SCHOOL OF LAW
CASE WESTERN RESERVE UNIVERSITY

Case Western Reserve Law Review

Volume 73 | Issue 2 Article 11

2022

Blunt Forces: A Case Study of Administrative Exhaustion Under the Controlled Substances Act

Kennedy Dickson

— Note —

BLUNT FORCES: A CASE STUDY OF ADMINISTRATIVE EXHAUSTION UNDER THE CONTROLLED SUBSTANCES ACT

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INTRODUCTION

Mother Jane is potentially subject to criminal prosecution for obtaining and transporting an organic substance to treat her child's severe autism. That substance is marijuana. Here, the problem she faces is that marijuana is legal in some states, but not all. The substance is also federally outlawed. While the problem of marijuana legalization is multifaceted, one major issue is the lack of judicial review of Drug Enforcement Agency (DEA) action. After over fifty years since the enactment of the Controlled Substances Act (CSA),[1] the DEA refuses to reschedule marijuana out of the restrictive class of Schedule I. A Schedule I drug is a substance with no recognized medical use, a high

1. 21 U.S.C. § 801 et seq.

potential for abuse, and inadequate scientific research on its effects.[2] Recently, federal courts have declined to review the DEA's refusal to reschedule marijuana on the mistaken application of the administrative exhaustion doctrine.

In general, judicial review of agency action is constrained by constitutional, statutory, and prudential considerations. Constitutional considerations arise from the Article III mandate that federal courts only hear "Cases" and "Controversies."[3] Statutory considerations reflect an agency's own enabling statute, which may entirely preclude judicial review.[4] Or an agency's action could be insulated from judicial review because a decision is legally committed to the agency's discretion.[5] This means that the agency's enabling "statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion."[6]

Less well defined are the prudential considerations, like exhaustion, which may limit the availability of judicial review.[7] While important, "[a]dherence to these prudential standards has been variable, giving rise to occasional suspicions that they are simply manipulated . . . [for obtaining] review on essentially political grounds."[8]

Exhaustion of administrative remedies is a "long-settled rule of judicial administration that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted."[9] Exhaustion operates to limit the exercise of federal jurisdiction by delaying a plaintiff's day in court until after all administrative proceedings have concluded. A statutorily created exhaustion requirement is mandatory. There are "modest" duties to exhaust administrative remedies in the Administrative Procedure Act (APA)[10] and much more elaborate duties to exhaust in some agency

2. *Id.* § 812. Other examples of Schedule I drugs include heroin, ecstasy, and psychedelic mushrooms.

3. U.S. CONST. art. III, § 2. *See generally* Lujan v. Defenders of Wildlife, 504 U.S. 555, 559–61 (1992).

4. PETER L. STRAUSS, ADMINISTRATIVE JUSTICE IN THE UNITED STATES 305 (2d ed. 2002).

5. 5 U.S.C. § 701(a); STRAUSS, *supra* note 4, at 305–12.

6. Heckler v. Chaney, 470 U.S. 821, 830 (1985).

7. While this Note will focus only on exhaustion, other prudential considerations include ripeness and the availability of judicial relief. For a more in-depth discussion and analysis of the other prudential considerations, see STRAUSS, *supra* note 4, at 312–34.

8. *Id.* at 313.

9. Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50–51 (1938).

10. Administrative Procedure Act, 5 U.S.C. §§ 551–559.

enabling statutes.[11] In contrast, common law, also known as judicially created exhaustion, is applied at a judge's discretion and subject to flexibility.[12] The remainder of this Note will focus exclusively on exhaustion and its application in judicial review of challenges to federal marijuana regulation.

The convoluted and complex state of marijuana laws in the United States is partly due to a lack of judicial review of DEA action following improper application of the exhaustion doctrine. Marijuana is "the most commonly cultivated, trafficked, and abused drug worldwide."[13] Just over a quarter of a century ago, marijuana was illegal throughout the entire United States.[14] But as of October 2022, nineteen states and the District of Columbia permit recreational use of marijuana.[15] Additionally, all fifty states allow for the therapeutic usage of marijuana in some form.[16]

Despite sweeping changes in marijuana legality on the state level, the drug remains a Schedule I substance under the CSA.[17] The DEA is an executive agency charged with the administration, enforcement, and interpretation of the CSA. The DEA has kept marijuana in the most highly regulated and restricted schedule since the CSA was passed in 1970.[18] Since the passage of the CSA, many advocates have

11. KRISTEN E. HICKMAN & RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 17.3, at 1484 (6th ed. 2019).

12. McCarthy v. Madigan, 503 U.S. 140, 144 (1992).

13. Kennedy Dickson, Catherine Janasie & Kristine L. Willett, *Cannabinoid Conundrum: A Study of Marijuana and Hemp Legality in the United States*, 10 ARIZ. J. ENV'T L & POL'Y 132, 134 (2019).

14. JONATHAN H. ADLER, MARIJUANA FEDERALISM: UNCLE SAM AND MARY JANE 1 (Jonathan H. Adler ed., 2020).

15. Claire Hansen, Horus Alas & Elliott Davis, Jr., *Where Is Marijuana Legal? A Guide to Marijuana Legalization*, U.S. NEWS & WORLD REP. (Oct. 7, 2022, 2:24 PM), https://www.usnews.com/news/best-states/articles/where-is-marijuana-legal-a-guide-to-marijuana-legalization [https://perma.cc/HJ2V-XY53].

16. Medical Marijuana Laws, NORML, https://norml.org/laws/medical-laws/ [https://perma.cc/5ZWE-XECB] (last visited Oct. 30, 2022). While states like Nebraska and Kansas have not legalized recreational marijuana or marijuana used for medical purposes, FDA-approved marijuana-derived drugs are still available in those states with a prescription. *See* Ben Tinker, *First FDA-Approved Cannabis-Based Drug Now Available in the US*, CNN (Nov. 2, 2018, 10:36 AM), https://www.cnn.com/2018/11/01/health/marijuana-drug-epidiolex-prescription/index.html [https://perma.cc/E3TR-B3JC].

17. Dickson et al., *supra* note 13, at 135.

18. *Id.* at 136–37. Prior to 1970, the federal government banned marijuana under different statutory schemes like the Marihuana Tax Act of 1937. This law barred marijuana distribution without first registering with the

unsuccessfully petitioned the DEA to reschedule marijuana.[19] After an unsuccessful petition, advocates move to the judiciary for review of the DEA's denial. In the courts, advocates are met with additional obstacles that prevent serious review on the merits of DEA actions. Recently, circuit courts have held that petitioners must return to the DEA to fully exhaust their administrative remedies before seeking judicial review.[20]

This Note explores the current exhaustion doctrine through the lens of a timely case study. Part I describes the background of marijuana regulation by the DEA under the CSA and recent attempts at judicial review. Part II discusses the legal foundation of the exhaustion doctrine and recent applications of both statutory and common law rules. Finally, Part III provides an analysis of erroneous exhaustion requirements applied by federal courts in the DEA and marijuana context.

This Note argues that there are two critical and related issues in this context. First, the DEA's interpretation of the CSA is flawed and creates a Catch-22. To reschedule a Schedule I substance, there needs to be rigorous clinical research showing the drug's medical efficacy.[21] But because marijuana is regulated by the most restrictive standards, the necessary research to reschedule is prevented.[22] Second, because of the restrictions put on Schedule I substances, petitioners seek review of the DEA's regulation of marijuana in federal courts. But judicial review is limited as federal courts incorrectly require exhaustion. Exhaustion should not act as a barrier to judicial review of marijuana petitions. Neither the APA nor Supreme Court precedent requires exhaustion in this context.[23]

I. Marijuana Background

Federal drug policy in the United States is a complex structure of statutory and administrative rules centered around the CSA. This Part will first provide an overview of the DEA's regulatory authority under the CSA. Second, this Part will describe how marijuana is currently regulated. Finally, this Part will describe past attempts at rescheduling

federal government and paying a tax. *See* Marihuana Tax Act, ch. 553, 50 Stat. 551 (1937) (repealed 1970). For a more comprehensive description of the history of marijuana regulation in the United States, see Erwin Chemerinksy, Jolene Forman, Allen Hooper & Sam Kamin, *Cooperative Federalism and Marijuana Regulation*, 62 UCLA L. Rev. 74, 81–90 (2015).

19. *See* Alexander W. Campbell, *The Medical Marijuana Catch 22: How the Federal Monopoly on Marijuana Research Unfairly Handicaps the Rescheduling Movement*, 41 Am. J.L. & Med. 190, 196–99 (2015).

20. *See* Washington v. Barr, 925 F.3d 109, 122 (2d Cir. 2019).

21. *See infra* notes 183–99 and accompanying text.

22. *Id.*

23. *See infra* Part III.B.

or descheduling marijuana and the most recent circuit court decisions applying exhaustion requirements.

A. DEA's Regulatory Power

The CSA creates a classification system by placing different substances into "schedules" based on their "currently accepted medical use," their "potential for abuse," and the likelihood of causing dependence when abused.[24] The CSA was not initially intended as purely "punitive" legislation, but "most of the bill's administrative teeth comes by way of enforcement actions brought by the [Department of Justice (DOJ)] and the DEA."[25] Though the CSA creates a method to differentiate and control potentially dangerous substances, "the individuals making those scheduling determinations are often law enforcement officials and government bureaucrats applying multiple, multi-level factor tests."[26] Multi-level factor tests may suggest that officials making scheduling decisions are sensitive to nuance. However, the main issue is that the DEA officials who make final scheduling determinations based on scientific nuance do not have any scientific expertise.[27]

The DEA and the Department of Health and Human Services (HHS) consider an eight-factor test for each "substance proposed to be controlled or removed from the schedules."[28] Once the agencies determine that scheduling is proper for the substance, they use the CSA's three-factor guideline to place that substance in an appropriate schedule.[29] For example, a Schedule I drug under the CSA has a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use of the drug . . . under medical supervision."[30] The DEA believes that all substances

24. *See* 21 U.S.C. § 812(b) (describing the scheduling criteria for a substance's placement in a particular schedule).

25. Joseph Hartunian, *Getting Back on Schedule: Fixing the Controlled Substances Act*, 12 ALB. GOV'T L. REV. 199, 200 (2018). For a general discussion on the regulatory issues of the DEA and the CSA, see Alex Kreit, *Controlled Substances, Uncontrolled Law*, 6 ALB. GOV'T L. REV. 332 (2013).

26. Hartunian, *supra* note 25, at 201.

27. *See id.* at 201–02.

28. The factors include (1) the drug's actual or relative potential for abuse; (2) scientific evidence of the drug's pharmacological effect; (3) the state of current scientific knowledge about the substance; (4) the drug's history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) possible risks to public health; (7) the drug's psychic or physiological dependence liability; and (8) whether the drug is an immediate precursor of another controlled substance. *See* 21 U.S.C. § 811(c).

29. 21 U.S.C. § 812(b).

30. *Id.*

without a "currently accepted medical use" must be placed in Schedule I.[31]

In 1992, the DEA created a five-factor test to interpret the statutory language of "currently accepted medical use."[32] The five factors are "(1) the drug's chemistry is known and reproducible; (2) adequate safety studies have been conducted; (3) adequate and well-controlled studies proving efficacy have been conducted; (4) the drug is accepted by qualified experts; (5) the scientific evidence is widely available."[33] Schedule I drugs, like marijuana, may be rescheduled or descheduled if the DEA makes a finding that the substance has a currently accepted medical use.[34]

B. History of DEA Petitions for Marijuana Rescheduling

Rescheduling or descheduling a drug operates through an administrative rulemaking process.[35] Any interested person can petition the DEA to change the schedule of a drug.[36] The interested person files a petition with the Attorney General, who requests that HHS conduct a scientific and medical evaluation and provide recommendations about whether the substance should remain under or be removed from control.[37] Then, the DEA conducts its own independent review of the evidence and makes a final scheduling decision that it publishes in the Federal Register.[38] Publishing in the Federal Register triggers the rulemaking procedure for controlling, rescheduling, or removing a drug from the CSA.[39]

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31. *See* Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 66 Fed. Reg. 20038 (Apr. 18, 2001).

32. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504–05 (Mar. 26, 1992).

33. In creating this test, the DEA explained that the congressional intent was to follow the way other federal drug legislation views the legal status of drugs. *Id.* at 10504 (describing how "the pattern of initial scheduling of drugs" in the CSA is similar to that in the Food, Drug, and Cosmetic Act).

34. Ams. for Safe Access v. DEA, 706 F.3d 438, 451 (D.C. Cir. 2013).

35. *See* 21 U.S.C. § 811.

36. *Id.* § 811(a). An interested party could be a drug manufacturer, public interest group, medical society, or an individual citizen. Drug Enforcement Agency, Drugs of Abuse: A DEA Resource Guide 7 (2020).

37. 21 U.S.C. § 811(b). The CSA also provides that the Attorney General may initiate formal rulemaking procedures to make scheduling changes on their own motion or by request of the Secretary of HHS. 21 U.S.C. § 811(a).

38. Drug Enforcement Agency, *supra* note 36, at 10.

39. *Id.*

For the last fifty years, the DEA has denied petitions to reschedule or deschedule marijuana on an almost constant basis.[40] In each petition denial, the DEA recounts the HHS scientific evaluation and inevitably concludes that marijuana does not satisfy the five-factor medical-use test.[41] Most recently, in January 2020, private citizens Stephen Zyszkiewicz and Jeramy Bowers filed a petition urging the removal of marijuana from Schedule I.[42] The DEA denied the petition by email in April 2020.[43] The DEA supported its denial by referring to evidence from a 2016 comprehensive study of marijuana conducted by HHS. The Agency further asserted that through the application of its five-factor medical-use test, marijuana did not have a currently "accepted medical use."[44]

C. Judicial Review of Marijuana Petitions

If the DEA denies a petition for rescheduling or descheduling, the petitioner may obtain judicial review.[45] A reviewing court will set aside an agency's final decision only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[46] The CSA directs a court to review the Agency's findings of fact for substantial evidence.[47] Thus, DEA decisions founded in "record-based factual conclusion[s]" must be supported by substantial evidence, while the Agency's overall reasoning and decision-making must not be arbitrary and capricious.[48]

40. *See, e.g.*, Petition to Remove Marihuana from Control or in the Alternative to Control Marihuana in Schedule V of the Controlled Substances Act, 37 Fed. Reg. 18097 (Sept. 7, 1972); Notice of Denial of Petition, 66 Fed. Reg. 20038 (Apr. 7, 2001); Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40552 (July 8, 2011); Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53767 (Aug. 12, 2016); Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688 (Aug. 12, 2016).

41. *See, e.g.*, Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 81 Fed. Reg. 53688 (Aug. 12, 2016).

42. *See* Sisley v. DEA, 11 F.4th 1029, 1032–33 (9th Cir. 2021).

43. *Id.* at 1033.

44. *Id.* at 1032–34 (summarizing Zyszkiewicz's petition and the DEA's response).

45. 21 U.S.C. § 877.

46. 5 U.S.C. § 706(2)(A).

47. 21 U.S.C. § 877. A "substantial evidence" standard requires that a court "ask whether a 'reasonable mind might accept' a particular evidentiary record as 'adequate to support a conclusion.'" Dickinson v. Zurko, 527 U.S. 150, 162 (1999) (quoting Consol. Edison Co. v. Nat'l Lab. Rels. Bd., 305 U.S. 197, 229 (1938)). The substantial evidence test is part of the APA. *See* 5 U.S.C. § 706(2)(E).

48. *See Dickinson*, 570 U.S. at 162–64.

Early judicial review cases of marijuana petition denials do not address exhaustion of DEA remedies. A series of cases spanning from 1977 to 2011 dealt with review of a denied rescheduling petition.[49] The final level of administrative appeals in the DEA involves the DEA Administrator. Courts will look to see if the DEA Administrator's decision was based on substantial evidence.[50] The longevity of this litigation and outcomes of these cases undoubtedly influenced modern marijuana law and legality, but their complex procedural posture is not the focus of this Note.[51] However, one of the most important outcomes of that line of litigation and administrative action is the creation and application of the five-factor medical-use test for determining whether a substance has a "currently accepted medical use."[52] More recent judicial review of petition denials has also been largely unsuccessful.[53]

But not all judicial review has occurred as a product of petition denial. In *Washington v. Barr*,[54] plaintiffs did not file a petition with the DEA before seeking judicial review. Instead, they initiated suit in district court raising constitutional arguments against marijuana's Schedule I status. The district court granted the government's motion to dismiss for failure to state a claim.[55] On appeal, the plaintiffs alleged that marijuana's status violated the Commerce Clause, was arbitrary and capricious, and infringed on their First, Fifth, and Ninth Amendment rights.[56] The plaintiffs were individuals who alleged that the lack

49. The first petition to reschedule marijuana was filed in 1972 and appeared in federal court four times before ultimately being denied in 1994. *See* All. for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1133–37 (D.C. Cir. 1994); Petition to Remove Marihuana from Control or in the Alternative to Control Marihuana in Schedule V of the Controlled Substances Act, 37 Fed. Reg. 18097 (Sept. 7, 1972).

50. *See, e.g.*, NORML v. DEA, 559 F.2d 735, 743 (D.C. Cir. 1977). Within the appeals process, the DEA Administrator will look over recommendations from an administrative law judge. *See* DRUG ENFORCEMENT AGENCY, *supra* note 36, at 10.

51. For a more in-depth summary of marijuana petition litigation, see Campbell, *supra* note 19, at 193–99.

52. The DEA created the five-factor medical-use test in a denial of a marijuana petition. Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499 (Mar. 26, 1992). The D.C. Circuit has treated this test as a permissible interpretation of the CSA. *See* Ams. for Safe Access v. DEA, 706 F.3d 438, 450 (D.C. Cir. 2013). The five-factor test operates as a blockade to establishing a Schedule I substance's "currently accepted medical use" and contributes to the lag in marijuana's legalization. *See infra* Part II.A.

53. *See, e.g.*, *Ams. for Safe Access*, 706 F.3d at 440.

54. 925 F.3d 109 (2d Cir. 2019).

55. *See* Washington v. Sessions, No. 17 Civ. 5625, 2018 WL 1114758, at *10 (S.D.N.Y. Feb. 26, 2018).

56. *Washington*, 925 F.3d at 114.

of access to marijuana poses a "life-or-death threat" to their health.[57] The Second Circuit ultimately decided the case on exhaustion grounds. The court noted that while "the CSA does not expressly mandate the exhaustion of administrative remedies . . . . it is generally required as a prudential rule of judicial administration."[58] The court held that the plaintiffs must "first bring this challenge to the [DEA]."[59] But because the court felt that "future action . . . . may become appropriate" it held the case in abeyance until after administrative remedies had been sought or the DEA took action.[60] The court acknowledged that the administrative process may problematically prolong this situation to a point where exhaustion may no longer be appropriate.[61]

Most recently, in *Sisley v. U.S. Drug Enforcement Agency*,[62] a group of scientists and veterans appealed the Zyszkiewicz petition denial.[63] The *Sisley* plaintiffs argued that the DEA's classification was both unconstitutional and arbitrary and capricious, and that the DEA misinterpreted the CSA. Because the plaintiffs in this case were not parties to the original petition, the government challenged their standing.[64] The court disagreed and held that plaintiffs had standing because they allegedly suffered "direct and particularized harms due to the misclassification of cannabis."[65] The Ninth Circuit ultimately

57. *Id.* at 113.

58. *Id.* at 115.

59. *Id.*

60. *Id.* at 121. The majority said the court will retain jurisdiction if the agency fails to act "promptly" or "with adequate dispatch" or "[with] appropriate speed" or "with alacrity." *Id.* at 121–22. This unusual disposition, as the dissent complained, was without any "content" and "is of no help." *Id.* at 123 (Jacobs, J., dissenting). The DEA would be unlikely to acknowledge its failure to act promptly, so it would be unclear when the plaintiffs' jurisdiction would "materialize." *Id.* at 122–23 (Jacobs, J., dissenting).

61. The court emphasized that it takes nine years on average for the DEA to reach a decision on a rescheduling petition. *Id.* at 120–21.

62. 11 F.4th 1029 (9th Cir. 2021).

63. *See supra* notes 42–44 and accompanying text. Zyszkiewicz tried obtaining judicial review himself, but the court dismissed his action because there was no "clear right to relief nor a clear duty for the government to act." *See* Zyszkiewicz v. Barr, No. 20-1599, 2020 WL 3572908, at *1 (D.D.C. June 30, 2020).

64. The government argued that these plaintiffs improperly asserted only a "generalized grievance." *Sisley*, 11 F.4th at 1031–32, 1034. In concurrence, Judge Collins was "skeptical" about the majority's standing holding because it was not clear to him that plaintiff's injuries were "fairly traceable" to Zyszkiewicz's petition denial. *Id.* at 1037 (Collins, J., concurring) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)).

65. Their alleged harm includes prevention of research and access to medical treatment through the Department of Veteran Affairs. *Id.* at 1034–35.

dismissed the action for petitioners' failure to exhaust their administrative remedies.[66] The court recognized that administrative exhaustion under the CSA is "judge-made law, applied by courts in their discretion."[67] "The CSA does not, in terms, require exhaustion of administrative remedies."[68] Here, the Ninth Circuit agreed with the Second Circuit that requiring exhaustion in these circumstances is "consistent with congressional intent."[69]

The court reasoned that the plaintiffs should have filed their own petition before the DEA, instead of resurrecting Zyszkiewicz's petition. To support this proposition the court relied on section 811(a) of the CSA, which tasks the Attorney General with scheduling decisions, and "not the courts directly."[70] The court found exhaustion appropriate because "the CSA provides for judicial review of final agency action, [and] not judicial decisionmaking in the first instance."[71]

Since the CSA's enactment over fifty years ago, marijuana advocates have unsuccessfully challenged the DEA's strict classification of and control over marijuana. As state legalization of the medical and recreational use of marijuana continues, the drug's status as a Schedule I substance is the chief roadblock for similar changes on the federal level. The stagnancy of federal marijuana reform is enhanced by the courts' recent application of exhaustion requirements. Imposing exhaustion restraints in this context prevents plaintiffs from obtaining judicial review of marijuana's status as a Schedule I drug on the merits.

II. The Law of Exhaustion of Administrative Remedies

Prudential considerations dictating the availability of judicial review allocate decision-making authority between courts and agencies. Requiring exhaustion is "not a necessary feature" of administrative agencies' internal appeal procedures.[72] But many agencies require that individuals exhaust every resource the agency can offer before involving the courts. This Part will describe the types of exhaustion and how courts apply this doctrine in the context of rulemakings and

66. *Id.* at 1036.

67. *Id.* (internal quotations omitted) (quoting Washington v. Barr, 925 F.3d 109, 119 (2d Cir. 2019)).

68. *Id.* at 1035.

69. *Id.* (quoting *Washington*, 925 F.3d at 118).

70. The court noted that the CSA prescribes steps for the Attorney General to initiate rescheduling proceedings and details to consider. *Id.* (citing 21 U.S.C. § 811).

71. *Id.* (citing 21 U.S.C. § 877).

72. Marcia R. Gelpe, *Exhaustion of Administrative Remedies: The Lesson from Environmental Cases*, 53 Geo. Wash. L. Rev. 1, 10 (1985).

adjudications. Importantly, this Part will also describe the recognized exceptions to the exhaustion doctrine.

A. Exhaustion Generally

Exhaustion of administrative remedies can act as a roadblock to judicial review. In some instances, exhaustion is a necessary and positive tool. But in others, its application can be confusing and unpredictable.[73] The exhaustion doctrine requires a party challenging an agency decision to pursue all administrative remedies before seeking judicial review.[74] This assumes that administrative remedies are "more or less" immediately available to a party on his own initiative and "will substantially protect his claim of right."[75] The policies that define and limit exhaustion are the protection of agency autonomy,[76] the promotion of judicial efficiency,[77] and the tailoring of the doctrine to the specific administrative scheme at issue.[78] The doctrine is not meant to prevent judicial review, but rather to defer it until after the agency renders a final decision.[79]

In determining how the exhaustion doctrine applies to a particular case, three main questions are posed: (1) Is the exhaustion requirement statutorily imposed or judicially created?; (2) Is the relief sought related to the result of an individual adjudication or a rulemaking procedure?; and (3) Do any of the exceptions to the exhaustion doctrine apply?

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73. *Id.* at 3.

74. Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50–51 (1938).

75. Louis L. Jaffe, *The Exhaustion of Administrative Remedies*, 12 BUFF. L. REV. 327, 327 (1963).

76. McCarthy v. Madigan, 503 U.S. 140, 145 (1992). "Exhaustion is generally required as a matter of preventing premature interference with agency processes, so that the agency may function efficiently . . . to correct its own errors." Weinberger v. Salfi, 422 U.S. 749, 765 (1975).

77. This policy recognizes that agencies possess expertise and specialized knowledge that assist in building factual records in individual cases. If litigants were not required to exhaust their administrative remedies, then that factual record would never be made by the agency, and the courts would be bogged down if they had to build their own factual records. *See McCarthy*, 503 U.S. at 145; Jeffrey S. Lubbers, *Fail to Comment at Your Own Risk: Does Issue Exhaustion Have a Place in Judicial Review of Rules?*, 70 ADMIN. L. REV. 109, 111 (2008); *see also* Donnelly v. Controlled Application Rev. & Resol. Program Unit, 37 F. 4th 44, 52–53 (2d. Cir. 2022) (emphasizing that a petitioner's failure to attend an appellate review hearing undermined judicial efficiency).

78. McKart v. United States, 395 U.S. 185, 193 (1969).

79. *McCarthy*, 503 U.S. at 145 (noting that "the exhaustion doctrine recognizes the notion, grounded in deference to Congress' delegation of authority . . . that agencies, not the courts, ought to have primary responsibility for the programs that Congress has charged them to administer"); Lubbers, *supra* note 77, at 111.

B. Statutory and Judicial Exhaustion

Exhaustion can be mandated by statute, regulation, or judicial action. First, when exhaustion is mandated by statute, it is usually considered a jurisdictional prerequisite to maintaining an action in court.[80] For example, in *Forest Guardians v. U.S. Forest Service*,[81] the Tenth Circuit applied a statutory provision that required exhaustion "before the person may bring an action in a court of competent jurisdiction against" the Department of Agriculture.[82] The court considered this exhaustion requirement mandatory.[83]

But most agency enabling statutes do not address exhaustion. Further, a "mere reference" to the duty to exhaust is not enough to create a statutory duty to exhaust certain administrative remedies.[84] Because "not all statutory exhaustion requirements are created equal," failure to exhaust will only deprive federal jurisdiction when "'sweeping and direct' [statutory] language" indicates an exhaustion requirement.[85] For example, the Eighth Circuit found that absent statutory language "directed at courts or limiting federal district court jurisdiction," there was no jurisdictional exhaustion requirement under the Federal Crop Insurance Act.[86] Another example is that courts interpret statutory language in the Prison Litigation Reform Act (PLRA)[87] as simply a codification of the common law duty to exhaust.[88] The PLRA states that "no action shall be brought . . . until such administrative remedies

80. *See* Calhoun v. USDA Farm Serv. Agency, 920 F. Supp. 696, 700 (N.D. Miss. 1996) (citing several cases where courts have found statutory exhaustion as a prerequisite for federal jurisdiction).

81. 641 F.3d 423 (10th Cir. 2011).

82. 7 U.S.C. § 6912(e).

83. *Forest Guardians*, 641 F.3d at 432. While most statutory prerequisites to judicial review are considered mandatory, they are not necessarily jurisdictional. *See* Hoogerheide v. IRS, 637 F.3d 634, 636–38 (6th Cir. 2011); Koretoff v. Vilsack, 614 F.3d 532, 540–41 (D.C. Cir. 2010); Union Pac. R.R. Co. v. Bhd. of Locomotive Eng'r's & Trainmen Gen. Comm. of Adjustment, 558 U.S. 67, 81–83 (2009).

84. HICKMAN & PIERCE, *supra* note 11, § 17.3, at 1488; *see* Fort Bend Cnty. v. Davis, 139 S. Ct. 1843, 1851 (2019); Ace Prop. & Cas. Ins. Co. v. Fed. Crop Ins. Corp., 440 F.3d 992, 999 (8th Cir. 2006).

85. McBride Cotton & Cattle Corp. v. Veneman, 290 F.3d 973, 980 (9th Cir. 2002) (first quoting Anderson v. Babbitt, 230 F.3d 1158, 1162 (9th Cir. 2000); and then quoting Rumbles v. Hill 182 F.3d 1064, 1067 (9th Cir. 1999)); *see also* Weinberger v. Salfi, 422 U.S. 749, 757 (1975).

86. *Ace Prop.*, 440 F.3d at 998; Avocados Plus Inc. v. Veneman, 370 F.3d 1243, 1248 (D.C. Cir. 2004) (noting that exhaustion is not a jurisdictional prerequisite under the Avocado Act in the absence of "sweeping and direct" language requiring exhaustion or limiting federal jurisdiction).

87. Prison Litigation Reform Act of 1996, Pub. L. No. 104-134, 110 Stat. 1321.

88. *See generally* Chelette v. Harris, 229 F.3d 684, 687 (8th Cir. 2000).

as are available are exhausted."[89] Courts do not consider this language as an independent jurisdictional statutory requirement.

Where statutes do not explicitly require exhaustion, it is common for an agency's regulations to require exhaustion of their administrative processes. For example, in *Shawnee Trail Conservancy v. U.S. Dept. of Agriculture*,[90] the Seventh Circuit described a mandatory exhaustion requirement created by a U.S. Forest Service regulation. The regulation stated that "any filing for Federal judicial review of a decision . . . . is premature and inappropriate unless the plaintiff has first sought to invoke and exhaust the procedures available [under these regulations]."[91] Courts have applied agency-created exhaustion requirements that appear in far less explicit language. In *Conservation Force v. Salazar*,[92] the District Court for the District of Columbia applied a mandatory exhaustion requirement in U.S. Fish and Wildlife Service regulations. The regulations created an administrative process through which import permit denials could be appealed to reach a "final administrative decision."[93] The court considered the appeals process mandatory despite the regulation's language indicating that a person "may" request reconsideration or appeal of an adverse decision.[94] The court found that the "purpose of this procedure is to provide the agency's top level an opportunity to review the action before federal courts intervened."[95]

Although federal courts have a "virtually unflagging obligation . . . to exercise the jurisdiction given [to] them,"[96] in the absence of statutory language requiring otherwise, courts often create their own exhaustion doctrines.[97] Judicially created exhaustion requirements are applied purely as a matter of the court's discretion.[98] Legislative intent will guide the courts in determining whether the doctrine would be consistent with the statutory scheme.[99] This usually involves balancing

89. 42 U.S.C. § 1997e.

90. 222 F.3d 383 (7th Cir. 2000).

91. *Id.* at 389 (quoting 36 C.F.R. § 217.18 (1999)).

92. 919 F. Supp. 2d 85, 91 (D.D.C. 2013).

93. *Id.* at 90.

94. *Id.*

95. *Id.*

96. Colo. River Water Conservation Dist. v. United States, 424 U.S. 800, 817 (1976) (citations omitted).

97. *See* Taylor v. U.S. Treasury Dep't, 127 F.3d 470, 475–76 (5th Cir. 1997).

98. Gail Fuller McIntyre, Comment, *Exhaustion of Administrative Remedies: Exceptions and Predictability*, 66 U. DET. L. REV. 239, 244 (1988).

99. Shearson v. Holder, 725 F.3d 588, 593–94 (6th Cir. 2013) (quoting McCarthy v. Madigan, 503 U.S. 140, 144 (1992)).

the agency's interests against the petitioner's interest in a speedy resolution of the case.[100]

In *Huang v. Ashcroft*,[101] the Ninth Circuit required an alien to exhaust administrative remedies at the Immigration and Naturalization Service (INS) to gain protection under an international treaty.[102] The court noted that exhaustion in this context was purely prudential. But exhaustion was appropriate because INS could apply its expertise, ensure consistency in resolving similar disputes, and develop an administrative record that may be needed for future judicial consideration of this issue.[103]

Judicially created exhaustion requirements are limited in application to cases where the APA applies. The Supreme Court clarified this point in *Darby v. Cisneros*.[104] In *Darby*, a real estate developer violated Department of Housing and Urban Development (HUD) regulations by illicitly obtaining mortgage insurance on multiple properties.[105] After the developer defaulted on his loan payments, HUD issued a one-year prohibition on his participation in any housing program receiving federal funding. HUD then proposed a permanent restriction on his ability to contract with federal agencies for financial assistance.[106] An administrative law judge (ALJ) ended up imposing an eighteen-month restriction. Under HUD regulations, a hearing officer's decision becomes final after thirty days, unless the Agency decides to review it.[107] A petitioner is also able to request a review of the ALJ's decision.[108] Neither the developer nor the Agency sought further administrative review of the ALJ's decision. The developer did, however, seek judicial review the ALJ's decision.[109] At the district court, HUD argued that the developer's petition should be dismissed because the developer did not exhaust the internal agency review process before coming to federal court.[110] Ultimately, the district court denied HUD's motion, thus not

100. McIntyre, *supra* note 98, at 244.

101. 390 F.3d 1118 (9th Cir. 2004).

102. *Id.* at 1123–24.

103. *Id.*

104. 509 U.S. 137 (1993).

105. The developer's actions violated HUD's "rule of seven," which "prevented rental properties from receiving single-family mortgage insurance if the mortgagor already had financial interests in seven or more similar rental properties" in a single location. *Id.* at 139–40.

106. *Id.* at 140–41.

107. 24 C.F.R. § 24.314(c) (1992).

108. *Id.*

109. *Darby*, 509 U.S. at 142.

110. *Id.*

requiring exhaustion.[111] On appeal, the Fourth Circuit reversed, requiring the developer to exhaust his HUD remedies.[112] The Supreme Court held that because neither the HUD statute nor the Agency's regulations expressly mandated exhaustion, it was not required before the developer sought judicial review.[113]

A "final" agency decision is required before a party seeks judicial review. The APA declares that if an agency's action is "otherwise final," the fact that a petitioner did not seek any form of appeal or reconsideration from a superior agency authority has no bearing on that action's finality.[114] Therefore, unless a statute or agency regulation expressly requires administrative exhaustion, the lower federal courts cannot mandate it.[115] The Supreme Court's holding in *Darby* restricts lower federal courts from enforcing judicially created exhaustion doctrines when a case arises under the APA.[116] Scholars note that despite the seemingly simple rule that comes out of *Darby*, many courts are still confused by the exhaustion doctrine and irregularly apply it.[117]

C. Rulemaking, Adjudication, and Remedies

Agencies make final decisions in two ways: rulemaking and adjudication. The exhaustion doctrine applies in both instances.[118] And agencies often have the power to use either technique when making final decisions.[119] The available administrative remedies differ in either circumstance.

Rulemaking resembles the legislative process. The product of a rulemaking is a final rule that has the force and effect of law and that

111. The district court determined that exhaustion of administrative remedies would have been futile. *Id.*

112. The Fourth Circuit recognized that while neither HUD's enabling statute nor its own regulations mandated exhaustion, "there was no evidence to suggest that further [administrative] review would have been futile." *Id.*

113. *Id.* at 153–54.

114. 5 U.S.C. § 704 ("[A]gency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.").

115. *Darby*, 509 U.S. at 154. Further, the court may "postpone the effective date of [an] agency action" pending conclusion of the judicial review. *See* 5 U.S.C. § 705.

116. *Darby*, 509 U.S. at 153–54. However, the Court notes that judicial discretion still governs in cases not governed by the APA. *Id.*

117. William Funk, *Exhaustion of Administrative Remedies—New Dimensions Since* Darby, 18 PACE ENV'T L. REV. 1, 11 (2000).

118. *Id.* at 13–15.

119. JEFFREY S. LUBBERS, A GUIDE TO FEDERAL AGENCY RULEMAKING 113 (5th ed. 2012).

applies generally, not only to the immediate parties of an agency proceeding.[120] The APA provides a petition mechanism by which any party can request an agency to issue, amend, or repeal a rule.[121] Agencies may also establish their own petition requirements.[122] But reviews of rulemakings are potentially biased because when an individual petitions the agency to reconsider a rulemaking, "the same administrative body that made the initial decision" addresses the petition.[123]

Whether exhaustion is required for a rulemaking decision depends on whether a party presents any new factual or legal claims in the petition for judicial review. This situation is known as "issue exhaustion," which refers to the need to raise an issue with the agency before raising it with a court.[124] The idea at the core of issue exhaustion is that exhaustion should not be required when a petitioner does not present new issues. When the same administrative body reviews the same issues, the agency's position is unlikely to change.[125] Thus, the principles of exhaustion are not supported.[126] In contrast, if new facts or claims are introduced, the agency has not had the opportunity to make a final decision based on all the issues. Exhaustion here gives "courts the benefit of the agency's expertise" and "preserve[s] the limited scope of [judicial] review."[127]

Some enabling statutes or agency regulations codify rulemaking issue exhaustion. For example, when reviewing Federal Communications Commission rulemakings, courts have found an exhaustion requirement in the Agency's enabling statute. The statute requires exhaustion of the Agency's procedures if "the party seeking such review . . . relies on questions of fact or law upon which the Commission . . .

120. *Id.* at 124; *see also* 5 U.S.C. § 551(4) (defining "rule").

121. 5 U.S.C. § 553(e).

122. For example, the FDA issued regulations that lay out specific requirements petitioners must follow. 21 C.F.R. §§ 10.20, .30, .33 (2021).

123. Gelpe, *supra* note 72, at 58. While bias may exist in intra-agency reviews of adjudications, it may be less likely to affect outcomes because bias is recognized as grounds for disqualification of an administrator performing an adjudicative activity. Further, administrative adjudications are built on due process considerations in that there must be a fair, rational, and open-minded adjudicator. *See* Daniel B. Rodriguez, *Whither the Neutral Agency? Rethinking Bias in Regulatory Administration*, 69 BUFF. L. REV. 375, 381, 389, 391 (2021).

124. Funk, *supra* note 117, at 11.

125. This is true regardless if the party seeking review was the party who raised the issues in the first instance. Gelpe, *supra* note 72, at 58–59.

126. *Id.* at 58–59.

127. *Id.* at 59–60.

has been afforded no opportunity to pass."[128] Therefore, based on both *Darby* and the APA, there is no issue exhaustion requirement that precludes judicial review without a statute or regulation mandating it.[129]

Agency adjudication is like a court making decisions by hearing cases. The APA defines adjudication as the "agency process for the formulation of" any "final disposition" other than rulemaking.[130] Since adjudications deal with a specific plaintiff, the final decisions are tailored to a discrete problem. Adjudications can move through different levels of appeal panels within the agency itself. The appeal panels are made up of different individuals than the initial agency decision maker a plaintiff would face. This differs from rulemaking, where an agency head who makes the initial decision presumably will make any subsequent decision. Appeal panels in adjudications are considered "higher up in the agency and so should have a broader overview of related facts" and "greater political responsibility."[131] The issue with adjudication is that the outcome is less accessible than rulemaking, because "the law" is buried in the facts of a particular case. In contrast, rulemaking creates a "direct statement of positive law."[132]

"Exhaustion should usually be required if the [final decision and] remedy is administrative appeal."[133] Here, the agency's enabling statute or regulations provide a hierarchy of panels within the agency that a party must move through to gain the relief they seek.[134] For example, a Social Security Administration petitioner must move through three levels of appeals after an initial denial of benefits before reaching federal court. After an initial denial, a petitioner requests reconsideration from the Agency.[135] Next, the petitioner requests a hearing before an ALJ.[136] Finally, the petitioner requests an appeal to the Appeals Council, which will either decide the case or return it back to the ALJ for further action.[137] Once the Agency has reached a final decision, the petitioner may file a civil action against the Agency in federal court.[138]

128. *See* 47 U.S.C. § 405(a).

129. Funk, *supra* note 117, at 17–18 (discussing the exhaustion requirement in 47 U.S.C. § 405(a)).

130. 5 U.S.C. § 551(6), (7).

131. Gelpe, *supra* note 72, at 58.

132. STRAUSS, *supra* note 4, at 259.

133. Gelpe, *supra* note 72, at 57.

134. *Id.* at 58.

135. 20 C.F.R. § 404.900 (2021).

136. 20 C.F.R. § 404.932 (2010).

137. 20 C.F.R. § 404.967 (2021).

138. 20 C.F.R. § 422.210 (2020).

In one of the first cases recognizing exhaustion, the Supreme Court stated that "no one is entitled to judicial relief . . . until the prescribed administrative remedy has been exhausted."[139] Despite this clear statement, the exhaustion doctrine has become uncertain in some instances when the law is not clearly defined. Scholars believe that when "courts fail to require exhaustion, they sacrifice the benefits behind the doctrine."[140] This inconsistency creates a potential hardship for parties deciding whether to pursue further administrative review or go to court.

D. Common Law Exhaustion Exceptions

Courts generally recognize exceptions to the exhaustion doctrine. These exceptions will excuse litigants from exhausting their available administrative remedies.[141] Courts will consider the exceptions as part of balancing "the interest of the individual . . . against countervailing institutional interests."[142] Exhaustion exceptions come in many forms but fall into three main categories: futility, agency competency, and undue prejudice.[143] Despite the seemingly simplistic nature of these exceptions, it is often unclear how and when the exceptions apply. Because exceptions are fundamentally based on a balancing test and the facts of an individual case, they are inconsistently applied across jurisdictions. And they are not readily and fully defined.[144]

To add to the confusion, there is some debate about whether the traditional exhaustion exceptions survive after *Darby*.[145] Scholars argue that because the APA "specifies the situations in which exhaustion may be required," "[the statute] precludes a court from excusing someone from having to exhaust their [statutorily imposed] administrative remedies."[146] However, courts deciding cases after *Darby* still evaluate the applicability of the exceptions.[147]

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139. Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41, 50–51 (1938).

140. Gelpe, *supra* note 72, at 25.

141. McCarthy v. Madigan, 503 U.S. 140, 146 (1992).

142. *Id.*

143. *See id.* at 146–48.

144. Gelpe, *supra* note 72, at 25–27 (noting that difficult-to-apply exceptions "that must be weighed and balanced [will] burden the court's decision-making process").

145. Funk, *supra* note 117, at 9; *see also* HICKMAN & PIERCE, *supra* note 11, § 17.3, at 1507 ("Judges cannot excuse a petitioner from its duty to exhaust a remedy that is made mandatory by a statute . . . .").

146. Funk, *supra* note 117, at 9.

147. *See* Jech v. Dep't of Interior, 483 F. App'x 555, 560 (10th Cir. 2012) (evaluating the futility exception in the context of a statutorily mandated exhaustion requirement); Gilmore v. Salazar, 748 F. Supp. 2d 1299, 1312–13 (N.D. Okla. 2010) (evaluating undue prejudice and futility in the

Despite the uncertainty about this aspect of the exhaustion doctrine, this Subpart will describe the exceptions as they are currently understood. Excusing exhaustion is not appropriate in all cases, nor is it appropriate in a majority of cases. Some scholars argue that litigation over exhaustion may affect an agency's determination of the case on its merits.[148] In one circumstance, having already faced a party in court, the agency may treat the party as adversarial and deny their requested relief without seriously considering their individual case.[149] In another circumstance, the agency may fear that the party is overly litigious and will grant unjustified relief to avoid further litigation.[150] Both of these outcomes are undesirable. But recognizing established exceptions to exhaustion is necessary to address unique circumstances that would not otherwise support the rationale underlying the doctrine. The case law described below shows how litigants in various agency contexts can successfully justify excusing exhaustion in the appropriate factual circumstances.

1. Futility

Courts apply this exception when exhaustion of administrative remedies would be pointless because it is clear that the agency will not grant relief.[151] Courts will find futility when the policies underlying exhaustion are not served by further appeals. Sometimes an agency makes the futility obvious. In *Skubel v. Fuoroli*,[152] Medicaid patients brought an action against the Secretary of HHS, challenging the Agency's denial to pay for nurses to accompany them outside the home. The patients filed suit challenging the validity of HHS's home health care regulation without pursuing administrative remedies.[153] Normally if a plaintiff challenges a regulation's validity, the exhaustion doctrine requires that "the plaintiff petition the agency for rulemaking."[154] The Second Circuit acknowledged that "there is no question that [the

context of a judicially created exhaustion requirement); Shawnee Trail Conservancy v. U.S. Dep't of Agric., 222 F.3d 383, 388–90 (7th Cir. 2000) (evaluating futility in the context of a statutorily mandated exhaustion requirement).

148. Gelpe, *supra* note 72, at 28.

149. *Id.*

150. *Id.*

151. *See* McCarthy v. Madigan, 503 U.S. 140, 148 (1992) (citing Gibson v. Berryhill, 411 U.S. 564, 575 n.14 (1973)).

152. 113 F.3d 330 (2d Cir. 1997).

153. The patients claimed that the Agency's regulations violated the APA. *Id.* at 333.

154. *Id.* at 334 (citing S. Hills Health Sys. v. Bowen, 864 F.2d 1084, 1095 (3d Cir. 1995)).

patients] failed to exhaust their administrative remedies."[155] Yet the patients were ultimately excused from filing a petition for rulemaking because the Agency had "no plans to amend" the home health care regulation, which meant that filing such a petition likely "would have been futile."[156]

But the futility of agency action is not always easily demonstrated. So "courts should not allow a litigant to avoid exhaustion merely because the past pattern of an agency's decisions shows that the agency will probably deny relief."[157] Excusing exhaustion is permissible when it would be "clearly useless"[158] and an adverse decision is certain.[159] Relevant to the healthcare context, exhaustion can become futile when "the delay attending exhaustion would subject claimants to deteriorating health."[160] Futility can also be found in several other forms, including "bad faith on the part of the agency, past patterns of an agency's decision making, the agency's position on the merits of a case in litigation over exhaustion, or other statements by the agency on the issue."[161]

2. Agency Competency

This exception applies when an administrative remedy may be inadequate due to a lack of institutional competence to resolve the issue presented.[162] An agency can be incompetent in granting effective relief when there is a legal determination to be made. "It makes little sense to require litigants to present claims to adjudicators who are powerless to grant the relief requested" as this does not "'protec[t] . . . agency authority' or 'promote judicial efficiency.'"[163] Legal questions are sometimes present when petitioners contend that the agency has violated some constitutional right or challenge the constitutionality of

155. *Id.*

156. *Id.* at 334–35.

157. Gelpe, *supra* note 72, at 40.

158. Randolph-Sheppard Vendors of Am. v. Weinberger, 795 F.2d 90, 105 (D.C. Cir. 1986).

159. Marine Mammal Conservancy, Inc. v. Dep't of Agric., 134 F.3d 409, 413 (D.C. Cir. 1998).

160. Abbey v. Sullivan, 978 F.2d 37, 46 (2d Cir. 1992); *see also* Marcus v. Sullivan, 926 F.2d 604, 614 (7th Cir. 1991) (finding exhaustion futile for social security disability applicants because any delay in receiving benefits would mean that claimants could not "purchase the very necessities of life," subjecting them to "deteriorating health, and even death").

161. Gelpe, *supra* note 72, at 40.

162. McCarthy v. Madigan, 503 U.S. 140, 147 (1992).

163. Carr v. Saul, 141 S. Ct. 1352, 1361 (2021) (quoting *McCarthy*, 503 U.S. at 145).

an agency statute.[164] Courts generally require that the constitutional question involved be substantial and unambiguous.[165] For example, in *Hettinga v. United States*,[166] the D.C. Circuit held that the Secretary of Agriculture was incompetent to address the constitutionality of amendments to the Agricultural Marketing Agreement Act[167] and that the Agency lacked authority to grant the plaintiffs' requested relief.[168]

In general, an agency has "the power to determine constitutional applicability" but not "the power to determine constitutionality of legislation."[169] This understanding extends to constitutional challenges of agency regulations. Some courts find that while "a constitutional attack upon a statute need not be raised before [an] agency[,] . . . a constitutional attack upon an agency's interpretation of a statute is subject to the exhaustion requirement."[170] This belief is flawed because administrative exhaustion is not required when "the issue is one of purely statutory interpretation"[171] or involves purely legal issues.[172] When there is no need for an agency to make factual determinations or

164. Jaffe, *supra* note 75, at 337.

165. To avoid an exhaustion requirement, first, a plaintiff should only allege constitutional issues. If the plaintiff alleges both constitutional and non-constitutional issues and a court does not require exhaustion, "the court would lose the value of the agency's expertise on the related factual issues" for the non-constitutional claims. *See* Gelpe, *supra* note 72, at 45–47. Second, the plaintiff should allege that the statute is unconstitutional on its face. *Id.*

166. 560 F.3d 498 (D.C. Cir. 2009).

167. 7 U.S.C. §§ 671–74.

168. *Hettinga*, 560 F.3d at 501 (holding that because the Secretary "lacks the power to provide a remedy, requiring exhaustion as a prudential matter would not protect administrative agency authority or advance judicial efficiency"). The plaintiffs requested an exemption from certain milk marketing requirements imposed by the statute at issue. The court noted that exhaustion was not required because their claims relied on statutory structure and legislative history, and any factual question "could as easily be addressed in the district court." *Id.* at 504, 506.

169. McGrath v. Weinberger, 541 F.2d 249, 251 (10th Cir. 1976) (quoting 3 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE § 20.04 (1958)).

170. *See* Adelphia Commc'ns Corp. v. FCC, 88 F.3d 1250, 1255–56 (D.C. Cir. 1996) (citations omitted); *see also* Jones Bros., Inc. v. Sec. of Lab., 898 F.3d 669, 679 (6th Cir. 2018) ("If the petitioner's grievance turns on the way the agency is interpreting or applying a statute, not the statute itself, why wouldn't Congress want him first to raise his claim to the agency? Congress deserves more credit than to want a petitioner to stay silent in front of the agency (when it can avoid the problem) and wait to raise an issue in court months later (when it is too late).").

171. Touche Ross & Co. v. SEC, 609 F.2d 570, 577 (2d Cir. 1979).

172. Bethlehem Steel Corp. v. EPA, 669 F.2d 903, 907 (3rd Cir. 1982).

apply its expertise, exhaustion is not required.[173] Thus, even though agencies can invalidate their own rules, "it is unlikely that further proceedings would produce such a result."[174]

3. Undue Prejudice

Finally, if a plaintiff would face undue prejudice by exhausting their administrative remedies, a court may excuse exhaustion.[175] Such prejudice may result from an "unreasonable or indefinite timeframe for administrative action," or when a particular plaintiff would suffer "irreparable harm to secure immediate judicial consideration of his claim" due to issues with the administrative decision-making schedule.[176] In other words, the potential prejudice's severity will affect how the court applies any judicially created or statutorily imposed exhaustion requirement.[177] Here, even if requiring exhaustion would serve the underlying policies of the doctrine, "the cost to the plaintiff is so high . . . it is best not to require [it]."[178]

In *Bowen v. City of New York*,[179] the Supreme Court found irreparable injury and excused exhaustion when "[t]he ordeal of having to go through the administrative process may trigger a severe medical setback."[180] Similarly, undue prejudice can excuse exhaustion when administrative proceedings result in delays of several years and subject a party to prejudice when seeking subsequent court action.[181]

Despite the potential uncertainty caused by recognizing exhaustion exceptions for litigants, the exceptions also provide great benefit. Because every case is different and based on many competing considerations, severely restricting judicial review in every case is untenable. Recognizing limited exceptions to the exhaustion doctrine will allow for timely judicial review when the underlying values of the doctrine are not being served.

173. *See* Finnerty v. Cowen, 508 F.2d 979, 982–83 (2d Cir. 1979).

174. *See Touche Ross & Co.*, 609 F.2d at 577. The Supreme Court has held that an agency "must waive its exhaustion requirements" when confronted with a constitutional challenge to a system-wide agency policy. *See* Bowen v. City of New York, 476 U.S. 467, 482–87 (1986). Exhaustion serves little purpose here because a well-established agency policy is unlikely to change, and the agency's expertise is not particularly helpful to the court.

175. McCarthy v. Madigan, 503 U.S. 140, 146–47 (1992).

176. *Id.*

177. McIntyre, *supra* note 98, at 256.

178. Gelpe, *supra* note 72, at 48.

179. 476 U.S. 467 (1986).

180. *Id.* at 483.

181. Mobil Expl. & Producing U.S., Inc. v. Babbitt, 913 F. Supp. 5, 14 (D.D.C. 1995).

III. Exhaustion Under the CSA: Marijuana Case Study

Both the Second and Ninth Circuits have recently required plaintiffs to exhaust their administrative remedies with the DEA before hearing marijuana rescheduling cases on the merits.[182] This Part will convey how the DEA's five-factor medical-use test in conjunction with exhaustion requirements inevitably bars meaningful judicial review of all marijuana rescheduling efforts. This Part will also describe why application of the exhaustion doctrine is inappropriate in cases brought under the APA, and in all other cases excusable under common law exceptions. This Part will conclude with a discussion of broader principles and concerns underlying improper exhaustion requirements.

A. Flawed Interpretation of the CSA

Scheduling under the CSA relies on three factors: (1) the drug's potential for abuse, (2) whether the drug has a "currently accepted medical use" in treatment, and (3) the available safety data for the drug's use.[183] The CSA differentiates Schedule I substances as having no "currently accepted medical use."[184] Drugs that fall into the lower regulated schedules (II–V) have a currently accepted medical use in the eyes of the DEA. Because marijuana is a Schedule I drug, in the eyes of the DEA it does not have any "currently accepted medical use." In 1992, the DEA promulgated a regulation defining "currently accepted medical use" as the fulfillment of a five-factor test.[185] The most difficult factor to demonstrate is the existence of adequate and well-controlled studies proving marijuana's medical efficacy. Those petitioning to change the schedule of marijuana must provide evidence of the drug's "currently accepted medical use" through FDA-caliber controlled clinical trials.[186] The DEA will consider a substance to have a currently accepted medical use only if fulfills all five elements.[187]

This interpretation is flawed and creates a Catch-22 situation. The federal prohibition on marijuana prevents its legalized use because fifty years ago it was classified as having no medicinal benefit. But as the regulations currently stand, researchers are prevented from conducting the studies needed to demonstrate marijuana's medicinal benefit. Because access to Schedule I drugs for research purposes is extremely limited, the required FDA-caliber clinical trial data needed to

182. *See supra* notes 54–71 and accompanying text.

183. 21 U.S.C. § 812.

184. *Id.*

185. *See supra* Part I.A (discussing the five-factor test).

186. *See* Ams. for Safe Access v. DEA, 706 F.3d 438, 452 (D.C. Cir. 2013).

187. Denial of Petition to Initiate Proceedings to Reschedule Marijuana, 76 Fed. Reg. 40579 (July 8, 2011).

demonstrate a "currently accepted medical use" is nonexistent.[188] Individuals interested in researching marijuana must wade through a "quagmire of bureaucracy."[189] Any application for Schedule I substance research is subject to a lengthy review by HHS, the DOJ, and the DEA.[190] But both the "DEA and DOJ have ample ability to deny applications before they are formally received from HHS."[191] And despite potential influence from other agencies, the DEA retains authority for all final scheduling decisions.

Beyond the application process to study the substance, researchers must have access to marijuana itself. The DEA significantly restricts the ability of research institutions to cultivate marijuana for research purposes.[192] There are many applications to grow marijuana for research purposes that the DEA has not acted on.[193] Despite almost 600 DEA-licensed researchers in the United States, for the last fifty years the Agency allowed only the University of Mississippi to grow marijuana.[194] Finally, in May 2021, the DEA announced preliminary approval for three new companies to cultivate cannabis for research.[195] Overall, researchers seeking authorization to grow marijuana must complete a burdensome approval process with the DEA, the National Institute on Drug Abuse, and the FDA.[196]

Relatedly, there has not been a serious judicial review of the DEA's five-factor medical-use test. Before the test existed, courts generally deferred to the DEA's authority to interpret the statutory language of

188. *See* Michael H Andreae, Evelyn Rhodes, Tyler Bourgoise, George M. Carter, Robert S. White, Debbie Indyk, Henry Sacks & Rosamond Rhodes, *An Ethical Exploration of Barriers to Research on Controlled Drugs*, 16 AM. J. BIOETHICS 36, 40–42 (2016).

189. Hartunian, *supra* note 25, at 208 (providing a comprehensive summary of the bureaucratic process to obtain a Schedule I research license).

190. 21 U.S.C. §§ 823, 824.

191. Hartunian, *supra* note 25, at 208.

192. There is a significant disparity between the demand for and availability of marijuana for research.

193. *See DEA Continues to Prioritize Efforts to Expand Access to Marijuana for Research in the United States*, DEA (May 14, 2021), https://www.dea.gov/stories/2021/2021-05/2021-05-14/dea-continues-prioritize-efforts-expand-access-marijuana-research [https://perma.cc/BG9U-NKFG].

194. *Id.*; Will Stone, *After 50 Years, U.S. Opens the Door to More Cannabis Crops for Scientists*, NPR (May 30, 2021, 6:00 AM), https://www.npr.org/sections/health-shots/2021/05/30/1000867189/after-50-years-u-s-opens-the-door-to-more-cannabis-crops-for-scientists [https://perma.cc/6ZSG-CK5W].

195. Stone, *supra* note 194.

196. See Hartunian, *supra* note 25, at 209–10 for a detailed description of the cultivation approval process.

"currently accepted medical use"[197] under the doctrine established in *Chevron U.S.A., Inc. v. Natural Resource Defense Council, Inc.*[198] The lack of judicial review of the five-factor medical-use test is partly due to the courts' avoidance of the topic by dismissing cases on jurisdictional grounds and never reaching their merits.[199]

The marijuana Catch-22 limits treatment options to individuals[200] and potentially subjects medical providers to federal criminal prosecution for prescribing the drug.[201] Despite the federal prohibition, states will continue to allow greater access to marijuana and the drug will become more widely available nationwide. Recently, Justice Thomas criticized the federal government's "half-in, half-out regime that simultaneously tolerates and forbids local use of marijuana."[202] This regulatory structure leads ordinary people to believe that the federal government has legalized marijuana. Justice Thomas argued that in reality, it creates "traps for the unwary."[203] He found the federal government's inconsistent, "laissez-faire" approach to marijuana regulation untenable.[204]

B. Flawed Application of an Exhaustion Requirement Under the CSA

The lack of judicial review of DEA decision-making stems in part from circuit courts' recent requirement of exhaustion in marijuana rescheduling litigation. While the CSA creates an administrative

197. Grinspoon v. DEA, 828 F.2d 881, 892 (1st Cir. 1987). While the court held that the DEA's old interpretation of the CSA conflicted with congressional intent, it stressed that the Agency has "legitimate discretion to develop a legally acceptable standard" without judicial interference. *Id.*; *see also* All. for Cannabis Therapeutics v. DEA, 930 F.2d 936, 939 (D.C. Cir. 1991).

198. 467 U.S. 837 (1984). *Chevron* deference applies when Congress has not spoken on the issue and the agency's interpretation is reasonable. For a more in-depth analysis of what *Chevron* deference is and how courts apply it, see VALERIE C. BRANNON & JARED P. COLE, CONG. RSCH. SERV., R44954, CHEVRON *DEFERENCE: A PRIMER* (2017).

199. *See* Sisley v. DEA, 11 F.4th 1029, 1035 (9th Cir. 2021).

200. Shelly B. DeAdder, *The Legal Status of Cannabidiol Oil and the Need for Congressional Action*, 9 N.C. CENT. UNIV. SCI. & INTELL. PROP. L. REV. 68, 70–72 (2016).

201. *See* 21 U.S.C. § 823(f).

202. Standing Akimbo, LLC v. United States, 141 S. Ct. 2236, 2236–37 (2021) (Thomas, J., respecting denial of certiorari). *Standing Akimbo* dealt with a medical marijuana dispensary in Colorado, where distribution of the drug is legal on the state level. But because of confusion with the federal Tax Code for companies that deal with controlled substances, the dispensary may have violated a business tax deduction provision. *Id.* at 2238.

203. *Id.* at 2237.

204. *Id.* at 2238.

process for the scheduling and rescheduling of drugs, it does not mandate exhaustion. The CSA authorizes the Attorney General to make scheduling decisions through rulemaking.[205] Proceedings can be initiated by the Attorney General himself, at the request of HHS, or by any interested party.[206] Section 877 of the CSA provides for judicial review of all final decisions made by the Attorney General.[207] The text of section 877 makes no reference to further appeals that must be made or the duty of petitioners to exhaust any other administrative remedy from the DEA before seeking judicial review. Further, there is no DEA regulation mandating exhaustion of the Agency's administrative remedies.

The Second and Ninth Circuits recognize that exhaustion is not mandated by the CSA.[208] Despite the lack of textual support, both courts have dismissed challenges to the scheduling of marijuana on exhaustion grounds.[209] The exhaustion requirements in both cases arose in different circumstances. *Sisley* dealt with a denied DEA petition under the APA. This Subpart will first describe how the *Sisley*-type exhaustion requirement directly conflicts with the APA and the Supreme Court's holding in *Darby v. Cisneros*.[210] *Washington* dealt with a constitutional challenge to the DEA's scheduling of marijuana without a prior agency petition. This Subpart will then describe how the *Washington*-type exhaustion requirement in cases not arising from a petition denial and not brought under the APA is inappropriate because the common law exceptions are applicable.

1. *Sisley*-Type Exhaustion Requirement

Sisley meets all the prerequisites for *Darby's* application; it is an APA case that involves a final agency decision, and neither the statute nor the agency mandates exhaustion. But the court never cites or mentions *Darby*. It instead cites *McCarthy*, which describes judicially created prudential exhaustion.[211] *Darby* definitively states that

205. 21 U.S.C. § 811(a).

206. *Id.*

207. 21 U.S.C. § 877.

208. "The exhaustion requirement under the CSA is, however, prudential, not jurisdictional. It is not mandated by the statute. Rather, it is a judicially-created administrative rule, applied by courts in their discretion." Washington v. Barr, 925 F.3d 109, 119 (2d Cir. 2019); Sisley v. DEA, 11 F.4th 1029, 1035 (9th Cir. 2021) (quoting *Washington*, 925 F.3d at 119).

209. *See Washington*, 925 F.3d at 122; *Sisley*, 11 F.4th at 1036.

210. 509 U.S. 137, 154 (1993) (explaining that "[c]ourts are not free to impose an exhaustion requirement as a rule of judicial administration once agency action has become final" when neither Congress nor the agency has mandated exhaustion).

211. *Sisley*, 11 F.4th at 1035 (citing McCarthy v. Madigan, 503 U.S. 140, 144 (1992)).

section 704 of the APA renders *McCarthy* inapplicable in APA cases.[212] Permitting courts "to impose additional exhaustion requirements beyond those provided by Congress or the agency . . . . would transform [section 704] from a provision designed to remove obstacles to judicial review of agency action, into a trap for unwary litigants."[213]

A *Sisley*-type exhaustion requirement is invalid. *Darby* tells us that absent a statutory mandate from the CSA, federal courts may not impose an exhaustion requirement on plaintiffs challenging the DEA's actions under the APA. The *Sisley* court's decision to apply an amorphous exhaustion requirement "under the circumstances" or when "appropriate" will further impede meaningful judicial review of the DEA's five-factor test.[214]

2. *Washington*-Type Exhaustion Requirement

The Second Circuit's exhaustion requirement in *Washington* was judicially created and applied to dismiss a constitutional challenge to marijuana's scheduling under the CSA in federal court.[215] Unlike *Sisley*, which was brought as a challenge of a petition denial under the APA, the *Darby* reasoning will not apply to constitutional challenges like *Washington*.[216] In requiring exhaustion, the *Washington* court relied on the structure of the CSA, noting that "Congress wanted aggrieved parties to pursue reclassification through agencies, and not, in the first instance, through the federal courts."[217] The court also emphasized that the two goals of exhaustion are fulfilled by requiring it in this case. First, it protects the DEA's authority to use its expertise to schedule

212. Darby v. Cisneros, 509 U.S. 137, 153–54 (1993) (discussing *McCarthy*).

213. *Id.* at 146–47 (cleaned up).

214. *Sisley*, 11 F.4th at 1036. In addition to ignoring *Darby*, the *Sisley* court seems to limit who can seek judicial review under the CSA. The Ninth Circuit notes that only the party who files a petition under section 811 of the CSA can obtain any judicial review of the resulting final decision. *Id.* at 1035–36. To the contrary, section 877 extends judicial review to "any person" "aggrieved" by the DEA's action. *See* 21 U.S.C. § 877. Limiting judicial review to only parties who participated in DEA proceedings is inconsistent with previous interpretations of the CSA. Bonds v. Tandy, 457 F.3d 409, 415 n.10 (5th Cir. 2006) (citing Supreme Court cases giving similar language a broad reading). The *Sisley* court also debated whether the government's email response to Zyszkiewicz's petition constituted a "final" DEA action. Because the government failed to argue to the contrary, the court was "willing to assume" that the DEA's response was a denial of that petition and a final agency action under the APA. *Sisley*, 11 F.4th at 1036.

215. Washington v. Barr, 925 F.3d 109, 115 (2d Cir. 2019).

216. Therefore, barring the application of any exceptions, the judicially created exhaustion doctrine "continues to apply as a matter of judicial discretion." *Darby*, 509 U.S. at 153–54.

217. *Washington*, 925 F.3d at 116–17.

drugs.[218] Second, it promotes judicial efficiency by requiring the plaintiffs to file a petition with the DEA to reschedule marijuana.[219] The court noted that "in response to a petition from Plaintiffs . . . the DEA would reschedule marijuana," and if it did not, "the administrative process would generate a comprehensive record that would aid in eventual judicial review."[220]

The *Washington* plaintiffs argued for the application of several exceptions to exhaustion, but the Second Circuit rejected each argument.[221] The plaintiffs argued that exhaustion would have been futile based on public statements from Attorney General Jeff Sessions and Acting Administrator of the DEA Charles Rosenberg that "suggest[ed] the administrative process" is biased against medical and scientific evidence of marijuana's effectiveness.[222] The court found that the plaintiffs had no "plausible allegations of bias" given that the Secretary of HHS's opinions are what is relevant in this situation, "not the judgment of the Attorney General or head of the DEA."[223] The court then rejected the plaintiffs' claim that their desired remedy of marijuana rescheduling was not available through the administrative process. Finally, the court did not find the plaintiffs' arguments of undue prejudice convincing because "the existing classificatory scheme [of the CSA] has not prevented" them from obtaining their medical marijuana.[224] The court found that despite the plaintiffs' "concededly difficult position, [they] are not currently entitled to bypass judicial review."[225]

The Second Circuit's rejection of all three exhaustion exceptions is flawed. The factual circumstances surrounding marijuana's scheduling, the CSA, and the DEA's general attitude toward the drug support excusing exhaustion. A *Washington*-type exhaustion requirement is invalid because, in this context, all three exceptions apply and overlap, with a finding of one leading to the finding of another.

An administrative process is futile "if the agency will almost certainly deny any relief either because it has a preconceived position on, or lacks jurisdiction over, the matter."[226] Courts will look to

218. *Id.* at 117.

219. *Id.*

220. *Id.*

221. *Id.* at 118–19.

222. *Id.* at 118.

223. *Id.* at 118–19.

224. *Id.* at 119.

225. *Id.*

226. Randolph-Sheppard Vendors of Am. v. Weinberger, 795 F.2d 90, 107 (D.C. Cir. 1986).

agencies' intentions when determining whether they will grant relief.[227] The DEA has determined the issue of marijuana scheduling by denying petitions on the subject for the last fifty years.[228] The Second Circuit's characterization of exhaustion in this context as "sensible" is plainly erroneous.[229] It is obvious that the DEA is unwilling to change its position, at least in the absence of new research—which the Agency itself prohibits. One of the purposes of the DEA is limiting access to and controlling drugs.[230] Thus, there is no real motivation for the DEA to encourage more research on controlled substances or to lessen its regulations making make drugs easier to obtain.

No petition for rescheduling will be successful as long as the DEA requires FDA-caliber clinical trials and fulfillment of its five-factor medical-use test. The research required is practically impossible; thus, no "currently accepted medical use" will be found and exhaustion will be futile.

Exhaustion of administrative remedies may be inappropriate when the agency's remedy is inadequate "because of some doubt as to whether the agency was empowered to grant effective relief."[231] In *Washington*, the plaintiffs argued that the CSA violated their constitutional rights and that they were personally injured by the DEA's administration of the statute.[232] The Supreme Court has recognized that agencies are "ill suited to address structural constitutional challenges," which fall outside the scope of their "technical expertise."[233] An administrative proceeding with the DEA is an inadequate forum to determine the constitutionality of the Agency's own enabling statute. Any interested party, like the plaintiffs in *Washington*, should be able to challenge the constitutionality of CSA scheduling and scheduling criteria without first exhausting remedies available with the DEA. The DEA is incompetent to hear constitutional

227. *See id.*

228. *See supra* Part I.B (discussing DEA petitions).

229. The court noted that exhaustion of administrative remedies furthers two goals: protecting agency authority and promoting judicial efficiency. *See Washington*, 925 F.3d at 117.

230. *See DEA Mission Statement*, U.S. DRUG ENF'T. ADMIN., https://www.dea.gov/about/mission [https://perma.cc/VE7V-QKKM] ("The mission of the [DEA] is to enforce the controlled substances laws . . . [and] reduc[e] the availability of illicit controlled substances on the domestic and international markets.").

231. Gibson v. Berryhill, 411 U.S. 564, 575 n.14 (1973); *see also* McCarthy v. Madigan, 503 U.S. 140, 146–47 (1992) (finding that exhaustion was not required because the available administrative remedy would be inadequate).

232. 925 F.3d 109 at 114–15.

233. Carr v. Saul, 141 S. Ct. 1352, 1360 (2021) (citing other instances in which the Court has excused exhaustion in the context of constitutional challenges).

challenges to the CSA; therefore, any remedy the Agency could render is inadequate.[234]

Furthermore, if plaintiffs challenged the constitutionality of the DEA's five-factor medical-use test, they should not be required to exhaust administrative remedies.[235] It is unlikely that the DEA will declare its own test invalid. The validity of the five-factor medical-use test is purely an issue of statutory interpretation of the language "currently accepted medical use." Review and consideration of statutory interpretation is the court's role, where an agency's expertise is not particularly helpful.[236] The DEA's law enforcement expertise is not needed to determine the validity of the five-factor test or evaluate nuanced developments in medical marijuana research to properly schedule the drug. Hence, the principles underlying exhaustion are not supported because any remedy with the DEA is inadequate. Once the validity of the five-factor medical-use test is before a federal court, the court may then use its discretionary authority to defer to the DEA's interpretation of the CSA, or it may find the interpretation unreasonable.[237]

Exhaustion may also be excused where the remedy would "occasion undue prejudice to subsequent . . . state action," such as an "unreasonable . . . timeframe" for administrative action.[238] The Second Circuit aptly notes that the average administrative proceeding with the DEA takes about nine years to complete.[239] A long delay of this kind "cast[s] doubt on the appropriateness of requiring exhaustion."[240] Medical marijuana patients already face restricted access to certain federal and state services.[241] Their right to travel with medically

234. *See supra* Part II.D.2.

235. If exhaustion were excused in this instance, the five-factor test would finally receive a genuine review by a court.

236. *See supra* notes 169–74 and accompanying text.

237. *See supra* note 198 (discussing *Chevron* deference).

238. McCarthy v. Madigan, 503 U.S. 140, 146–47 (1992).

239. Washington v. Barr, 925 F.3d 109, 120 (2d Cir. 2019).

240. *Id.* (citing Gibson v. Berryhill, 411 U.S. 564, 575 n.14 (1973)).

241. For example, even when a patient lives in a cannabis-legal state, Medicare does not cover the cost of the marijuana. Zia Sherrell, *Does Medicare Cover Medical Cannabis?*, MEDICALNEWSTODAY (Sept. 30, 2020), https://www.medicalnewstoday.com/articles/does-medicare-cover-medical-cannabis [https://perma.cc/K8GQ-HCPC]. Out-of-pocket costs that a medical marijuana patient could face include visits to a doctor's office, the marijuana itself, fees for a medical marijuana card, and fees for using that card at a dispensary. *Id.* Medical cannabis use also does not qualify for protections under the Americans with Disabilities Act (ADA). James v. City of Costa Mesa, 700 F.3d 394, 405 (9th Cir. 2012). In *James*, the plaintiffs alleged that the threats of closures of local marijuana

necessary cannabis onto or across federal property is also severely inhibited by federal marijuana regulation.[242] Forcing these patients to exhaust their administrative remedies and wait at least nine years for DEA decision-making on marijuana scheduling is unduly prejudicial.

The Second Circuit even recognizes that undue delay could make each *McCarthy* exception applicable to excuse exhaustion. "[U]ndue delay, if it in fact results in catastrophic health consequences, could make exhaustion futile. Moreover, the relief the agency might provide could, because of undue delay, become inadequate. And finally, and obviously, Plaintiffs could be unduly prejudiced by such delay."[243] The Second Circuit does not consider an almost decade-long administrative process during which individuals will face indefinite uncertainty about their access to lifesaving medication to be unduly prejudicial. That is plainly illogical. Undue prejudice is even more problematic in the context of healthcare.[244] Medical marijuana patients should not be subject to dire uncertainty while they exhaust inadequate remedies with the DEA. Because plaintiffs who utilize the administrative process to challenge the DEA will face undue prejudice, courts should not deny judicial review due to a failure to exhaust administrative remedies.

C. The Big Picture

This Note began with a larger interest in the separation of powers—more specifically an inquiry into when and how the separate branches of government interact and limit each other's power. The so-called "Article II legislators," who are executive branch rule makers housed in agencies, are afforded great deference and wield considerable political

dispensaries violated the ADA's prohibition against discrimination in the provision of public services. *Id.* at 396–97. The plaintiffs were severely disabled California residents who argued that "[c]onventional medical services, drugs, and medications" had not alleviated their pain. *Id.* at 396. While the court sympathized with the plaintiffs' impairments, it held that the ADA does not protect disabled individuals who use illegal drugs. Despite marijuana's legal status in California, the ADA defines "illegal drugs" as those that are unlawful under the CSA. *See* 42 U.S.C. § 12210. Recently, the Third Circuit held that as a matter of first impression, the use of marijuana for medical purposes, even when authorized by state law, remains a violation of federal law for the purposes of the Bail Reform Act. United States v. Cannon, 36 F.4th 496, 499–501 (3d Cir. 2022). *See also* Nation v. Trump, 818 F. App'x 678, 680–81 (9th Cir. 2020) (requiring a medical cannabis patient, who was evicted from public housing, to exhaust administrative remedies with the DEA before vindicating her constitutional rights in federal court).

242. *See* United States v. Gilmore, 886 F.3d 1288, 1290–91 (9th Cir. 2018).

243. Washington v. Barr, 925 F.3d 109, 120–21 (2d Cir. 2019).

244. Abbey v. Sullivan, 978 F.2d 37, 46 (2d Cir. 1992) ("[I]f the delay attending exhaustion would subject claimants to deteriorating health . . . then waiver [of exhaustion] may be appropriate.").

power in making rules with the force of law.[245] Even with an agency's significant political power, it is important to remember that an agency is "neither Congress nor President nor Court, but an inferior part of government."[246] Agencies can and should be subject to control from the constitutionally created branches of government. This control comes in two forms. First, Congress delegates authority to agencies through statutes. Second, courts must have the ability to ensure the legality and constitutionality of an agency's actions under Congress's delegation.[247] In the second form, many plaintiffs turn to the APA as the mechanism for judicial review of potentially inappropriate agency action. Plaintiffs can argue that the agency action was arbitrary, capricious, an abuse of discretion, or violative of some federally protected right.[248] Plaintiffs may also seek judicial review by raising constitutional challenges to an agency's action.[249]

When determining whether judicial review is available, federal courts rely on several factors, including constitutional, statutory, and prudential considerations.[250] Prudential considerations limiting judicial review, like the exhaustion doctrine, impair the courts' ability to exercise their essential role in checking agency decision-making. These tools are sometimes used to allow courts to punt important decisions for another day.[251] When review of an agency's self-interested interpretations or actions is withheld, it essentially allows the agency to act as its own judge. Likewise, erroneous application of the exhaustion doctrine allows courts to avoid their own duty of providing impartial review of agency action. Plaintiffs seeking judicial review face grave uncertainty in the face of the potential imposition of an improper exhaustion requirement.

245. Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV, 573, 575 (1984).

246. This level of control ensures intergovernmental functionality within the larger conception of the separation of powers. *Id.* at 579.

247. *Id.* at 579–80 n.18 (noting that "availability of at least limited judicial review . . . [is] an essential element of the grant of rulemaking authority").

248. *See* 5 U.S.C. § 706.

249. *Id.*; *see also* STRAUSS, *supra* note 4, at 335–40.

250. *See supra* notes 3–6 and accompanying text.

251. Prudential limitations are largely "judge-empowering at the expense of democratically accountable bodies, thereby distorting the role of the Judiciary in its relationship to the Executive and the Legislature." Fred O. Smith, Jr., *Undemocratic Restraint*, 70 VAND. L. REV. 845, 850 (2017) (cleaned up) (quoting Hein v. Freedom from Religion Found., Inc., 551 U.S. 587, 635–36 (2007) (Scalia, J., concurring)). Further, "[r]elegating a jurisdictional requirement to 'prudential' status is a wondrous device, enabling courts to ignore the requirement whenever they believe it 'prudent'—which is to say, a good idea." *Id.* (quoting United States v. Windsor, 133 S. Ct. 2675, 2701 (2013) (Scalia, J., dissenting)).

In the context of marijuana regulation and the DEA, the lack of judicial review is based on an erroneous application of the exhaustion doctrine. While the DEA maintains full authority to reschedule or deschedule drugs, the Agency has made it clear that the federal control over marijuana will not change anytime soon. For example, former acting head of the DEA Robert Patterson was quoted as stating, "The reason why [marijuana] remains in Schedule I is the science."[252] Despite decades of scientific and medical data and 5.4 million American medical marijuana patients, the DEA maintains that "marijuana has never been determined to be medicine."[253] These frustratingly ignorant remarks exemplify the DEA's incompetence and inability to act as its own judge when faced with challengers seeking federal marijuana reform.

The DEA is both a textual and physical gatekeeper restricting the science needed to facilitate rescheduling. The DEA acts as the textual gatekeeper by maintaining an untenable five-factor test for determining whether a substance has a currently accepted medical use. Marijuana will always fall short of fulfilling the five factors because the DEA's role as the physical gatekeeper will not allow for more expansive research on the drug. Judicial review of marijuana scheduling and DEA action on the merits could potentially demonstrate both APA and constitutional violations.

The Second and Ninth Circuits' recent treatment of marijuana plaintiffs could set a dangerous precedent for exhaustion doctrine application. Exhaustion requirements at odds with the APA and recognized common law exceptions may occur again in other agency contexts outside of the DEA and subject different classes of plaintiffs to uncertainty and unfairness.

CONCLUSION

The current marijuana regulatory scheme is a Catch-22. The DEA has created a five-factor test that must be fulfilled to demonstrate a drug's "currently accepted medical use." To reschedule marijuana out of the restrictive Schedule I category, the five factors must be fulfilled.[254] However, the test requires rigorous, FDA-caliber clinical research. But marijuana's designation as a Schedule I drug prevents the necessary

252. *Challenges and Solutions in the Opioid Abuse Crisis Before the H. Comm. on the Judiciary*, 115th Cong. at 14 (2018) (statement of Robert Patterson, acting head of the DEA).

253. David Downs, *The Science Behind the DEA's Long War on Marijuana*, SCI. AM. (Apr. 19, 2016), https://www.scientificamerican.com/article/the-science-behind-the-dea-s-long-war-on-marijuana/ [https://perma.cc/Z5AD-BENT]; *Medical Marijuana Patient Numbers*, MARIJUANA POL'Y PROJECT, https://www.mpp.org/issues/medical-marijuana/state-by-state-medical-marijuana-laws/medical-marijuana-patient-numbers/ (last updated May 27, 2021) [https://perma.cc/24SX-7EYR].

254. Ams. for Safe Access v. DEA, 706 F.3d 438, 450–52 (D.C. Cir. 2013).

research to facilitate rescheduling. It is ironic that the DEA has refused to recognize marijuana's "currently accepted medical use" when every state makes the drug available in some way for medical purposes.[255] While administrative progress with the DEA remains stagnant, the federal prohibition of marijuana will continue. Federal marijuana illegality jeopardizes the health and well-being of its users. The quickly changing state legal landscape for marijuana will direct more pressure on not only the DEA, but also the courts.

Judicial review is an imperative check on administrative agency action.[256] But recently, courts hearing marijuana rescheduling cases have denied review on the basis that the plaintiffs must exhaust their administrative remedies. This exhaustion requirement is judicially created and not mandated under the CSA. An exhaustion requirement in this context is inappropriate in two ways. First, in APA cases, application of the doctrine directly violates the precedent set in *Darby v. Cisneros*. *Darby* holds that courts may not require a plaintiff to exhaust administrative remedies before seeking judicial review under the APA when neither a statute nor a rule mandates exhaustion.[257] Second, in all other cases, the common law exceptions to exhaustion are applicable.[258] The balance of interests weighs in favor of judicial review because exhaustion neither protects agency authority nor enhances judicial efficiency.

255. *See supra* notes 14–16 and accompanying text.

256. Kucana v. Holder, 558 U.S. 233, 237 (2010) (stating that the separation of powers "caution[s] us against reading legislation, absent clear statement, to place in executive hands authority to remove cases from the Judiciary's domain").

257. Darby v. Cisneros, 509 U.S. 137, 153–54 (1993).

258. *See supra* Part II.D.

The Supreme Court has held that when lower courts impose exhaustion requirements not required by statute, they "exceed[] the proper limits of the judicial role."[259] As long as plaintiffs are met by the blunt forces of the DEA's interpretive roadblocks and improper exhaustion requirements in the courts, marijuana policy in the United States will remain dangerously impracticable.

Kennedy Dickson[†]

259. Jones v. Bock, 549 U.S. 199, 203 (2007).

† J.D., 2023, Case Western Reserve University School of Law; B.S. Forensic Chemistry, 2019, University of Mississippi Sally McDonnell Barksdale Honors College. I want to thank Dr. Kristine Willett for encouraging me to blaze my own path and pursue research that is important to me, Professor Katharine Van Tassel for her guidance in the early stages of crafting this topic, and Professor Jonathan Entin for his support and expert commentary. I am lucky to have been one of his students. Finally, thank you to my parents and Matt Borcas for always listening to my impromptu lectures about federal marijuana reform.