact Justice Scalia warned of—*Auer* deference causes, where a reviewing court all too readily defers to an Agency's interpretation of its regulation even though its interpretation is unreasonable.

The deference the Eleventh Circuit awarded the DEA's interpretation of § 1306.04(a) demonstrates the need for the Court to abolish *Auer* deference. Though the Court's decision in *Kisor* limits the zone of ambiguity in which an agency's interpretation must come within to what is considered reasonable after a court has employed its interpretative tools to the agency's regulation, this zone does not capture a court's prior interpretation of other relevant statutes and regulations, under which an agency's interpretation may be unreasonable. *See* 139 S. Ct. at 2415-16. In this case, though the Court's decision in *Global-Tech*

Appliances, Inc., 563 U.S. at 769, was in reference to 35 U.S.C. § 271(b), it nonetheless is relevant to the DEA's interpretation of knowingly under § 1306.04(a). Because the DEA's interpretation is unreasonable under this decision, it exceeds the zone of ambiguity under which *Auer* deference is appropriate.

For the foregoing reasons, the Acting DEA Administrator's interpretation of § 1306.04(a) is unreasonable, thereby exceeding the zone of ambiguity identified by the Court in *Global-Tech Appliances, Inc.,* and therefore, *Auer* deference is not appropriate. *Kisor*, 139 S. Ct. at 2415-16. Instead, § 1306.04(a) should be enforced consistent with this Court's characterization of willful blindness, requiring a determination of the legitimacy of the prescriptions filled by a pharmacist or pharmacy, and further, that such a determination be made by a qualified professional with medical expertise. The Acting Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should therefore be reversed.

C. Even If the DEA's Interpretation of § 1306.04(a) Were Reasonable Its Interpretation Is Still Not Entitled to *Auer* Deference Because Its Interpretation Removes the Regulation from the Highly Technical Sphere of Science and Medicine.

Even if the DEA's interpretation of § 1306.04(a) were reasonable, *Auer* deference is still inappropriate. Recall, where an agency's interpretation is held reasonable, an independent inquiry into the character and context of the agency's interpretation is necessary to determine if *Auer* deference is appropriate. *Kisor*, 139 S. Ct. at 2415-16 (observing " . . . we give *Auer*

deference because we presume, for a set of reasons relating to the comparative attributes of courts and agencies, that Congress would have wanted us to." (citation omitted)). As part of this inquiry, the Court considers whether the agency's interpretation involves its substantive expertise, like for subject matter that involves highly technical and specialized knowledge or experience. *See Id.* at 2417. When a rule is technical, agencies generally possess a nuanced understanding of the regulations they administer, and the case for *Auer* deference is strengthened. *See Id.* On the other hand, when a rule is less technical and further removed from an agency's substantive expertise, the case for *Auer* deference wanes. *Id.*

In this case, not only is *Auer* deference is inappropriate given the issue before the Court involves the interpretation of a common-law term: willful blindness, but *Auer* deference is further disfavored because the DEA's interpretation of § 1306.04(a) has removed the regulation from the highly technical sphere of science and medicine. *Kisor*, 139 S. Ct. at 2415-16 (recognizing *Auer* deference is inappropriate for interpretive issues akin to the elucidation of a simple common-law property term that more naturally falls into a judge's bailiwick).

Rather than interpreting § 1306.04(a) as requiring a medical expert to determine the legitimacy of a prescription for a controlled substance, the DEA's interpretation empowers a DEA Administrator, with no formal medical training, to determine whether a pharmacy has violated § 1306.04(a) by only using "red flags" that are unsupported by scientific or medical research. *See Holiday CVS, LLC*, 77 Fed. Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC;*

Decision and Order, 85 Fed. Reg. at 73774-75; Op. Issued by Ct. at 14-17. This interpretation removes the highly technical and scientific layer Congress had in mind when it drafted the CSA. *See Gonzales*, 546 U.S. at 266. *Auer* deference is therefore inappropriate because the DEA's interpretation of § 1306.04(a) does not involve its substantive expertise in an area involving highly technical and specialized knowledge. *See Kisor*, 139 S. Ct. at 2415-17. Instead, the Court should preserve Congress' intent in drafting the CSA and hold a violation of § 1306.04(a) requires a determination of whether a prescription was in fact not issued for a legitimate medical purpose, and further, as Congress intended, that such a determination be made by a medical expert (and not by the then-Acting DEA Administrator). *See Gonzales*, 546 U.S. at 266 (affirming "[t]he structure of the CSA [] conveys unwillingness to cede medical judgments to an executive official who lacks medical expertise.").[10]

For the foregoing reasons, the DEA's interpretation of § 1306.04(a) is not entitled to *Auer* deference. Instead, § 1306.04(a) should be enforced in a way that is both consistent with Congress' intent in drafting the CSA and with this Court's characterization of willful blindness, requiring a qualified professional with medical expertise to determine whether a prescription was issued for a legitimate medical purpose. As

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[10] Though in *Gonzales* the executive official who the Court refused to cede medical judgements to was the Attorney General, the Court's holding should apply to the then-Acting DEA Administrator, Timothy Shea, as well as all DEA Administrators, since these DEA Administrators are executive officials who also lack the medical expertise Congress intended when making medical judgments under the CSA.

such, the Acting DEA Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should be reversed.

D. The DEA's Interpretation of § 1306.04(a) Is Not Entitled to *Auer* Deference Because Its Interpretation Does Not Reflect Its Fair and Considered Judgment and Creates an "Unfair Surprise" to Regulated Parties.

While the Court has clarified § 4 of the Administrative Procedure Act (APA) specifically exempts interpretative rules, like the DEA's interpretation of § 1306.04(a), from notice-and-comment requirements, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 95-97, 101-03 (citing 5 U.S.C. § 553(b)(A)), *Auer* deference is still inappropriate where an agency's interpretation of its regulation does not reflect its fair and considered judgment and creates an "unfair surprise" to regulated parties. *Kisor*, 139 S. Ct. at 2406 (citing *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 170 (2007)). There, the Court held valid the Department of Labor's (DOL) interpretation of 29 C.F.R. § 552.109(a) from the FLSA because the interpretation reflected the agency's fair and considered judgment, and because, though it was not required to, the DOL followed full public notice-and-comment procedures, making any "unfair surprise" unlikely. *See Long Island Care at Home, Ltd.*, 551 U.S. at 161-63, 170-71 (holding " . . . as long as interpretive changes create no unfair surprise-and the Department's recourse to notice-and-comment rulemaking in an attempt to codify its new interpretation[] makes any such surprise unlikely here-the change in interpretation alone presents no separate

ground for disregarding the Department's present interpretation." (citations omitted)).

In this case, the DEA's interpretation of § 1306.04(a) falls short of the fair and considered judgment that makes *Auer* deference appropriate. *See Id*. 551 U.S. at 171 (holding " . . . here, [] [the] agency's course of action indicates that the interpretation of its own regulation reflects its considered views-the Department has clearly struggled with the third-party-employment question since at least 1993 . . . " (citation omitted)). Rather than fair and considered judgment, the DEA simply adopted a parroting regulation "nearly equivalent" to the statutes Congress drafted under the CSA. *Gonzales*, 546 U.S. at 256-57, 262. After doing so, the DEA wishes to interpret § 1306.04(a) opportunistically to streamline the revocation of provider registrations by not requiring the Administrator to determine the legitimacy of a prescription at all, much less through the use of a medical expert, so long as it is filled in the face of unresolved "red flags". *See Holiday CVS, LLC*, 77 Fed. Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; Op. Issued by Ct. at 14-17. As the Court has acknowledged though, it is unfathomable that Congress intended for an executive official who lacks medical expertise to interpret what constitutes a "legitimate medical purpose". *Gonzales*, 546 U.S. at 266. It seems equally unfathomable that Congress would enact a loophole so that rather than trying to determine what constitutes a "legitimate medical purpose", an executive official lacking medical expertise, such as the DEA Administrator, could simply bypass

the language altogether and completely avoid determining the legitimacy of prescriptions where there are unresolved "red flags".[11]

The DEA also did not follow notice-and-comment rulemaking before adopting its unreasonable interpretation of § 1306.04(a). Instead, without notice, DEA Administrators could simply decide pharmacies filled a prescription for a controlled substance that was not issued for a legitimate medical purpose solely based on the presence of unresolved "red flags", without actually determining the legitimacy of the underlying prescription. *See Holiday CVS, LLC*, 77 Fed. Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; Op. Issued by Ct. at 14-17. This creates an "unfair surprise" for pharmacies, not only because the CSA's statutes contain identical language but are enforced disparately (*i.e.*, requiring each element of the statute to be proven including an expert determination of medical legitimacy), but also because the plain language of the regulation includes clear and explicit language instructing pharmacies that to violate their corresponding responsibility a prescription must have not been issued for a legitimate medical purpose. *See* 21 C.F.R. § 1306.04(a); *see also Ruan*, 597 U.S. ___

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[11] Alternatively, if as the DEA claims, it is interpreting "legitimate medical purpose" to include prescriptions that are filled where there are "red flags", this is still unfathomable because, as discussed, the Administrator draws his authority under the CSA from the Attorney General and therefore cannot have any greater authority than he does. *See Holiday CVS, LLC,* 77 Fed. Reg. at 62341; *see also Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order,* 85 Fed. Reg. at 73774-75.

(slip op. at 3) (affirming " . . . a prescription is "authorized" and therefore lawful if it satisfies this standard [issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice].").

For the foregoing reasons, *Auer* deference is inappropriate and § 1306.04(a) should be interpreted in a way that is consistent with Congress' intent in enacting the CSA, while also allowing adequate notice to pharmacists and pharmacies of when a violation of the regulation occurs. As such, the regulation should be interpreted as requiring a qualified professional with medical expertise to determine whether a prescription was issued for a legitimate medical purpose. The Acting DEA Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should therefore be reversed.

E. The DEA's Interpretation of § 1306.04(a) Is Not Entitled to *Auer* Deference Because It Is Not Supported by "Clear Congressional Authorization" in the CSA.

The Court's recent decision in *West Virginia v. EPA* reminds us that oftentimes an agency must point to "clear congressional authorization" for the authority it claims. No. 20-1530 (2022) (slip op. at 17-19). In "extraordinary cases", those in which "history and the breadth of the authority that [the agency] has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority", precedent advises that an agency must point to "clear congressional authorization" for the authority it claims. *Id.* at 17 (quotations and citation omitted). The DEA's

interpretation of § 1306.04(a) is clearly an "extraordinary case" given the Court's findings in *Gonzales*, 546 U.S. at 265-66.

There, the Court held the Attorney General exceeded the authority granted to him under the CSA when he tried to make medical judgments regarding assisted suicide. *Id*. at 262 (observing "the Attorney General claims extraordinary authority."). The Court found that Congress limited the Attorney General's authority to registering physicians to prescribe controlled substances and scheduling drugs, but that by making medical judgments, the Attorney General declared an entire class of activity (*i.e.*, assisted suicide) as outside the course of professional practice (*i.e.*, not medically legitimate), and therefore, a criminal violation of the CSA. *Id*. Moving forward, the *Gonzales* decision reinforced that the Attorney General did not have the "extraordinary authority" he claimed, and that he could not determine what classes of activity were criminal violations of the CSA.

In this case, the DEA tries to claim this "extraordinary authority" the Attorney General declared in *Gonzales*, 546 U.S. at 262, 265-66. That is, as discussed, the DEA's interpretation of § 1306.04(a) has allowed the DEA Administrator to declare an entire class of activity (*i.e.*, filling (*i.e.*, dispensing under § 841(a)) a prescription for a controlled substance with unresolved "red flags" whether or not the prescription was issued for a legitimate medical purpose) as outside the course of professional practice, and therefore, a criminal violation of the CSA.[12] *See Holiday CVS, LLC*, 77 Fed.

[12] As discussed, due process under the U.S. Constitution requires a qualified professional with medical expertise to determine whether a prescription was not issued for a legitimate medical

Reg. at 62341; *Suntree Pharmacy and Suntree Medical Equipment, LLC; Decision and Order*, 85 Fed. Reg. at 73774-75; 21 U.S.C. § 841(a); *see also* H.R. Rep No. R45948, at 17. However, the DEA Administrator draws his authority under the CSA from the Attorney General. 21 U.S.C. § 871; *See Final Rule: Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official*, 75 Fed. Reg. at 4982-83. The Administrator therefore cannot have any greater authority than the Attorney General does under the Act. The fact that the Administrator has nonetheless claimed such "extraordinary authority" represents an "extraordinary case" where the breadth of the authority the DEA has claimed should provide the Court reason to hesitate before concluding that Congress meant to confer the DEA with such authority. *West Virginia*, No. 20-1530 (slip op. at 17-19).

Given this is an "extraordinary case", the DEA must point to "clear congressional authorization" for the authority it claims under its interpretation of § 1306.04(a). *Id.* Nowhere in the CSA does it authorize the Attorney General or the DEA Administrator to determine what classes of activity qualify as criminal violations of the Act. *See* 21 U.S.C. § 801 et seq.; *Gonzales*, 546 U.S. at 262; *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U.S. 726, 744 (1973). This lack of "clear congressional authorization" further

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purpose outside the course of professional practice to sustain a conviction under the CSA. *See Ruan*, 597 U.S. ___ (slip op. at 1-3) (citing 21 U.S.C. § 841(a)); *see In re Winship*, 397 U.S. at 364; *Christoffel,* 338 U.S. at 89.; *see also Gonzales*, 546 U.S. at 266 ("the structure of the CSA [] convey[s] [Congress'] unwillingness to cede medical judgments to an executive official [Attorney General] who lacks medical expertise.").

supports that the Acting DEA Administrator's interpretation of § 1306.04(a) is not entitled to *Auer* deference given an independent inquiry into the character and context of the DEA's interpretation does not entitle it to controlling weight. *Kisor*, 139 S. Ct. at 2415-16 (observing " . . . we give *Auer* deference because we presume, for a set of reasons relating to the comparative attributes of courts and agencies, that Congress would have wanted us to." (citation omitted)).

For the foregoing reasons, *Auer* deference is inappropriate and § 1306.04(a) should be interpreted in a way that is consistent with the authority Congress granted to the Attorney General—and by extension the DEA—under the CSA. Because this authority is limited to deregistering physicians and scheduling drugs—and not declaring an entire class of activity unlawful—a qualified professional with medical expertise must determine the underlying legitimacy of prescriptions a pharmacist or pharmacy filled under § 1306.04(a). Therefore, the then-Acting DEA Administrator's decision finding Suntree Pharmacy violated § 1306.04(a), thereby revoking its registration, should be reversed.

CONCLUSION

For the foregoing reasons, the revocation of Suntree Pharmacy's registration should be reversed, and the Court should grant Petitioner's writ of certiorari to settle the important issues discussed throughout.

Respectfully submitted,

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