No. 11-1265

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICANS FOR SAFE ACCESS, *et al.*

Petitioners

v.

DRUG ENFORCEMENT ADMINISTRATION, *et al.*

Respondents.

PETITION FOR REVIEW OF A FINAL ORDER OF THE DRUG ENFORCEMENT ADMINISTRATION

PETITIONERS' CORRECTED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

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INTRODUCTION

Petitioners Americans for Safe Access ("ASA"), William Britt ("Britt"), the Coalition to Reschedule Cannabis ("CRC"), Cathy Jordan ("Jordan"), Michael Krawitz ("Krawitz"), Rick Steeb ("Steeb"), and Patients Out of Time (collectively Petitioners) hereby petition this Court, pursuant to Circuit Rules 27 and 35, and Fed.R.App.P. 35 and 40, for rehearing *en banc* and by the panel of the published opinion, dated January 22, 2013, affirming the decision of respondent Drug Enforcement Administration ("DEA") to deny Petitioners' marijuana rescheduling request. Although Petitioners recognize that such review is extraordinary and rarely granted, such review is warranted in this case to secure uniformity of this Court's decisions and to resolve an exceptionally important questions of law that annually affects the lives of millions of seriously ill persons. In particular, the panel decision in this case: (1) conflicts with *National Organization for the Reform of Marijuana Laws ("NORML") v. DEA*, 559 F.2d 735 (D.C. Cir. 1977), which held that the DEA must consider the relative abuse potential of controlled substances when making scheduling determinations under the Controlled Substances Act, 21 U.S.C. § 801 *et seq*. ("CSA"); (2) conflicts with *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987) (cited with approval in *Doe v. DEA*, 484 F.3d 561 (D.C. Cir. 2007)), which held that the DEA cannot treat the lack of FDA marketing approval as conclusive evidence that a substance has no "currently

accepted medical use in treatment in the United States," *see* 21 U.S.C. § 812(b)(1)(B); and (3) conflicts with the mandate of *Grinspoon* and its progeny that a "meaningful hearing" must be held by the Department of Health and Human Services ("HHS") after it issues its report in scheduling determinations, *see Grinspoon*, 828 F.2d at 890-91. Because these errors disrupt the harmony established by this and other courts' decisions, this case warrants the extraordinary remedy of panel rehearing and rehearing *en banc*. *See* Fed.R.App.P 35 & 40.

STATEMENT OF THE CASE

After nearly a decade of delay, the DEA denied petitioners' request to reschedule marijuana under the CSA on July 8, 2011. *See Denial of Petition to Initiate Proceedings to Reschedule Marijuana*, 76 Fed. Reg. 40, 552 (July 8, 2011), Joint Appendix ("JA") 211-249; *see also In re: Coalition to Reschedule Cannabis*, No. 11-5121 (D.C. Cir. 2011) (writ petition to compel agency action unlawfully withheld).

Despite more than two hundred peer-reviewed studies demonstrating that marijuana does, in fact, have medical use, Joint Appendix ("JA") 96-104, a panel of this Circuit affirmed this denial by published decision, dated January 22, 2013. *Americans for Safe Access v. DEA*, 706 F.3d 438 (D.C. Cir. 2013) (attached hereto as Exhibit 1). Contrary to the commands of Congress in enacting the CSA in 1971, this Court did not balance the relative abuse potential of marijuana compared to

other controlled substances in affirming the scheduling determination. *See NORML v. DEA*, 559 F.2d 735, 748-50 (D.C. Cir. 1977). Compounding this error, this Court failed to properly consider evidence proffered by Petitioners that marijuana does, in fact, have medical use, even if it has not been approved by the FDA for marketing. *See* Appellant's Opening Brief ("AOB") at 29-32 (collecting citations). For these reasons, Petitioners request rehearing.

ARGUMENT

I. THE PANEL ERRED IN AFFIRMING THE DENIAL OF THE RESCHEDULING PETITION WITHOUT GIVING *ANY* CONSIDERATION TO MARIJUANA'S RELATIVELY LOW POTENTIAL FOR ABUSE

Whereas this Court previously flatly rejected "the assumption that placement in CSA Schedule I is automatically required if the substance has no currently accepted medical use in the United States," *NORML v. DEA*, 559 F.2d 735, 747 (1977), the panel in this case held, without discussion, that "[u]nder the terms of the CSA, marijuana cannot be rescheduled to Schedules III, IV, or V without a 'currently accepted medical use,'" *see* Opinion at 21 (citing 21 U.S.C. § 812(b)(3)-(5). The panel, then, simply ignored that marijuana has an extremely low abuse potential relative to other controlled substances, despite having been presented voluminous evidence that marijuana does not belong in Schedule I. *See* AOB at 37-48.

Under the CSA, by sharp contrast, as this Court explained in *NORML*, the DEA must engage in a "finely tuned balancing process involving several medical and scientific considerations" in making a scheduling determination. *See* 559 F.2d at 748. "If, as [the DEA] contends, a determination that the substance has no accepted medical use ends the inquiry, then presumably Congress would have spelled that out in its procedural guidelines." *Id*. Indeed, as this Court previously recognized, the House Report accompanying the enactment of the CSA specifically states that the DEA must consider numerous criterion, in addition to relative abuse potential, in making scheduling determinations. *See id*. at 748 n. 56 (citing H.R. Rep. No. 91-1444, pt. 1, at 35).

Thus, diverging completely from the panel's unexplained assumption that relative abuse potential is not part of the scheduling inquiry, *see* Opinion at 21, a unanimous panel of this Court previously declared as follows:

> Admittedly, Section 202(b), 21 U.S.C. § 812(b), which sets forth the criteria for placement in each of the five CSA schedules, established medical use as the factor that distinguishes substances in Schedule II from those in Schedule I. However, *placement in Schedule I does not appear to flow inevitably from lack of a currently accepted medical use*. Like that of Section 201(c), the structure of Section 202(b) contemplates balancing of medical usefulness along with several other considerations, including potential for abuse and danger of dependence. To treat medical use as the controlling factor in classification decisions is to render irrelevant the other "findings" required by Section 202(b). The legislative history of the CSA indicates that medical use is but one factor to be considered, and by no means the most important one.

NORML. 559 F.2d at 748 (emphasis added) (footnotes omitted). Under this Court's analysis in *NORML v. DEA*, the panel erred in failing even to consider marijuana's relatively low potential for abuse, which requires its placement in a schedule other than the most restrictive Schedule I. *See* AOB at 37-41; *cf. NORML v. DEA*, 559 F.2d 753, 748 n.58 (1977) ("[a] key criterion for controlling a substance . . . is the substance's potential for abuse") (quoting H.R. Rep. No. 91-1444, pt. 1, at 34).[1] Marijuana does not have nearly as high a potential for abuse as methamphetamine and cocaine, which are categorized in Schedule II. *See* AOB at 46-48 (citing Nutt, David, *et al.*, *Development of a Rational Scale to Assess the Harm of Drugs of Potential Abuse*, 369 Lancet 1047 (2007)); Smith, Annaliese, *Marijuana as Schedule I Substance: Political Ploy or Accepted Science?*, 40 Santa Clara L. Rev. 1137, 1164-65 (2000) ("With limited potential for physical and psychological dependence, rescheduling marijuana appears appropriate"). Without explanation, the panel failed to cite or distinguish this Court's opinion in *NORML v. DEA*, 559 F.2d 735 (D.C. Cir. 1977), which requires this inquiry.

[1] If it were otherwise, poppy straw would not have been deemed suitable for placement in Schedule II by Congress; however, Congress deemed this so, despite the admitted lack of any medical use for this substance. *See* 21 U.S.C. §§ 812(b)(2)(B) & (c), Schedule II(a)(3) & (4); *NORML*, 559 at 748 ("DEA's own scheduling practices support the conclusion that substances lacking medical usefulness need not always be placed in Schedule I. At the hearing before ALJ Parker DEA's Chief Counsel, Donald Miller, testified that several substances listed in CSA Schedule II, including poppy straw, have no currently accepted medical use.").

II. THE PANEL ERRED, AND DEPARTED FROM ESTABLISHED AUTHORITY, IN CONCLUDING THAT A SUBSTANCE DOES NOT HAVE A "CURRENTLY ACCEPTED MEDICAL USE IN TREATMENT IN THE UNITED STATES," UNLESS IT HAS RECEIVED FDA MARKETING APPROVAL

In *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), which was cited with approval by this Court in *DOE v. DEA*, 484 F.3d 561, 571 (D.C. Cir. 2007), the court held that "the absence of FDA approval for interstate commerce does not foreclose the possibility that a substance might still possess an accepted medical use or even be considered safe for use under medical supervision. It appears, instead, that blind reliance on the lack of FDA interstate marketing approval could cause a substance to be placed in Schedule I, even though one or two of the three requirements for placement of a drug in Schedule I have not been proven." *Id.* at 888. Stated succinctly, FDA approval is sufficient, but not necessary to a finding that a substance has a "currently accepted medical use for treatment in the United States" under the CSA. *See Grinspoon*, 828 F.2d at 890 ("the methaqualone legislation demonstrates Congress' belief that FDA approval is sufficient to establish the existence of an accepted medical use, but not that the lack of FDA approval – the issue in this case – necessarily negates the possibility that the substance in question has an accepted medical use and is safe for use under medical supervision"); *see also Doe v. DEA*, 484 F.3d 561, 571 (D.C. Cir. 2007)

("Whereas the *absence* of FDA marketing approval may not be a reasonable proxy for lack of currently accepted medical use, the *presence* of FDA marketing approval obviously *is* powerful evidence that a drug has currently accepted medical use" The Fact that the DEA has apparently accepted FDA marketing approval as *one* way to demonstrate currently accepted medical use is not the equivalent of a broad declaration saying FDA approval is the *only* way") (emphasis in original).

Based on these authorities, the government itself did not contend that Phase II or Phase III FDA-approved studies are necessary to a finding that a substance has a currently accepted medical use for treatment in the United States. *See* Respondents' Brief. Rather, the government simply noted that "[n]o Phase II or Phase III studies of marijuana have been conducted." Opinion at 25 (citing 76 Fed. Reg. at 40,579-80). Read in light of *Grinspoon* and its progeny, *see Doe v. DEA*, 484 F.3d at 571, this statement meant that petitioners could not establish "currently accepted medical use" simply by reference to FDA approval. It did not mean, as the panel construed it, that FDA approval was *necessary* to prove that a substance has an accepted medical use under the CSA. *Compare* Opinion at 26 ("The DEA interprets 'adequate and well-controlled studies' to mean studies similar to what the Food and Drug Administration ("FDA") requires for a New Drug Application ("NDA")) *with Doe,* 484 F.3d at 571; *Grinspoon*, 828 F.2d at 888 (FDA marketing

approval is not necessary to a finding of "currently accepted medical use" under the CSA).

Indeed, as the court observed in *Grinspoon*, "we fail to see how the interpretation of the Uniform CSA offered by the Commissioners has any bearing at all on the intent of Congress, which enacted the federal CSA *prior to* the creation of the Uniform CSA." 828 F.2d at 887 (emphasis in original). "[W]e find no necessary linkage between failure to obtain FDA interstate marketing approval and a determination that the substance in question is unsafe *and* has no medical use. Indeed, the FDCA does not even mention the term "medical use." In short, it is plainly possible that a substance may fail to obtain interstate marketing approval even if it has an accepted medical use." *Id.* (emphasis in original). Congress did not seek "to permit blind reliance on FDA standards as a legitimate shortcut in the general run of cases." *Id.* at 889; *see also id.* at 890 ("We believe . . . absolute reliance on the absence of FDA approval would be inappropriate and, indeed, contrary to the intent of Congress in enacting the CSA").

Were it otherwise, as the panel erroneously held, a substance could have medical use, yet be deemed not to have such medical use by the DEA, due to market barriers to FDA approval. As the court stated in *Grinspoon*, "the impermissibility of substituting Food and Drug Cosmetic Act ("FDCA") standards for CSA scheduling criteria becomes even more apparent when we compare the

dearth of support in the legislative history for such an interpretation with the language and history of several subsequent legislative enactments in the controlled substances field." *See Grinspoon*, 828 F.2d at 888-89.

Despite this authority, the panel in this case equated "currently accepted medical use" with FDA-approved studies. *See* Opinion at 26. It did so without warning to Petitioners, instead chiding them for responding to questions not raised by the government and posed for the first time at oral argument. *See* Opinion at 27. This Court should grant *en banc* review or panel rehearing to address thoroughly these issues, which impact more than a million seriously ill people.

III. THE PANEL ERRED IN FAILING TO CONSIDER PETITIONERS' ARGUMENT THAT THE DEA SHOULD HAVE HELD A MEANINGFUL HEARING *AFTER* RECEIPT OF THE DEA AND HHS' REPORT

Underscoring the panel's errors in this case was its failure even to consider Petitioners' argument that that the DEA failed to hold a meaningful hearing on the rescheduling petition after the agency denied the rescheduling petition. *See* AOB at 49-54. In *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir. 1987), the court emphasized a "need for a meaningful hearing" *after* receipt of the HHS report in scheduling determinations. *Id.* at 890 (emphasis in original). "It would surely be anomalous if the FDA's recommendation, based solely on the absence of approval for interstate marketing, sufficed to determine the ultimate conclusion prior to the

hearing." *Id.; accord NORML v. DEA*, 559 F.2d at 749 ("Only a formal referral and hearing will allow due weight to be given to [HHS'] findings.").

Whereas the DEA admits that it has an obligation under the CSA to consider "all other relevant data" available to it at the time of making a scheduling determination, 76 Fed. Reg. 40,552, 40,566 (July 8, 2011) (JA 226) (quoting 21 U.S.C. § 811(b)), the DEA failed to do so in this case, ignoring a plethora of scientific studies demonstrating that marijuana does, in fact, have medical use. *See* JA 96-104. This failure to conduct a hearing, or reopen the record after revealing to Petitioners the results of HHS' evaluations and recommendations in 2006 exacerbates the error committed by the panel, which found that Petitioners failed to respond to an argument that the government itself did not make – that "adequate and well-controlled studies" must be FDA-approved Phase II or III clinical trials. *See* Opinion at 21. "It was not the kind of agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process." *NORML v. Ingersoll*, 497 F.2d 654, 659 (D.C. Cir. 1974). Rehearing is necessary to harmonize the court's decision in *Grinspoon* regarding the need for a meaningful hearing with this Court's precedent.

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CONCLUSION

For the foregoing reasons, Petitioners respectfully request panel rehearing and rehearing *en banc* of this Court's published opinion, dated January 22, 2013.

DATED: March 27, 2013

Respectfully Submitted,

/s/ Joseph D. Elford
Joseph D. Elford

Counsel for Petitioners

CERTIFICATE OF COMPLIANCE PURSUANT TO CIRCUIT RULES 35 AND 40

I certify that pursuant to Circuit Rules 35 and 40, the attached petition for panel rehearing and rehearing *en banc* is in compliance with Fed.R.App. 32(c) and does not exceed 15 pages.

DATED: March 27, 2013

Respectfully Submitted,

/s/ Joseph D. Elford
Joseph D. Elford

Counsel for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that the foregoing were served via the ECF filing system upon the Lena Watkins, United States Attorney General's Office, 950 Pennsylvania, Avenue, N.W., Washington DC, 20530, and upon Carl Olsen, P.O. Box 4091, Des Moines, IA, 50333.

DATED: March 27, 2013 Respectfully Submitted,

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