

IN THE UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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AMERICANS FOR SAFE ACCESS,

Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
and UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants-Appellees.

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA  
No. C 07-01409 WHA

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BRIEF FOR THE APPELLEES

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### STATEMENT OF JURISDICTION

Plaintiff invoked the district court's jurisdiction under 28 U.S.C. § 1331 and the Administrative Procedure Act (APA), 28 U.S.C. §§ 704, 706. Jurisdiction was contested. The district court dismissed the complaint and entered final judgment for the government on November 20, 2007. Plaintiff filed a timely notice of appeal on December 20, 2007. This Court has appellate jurisdiction under 28 U.S.C. § 1291.

### STATEMENT OF THE ISSUE

Whether the district court correctly held that plaintiff could not bring suit under the Information Quality Act (IQA) or the Administrative Procedure Act to compel the Department of Health and Human Services (HHS) to declare that marijuana has a currently accepted use in treatment in the United States.

### STATEMENT OF THE CASE

Plaintiff, Americans for Safe Access, is a nonprofit corporation whose mission is "to ensure safe and legal access to cannabis (marijuana) for therapeutic uses and research." See <http://www.safeaccessnow.org/section.php?id=3>. Plaintiff believes that marijuana should not be listed in schedule I of the Controlled Substances Act. In this suit, plaintiff seeks to compel the Department of Health and Human Services to "correct" a statement made during consideration of a petition to reschedule marijuana that was denied by the Drug Enforcement Administration (DEA) in 2001. 66 Fed. Reg. 20038 (2001). As part of that

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proceeding, HHS provided its views on the medical uses of marijuana, stating that marijuana "has no currently accepted medical use in treatment in the United States." Id. at 20039.

In this suit, plaintiff urges that HHS should be required to replace this statement with the following declaration:

**"Marijuana has a currently accepted use in treatment in the United States."** ER34 (plaintiff's emphasis). As the legal basis for its claim, plaintiff invokes the Administrative Procedure Act and a provision codified as a note to the Paperwork Reduction Act that is generally referred to as the Information Quality Act.

The district court dismissed the complaint. The court held that the Information Quality Act does not create a judicially enforceable right to correct agency information. ER27-29 (citing Salt Institute v. Leavitt, 440 F.3d 156 (4th Cir. 2006)). The court further explained that plaintiff had not identified final agency action subject to APA review. ER29-30. After permitting plaintiff to amend its complaint, the court also rejected plaintiff's characterization of its suit as one to compel agency action unlawfully withheld or unreasonably delayed, concluding that plaintiff had "not shown that the action it seeks to compel is legally required." ER8.



## STATEMENT OF FACTS

### I. Statutory And Administrative Background

#### A. The Information Quality Act And Implementing Guidelines.

The Paperwork Reduction Act authorizes the Office of Management and Budget (OMB) to develop and oversee the implementation of policies, principles, standards, and guidelines for dissemination of public information. See 44 U.S.C. § 3504(d)(1). The provision known as the Information Quality Act was included in appropriations legislation for fiscal year 2001, and is codified as a note to the Paperwork Reduction Act. See 44 U.S.C. § 3516 note. The Information Quality Act directed OMB to issue "guidelines" that provide "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by the agencies. Ibid. OMB was to provide guidance for agencies to create their own guidelines for maximizing the quality of their information and for creating "administrative mechanisms allowing affected persons to seek and obtain correction of information[.]" Ibid.

OMB published final guidelines implementing the IQA in 2002. See 67 Fed. Reg. 8452 (Feb. 22, 2002). OMB recognized that it was "important that these guidelines do not impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other

technologies to disseminate information that can be of great benefit and value to the public." Id. at 8453. Accordingly, OMB explained that agencies "are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB." Id. at 8458.

OMB explained that the administrative mechanisms for obtaining correction of information "shall be flexible [and] appropriate to the nature and timeliness of the disseminated information[.]" Id. at 8459. The guidelines indicated that agencies should "specify appropriate time periods for agency decisions on whether and how to correct the information" and "establish an administrative appeal process to review the agency's initial decision." Ibid. OMB encouraged agencies to incorporate the standards and procedures "into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes." Id. at 8453; see also id. at 8459.

Following the issuance of the OMB guidance, HHS issued its own "Guidelines for Ensuring the Quality of Information Disseminated to the Public."<sup>1</sup> The HHS guidelines included

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<sup>1</sup> The HHS guidelines, first published in October 2002, are reproduced in the addendum to plaintiff's brief and are available at [www.hhs.gov/infoquality](http://www.hhs.gov/infoquality).

department-wide umbrella guidelines as well as agency-specific guidelines, such as the guidelines of the FDA. HHS indicated that it would endeavor to respond to correction requests within 60 days, and that, if more time was needed, it would advise the complainant of why and provide an estimated decision date. Id. at Part I, § E. HHS explained that "[e]xisting public comment procedures for rule-makings and other formal agency actions already provide well established procedural safeguards that allow affected persons to raise information quality issues on a timely basis," and that, "[a]ccordingly, agencies will use these existing procedures to respond to information quality complaints that arise in this process." Ibid. HHS noted that it may issue an earlier response "where in the agency's judgment issuing an earlier response would not unduly delay issuance of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product.'" Ibid.

#### **B. The Controlled Substances Act**

The Controlled Substances Act classifies controlled substances in five schedules. Gonzales v. Raich, 545 U.S. 1, 13 (2005). In enacting the Act, Congress classified marijuana in schedule I, which applies to substances that have "no currently accepted medical use in treatment in the United States," "a lack of accepted safety for use ... under medical supervision," and "a

high potential for abuse." United States v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 492 (2001) (quoting 21 U.S.C. § 812(b)(1)).

Congress established an exclusive set of statutory procedures under which a controlled substance may be transferred to another schedule. See 21 U.S.C. § 811(a). The statute "delegates authority to the Attorney General, after consultation with the Secretary of Health and Human Services, to add, remove, or transfer substances to, from, or between schedules." Raich, 545 U.S. at 14-15. The Attorney General has delegated his functions to the Administrator of DEA. See Gettman v. DEA, 290 F.3d 430, 432 (D.C. Cir. 2002).

To revise the schedules, DEA must initiate a rulemaking proceeding, which DEA may do on its own motion, at the request of HHS, or on the petition of any interested party. See Gettman, 290 F.3d at 432. If a rescheduling petition is filed with DEA, DEA must request a scientific and medical evaluation and a recommendation from HHS. See ibid. Although the recommendations of HHS are binding on DEA as to scientific and medical considerations, the ultimate classification decision is made by DEA. See ibid.

Final agency action on a rescheduling petition is subject to direct review in the court of appeals. See 21 U.S.C. § 877. This direct-review provision provides the exclusive means by which a scheduling determination may be challenged. See Doe v.

DEA, 484 F.3d 561, 565 (D.C. Cir. 2007). Since the original congressional classification of marijuana, the D.C. Circuit has considered petitions concerning the scheduling of marijuana on six occasions.

## II. Factual Background

### A. Petitions To Reschedule Marijuana

The present action concerns an evaluation provided by HHS to DEA in responding to a petition to reschedule marijuana filed in 1995 by an individual named Jon Gettman. DEA denied the Gettman petition in 2001. See 66 Fed. Reg. 20038 (2001). During the course of consideration of the petition, DEA consulted with HHS as contemplated by the Controlled Substances Act. See id. at 20038, 20039. In response, the Assistant Secretary for Health (who was also the Surgeon General) sent the DEA Administrator a letter recommending that marijuana continue to be subject to control under schedule I. See id. at 20039. The letter stated in relevant part that "marijuana has no currently accepted medical use in treatment in the United States," ibid., and attached analyses prepared by the Controlled Substances Staff of the Food and Drug Administration. See ibid.

In October 2002, after the Gettman petition was denied, plaintiff and other groups filed a new marijuana rescheduling petition with DEA, which is now pending. See ER 53. As required by statute, DEA requested an evaluation from HHS, which was submitted in 2006. See Tr., 7/12/2007, at 10 (Docket Entry #63).

DEA has not taken final action on the rescheduling petition and is free to request additional analysis and further consultation with HHS. Accordingly, the HHS submission has not been made public.

**B. Plaintiff's "Request for Correction of Information"**

In 2004, after filing its rescheduling petition with DEA, plaintiff filed a separate document with HHS, entitled "Request for Correction of Information Contained in HHS Review of the Marijuana Rescheduling Petition of 1995." ER33. Plaintiff's "Request for Correction" argued that statements made by HHS in connection with the Gettman petition did not meet standards of information quality set out in guidelines implementing the Information Quality Act. ER33-45. In particular, plaintiff took issue with the statement that marijuana "'has no currently accepted medical use in treatment in the United States.'" ER34 (quoting 66 Fed. Reg. 20038, 20039 (2001)). Plaintiff requested that HHS "replace this statement with the following statement: '**Marijuana has a currently accepted use in treatment in the United States.**'" ER34 (plaintiff's emphasis). Plaintiff's correction request stressed that "HHS's statements play a crucial role in the DEA's marijuana rescheduling determination," and argued that a decision to reschedule marijuana would "alleviat[e] the suffering of numerous medical marijuana patients throughout the United States represented by ASA[.]" ER42.

After several interim responses, HHS advised plaintiff that it was in the process of evaluating the publicly available peer reviewed literature on the efficacy of marijuana, in connection with the plaintiff's rescheduling petition. ER53.

Plaintiff sought reconsideration, noting that the HHS evaluation of its rescheduling petition would be time-consuming, and asserting that the HHS guidelines require the agency to respond to a correction request within 60 days. ER54-57, ER64. HHS denied the reconsideration request, explaining that a comprehensive review was consistent with the IQA guidelines and essential to ensure the accuracy of its evaluation. ER65-66.

### **III. District Court Proceedings.**

Plaintiff filed this suit, alleging that HHS had violated the Information Quality Act and implementing guidelines. The original complaint sought to compel HHS to "make appropriate corrections to all statements that it has disseminated that marijuana 'has no currently accepted medical use in treatment in the United States,'" and to enjoin the agency from disseminating contrary statements. Complaint, pp.11-12 (Docket Entry #1).

Citing the Fourth Circuit's decision in Salt Institute v. Leavitt, 440 F.3d 156 (4th Cir. 2006), the district court held that the IQA does not create a judicially enforceable right to correct information, ER27-29, and that HHS's response to plaintiff's correction request was not final agency action subject to judicial review under the APA, ER29-30. The court

dismissed plaintiff's action with leave to file an amended complaint.

Plaintiff's amended complaint added a claim seeking to compel HHS to "provide a valid substantive response" to plaintiff's correction request "within 45 days, with the court to retain jurisdiction to review the agency's substantive response under the APA." ER22. After further briefing, the district court dismissed the amended complaint, explaining that plaintiff had failed to show that the action it sought to compel was legally required. See ER8.

#### SUMMARY OF ARGUMENT

Plaintiff asserts that marijuana has "recognized medical benefits" (Pl. Br. 13) and believes that it is therefore not properly classified under schedule I of the Controlled Substances Act. Congress has provided an exclusive means for seeking to reschedule controlled substances, and plaintiff has invoked that procedure by filing a petition for rescheduling that is pending before DEA. A denial of that petition would be subject to direct appellate review under 21 U.S.C. § 877.

In this lawsuit, plaintiff seeks to circumvent these statutory provisions for review by seeking a judicial determination of the issue it has presented to the agencies in its pending rescheduling petition. Recognizing that a review of the pending rescheduling petition is plainly premature, it styles its action as a challenge to the conclusions expressed by HHS



during previous rescheduling proceedings that culminated in 2001. This tactic only compounds the jurisdictional defects. The 2001 rescheduling decision - like a decision resulting from the present petition - could be challenged only in accordance with the statutory direct review provision, 21 U.S.C. § 877. A district court has no jurisdiction to consider a challenge to the conclusions of the agencies expressed in those proceedings.

As the district court held, nothing in the Information Quality Act or the APA suggests otherwise. As the court explained, the IQA requires agencies to publish guidelines concerning the general quality of information and does not create judicially enforceable rights. The APA does not displace the exclusive scheme of direct appellate review established by the Controlled Substances Act, and plaintiff has identified no final agency action or action unlawfully withheld that could even give rise to APA jurisdiction.

#### STANDARD OF REVIEW

The order of dismissal is subject to de novo review in this Court. See Equity Lifestyle Properties, Inc. v. County of San Luis Obispo, 505 F.3d 860, 865 (9th Cir. 2007).

## ARGUMENT

The Information Quality Act And The APA Provide No Basis For Judicial Review Of Agency Assessments Of Whether Marijuana Has A Currently Accepted Use In Treatment In The United States.

- A. The Controlled Substances Act Creates The Exclusive Avenue Of Review Of Agency Determinations On Petitions To Reschedule Controlled Substances.

Marijuana is currently classified under schedule I of the Controlled Substances Act, which applies to substances that have "no currently accepted medical use in treatment in the United States," "a lack of accepted safety for use ... under medical supervision," and "a high potential for abuse." United States v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 492 (2001) (quoting 21 U.S.C. § 812(b)(1)).

The CSA provides the exclusive means for rescheduling of controlled substances, which may be initiated by DEA or by the petition of any interested party. 21 U.S.C. § 811(a). Final agency action on rescheduling petitions is subject to direct judicial review in the court of appeals. 21 U.S.C. § 877. Since the enactment of the CSA, the D.C. Circuit has considered petitions concerning the scheduling of marijuana on six occasions.<sup>2</sup>

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<sup>2</sup> See NORML v. Ingersoll, 497 F.2d 654 (D.C. Cir. 1974); NORML v. DEA, 559 F.2d 735 (D.C. Cir. 1977); NORML v. DEA, No. 79-1660 (D.C. Cir. Oct. 16, 1980); Alliance for Cannabis Therapeutics v. DEA, 930 F.2d 936 (D.C. Cir. 1991) (ACT I); Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131 (D.C. Cir. 1994) (ACT II); Gettman v. DEA, 290 F.3d 430 (D.C. Cir. 2002).

It is plaintiff's position that marijuana has currently accepted uses in treatment in the United States, and plaintiff has urged that view in a petition for rescheduling that it filed with DEA in 2002. In connection with that petition, HHS, as contemplated by statute, has provided views to DEA on scientific and medical considerations and may be called upon to provide additional views. 21 U.S.C. § 811(b). If DEA ultimately denies the petition, that determination will be subject to direct appellate review. 21 U.S.C. § 877.

Plaintiff does not assert that it can, at this juncture, seek judicial review of the views provided by HHS with regard to plaintiff's pending rescheduling petition. Nevertheless, it invoked the district court's jurisdiction to determine whether marijuana has currently accepted medical uses within the meaning of the CSA, an issue crucial to the question of rescheduling. Although plaintiff characterizes its suit as a challenge to conclusions made in earlier rescheduling proceedings that culminated in 2001, its action plainly seeks judicial resolution of issues it has presented in its pending petition for rescheduling.

Plaintiff's attempt to style its action as a challenge to a prior administrative proceeding only underscores the absence of jurisdiction. A challenge to the factual premises of the 2001 decision could have been raised only on direct review from that decision and cannot be belatedly challenged in district court.

See Fry v. DEA, 353 F.3d 1041, 1042-44 (9th Cir. 2003) (thirty-day deadline for filing petition for review under 21 U.S.C. § 877 is jurisdictional).

**B. The Information Quality Act Does Not Provide An Alternative Means For Seeking Review Of The Agency's Assessment Of Whether Marijuana Has A Currently Accepted Use In Treatment In The United States.**

Plaintiff's invocation of the Information Quality Act does not disguise the nature of its challenge, as plaintiff's request for a "correction" makes clear. After filing its pending petition for rescheduling, plaintiff filed with HHS its "Request for Correction of Information Contained in HHS Review of the Marijuana Rescheduling Petition of 1995." ER33. In seeking a "correction" under the IQA, plaintiff took issue with the statement that marijuana "'has no currently accepted medical use in treatment in the United States.'" ER34 (quoting 66 Fed. Reg. 20038, 20039 (2001)). Plaintiff requested that HHS "replace this statement with the following statement: '**Marijuana has a currently accepted use in treatment in the United States.**'" ER34 (plaintiff's emphasis).

The district court correctly rejected this reliance on the IQA as a means for bypassing statutory review procedures. As the Fourth Circuit explained in Salt Institute v. Leavitt, 440 F.3d 156 (4th Cir. 2006), the IQA does not provide a judicial means for challenging asserted inaccuracies in disseminated information. Instead, the statute simply directed "the Office of

Management and Budget to draft guidelines concerning information quality and specifies what those guidelines should contain." Id. at 159.

The IQA directed OMB, in its guidelines, to require individual agencies to issue their own "guidelines" and to establish an "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with [the agency's] guidelines." 44 U.S.C. § 3516 note. Congress did not thereby enmesh the courts in countless standardless disputes about the "quality" of information provided by federal agencies. Instead, Congress provided that agencies would "[r]eport periodically" to OMB as to "the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and ... how such complaints were handled by the agency." Ibid.

Plaintiff mistakenly asserts that Salt Institute did not involve a request to correct information. See Pl. Br. 30. As the Fourth Circuit explained, the plaintiffs in that litigation "filed a petition with the National Heart, Lung, and Blood Institute (NHLBI) 'seeking correction of information disseminated by NHLBI, which [information] directly states and otherwise suggests that reduced sodium consumption will result in lower blood pressure in all individuals.'" Salt Institute, 440 F.3d at 157.

Salt Institute makes clear that plaintiff's reliance on the IQA would be unavailing even if its suit did not interfere with an exclusive scheme of direct appellate review. Unlike plaintiff here, the plaintiffs in Salt Institute had no other apparent avenue for obtaining agency or judicial review of the assertedly inaccurate statements. Nevertheless, as the Fourth Circuit recognized, the IQA did not provide a means for obtaining the requested relief.

**C. The APA Does Not Allow Plaintiff To Circumvent Statutory Direct Review Provisions And, In Any Event, Plaintiff Identifies No Final Agency Action Subject To APA Review.**

Plaintiff's reliance on the APA only highlights the extent to which it attempts to skirt the statutory procedures for rescheduling and judicial review of rescheduling decisions. Presumptions of availability of APA review have no application when Congress has established a scheme for direct review. As this Court has held, "where a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Public Utility Commissioner of Oregon v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985) (citing Telecommunications Research & Action Center v. FCC, 750 F.2d 70 (D.C. Cir. 1984) (TRAC)). Indeed, "even where Congress has not expressly stated that statutory jurisdiction is 'exclusive' ... a statute which vests jurisdiction in a particular court cuts off original jurisdiction in other courts

in all cases covered by that statute." TRAC, 750 F.2d at 77. The APA thus does not allow plaintiff to circumvent the CSA's direct review procedure.

Even apart from this jurisdictional defect, plaintiff identifies no final agency action that would be subject to judicial review under the APA. Even assuming that a response to a request for a "correction" could give rise to judicial review under any circumstances, it would be necessary to establish that the response "'mark[ed] the "consummation" of the agency's decision-making process - it must not be of a merely tentative or interlocutory nature.'" City of San Diego v. Whitman, 242 F.3d 1097, 1101 (9th Cir. 2001) (quoting Bennett v. Spear, 520 U.S. 154, 177-78 (1997)). As the district court concluded, that is plainly not the case here. In response to plaintiff's request for a "correction" of past statements, HHS explained that the issues raised in the request would be considered in the course of proceedings under the Controlled Substances Act. ER52-53, ER65-66. The response thus did not "mark the consummation of the agency's decision-making process." City of San Diego, 242 F.3d at 1101 (quotation marks and citation omitted).

Nor do freestanding agency statements - divorced from regulatory proceedings - determine "'rights or obligations'" from which "'legal consequences [would] flow.'" City of San Diego, 242 F.3d at 1101 (quoting Bennett, 520 U.S. at 178). Plaintiff cannot rely on any asserted legal consequences of the 2001 HHS

statement because the district court had no jurisdiction under 21 U.S.C. § 877 to consider challenges to the 2001 rescheduling order. See Fry v. DEA, 353 F.3d 1041, 1042-44 (9th Cir. 2003); Doe v. DEA, 484 F.3d 561, 565 (D.C. Cir. 2007).

Accordingly, plaintiff insists that its sole claim of harm is that its members "were deterred from using marijuana to ease their suffering, in part, by HHS' statement that marijuana 'has no currently accepted medical use in treatment in the United States.'" ER12, ¶7. This thinly veiled attempt to avoid the exclusive scheme for judicial review cannot create district court jurisdiction. Moreover, even apart from the concerns presented by circumvention of a scheme for direct appellate review, it is established that agency reports, statements or other publications - whether made to the public, to another agency, or to Congress - are not final agency action subject to APA review. Thus, in Guerrero v. Clinton, 157 F.3d 1190 (9th Cir. 1998), this Court refused to review the adequacy of an agency's report to Congress, explaining that the report was not final agency action because it was "purely informational" and had "no legal consequences." Id. at 1194, 1995. See also Invention Submission Corp. v. Rogan, 357 F.3d 452, 453 (4th Cir. 2004) (Patent and Trademark Office advertising campaign alerting consumers to invention promotion scams); Flue-Cured Tobacco Cooperative v. EPA, 313 F.3d 852, 854 (4th Cir. 2002) (EPA report classifying environmental tobacco smoke as a carcinogen); Aerosource v. Slater, 142 F.3d 572, 581



(3d Cir. 1998) (FAA reports warning the aviation community that the plaintiff may have improperly maintained aircraft parts); Industrial Safety Equipment Association, Inc. v. EPA, 837 F.2d 1115 (D.C. Cir. 1988) (EPA report evaluating the effectiveness of respirators); Hearst Radio, Inc. v. FCC, 167 F.2d 225 (D.C. Cir. 1948) (FCC report on public service responsibilities of broadcast licensees); see also Trudeau v. FTC, 456 F.3d 178, 189 (D.C. Cir. 2006) ("we have never found a press release of the kind at issue here to constitute 'final agency action' under the APA").

As the Fourth Circuit observed, if the accuracy of agency statements could be challenged on the basis of their persuasive effect, "almost any agency policy or publication issued by the government would be subject to judicial review." Flue-Cured Tobacco, 313 F.3d at 861. Congress did not intend "to create private rights of action to challenge the inevitable objectionable impressions created whenever controversial research by a federal agency is published." Invention Submission, 357 F.3d at 459 (quoting Flue-Cured Tobacco, 313 F.3d at 861). "Such policy statements are properly challenged through the political process and not the courts.'" Ibid. "Under these circumstances, the presumption of reviewability of agency action is woefully inapposite." Guerrero v. Clinton, 157 F.3d 1190, 1196 (9th Cir. 1998) (quotation marks and citation omitted).<sup>3</sup>

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<sup>3</sup> Cases on which plaintiff seeks to rely only underscore the error of its position. Plaintiff observes that this Court has reviewed the INS's denial of an "immigrant investor visa," and

D. Plaintiff Cannot Create Jurisdiction By Styling Its Challenge As An Attempt To Compel Agency Action Unlawfully Withheld.

Plaintiff fares no better by attempting to recast its claim as a suit to compel agency action "unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1). Jurisdiction under § 706(1) of the APA is in the nature of mandamus, limited to the enforcement of "a specific, unequivocal command," "the ordering of a precise, definite act ... about which [an official] had no discretion whatever." Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 63 (2004) (quotation marks and citations omitted). "Absent such an assertion, a Section 706(1) claim may be dismissed for lack of jurisdiction." Alvarado v. Table Mountain Rancheria, 509 F.3d 1008, 1019-1020 (9th Cir. 2007) (citing Southern Utah, 542 U.S. at 64).

Plaintiff does not and could not assert a failure to act on its pending rescheduling petition. As discussed above, any relief related to that petition would have to be sought in accordance with the exclusive review procedures of the CSA. Public Utility Commissioner of Oregon v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985).

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the FAA's denial of a waiver of its "age 60 Rule." Pl. Br. 25-26. In those cases, in contrast to the present litigation, the agency action under review had legal consequences for the plaintiff. The cited military records and Privacy Act cases, see Pl. Br. 26, are similarly inapposite. Plaintiff is not seeking to have information in its own personnel files corrected; it is urging an agency to reconsider past statements of general public interest.

Nothing in any provision of law requires HHS to resolve the issue raised in plaintiff's "correction" request immediately, without regard to the proceedings on plaintiff's rescheduling petition. Indeed, even apart from the pendency of plaintiff's rescheduling petition, no provision of law requires the government to "correct" statements made in prior administrative proceedings that were subject to direct appellate review.

Inexplicably, plaintiff declares that its correction request is "legally unrelated" to its rescheduling petition. Pl. Br. 15. But as plaintiff cannot dispute, its rescheduling petition urges that marijuana has a "currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1). This is exactly the issue raised in plaintiff's "correction" request. Indeed, plaintiff's "correction" request candidly argued that "HHS's statements play a crucial role in the DEA's marijuana rescheduling determination," ER42, and urged that the rescheduling of marijuana would "alleviat[e] the suffering of numerous medical marijuana patients through the United States represented by ASA[.]" Ibid. The "correction" request is thus inextricably intertwined with the substance of plaintiff's pending rescheduling petition.

Plaintiff does not advance its position by relying on the HHS guidelines implementing the IQA. Far from establishing binding "legislative rules," as plaintiff asserts, Pl. Br. 36, these guidelines are an "an evolving document and process" that

the agency plans to "continually review" and revise in light of its experience. HHS Guidelines, Part I, § D(1). And in any event, the guidelines plainly do not compel HHS to address plaintiff's "correction" request outside the context of the proceedings on plaintiff's rescheduling petition. The guidelines contemplate that "[e]xisting public comment procedures for rule-makings and other formal agency actions already provide well established procedural safeguards that allow affected persons to raise information quality issues on a timely basis," and that, "[a]ccordingly, agencies will use these existing procedures to respond to information quality complaints that arise in this process." HHS Guidelines, Part I, § E.

Plaintiff notes that HHS may issue an earlier response "where in the agency's judgment issuing an earlier response would not unduly delay issuance of the agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination if the agency does not resolve the complaint prior to the final agency action or information product.'" Pl. Br. 23 (quoting HHS Guidelines, Part I, § E). Plaintiff cannot plausibly insist that this highly discretionary guideline is actually a mandate that leaves HHS with "no discretion whatever," Southern Utah, 542 U.S. at 63, to consider plaintiff's "correction" request in connection with plaintiff's rescheduling petition.

Plaintiff is even farther afield in urging that HHS was required by law to provide a substantive response to any "correction" request within 60 days. Although plaintiff asserts that the HHS guidelines "make 60 days the norm for acting on both initial petitions and appeals," Pl. Br. 47, HHS plainly did not commit itself to address the substance of every correction request, however complex, within 60 days. To the contrary, the guidelines simply note that HHS will respond to a request within 60 days and advise the complainant if more time is needed, see HHS Guidelines, Part I, § E, as occurred here.

In short, as the district court explained, plaintiff has "not shown that the action it seeks to compel is legally required." ER8.<sup>4</sup> Although the district court dismissed for failure to state a claim, issues of district court jurisdiction under the APA, standing and the availability of mandamus relief "essentially collapse" in this context. Guerrero v. Clinton, 157 F.3d 1190, 1191 (9th Cir. 1998). As we have explained above, the IQA creates no judicially enforceable rights, the statements that plaintiff seeks to challenge have no legal consequences and, for the same reasons, plaintiff has no redressable injury. See

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<sup>4</sup> The "TRAC factors" that plaintiff cites, see Pl. Br. 47, which are used to evaluate the reasonableness of an agency's delay, have no bearing absent a threshold showing that an agency has failed to take action that it is legally required to take. See, e.g., Brower v. Evans, 257 F.3d 1058, 1067 (9th Cir. 2001) (considering the TRAC factors after determining that the relevant "statutory language clearly and unambiguously required the Secretary to commence a study, consisting of abundance surveys and stress studies, on October 1, 1997") (emphasis omitted).

Guerrero, 157 F.3d at 1191 (because the agency reports "trigger no legal consequences, we conclude that the adequacy of the report is not reviewable, and the injury asserted by the [plaintiffs] is correspondingly not redressable"). Similarly, as the Fourth Circuit concluded in Salt Institute, 440 F.3d at 159, "[b]ecause the statute upon which appellants rely does not create a legal right to access to information or to correctness, appellants have not alleged an invasion of a legal right and, thus, have failed to establish an injury in fact sufficient to satisfy Article III."<sup>5</sup>

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<sup>5</sup> The Fair Housing Act cases on which plaintiff relies to establish standing, see Pl. Br. 31 n.12, are inapposite, because the Fair Housing Act "establishes an enforceable right to truthful information concerning the availability of housing." Havens Realty Corp. v. Coleman, 455 U.S. 363, 373 (1982).

CONCLUSION

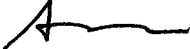
For the foregoing reasons, the case was properly dismissed.

Respectfully submitted,

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JUNE 2008

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)(C)  
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I hereby certify pursuant to Fed. R. App. P. 32(a)(7)(C) that the foregoing brief is monospaced, has 10.5 or fewer characters per inch and contains 5,337 words, according to the count of Corel WordPerfect 12.



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Alisa B. Klein



STATEMENT OF RELATED CASES

We are not aware of any pending related cases.

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 5th day of June, 2008, I caused copies of the foregoing brief to be sent to the Court and to the following counsel by federal express, overnight mail and by email:

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