NO. 24-525

In the Supreme Court of the United States

JOHN L. STANTON, M.D.,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

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

PETITION FOR REHEARING

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PETITION FOR REHEARING

Petitioner, John L. Stanton, respectfully petitions for rehearing of this Court's January 13, 2025, Order denying his petition for a writ of certiorari.

REASONS FOR GRANTING REHEARING

Rule 44.2 authorizes a petition for rehearing based on "intervening circumstances of a substantial . . . effect." Dr. Stanton's petition explained why this Court's review was warranted in this first instance—namely that the government has broadened the scope of enforcement under 21 U.S.C. § 841(a) past simply drug trafficking to convict physicians even where their prescriptions were for a legitimate medical purpose. This is significant given that such enforcement directly contradicts this Court's holding in *United States v. Moore*, 423 U.S. 122 (1975) that the harsh penalties under Section 841(a) are reserved only for drug trafficking. *Id.* at 137.

The American Society of Addiction Medicine (ASAM) is now specifically calling for this Court to rein in the government's enforcement of Title 21. In its recent public policy statement on December 12, 2024, which was not provided to the Court in Dr. Stanton's prior pleadings, the ASAM presses for the adoption of a conjunctive standard under Section 841(a).[1] That

[1] American Society of Addiction Medicine, *Reducing Risk of Federal Investigation or Prosecution for Prescribing Controlled Addiction Medications for Legitimate Medical Purposes* (Jan. 31, 2025),

public policy statement is provided in the appendix accompanying this petition and it reminds the government that Congress' intent in passing the Controlled Substance Act (CSA) "was to prevent the trafficking or dealing of drugs, not to ensure good quality medical treatment."[2] The statement then closes by recommending, *inter alia*, that this Court decide that the CSA and its regulations require a conjunctive standard.

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https://www.asam.org/advocacy/public-policy-statements/details/public-policy-statements/2025/01/03/reducing-risk-of-federal-investigation-or-prosecution-for-prescribing-controlled-addiction-medications-for-legitimate-medical-purposes.

[2] *Id.*

CONCLUSION

Accordingly, Dr. Stanton respectfully submits that the Court should grant his petition for rehearing to clarify that 21 U.S.C. § 841(a) requires that the government prosecute a physician under a conjunctive standard.

Respectfully submitted,

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RULE 44.2 CERTIFICATE

I hereby certify that that this Petition for Rehearing is presented in good faith and not for delay. In addition, the grounds of this petition are limited to intervening circumstances of a substantial or controlling effect or to other substantial grounds not previously presented.

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February 7, 2025

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AMERICAN SOCIETY OF ADDICTION MEDICINE PUBLIC POLICY STATEMENT

ASAM – American Society *of* Addiction Medicine

Public Policy Statement on Reducing Risk of Federal Investigation or Prosecution for Prescribing Controlled Addiction Medications for Legitimate Medical Purposes

Background

Addiction medications,* such as medications for opioid use disorder (MOUD), are lifesaving treatments for addiction. Methadone and buprenorphine (*i.e.*, agonist MOUD) are the current gold standard for treating opioid use disorder (OUD),[1] decreasing morta-

* Addiction medications are medications that are specifically indicated for and prescribed to treat substance use disorders as an initial lifesaving measure, as a motivational engagement strategy (*i.e.*, withdrawal management), and as part of a long-term treatment plan similar to medications used to treat other chronic conditions, such as bipolar disorder, hypertension, or diabetes.

[1] Klimas J, Hamilton MA, Gorfinkel L, Adam A, Cullen W, Wood E. Retention in opioid agonist treatment: a rapid review and meta-analysis comparing observational studies and randomized controlled trials. *Syst Rev*. Aug 6 2021;10(1):216. doi:10.1186/s13643-021-01764-9

lity risks by 50% among people with OUD.[2] Unfortunately, in 2023 fewer than 20% of people with OUD in the US received MOUD.[3] Several reasons exist for the underutilization of MOUD, including the limited number of practitioners who offer buprenorphine and the limited supply of opioid treatment programs. For example, an estimated 30% of counties lack buprenorphine prescribers, with particularly low rates in rural counties.[4] Despite the elimination of the federal waiver requirement, buprenorphine prescribing remains low.[5] Fear of intrusion into clinical practice by the Department of Justice (DOJ), including the Drug Enforcement Administration (DEA), is a key buprenorphine prescribing

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[2] Santo T, Jr., Clark B, Hickman M, et al. Association of Opioid Agonist Treatment With All-Cause Mortality and Specific Causes of Death Among People With Opioid Dependence: A Systematic Review and Meta-analysis. *JAMA Psychiatry*. 2021;78(9):979-993. doi:10.1001/jamapsychiatry.2021.0976

[3] Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2023 National Survey on Drug Use and Health (HHS Publication No. PEP24-07-021, NSDUH Series H-59). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration 2024.

[4] Corry B, Underwood N, Cremer LJ, Rooks-Peck CR, Jones C. County-level sociodemographic differences in availability of two medications for opioid use disorder: United States, 2019. *Drug Alcohol Depend*. Jul 1 2022;236:109495. doi:10.1016/j.drugalcdep.2022.109495

[5] Ali MM, Chen J, Novak PJ. Utilization of Buprenorphine for Opioid Use Disorder After the Practitioner Waiver Removal. *Am J Prev Med*. Sep 18 2024;doi:10.1016/j.amepre.2024.09.013

barrier.[6] [7] [8] [9] [10] [11] [12] Practitioners fear they will be investigated or prosecuted for well-intentioned actions that violate ambiguous federal law. Nevertheless, as compared to other known barriers to buprenorphine prescribing (*e.g.*, prior authorization requirements

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[6] Mendoza S, Rivera-Cabrero AS, Hansen H. Shifting blame: Buprenorphine prescribers, addiction treatment, and prescription monitoring in middle-class America. *Transcultural Psychiatry*. 2016;53:465-487. doi:10.1177/1363461516660884

[7] Nyaku AN, Zerbo EA, Chen C, et al. A survey of barriers and facilitators to the adoption of buprenorphine prescribing after implementation of a New Jersey-wide incentivized DATA-2000 waiver training program. *BMC Health Serv Res*. Feb 8 2024; 24(1):179. doi:10.1186/s12913-024-10648-2

[8] Andraka-Christou B, Capone MJ. A qualitative study comparing physician-reported barriers to treating addiction using buprenorphine and extended-release naltrexone in U.S. office-based practices. *International Journal of Drug Policy*. 2018;54:9-17. doi:10.1016/j.drugpo.2017.11.021

[9] Andrilla CHA, Coulthard C, Larson EH. Barriers Rural Physicians Face Prescribing Buprenorphine for Opioid Use Disorder. *Ann Fam Med*. Jul 2017;15(4):359-362. doi:10.1370/afm.2099

[10] Fenstemaker C, Abrams EA, Obringer B, King K, Dhanani LY, Franz B. Primary care professionals' perspectives on tailoring buprenorphine training for rural practice. *J Rural Health*. Mar 14 2024;doi:10.1111/jrh.12832

[11] Albright J, Ciaverelli R, Essex A, Tkacz J, Ruetsch C. Psychiatrist Characteristics That Influence Use of Buprenorphine Medication-Assisted Treatment. *Journal of Addiction Medicine*. 2010;4:197-203. doi:10.1097/ADM.0b013e3181c816f3

[12] Jones CM, McCance-Katz EF. Characteristics and prescribing practices of clinicians recently waivered to prescribe buprenorphine for the treatment of opioid use disorder. *Addiction*. 2019;114:471-482. doi:10.1111/add.14436

and lack of OUD treatment knowledge), advocates and policymakers have paid little attention to fear of DOJ or DEA intrusion as an important deterrent to practitioners' willingness to offer this MOUD.

Regardless of whether buprenorphine prescribing *actually* increases the risk of DOJ investigation/prosecution, the *perception* that buprenorphine prescribing could increase risks of investigation/prosecution is a prescribing barrier. Even if a DOJ investigation or prosecution does not result in a conviction, the costs (personal, professional, and financial) of responding to an investigation/prosecution could prevent practitioners from initiating and/or continuing to offer MOUD. The perceived risk of investigation/prosecution can be particularly powerful when combined with other barriers to prescribing, such as prior authorization burdens, inadequate reimbursement,[13] state law requirements for buprenorphine prescribing,[14,15] low self-confidence in treating OUD,16 and stigma against patients with OUD, potentially contributing to the belief that buprenorphine treatment is more complicated and "risky" than treatment for other

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[13] Huhn AS, Dunn KE. Why aren't physicians prescribing more buprenorphine? *Journal of Substance Abuse Treatment*. 2017;78:1-7. doi:10.1016/j.jsat.2017.04.005

[14] Andraka-Christou B, Golan OK, Williams M, Buksbaum S, Gordon AJ, Stein BD. A Systematic Review of State Office-Based Buprenorphine Treatment Laws Effective During 2022: Counseling, Dosage, and Visit Frequency Requirements. *Substance Use & Addiction Journal* 2024;In pressdoi:10.1177/29767342231223721

[15] Andraka-Christou B, Gordon AJ, Bouskill K, et al. Toward a Typology of Office-based Buprenorphine Treatment Laws: Themes from a Review of State Laws. *J Addict Med*. May 18 2021;16(2):192-207. doi:10.1097/ADM.0000000000000863

comparable chronic conditions.[16],[17] Given the high mortality rate of untreated OUD,[18] the effectiveness of buprenorphine for treating OUD and reducing the risk of death, and the limited supply of buprenorphine prescribers, it is imperative that policymakers and regulators take actions to encourage practitioners to enter and stay in the OUD treatment field.

Federal regulations implementing the CSA grant authority for prescribing controlled substances, like buprenorphine, for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[19] However, neither the CSA nor implementing federal regulations define "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Furthermore, federal circuit courts have been inconsistent in determining whether a CSA violation requires proof of *both* (a) violation of legitimate medical purposes and (b) deviation from the usual course of

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16 Louie DL, Assefa MT, McGovern MP. Attitudes of primary care physicians toward prescribing buprenorphine: a narrative review. *BMC Family Practice*. 2019;20(1)doi:10.1186/s12875-019-1047-z

17 Herman T, Hasgul Z, Lim TY, Jalali MS, Stringfellow EJ. Dynamics of prescribing and accessing medications for opioid use disorder: a community-based systems analysis. *Addiction Research & Theory*. 2024:1-12. doi:10.1080/16066359.2024.2420087

18 Larney S, Tran LT, Leung J, et al. All-Cause and Cause-Specific Mortality Among People Using Extramedical Opioids: A Systematic Review and Meta-analysis. *JAMA Psychiatry*. 2020;77(5):493-502. doi:10.1001/jamapsychiatry.2019.4170

19 21 C.F.R. § 1306.04(a).

professional practice,[20],[21] or whether proof of only one of these conditions is sufficient.[22] [23] [24] [25] [26] [27] [28] Jurisdictions that require proof of both conditions are said to use a conjunctive standard, whereas those requiring proof of only one condition are said to have a disjunctive standard. Courts have been increasingly using the disjunctive standard.[29]

The conjunctive standard does not separate "legitimate medical purpose" from "by an individual practitioner acting in the usual course of his professional practice." Importantly, a conjunctive standard is better

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[20] *United States v. Feingold*, 454 F.3d 1001, 1012 (9th Cir. 2006).

[21] *United States v. Smith*, 573 F.3d 639 (8th Cir. 2009).

[22] *United States v. Ruan*, 966 F.3d 1101 (11th Cir. 2020), vacated and remanded, 597 U.S. 450, 142 S.Ct. 2370, 213 L.Ed.2d 706 (2022), and *cert. granted, judgment vacated sub nom. Couch v. United States*, 142 S.Ct. 2895, 213 L.Ed.2d 1109 (2022), and adhered to in part, 56 F.4th 1291 (11th Cir. 2023).

[23] *United States v. Abovyan*, 988 F.3d 1288 (11th Cir. 2021).

[24] *United States v. Heaton*, 59 F.4th 1226, n17 (11th Cir. 2023).

[25] *United States v. Duldulao*, 87 F.4th 1239 (11th Cir. 2023).

[26] *United States v. Armstrong*, 550 F.3d 382 (5th Cir. 2008).

[27] *United States v. Nelson*, 383 F.3d 1227 (10th Cir. 2004).

[28] *United States v. Naum*, 832 F. App'x 137 (4th Cir. 2020), *cert. granted, judgment vacated*, 142 S.Ct. 2893, 213 L.Ed.2d 1108 (2022).

[29] Oliva JD, Dineen KK. Brief of Amici Curiae Professors of Health Law and Policy in Support of Ruan, *Ruan v. United States*, 597 U.S. 450, 142 S.Ct. 2370, 213 L.Ed.2d 706 (2022). 2022.

aligned with the original purposes of the CSA to prevent drug trafficking,[30] addresses concerns about the amorphous meaning of "the usual course of professional practice," and could decrease practitioners' fears about DOJ intrusion that serve as a prescribing barrier.

A disjunctive standard allows for prosecution with only proof of violation of the "usual course of professional practice." This standard has led to fear, because the "usual course of professional practice" is amorphous and ambiguous. The "usual course of professional practice" may vary among well-intentioned practitioners due to the heterogeneity of state regulations governing the practice of addiction medicine, as well as the heterogeneity of patients with substance use disorder (SUD), practitioners who treat SUD, and practice settings. Patients have a wide range of potential complexity. A practitioner may need to spend more time treating a patient with complex clinical problems than a patient with fewer health-related conditions or whose conditions have stabilized; therefore, the usual course of practice may differ significantly between practitioners who tend to treat more complex cases versus practitioners who tend to treat less complex cases. Similarly, a practitioner who is the only buprenorphine prescriber in a high-need community may have a significantly higher patient volume than a practitioner in a lower-need community with more prescribers per capita. Practitioners treating a higher proportion of patients with OUD involving fentanyl may need to use higher doses, on average, than practitioners treating OUD involving heroin or

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[30] *United States v. Rosenberg*, 515 F.2d 190 (9th Cir. 1975).

prescription opioids like oxycodone or hydrocodone, because OUD involving fentanyl is more effectively managed at higher doses.[31] Furthermore, practitioners serving vulnerable populations, including patients experiencing homelessness, patients living in remote and indigenous communities, pregnant and parenting individuals, or justice-involved individuals may need to utilize patient centered treatment plans that vary widely from typical practice, including low-threshold, flexible approaches, or off-label use of medications.

The DEA has explicitly described "red flags" of prescribing practices.[32] DOJ personnel, however, do not typically have the requisite medical expertise to accurately evaluate the *totality of the circumstances*[33] that may explain reasonable differences in prescribing practices across practitioners. In addition, rigidly comparing practitioner practices to guidelines or recommendations found in documents from medical professional organizations is inappropriate. Every patient is unique; practitioners must have the flexibility to exercise their professional judgment, and the pace of change in scientific knowledge and clinical practice often

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[31] Chambers LC, Hallowell BD, Zullo AR, et al. Buprenorphine Dose and Time to Discontinuation Among Patients With Opioid Use Disorder in the Era of Fentanyl. *JAMA Network Open*. 2023;6(9):e2334540-e2334540. doi:10.1001/jamanetworkopen.2023.34540

[32] Drug Enforcement Administration. Preventing diversion. Department of Justice. https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-13)%20Preventing%20Diversion.pdf.

[33] *United States v. Parasmo*, No. 19-CR-1 (JMA), 2023 WL 1109649 (E.D.N.Y. Jan. 30, 2023).

exceeds the speed of updates to these documents,[34] which involve a time-consuming and rigorous development process. For example, an April 2023 study found almost 90% of addiction medicine practitioners surveyed had substantially changed their MOUD prescribing practices over the last five years in response to the recent fentanyl crisis,[35] yet the ASAM clinical document directly addressing buprenorphine treatment for high-potency synthetic opioids like fentanyl, describing the need for high doses of buprenorphine, was not released until July 2023.[36] Additionally, while some practitioners have been prescribing psychostimulant medications off-label to treat stimulant use disorder for years, ASAM did not release a clinical practice guideline on the management of stimulant use disorder until 2024, noting that off-label prescribing of psychostimulant medications for stimulant use disorder may be appropriate for some patients.[37]

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[34] Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration. 2024.

[35] Weleff J, Christian NJ, Wang JX, et al. Navigating new norms: Addiction specialists' perspectives on opioid use disorder treatments and policy challenges in the fentanyl era. *The American Journal on Addictions*. 2024;doi:10.1111/ajad.13653

[36] Weimer MB, Herring AA, Kawasaki SS, Meyer M, Kleykamp BA, Ramsey KS. ASAM Clinical Considerations: Buprenorphine Treatment of Opioid Use Disorder for Individuals Using High-potency Synthetic Opioids. *Journal of Addiction Medicine*. 2023;17(6):632-639. doi:10.1097/adm.0000000000001202

[37] The ASAM/AAAP Clinical Practice Guideline on the Management of Stimulant Use Disorder. *J Addict Med*. May-Jun 01

It is important for regulatory agencies and the DOJ to consider Congress' intent in passing the CSA, which was to prevent the trafficking or dealing of drugs, not to ensure good quality medical treatment. Patients already have an alternative recourse – civil malpractice lawsuits – if they are harmed following deviation from the standard of care. Problematically, a disjunctive standard of the CSA allows for more severe punishment (including imprisonment) of a practitioner than civil malpractice lawsuits, without the need to prove patient harm.

The DOJ's expertise would best be utilized by focusing on practitioners prescribing for improper reasons – in other words, without a legitimate medical purpose. Although the CSA and its regulations do not define "legitimate medical purpose," case law suggests it means having the intention to improve a patient's health-related condition.[38] [39] [40] [41] Practitioners may be unsure whether they are following the "usual course of professional practice," but they know whether they have the intention to improve a patient's health-related condition. Therefore, practitioners are far

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2024;18(1S Suppl 1):1-56. doi:10.1097/adm.0000000000001299

[38] *City & Cnty. of San Francisco v. Purdue Pharma L.P.*, 620 F. Supp. 3d 936 (N.D. Cal. 2022). United States District Court, N.D. California.

[39] *United States v. Moore*, 423 U.S. 122, 126, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975).

[40] *United States v. Tran Trong Cuong*, 18 F.3d 1132 (4th Cir. 1994).

[41] *Ruan v. United States*, 597 U.S. 450, 142 S.Ct. 2370, 213 L.Ed.2d 706 (2022) (Alito, Thomas, & Barret, concurring).

less likely to fear DOJ intrusion if the DOJ focuses on violations of "legitimate medical purpose" rather than on violations of the "usual course of professional practice." An amicus brief in the recent US Supreme Court Case, *Ruan v. United States* (2022), argued that a conjunctive standard would address the problem: "Because the standard of care is increasingly used as a proxy for the 'usual course' standard, a mistaken or even somewhat careless prescriber could only be saved from criminal sanction because of her legitimate medical purpose."

A practitioner prescribing without a legitimate medical purpose inherently differs from a well-intentioned practitioner providing atypical or even low-quality care. Criminal sanctions should be reserved for practitioners without a legitimate medical purpose. Citing Supreme Court precedent, the 9th Circuit in *Feingold* said juries in CSA cases should "determine whether a practitioner has acted not as a doctor, or even as a bad doctor, but as a "pusher" whose conduct is without a legitimate medical justification."

Potential indicators of legitimate medical purpose – *i.e.*, intention to prevent, treat, or manage a health-related condition – include but are not limited to assessing a patient, and weighing the risks and benefits of clinical options before treatment. For example, using a person-centered approach, practitioners may weigh the relative risks and benefits of continued buprenorphine prescribing to patients who sometimes misuse their medication and decide that treatment

cessation would pose a greater risk of harm (*e.g.*, overdose) to the patient than continued treatment.[42]

Recommendations

1. The US Attorney General should address relevant federal regulations to clarify that "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" is a conjunctive standard.
2. To avoid confusion about the definition of "legitimate medical purpose," the US Attorney General should address relevant federal regulations to clarify that "legitimate medical purpose" means "for the purpose of preventing, treating, or managing a patient's health-related condition."
3. When enforcing controlled substance prescribing requirements under the CSA, the DOJ and DEA should focus their efforts on practitioners who are not prescribing controlled substances for legitimate medical purposes.
4. Federal circuit courts should adopt a conjunctive standard rather than a disjunctive standard.
5. The US Supreme Court should decide that the CSA and its regulations require a conjunctive standard. The US Supreme Court could base their rationale on the following: a) the original purpose of the CSA was to stop drug trafficking rather than to regulate the practice of medicine; b) the DOJ violates bedrock principles of federalism

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[42] Jakubowski A, Fox A. Defining Low-threshold Buprenorphine Treatment. *J Addict Med*. Mar/Apr 2020;14(2):95-98. doi:10.1097/ADM.0000000000000555

when it prosecutes practitioners merely for veering from the usual course of professional practice; and c) the plain text of the existing relevant federal regulation does not separate "legitimate medical purpose" from "by an individual practitioner acting in the usual course of his professional practice."

Adopted by the ASAM Board of Directors on December 12, 2024.