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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO

AMERICANS FOR SAFE ACCESS, Plaintiff, v. The U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and the U.S. FOOD AND DRUG ADMINISTRATION, Defendants.	No. C 3:07-01049-WHA Date: August 9, 2007 Time: 8:00 a.m. **DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS PLAINTIFF'S COMPLAINT**

Notice of Motion and Motion to Dismiss Plaintiff's Complaint, set for hearing on August 9, 2007 at 8:00 a.m. or as soon thereafter as counsel may be heard.

Defendants hereby move the Court to dismiss plaintiff's Complaint in its entirety for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) or, in the alternative, for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6), for the reasons more fully set forth in defendants' accompanying memorandum of points and authorities.

Dated May 25, 2007

Respectfully Submitted,

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AMERICANS FOR SAFE ACCESS,

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The U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and the U.S. FOOD AND DRUG ADMINISTRATION,

Defendants.

No. C 3:07-01049-WHA

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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INTRODUCTION

In 2001, the Drug Enforcement Administration ("DEA"), after consulting with the Department of Health and Human Services ("HHS"), denied an individual's request for a rulemaking to"reschedule" marijuana under the Controlled Substances Act and thereby ease some of the restrictions on that drug's distribution under federal law. Dissatisfied with DEA's decision, plaintiff Americans for Safe Access, a non-profit corporation, has joined with other groups to file another petition asking DEA to reschedule marijuana. While that DEA petition remains pending, plaintiff asks this Court to order HHS to "correct" its 2001 statement to DEA that marijuana has no currently accepted medical use in the United States. For a number of reasons, this Court should dismiss plaintiff's Complaint.

As an initial matter, plaintiff lacks standing to pursue its claim. Plaintiff has failed to establish standing on behalf of its individual members because it has failed to identify a single member that has suffered a cognizable injury from HHS's allegedly incorrect statement concerning marijuana. And even if there were such individual members, their participation in this litigation would be necessary to establish that they had suffered a cognizable injury fairly traceable to HHS's statement and redressable by injunctive relief. Regardless, plaintiff's effort at "correction" of HHS's statement is not (as it must be to establish standing) germane to plaintiff's stated organizational purpose of "ensur[ing] safe and legal access to cannabis (marijuana) for therapeutic uses and research." See http://www.safeaccessnow.org/section.php?id=3 (last visited May 25, 2007). While plaintiff may argue that public rejection of HHS's statement could encourage some individuals to use illegal drugs, it would not make such use any more or less safe or legal. Similarly, plaintiff also lacks standing to press its claim on its own behalf as an organization because it has not alleged a cognizable injury; plaintiff's interest in marijuana policy, disagreement with the policy of the United States, and use of resources advocating something different amount to a generalized grievance, not constitutional standing. Moreover, plaintiff lacks prudential standing because the ease of its advocacy is not within the zone of

interests regulated by the source of law on which plaintiff relies, the Information Quality Act ("IQA"), which serves to guide federal agencies.

Even if plaintiff could demonstrate a cognizable injury, its alleged injury is not redressable by injunctive or declaratory relief. In particular, to the extent HHS's statement makes it more difficult for plaintiff to effectively advocate marijuana use, "correcting" the statement would not change the fact that marijuana is a schedule I controlled substance under federal law, illegal to distribute except under very limited circumstances.

Moreover, plaintiff also lacks a cognizable injury because, as every court to consider the matter has found, the IQA does not create any judicially enforceable right for plaintiff to obtain the correction of federal agency information in this Court. Because plaintiff cannot show any invasion of a legal right subject to redress in federal court, it has no grounds for relief under the Administrative Procedure Act ("APA"). Similarly, plaintiff's attempt to state an APA cause of action also fails because the underlying agency action – HHS's alleged dissemination of a statement to DEA – is not "final agency action" subject to APA review. Likewise, plaintiff's claim is inappropriate under the APA because plaintiff has an adequate remedy to complain about the statement at issue under the Controlled Substances Act itself; plaintiff cannot use either the APA or the IQA to evade that exclusive statutory review provision. In addition, the determination as to whether the information in HHS's statement regarding marijuana lacks sufficient "quality" such that it is appropriate for correction is within the agency's discretion and expertise to resolve, and is not the kind of issue for which a court is well-equipped to second-guess the agency's conclusions.

Finally, even if plaintiff's claim was justiciable (which it is not), plaintiff has failed to state a claim upon which relief can be granted under the IQA and APA. The IQA applies to "dissemination" of information; here, the only dissemination of HHS's statement that plaintiff has alleged or identified was made not by defendants but by DEA when DEA published correspondence from HHS to DEA in the Federal Register. Plaintiff, however, has not sought any relief (administratively or in this Court) from DEA.

For all of these reasons, this Court should grant defendants' motion and dismiss plaintiff's Complaint.

BACKGROUND

I. Statutory and Regulatory Background

A. The Information Quality Act

The IQA resides in section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 and directs 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 (including statistical information) disseminated by Federal agencies . . . ." Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515] (Dec. 21, 2000) (published at 44 U.S.C. § 3516 note). The IQA also directs OMB to include three specific requirements in its guidelines: (1) that federal agencies develop their own information quality guidelines within one year of the issuance of OMB's guidelines; (2) that federal agencies establish administrative mechanisms for affected persons to seek correction of information that does not comply with OMB's guidelines; and (3) that federal agencies report periodically to OMB on the number and nature of complaints that they receive regarding the accuracy of the information they disseminate. See id. at § 515(b)(2). Neither the IQA itself nor its legislative history provides a mechanism for judicial review of an administrative decision concerning a request for correction of information or of the quality of information.[1] Indeed, the IQA provides no avenue for judicial relief at all.

1. OMB Guidelines

OMB issued proposed guidelines implementing the IQA on June 28, 2001, 66 Fed. Reg. 34489 (June 28, 2001), then, after a period for public comment, published revised guidelines on

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1 The legislative history regarding the IQA includes the following sentence in the Conference Report and Committee Report accompanying the omnibus appropriations bill: "The conferees include a new provision requiring OMB to develop guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by Federal agencies as proposed by the House." H.R. CONF. REP. NO. 106-1033, at 396 (2000); see also H.R. REP. NO. 106-756, at 83 (2000) (committee report containing nearly identical language).

September 28, 2001, 66 Fed. Reg. 49718 (Sept. 28, 2001). Following another period for additional comment, OMB published final guidelines on February 22, 2002. See 67 Fed. Reg. 8452 (Feb. 22, 2002). In its final guidelines, OMB provides guidance to federal agencies for ensuring and maximizing the quality of the information they disseminate to the public. Generally, the guidelines require federal agencies to undertake four principal responsibilities: (1) to "adopt specific standards of quality that are appropriate for the various categories of information they disseminate"; (2) to "develop a process for reviewing the quality . . . of information before it is disseminated"; (3) to "establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines"; and (4) to provide OMB with reports regarding the agencies' information quality guidelines and any information quality complaints they receive. 67 Fed. Reg. at 8458-59.[2]

The consistent theme throughout the OMB guidelines is that "agencies must apply these standards flexibly," "in a common-sense and workable manner," and that the "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. For example, the OMB guidelines provide that federal agencies are to "adopt a basic standard of quality . . . as a performance goal," and "[q]uality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated." Id. Recognizing that the guidelines "cannot be implemented by each agency in the same way," OMB directs agencies to "incorporate [quality standards] into their *existing agency information resources management and administrative practices* rather than create new and potentially duplicative or contradictory processes." Id. (emphasis added).

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2 The OMB guidelines explain that an agency's "pre-dissemination review" of information applies only "to information that the agency first disseminates on or after October 1, 2002," while the "agency's administrative mechanisms . . . apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information." Id. at 8458.

Agencies thus maintain substantial discretion in determining how best to ensure the quality of the information they disseminate.

With respect to the administrative correction mechanisms, the OMB guidelines require agencies to "specify appropriate time periods for agency decisions on whether and how to correct the information" and to "establish an administrative appeal process to review the agency's initial decision." Id. at 8459. OMB makes clear, however, that agencies should correct information only "where appropriate," and that "[t]hese administrative mechanisms shall be flexible" and "appropriate to the nature and timeliness of the disseminated information." Id. As explained in the preamble to the OMB guidelines:

> Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and **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 (emphasis added).

By their terms, the OMB guidelines apply only to "information" that is "disseminated" by a federal agency. Id. The term "information" includes "any communication or representation of knowledge such as facts or data," but "does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views." Id. at 8460. The term "dissemination" means "agency initiated or sponsored distribution of information to the public," but "does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." Id.

2. HHS Guidelines

On October 1, 2002, pursuant to the IQA and the OMB guidelines, the Department of Health and Human Services implemented its own "Guidelines for Ensuring the Quality of

Information Disseminated to the Public." See www.hhs.gov/infoquality.[3] The HHS guidelines include department-wide umbrella guidelines and agency-specific guidelines, including the guidelines of the FDA.[4]

In its guidelines, HHS declares its commitment "to integrating the principle of information quality into every phase of information development, including creation, collection, maintenance, and dissemination." Id. at § A. HHS recognizes that it has flexibility in implementing its guidelines given that OMB understood that OMB's guidelines could not be implemented in the same way by all agencies and wanted agencies, instead, to apply their guidelines "in a common sense, workable manner." Id. at § B. HHS views its guidelines as "an evolving document and process." Id. at § D.1. Consistent with OMB guidance, the HHS guidelines do not apply to press releases, archival material, or opinions apart from the agency's views. Id.

The HHS guidelines also establish a process for information correction requests and appeals. Id. at § E. Nothing in the HHS guidelines abrogates the OMB guideline statement that the agency must undertake only the degree of correction it deems appropriate. See generally id. HHS reminds complainants that they bear the burden of proof to establish the need for and the type of correction sought. Id. A correction request must include specific reasons for asserting that the information at issue violates OMB, HHS, or agency-specific guidelines and "specific recommendations for correcting the information." Id. The agency aims to respond to correction requests within 60 days of receipt, and a party may appeal the agency's decision within 30 days after that. Id. Such an appeal involves "reconsideration within the agency." Id. The agency strives to decide any appeals within 60 days. Id. "If the request requires more than 60 calendar days to resolve, the agency will inform the complainant" and provide an "estimated decision

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3 HHS initially posted draft guidelines on May 1, 2002 and solicited public comments for a sixty day period. See 67 Fed. Reg. 61343, 61344 (Sept. 30, 2002).

4 The FDA information quality guidelines implement and reiterate the OMB and HHS guidelines. See http://aspe.hhs.gov/infoquality/Guidelines/fda.shtml.

date." Id.

The HHS guidelines specifically state that "[e]xisting . . . 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. Accordingly, agencies will use these existing procedures to respond to information quality complaints that arise in this process." Id.

B. The Controlled Substances Act

The Controlled Substances Act, 21 U.S.C. § 801, et seq. ("CSA"), makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. § 841(a)(1); see United States v. Moore, 423 U.S. 122, 131, 135 (1975). The CSA imposes criminal and civil penalties for violations. See 21 U.S.C. §§ 841-863.

The CSA classifies controlled substances according to their inclusion in one of five schedules. The listing of a drug or other substance in one of the five schedules depends on whether (and to what extent) it has a currently accepted medical use,[5] its relative potential for abuse, and the degree of psychological or physical dependence to which its use may lead. 21 U.S.C. § 812(b). The CSA imposes restrictions on the manufacture, distribution, and dispensing of the substance according to the schedule in which it has been placed. See 21 U.S.C. §§ 821-829. Marijuana is included in schedule I, the most restrictive schedule, because it 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 . . . under medical supervision." 21 U.S.C. § 812(b)(1)(A)-(C); U.S. v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 492 (2001).

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5 The DEA Administrator has applied a "five-part test for determining whether a drug is in 'currently accepted medical use': '(1) The drug's chemistry must be known and reproducible; (2) there must be adequate safety studies; (3) there must be adequate and well-controlled studies proving efficacy; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available.'" Alliance for Cannabis Therapeutics v. DEA ("ACT"), 15 F.3d 1131, 1135 (D.C. Cir. 1994) (quoting 57 Fed. Reg. 10499, 10506 (March 26, 1992)).

The CSA establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. REP. NO. 91-1444 at 6 (1970), reprinted in 1970 U.S.C.C.A.N. 4566, 4571; see also Moore, 423 U.S. at 141 (The Act "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal") (quoting H.R. REP. NO. 1444, supra, at 3, reprinted in 1970 U.S.C.C.A.N. at 4589). Only persons registered with the Drug Enforcement Administration ("DEA") may manufacture, distribute, or dispense controlled substances, and only to the extent authorized by their DEA registration. 21 U.S.C. § 822(a), (b).

Schedule I controlled substances such as marijuana carry even greater restrictions under federal law. No individual or entity may distribute or dispense a schedule I controlled substance except as part of a strictly controlled research project that has been registered with DEA and approved by the Food and Drug Administration ("FDA"). 21 U.S.C. § 823(f); 21 C.F.R. §§ 1301.18, 1301.32; 28 C.F.R. § 0.100(b). By contrast, drugs listed in schedules II through V may be dispensed and prescribed for medical use. Physicians, pharmacies, and other legitimate handlers of drugs listed in schedules II through V are the core participants in the closed distribution chain created by Congress to maintain adequate controls over controlled substances. See S. REP. NO. 98-225 at 261-62 (1983), reprinted in 1984 U.S.C.C.A.N. 3182, 3443-44; 21 U.S.C. §§ 822-23. They must therefore comply with stringent statutory and regulatory provisions that mandate registration with DEA, establish security controls, impose recordkeeping and reporting obligations, require distributors to use DEA-issued order forms for all distributions of schedule I and II drugs, and allow controlled substances to be dispensed only pursuant to prescriptions issued in the manner specified in the DEA regulations. See 21 U.S.C. §§ 821-829; 21 C.F.R. §§ 1301-1306.

The CSA also establishes an exclusive set of statutory procedures under which controlled substances that have been placed in schedule I (or any other schedule) may be transferred to another schedule or be entirely removed from the schedules. 21 U.S.C. § 811(a). See 21 U.S.C. § 811(a); Alliance for Cannabis Therapeutics v. DEA, 15 F.3d 1131, 1137 (D.C. Cir. 1994) ("ACT") (upholding Administrator's decision declining to transfer marijuana from schedule I to

schedule II). The responsibility for determining whether a drug should be rescheduled "is assigned to the Attorney General in consultation with the Secretary of Health and Human Services ("HHS"). The Attorney General has delegated his functions to the Administrator of the DEA." Gettman v. DEA, 290 F.3d 430, 432 (D.C. Cir. 2002) (citing 21 U.S.C. § 811(b) and 28 C.F.R. § 0.100(b)).

II. Factual and Procedural Background

A. Jon Gettman's Unsuccessful Petition to the Drug Enforcement Administration Seeking Rescheduling of Marijuana and HHS's Statements to DEA

On July 10, 1995, Jon Gettman petitioned the DEA under the rescheduling provisions of the CSA to reschedule certain controlled substances, including marijuana. See Department of Justice, Drug Enforcement Administration, "Notice of Denial of Petition," 66 Fed. Reg. 20038 (April 18, 2001). Pursuant to the CSA, the Administrator of the DEA consulted with HHS. Id. at 20038, 20039. In response, an HHS official, the Assistant Secretary for Health and Surgeon General, sent a letter and attached analysis to the DEA Administrator. Id. at 20039. DEA chose to publish the Assistant Secretary and Surgeon General's letter and accompanying analysis in the Federal Register. Id. The Assistant Secretary and Surgeon General's letter includes the statement that plaintiff now seeks to challenge that marijuana has no currently accepted medical use in treatment in the United States. See id. at 20039; Compl. ¶ 9 (citing 66 Fed. Reg. 20039) see also 66 Fed. Reg. 20038, 20051 (repeating statement in a heading).

"Based on the HHS evaluation and all other relevant data, DEA . . . concluded that there is no substantial evidence that marijuana should be removed from schedule I" under the CSA. 66 Fed. Reg. at 20038. Accordingly, DEA denied Mr. Gettman's petition. Id.; see also generally Gettman, 290 F.3d 430.

B. Plaintiff's IQA Request for Correction

On October 6, 2004, HHS received a request from plaintiff for correction of certain statements pursuant to the IQA and the OMB and HHS IQA guidelines. See Request for Correction, available at http://aspe.hhs.gov/infoquality/requests.shtml (request no. 20). Plaintiff

requested correction of four statements[6] contained in the Surgeon General's letter to the DEA Administrator and the accompanying HHS analysis that DEA published in the Federal Register. Id. 1-2, citing 66 Fed. Reg. 20038, 20039, 20051, 20052. Following three interim responses, HHS responded to plaintiff's Request for Correction on April 20, 2005, noting in pertinent part:

> Both the Office of Management and Budget (OMB) and the HHS Information Quality Guidelines provide that federal government agencies may use existing processes that are in place to address correction requests from the public. In the case of marijuana HHS currently is in the process of conducting a review in response to the petition for change [in scheduling under the CSA] that was submitted to DEA in October 2002 by the Coalition for Rescheduling Cannabis (CRC), an association of public-interest groups and medical cannabis patients that includes the ASA. In the course of the review, HHS will evaluate all the publicly available peer reviewed literature on the efficacy of marijuana.

April 20, 2005 Response, available at http://aspe.hhs.gov/infoquality/requests.shtml (request no. 20) (footnote omitted). HHS received plaintiff's Request for Reconsideration on May 20, 2005. See Request for Reconsideration, available at http://aspe.hhs.gov/infoquality/requests.shtml

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6 Those four statements were:

- "[T]here have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition" Request for Correction 1-2, quoting 66 Fed. Reg. 20051 (plaintiff's Request mis-cited this statement as appearing on page 20052);
- "A material conflict of opinion among experts precludes a finding that marijuana has been acccepted by qualified experts. *At this time*, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana." See Request for Correction at 2, quoting 66 Fed. Reg. 20051-52 (emphasis added; italicized portion not quoted by plaintiff) (plaintiff's Request mis-cited this statement as appearing in full on page 20052);
- "[A] complete scientific analysis of all the chemical components found in marijuana has not been conducted." See Request for correction at 2, quoting 66 Fed. Reg. 20051; and
- Marijuana "has no currently accepted medical use in treatment in the United States[.]" See Request for Correction at 2, quoting 66 Fed. Reg. 20039 (January 17, 2001 letter from the Surgeon General to the DEA Administrator).

As noted in the text, in its Complaint plaintiff purports to challenge HHS's alleged denial of plaintiff's request for correction of only the fourth statement listed above. See Compl. ¶¶ 7, 16, Request for Relief. Cf. supra note 5 (discussing five-part test used by the DEA Administrator to evaluate whether a drug has a currently accepted medical use in treatment in the U.S.).

(request no. 20). In its Request for Reconsideration, plaintiff complained that the government's response to the rescheduling petition may take a long time. Id. Following six interim responses, HHS responded to plaintiff's Request for Reconsideration on June 12, 2006. See Response to Request for Reconsideration, available at http://aspe.hhs.gov/infoquality/requests.shtml (request no. 20). The agency acknowledged that plaintiff was arguing that "the CSA process should not be utilized because of the length of time it involves," but stated that "a comprehensive review is essential to ensure that our recommendation [to DEA] is accurate." Id.

Plaintiff filed its Complaint in this action on February 21, 2007. Plaintiff's Complaint seeks declaratory and injunctive relief concerning only one of the four statements identified in its administrative request, the statement that marijuana "has no currently accepted medical use in treatment in the United States[.]" Compl. ¶¶ 7, 16, Request for relief, all quoting 66 Fed. Reg. 20039 (January 17, 2001 letter from the Assistant Secretary for Health and Surgeon General to the DEA Administrator). Although HHS has not denied plaintiff's request for correction, plaintiff alleges that the Response to Request for Reconsideration "effectively" did so. Id. ¶ 22.

ARGUMENT

III. Plaintiff's Claims Fail the Case-or-Contoversy Requirements of Article III.

"Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is the power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 94 (1998) (quoting Ex parte McCardle, 74 U.S. 506, 514 (1968)). As explained below, plaintiff has failed its burden to establish this Court's subject matter jurisdiction over its claims because they do not meet the "bedrock" constitutional requirement that they present a justiciable "case or controversy" for this Court's decision. See Valley Forge Christian Coll. v. Am. United for Separation of Church & State, 454 U.S. 464, 471 (1982).

A. Plaintiff Lacks Standing to Pursue Its Claims in This Court.

Article III of the U.S. Constitution "confines the federal courts to adjudicating actual 'cases' and 'controversies.'" Allen v. Wright, 468 U.S. 737, 750 (1984). The doctrine of

"standing is an essential and unchanging part of the case-or-controversy requirement of Article III," Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). "[T]he party invoking federal jurisdiction bears the burden of establishing its existence." Steel Co., 523 U.S. at 104. Thus, at the pleadings stage "'[i]t is the responsibility of the complainant clearly to allege facts demonstrating that he is a proper party to invoke . . . the exercise of the court's remedial powers.'" Renne v. Geary, 501 U.S. 312, 315 (1991), quoting Bender v. Williamsport Area School Dist., 475 U.S. 534, 546 n.8 (1986). Because standing goes to the power of a federal court to adjudicate a case, resolution of the standing question is necessarily antecedent to any decision on the merits. Steel Co., 523 U.S. at 94.

The standing requirement of Article III requires a plaintiff, "at an irreducible minimum," to show: (1) a distinct and palpable injury, actual or threatened; (2) that the injury is fairly traceable to the defendant's conduct; and (3) that a favorable decision is likely to redress the complained-of injury. E.g., Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180-81 (2000); Bennett v. Spear, 520 U.S. 154, 162 (1997); Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992); Valley Forge Christian Coll., 454 U.S. at 472; Look v. United States, 113 F.3d 1129, 1130 (9th Cir. 1997). Moreover, a plaintiff must also satisfy the prudential requirements for standing that have been adopted by the judiciary. See Elk Grove Unified Sch. Dist. v. Newdow, 542 U.S. 1, 11-12 (2004).

An organizational plaintiff such as ASA must meet these standing requirements. An organization may have standing to sue either on its own behalf ("organizational" standing) or on behalf of its members ("representational" standing). See, e.g., Smith v. Pacific Properties and Dev. Corp., 358 F.3d 1097, 1101 (9th Cir. 2004). An organization's "representational standing is contingent upon the standing of its members to bring suit," while its "organizational standing is separate from the standing of its members, turning instead on whether the organization itself has suffered an injury in fact." Id. (citations omitted). Furthermore:

> [t]o establish representational standing, [an organization] must demonstrate that: "(a) its members would have standing to sue in their own right; (b) the interests it seeks to

vindicate are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit."

Id. at 1101-02, quoting Hunt v. Washington Apple Adver. Comm'n, 432 U.S. 333, 343 (1977). Here, plaintiff appears to argue that it has both representational and organizational standing. See, e.g., Compl. ¶ 7. Both claims are mistaken.

1. Plaintiff Lacks Representational Standing.

As noted above, to establish standing to sue as a representative of its membership, plaintiff must show three things. First, the group must identify actual members who have suffered an injury "of the sort that would make out a justiciable case had the members themselves brought suit." Warth v. Seldin, 422 U.S. at 511; see also Arizonans for Official English v. Arizona, 520 U.S. 43, 65-66 (1997) ("association has standing to sue" on behalf of its members "only if its members would have standing to sue in their own right" on basis of "concrete injury"). Second, the group must show that "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." United Food & Commercial Workers Local 751 v. Brown Group, Inc., 517 U.S. 544, 553 (1996) (quoting Hunt, 432 U.S. at 343). Third, the group must show that "the interests it seeks to protect are germane to the organization's purpose." Id. (quoting Hunt, 432 U.S. at 343). Plaintiff meets none of these tests here.

At the outset, plaintiff does not identify a single member who is suffering any alleged injury fairly traceable to HHS's statement that marijuana has no currently accepted medical use. To the contrary, the only members plaintiff does identify are those who (it alleges) have obtained and used marijuana regardless of what HHS says.[7] See Compl. ¶ 8.a-d.

Even if plaintiff had identified an individual member with a potentially justiciable claim for relief, however, resolution of that claim would require the participation of that individual.

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7 To the extent plaintiff alleges that the individual members it does identify suffered a delay in marijuana use as a result of the HHS statement, a past injury without likelihood of recurrence is not cognizable for standing purposes. See Fortyune v. Am. Multi-Cinema, Inc., 364 F.3d 1075, 1081-82 (9th Cir. 2004).

Associational standing does not exist where "claims are not common to the entire membership, nor shared by all in equal degree," but rather "whatever injury may have been suffered is peculiar to the individual members concerned, and both the fact and extent of the injury would require individualized proof." Lake Mohave Boat Owners Ass'n v. Nat'l Park Serv., 78 F.3d 1360, 1367 (9th Cir. 1996) (citing Warth, 422 U.S. at 515-16, and Associated Gen. Contractors, Inc. v. Coal. for Econ. Equity, 950 F.2d 1401, 1408 (9th Cir. 1991)). Individual participation would be necessary here to determine, e.g., whether the individuals were actually aware of HHS's statement in question; whether they relied on it; whether they were actually injured by any such reliance; and whether plaintiff's requested injunctive and declaratory relief would redress any such injury although, e.g., marijuana would nonetheless remain a schedule I controlled substance under federal law. For numerous reasons, therefore, the "individual participation of each injured party" would be "indispensable to proper resolution of the case." Warth, 422 U.S. at 511.

With respect to the third element necessary for representational standing, plaintiff has not sufficiently alleged that its interest in HHS's statement concerning the medical community's acceptance of marijuana is germane to plaintiff's organizational purpose. According to the Complaint, plaintiff "has as its primary purpose working to expand and protect the rights of patients to use marijuana for medical purposes," which the Complaint construes to "includ[e] providing outreach and education to the public regarding the use of marijuana for medical purposes." Compl. ¶ 7. Plaintiff's website, however, includes a different self-described "mission" statement, which reads in full: "The mission of Americans for Safe Access is to ensure safe and legal access to cannabis (marijuana) for therapeutic uses and research." See http://www.safeaccessnow.org/section.php?id=3 (last visited May 25, 2007) (describing "Our Mission"). Plaintiff has not alleged how a correction of defendants' statement concerning the medical community's acceptance of marijuana would impact the safety or legality of the drug. Plainly, it would not make marijuana use any more (or less) safe. Nor would a correction change the fact that DEA continues to list marijuana as a schedule I drug. Accordingly, the relief

plaintiff seeks here is not germane to plaintiff's stated core mission of ensuring that marijuana use for medical purposes is safe and legal.

For all of these reasons, plaintiff lacks representational standing.

2. Plaintiff Lacks Organizational Standing.

Plaintiff's claims fare no better to the extent that the group seeks to assert standing in its own right. For an association to sue on its own behalf as an organization, it "must, like any other plaintiff, satisfy the constitutional and prudential considerations of standing." J.L. v. SSA, 971 F.2d 260, 268 n.8 (9th Cir. 1992) (citing Hong Kong Supermarket v. Kizer, 830 F.2d 1078, 1081 (9th Cir. 1987)). Plaintiff fails both tests. First, the group has suffered no injury to its ability to function as an advocacy organization. Second, an interest in functioning as an advocacy organization is not within the zone of interests protected or regulated by the IQA.

a. Plaintiff Has Alleged No Legally Cognizable Injury to Its Ability to Function as an Organization.

As a general rule, every plaintiff "must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." Warth, 422 U.S. at 499. The federal courts are not a soapbox to air arguments "at the behest of organizations or individuals who seek to do no more than vindicate their own value preferences," Sierra Club v. Morton, 405 U.S. 727, 740 (1972), or assert "generalized grievances more appropriately addressed in the representative branches." Elk Grove, 542 U.S. at 12 (citation omitted). Thus, a mere policy ''interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem" is insufficient to create standing. Sierra Club, 405 U.S. at 739.

> [I]f a 'special interest' in [a] subject were enough to entitle [one organization] to commence this litigation, there would appear to be no objective basis upon which to disallow a suit by any other bona fide 'special interest' organization however small or short-lived. And if any group with a bona fide special interest could initiate such litigation, it is difficult to perceive why any individual citizen with the same bona fide special interest would not also be entitled to do so.

Id. Where the "[f]rustration of an organization's objectives" alleged in a complaint is a policy-oriented "[c]onflict between a defendant's conduct and an organization's mission," it falls under

the rubric of "the type of abstract concern that does not impart standing," Ctr. for Law & Educ. v. Dep't of Educ., 396 F.3d 1152, 1161-62 (D.C. Cir. 2005) (quoting NTEU v. United States, 101 F.3d 1423, 1429 (D.C. Cir. 1996)), and the policy dispute does not lose this non-justiciable character merely because the organization may have committed "substantial labors and resources" to advise supporters and interested parties about how to cope with the policy. Yniguez v. Mofford, 130 F.R.D. 410, 414 (D. Ariz. 1990), aff'd in part, rev'd in part on other grounds, 939 F.2d 727 (9th Cir. 1991), on rh'rg en banc, 69 F.3d 920 (9th Cir. 1995), rev'd, 520 U.S. 43 (1997).

In this case, plaintiff alleges that it "has devoted significant resources to combat" HHS's allegedly "false statement, including" those aimed at "producing and disseminating educational materials" disagreeing with the government. Compl. ¶ 7. The mere fact that the group may be spending more on its activities apparently advocating marijuana use is insufficient to confer standing. See Resident Councils of Wash. v. Thompson, No. C04-1691Z, 2005 WL 1027123 at * 7 (W.D. Wash. May 2, 2005) (allegation that organization "has devoted resources towards assisting in developing [a] pilot program" insufficient to establish standing where "these activities amount to mere issue advocacy, rather than harm to the organization's ability to offer services to its members").[8]

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8 The Supreme Court's decision in Havens Realty Corp. v. Coleman, 455 U.S. 363 (1982), is not to the contrary. In that case, a group dedicated to helping potential home buyers acquire truthful information about the availability of houses for sale alleged that its efforts were being frustrated by dishonest real estate agents, who were telling people lies about the availability of housing in hopes of steering black buyers and white buyers into different markets. The organization alleged that this racially-motivated deception "perceptibly impaired [its own] ability to provide counseling and referral services for low- and moderate-income homeseekers" and caused a "consequent drain on the organization's resources" when it had to work that much harder to disseminate truthful information. Id. at 379. That direct impairment of informational efforts was held to be a "concrete and demonstrable injury" sufficient to give the organization standing to sue on its own behalf. Id. Nothing in Havens, however, remotely suggests that the organization would similarly have standing to challenge any *government* policy or dissemination of information merely because the organization might disagree with the government's underlying judgment and want to give its clients competing information. By that logic, an organization that (continued...)

Moreover, it bears repeating that these alleged advocacy expenditures are not directly related to plaintiff's stated organizational mission of "ensur[ing] safe and legal access to cannabis (marijuana) for therapeutic uses and research." See http://www.safeaccessnow.org/section.php?id=3 (last visited May 25, 2007) (describing "Our Mission"). As noted, plaintiff's statements disagreeing with HHS's judgment may encourage individuals to use marijuana, but they do not make such use any more or less safe or legal.

b. The Organizational Interests of Plaintiff Are Not Within the Zone of Interests Protected or Regulated by the IQA.

Even if the plaintiff could show some injury to its ability to function as an advocacy organization, it would still lack standing because its ability to function as an advocacy organization is not within the "zone of interests protected by the law invoked." Elk Grove, 542 U.S. at 12 (quoting Allen v. Wright, 468 U.S. at 751). A plaintiff cannot meet this test merely by alleging that a regulatory scheme protects or regulates someone else's interests in a way that might indirectly affect his own. See Air Courier Conference v. Am. Postal Workers Union, 498 U.S. 517, 522-31 (1991); Lujan, 497 U.S. at 883. He must show that "the procedures in question are *designed* to protect [or regulate] some concrete interest of his that is the ultimate basis of his standing." Ctr. for Law, 396 F.3d at 1157 (quoting Lujan, 504 U.S. at 573 n.8) (emphasis in Ctr. for Law). In determining the "zone of interest," the relevant provision is the "statutory provision whose violation forms the legal basis for [plaintiffs '] complaint." Lujan, 497 U.S. at 883. See also Clarke v. Securities Industry Ass'n, 479 U.S. 388, 40 n.16 (1987) (noting that in the context of an APA claim, the "zone of interests" test "is most usefully understood as a gloss on the meaning of [5 U.S.C.] § 702."). Here that provision is the IQA, and plaintiff does not meet its burden.

8(...continued)
believes the federal income tax to be unconstitutional would have standing to challenge government warnings about the consequences of tax evasion.

As discussed supra, the IQA directs 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 (including statistical information) disseminated by Federal agencies . . . ." See 44 U.S.C. § 3516 note (emphasis added). Indeed, the IQA simply makes no "mention of advocacy organizations' interests." Ctr. for Law, 396 F.3d at 1157. Nor does it regulate the conduct of or information dissemination by advocacy groups. The organizational concerns of the plaintiff are therefore not within the zone of interests of the relevant statute. Nor can plaintiff argue its organizational advocacy concerns are within the zone of interests of the other source of law it identifies, the OMB and HHS IQA guidelines, since those guidelines simply implement the IQA. See HHS Guidelines at ¶ D.1. ("The Guidelines provide policy and procedural guidance to HHS staff and are intended to inform the public about agency quality assurance policies and procedures."); OMB Guidelines, 67 Fed. Reg. at 8452 ("OMB has designed the guidelines to help agencies . . ."). Cf. INS v. Legalization Assistance Project, 510 U.S. 1301, 1305 (1993) (O'Connor, Circuit Justice) (zone of interests test equally applicable in the case of litigants who wish to invoke regulations).

For all of these reasons, plaintiff also lacks organizational standing, and its claim should be dismissed.

B. Plaintiff's Alleged Harm is Not Redressable in This Court

To meet the case or controversy requirement of Article III, a plaintiff must also show that it is "'likely,' as opposed to merely 'speculative,' that its alleged injury will be 'redressed by a favorable decision.'" Lujan, 504 U.S. at 561 (citation omitted). Accordingly, "[r]elief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." See Steel Co., 523 U.S. at 107. Here, the relief plaintiff seeks is a declaration that the agency's response to plaintiff's IQA petition was improper, and an injunction "enjoining defendants from continuing to disseminate statements that marijuana 'has no currently accepted medical use in treatment in the United States;' and . . . requiring HHS to make appropriate corrections to all [such] statements that it has

disseminated[.]" Compl., Part VII ("Relief Sought"). As we will discuss in more detail below, plaintiff's Complaint fails to state a claim upon which relief may be granted because HHS has not "disseminated" the statement in question under the terms of the IQA and, moreover, the APA waiver of sovereign immunity does not apply to plaintiff's claim for a number of reasons. Even if plaintiff had stated a proper claim, and this Court could adjudicate that claim, it still fails because plaintiff's alleged injury would not be redressed by a decision in plaintiff's favor.

"[M]arijuana is a controlled substance within the meaning of [21 U.S.C.] § 841(a)," the CSA.[9] See U.S. v. Cannabis Cultivators Club, 5 F. Supp. 2d 1086, 1099 (N.D. Cal. 1998). As discussed above, it is a schedule I controlled substance under the CSA. Accordingly, under the CSA no individual or entity may distribute or dispense marijuana except as part of a strictly controlled research project that has been registered with DEA and approved by the FDA. 21 U.S.C. § 823(f); 21 C.F.R. §§ 1301.18, 1301.32; 28 C.F.R. § 0.100(b).

This would remain the case even if this Court were to grant plaintiff the relief it seeks and order HHS to somehow "correct" its 2001 statement that marijuana has no currently accepted medical use. It would therefore remain difficult for plaintiff to effectively convince its members to use marijuana, such use would remain "impeded," Compl. ¶ 24, and unspecified individual patients' "access" to marijuana, id. ¶ 23, would remain sharply limited, since distribution of the drug outside already-permissible, albeit strictly controlled, circumstances would remain a crime. For these reasons, plaintiff's purported injuries are not redressable in this Court and plaintiff's Complaint should be dismissed for failure to meet the case-or-controversy requirements of Article III.[10]

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9 The Ninth Circuit has held that the Controlled Substances Act's prohibition on the distribution, cultivation, or possession of marijuana and other controlled substances "is constitutional under the Commerce Clause." United States v. Bramble, 103 F.3d 1475, 1479 (9th Cir. 1996). [add cite to Raich in SCT, which says it reaches iintrastate growing for pers med use.]

10 Put another way, these alleged harms are not fairly traceable to the fact that HHS has not granted plaintiff's IQA request for correction.

Plaintiff's claim is not redressable even though plaintiff may seek (indeed, has sought) to avail itself of the CSA procedure by which DEA may choose to list marijuana under a less restrictive schedule. See ACT, 15 F.3d at 1133 (discussing unsuccessful petitions to reschedule marijuana). It is that existing, established procedure through which HHS informed plaintiff it would consider the merits of plaintiff's Request for Correction. See April 20, 2005 Response, available at http://aspe.hhs.gov/infoquality/requests.shtml (request no. 20).

The CSA requires DEA to consider eight factors concerning a controlled substance when reviewing a rescheduling petition on that substance:

> (1) Its actual or relative potential for abuse.
> (2) Scientific evidence of its pharmacological effect, if known.
> (3) The state of current scientific knowledge regarding the drug or other substance.
> (4) Its history and current pattern of abuse.
> (5) The scope, duration, and significance of abuse.
> (6) What, if any, risk there is to the public health.
> (7) Its psychic or physiological dependence liability.
> (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

21 U.S.C. § 811(c). "Although the recommendations of HHS are binding on the DEA as to scientific and medical considerations involved in the eight-factor test, the ultimate decision as to whether to initiate rulemaking proceedings to reschedule a controlled substance is made by the DEA." Gettman, 290 F.3d at 432 (citing 21 U.S.C. § 811(a), (b)).[11] As an initial matter, the exclusive means to seek judicial review of a rescheduling decision is contained in the CSA itself, 21 U.S.C. § 877, not the IQA or the APA. In any event, an argument in favor of redressability that rests on possible future actions by a non-party (DEA) cannot succeed because where, as here, "a plaintiff seeks injunctive or declaratory relief only, . . . standing will not lie if adjudication . . . rests upon contingent future events that may not occur as anticipated or indeed may not occur at all." Pryor v. National Collegiate Athletic Ass'n, 288 F.3d 548, 561 (3rd Cir. 2002) (internal quotation marks and citations omitted). In such cases, where

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11 A drug would not be appropriate for schedule I if the DEA determines it has a currently accepted medical use in this United States. See 21 U.S.C. § 812(b). Such a drug may be appropriate for schedule II. Id.

> [t]he existence of one or more of the essential elements of standing depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict, . . . it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to . . . permit redressability of injury.

Lujan, 504 U.S. at 562 (internal citations omitted). Absent such a showing by plaintiff, an assessment of redressability would be pure speculation insufficient to establish a case or controversy. See University Medical Center v. Shalala, 173 F.3d 438, 441-42 (D.C. Cir. 1999); cf. Linda R.S. v. Richard D., 410 U.S. 614, 618 (1973) (discussing speculative nature of redressability).

IV. HHS's Decision on Plaintiff's IQA Petition is Not Subject to Judicial Review Under the Administrative Procedure Act.

"Under settled principles of sovereign immunity, 'the United States, as sovereign, is immune from suit, save as it consents to be sued . . . and the terms of its consent to be sued in any court define that court's jurisdiction to entertain the suit.'" United States v. Dalm, 494 U.S. 596, 608 (1990), quoting United States v. Testan, 424 U.S. 392, 399 (1976) (quoting United States v. Sherwood, 312 U.S. 584, 586 (1941)). "A necessary corollary of this rule is that when Congress attaches conditions to legislation waiving the sovereign immunity of the United States, those conditions must be strictly observed, and exceptions thereto are not to be lightly implied." Block v. North Dakota, 461 U.S. 273, 287 (1983). Plaintiff invokes the APA's waiver of sovereign immunity, but that waiver "contains several limitations. Of relevance here is 5 U.S.C. § 704, which provides that only '[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court, are subject to judicial review.' 5 U.S.C. § 704." Gallo Cattle Co. v. Department of Agriculture, 159 F.3d 1194, 1198-99 (9th Cir. 1998). Plaintiff's claim is barred by each and every one of these limitations: the action of which it complains is not made reviewable by statute, it does not qualify as final agency action under the APA, and plaintiff has another adequate (and exclusive) remedy under the CSA. Another APA provision, 5 U.S.C. § 701(a)(2), also bars plaintiff's claim here because the agency's response to plaintiff's IQA Request for Correction is "committed to agency discretion by law."

A. Agency Statements Lacking the Force and Effect of Law Are Not Subject To Judicial Review Under the APA.

Plaintiff contends that the statutory basis for its suit is the APA, Compl. ¶ 26, which authorizes judicial review of "final agency action" for which there is no other remedy in a court. 5 U.S.C. § 704. It is well established, however, that an agency's reports and other statements lacking the force and effect of law do not constitute final agency action within the meaning of the APA.

Plaintiff purports to challenge not a rulemaking (or a DEA rescheduling decision) but the alleged dissemination of HHS's statement that marijuana has no currently accepted medical use in the United States. Dissemination of the agency's correspondence to DEA, like the correspondence itself, is not "final agency action" reviewable under the APA. Lujan, 497 U.S. at 882, 890, 894 (discussing principle of "final agency action" under APA); FTC v. Standard Oil Co. of Cal., 449 U.S. 232 (1980); Franklin v. Massachusetts, 505 U.S. 788, 798 (1992) (agency report that carried "no direct consequences" was not "final agency action"); see also, e.g., Center for Biological Diversity v. Veneman, 335 F.3d at 853 ("final agency action" must have "'an actual or immediate threatened effect,"' "must mark the 'consummation' of the agency's decision-making process, and must 'be one by which rights or obligations have been determined, or from which legal consequences will flow"') (citations omitted); Nippon Miniature Bearing Corp. v. Weise, 230 F.3d 1131, 1137 (9th Cir. 2000) ("final agency action" must have "legal consequences"); Ecology Ctr., Inc. v. U.S. Forest Serv., 192 F.3d 922, 925 (9th Cir. 1999) (no "final agency action" where "legal consequences d[id] not necessarily flow" from agency's action, "nor d[id] rights or obligations arise from it"); Mt. Adams Veneer Co. v. United States, 896 F.2d 339, 343 (9th Cir. 1990) (stating numerous indicia of finality under APA, including that "action should have the status of law"); Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852, 861 (4th Cir. 2002) ("if we were to adopt the position that agency actions producing only pressures on third parties were reviewable under the APA, then almost any agency policy or publication issued by the government would be subject to judicial review. . . .

We do not think that Congress intended to create private rights of actions to challenge the inevitable objectionable impressions created whenever controversial research by a federal agency is published.").

As to finality under the APA, the "core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." Franklin, 505 U.S. at 797. The 2001 HHS correspondence to DEA that plaintiff now seeks to challenge did not have "the status of law," see Mt. Adams Veneer Co., 896 F.2d at 343, in any manner that would "directly affect" plaintiff, Franklin, 505 U.S. at 797. Rather, the DEA Administrator's final decision concerning whether to reschedule marijuana under the CSA in response to the Gettman petition was the final agency action in that process, and the action from which legal consequences flowed. Plaintiff's sole avenue to challenge that final agency action lies not here, however, but under the exclusive review mechanism of the CSA itself, as defendants discuss below. See 21 U.S.C. § 877. Accordingly, because the alleged dissemination of the HHS statement was not final agency action for purposes of plaintiff's APA challenge, HHS's response to plaintiff's IQA Request for Correction is also not final agency action under the APA. Contrary to plaintiff's apparent premise that the administrative IQA process (which, as we discuss infra, provides plaintiff with no judicially enforceable right) transforms an agency statement into reviewable final agency action, "it is not at all anomalous that Congress could permit them . . . to participate in agency proceedings, and yet they be unable to seek review in federal courts." Gettman, 290 F.3d at 434. As the Supreme Court has explained, exhaustion and finality are distinct requirements, and the exhaustion of administrative remedies does not make otherwise non-final agency action final. See FTC v. Standard Oil Co., 449 U.S. 232, 243 (1980) (holding that plaintiffs' exhaustion of administrative remedies did not transform the FTC's issuance of a complaint into final agency action, and explaining that the plaintiff had "mistaken exhaustion for finality"). Accord Aerosource v. Slater, 142 F.3d 572, 579 (3rd Cir. 1998) ("After all, if a court treated the denial of an application to reconsider an action which is not in itself a final order as a final order, then a petitioner simply by asking for reconsideration could convert a

nonfinal action into a final order. Of course, this conversion should not be permitted.") (citing Standard Oil).

Defendants do not take issue with the unexceptionable proposition that agency rules (legislative or interpretive) and/or policy statements, as well as agency decisions not to adopt such proposals, are subject to judicial review in appropriate cases – e.g., cases in which the agency has failed to take action compelled by statute, 5 U.S.C. § 706(1), or there has been final agency action, id. at § 706(2). These conditions, however, have not been satisfied here. Accordingly, this Court should dismiss plaintiff's Complaint.

B. The APA Waiver of Sovereign Immunity Does Not Apply Action Because Plaintiff Has An Adequate Remedy in a Court Under the CSA.

The APA requires not only a "final agency action" before suit may be brought, but such an action where plaintiff has no adequate remedy in a court. 5 U.S.C. § 704. This preclusion of suits challenging agency action for which there exists another adequate remedy in court reflects Congress's intent that the APA not create an additional remedy for particular agency action for which Congress has established a specific review process. Bowen v. Massachusetts, 487 U.S. 879, 903 (1988).

Here, plaintiff seeks to challenge a statement made by HHS to DEA in the CSA rescheduling process. The CSA provides plaintiff with an adequate – indeed, an exclusive – remedy for a plaintiff who is aggrieved by such a conclusion. The CSA, 21 U.S.C. § 877, provides:

> All final determinations, findings, and conclusions of the [DEA] under this subchapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by a final decision of the [DEA] may obtain review of the decision in the United States Court of Appeals for the District of Columbia or for the circuit in which his principal place of business is located upon petition filed with the court and delivered to the Attorney General within thirty days after notice of the decision. Findings of fact by the [DEA], if supported by substantial evidence, shall be conclusive.

Thus, plaintiff's challenge to HHS's recommendation to DEA, which DEA adopted and published in the Federal Register, is fully cognizable, and was required to be made, under the CSA itself. John Doe, Inc. v. DEA, --- F.3d ----, 2007 WL 1225381, *6 (D.C. Cir. April 27,

2007) (Title "21 U.S.C. § 877 vests exclusive jurisdiction in the courts of appeals over '[a]ll final determinations, findings, and conclusions' of the DEA applying the CSA"); Oregon v. Ashcroft, 368 F.3d 1118, 1121 n.1 (9th Cir. 2004). The waiver of immunity in the APA, by its terms, does not "affect [] other limitations on judicial review. . . ." 5 U.S.C. § 702. Moreover, the APA expressly creates an exception to the provisions authorizing judicial review where other "statutes preclude judicial review. . . ." 5 U.S.C. § 701(a). Accordingly, plaintiff cannot bypass the exclusive right of review in the CSA with an APA challenge in this Court.

That the CSA's limitations period may prevent plaintiff from now maintaining its claim under that Act does not alter the conclusion that the CSA, 21 U.S.C. § 877, is an adequate remedy within the meaning of 5 U.S.C. § 704. See Sable Communications of California, Inc. v. FCC, 827 F.2d 640, 642 (9th Cir. 1987) (statutory review provision was "adequate" for APA purposes even though plaintiff's petition under that review provision was dismissed as untimely) (citing FCC v. ITT World Communications, Inc., 466 U.S. 463, 469 (1984) (rejecting argument that review in the court of appeals is inadequate and that APA action in district court could therefore proceed) and Telecommunications Research and Action Center v. FCC, 750 F.2d 70, 78 (D.C. Cir. 1984) ("Where statutory review is available in the Court of Appeals it will rarely be inadequate.")); Mitchell v. United States, 930 F.2d 893, 897 (Fed. Cir. 1991) (available remedy in Claims Court was adequate even though the plaintiff's claim in that court may have been time-barred). Section 704 is triggered whenever Congress has provided an adequate remedy for a particular agency action, notwithstanding the fact that the plaintiffs before the court may not be entitled to that remedy. See Sable, 827 F.2d at 642; Mitchell, 930 F.2d at 897. For that reason, plaintiff cannot invoke the APA waiver of sovereign immunity here and, accordingly, its claim should be dismissed.

C. The IQA Does Not Create a Judicially Enforceable Right for Plaintiff to Obtain the Correction of Agency Information.

Plaintiff relies on the IQA to sue defendants under the APA for HHS's alleged failure to correct a statement. This claim must fail because the "IQA . . . does not create any legal right to

information or its correctness" enforceable in this Court. See Salt. Inst. v. Leavitt, 440 F.3d at 159. Because plaintiff's claim of a judicially enforceable right to correction under the IQA is illusory, HHS could not be acting arbitrarily, capriciously, or contrarily to law by not producing or correcting its pertinent statement. Cf. Oregon Natural Resources Council v. Thomas, 92 F.3d 792, 798 n.11 (9th Cir. 1996) ("As plaintiffs' 'arbitrary and capricious' claims don't invoke any other statute, plaintiffs have no standing to raise them under section 702."). That fact, standing alone, is sufficient to prevent plaintiff from using the IQA as a basis to sue under the APA for correction of agency information. Put another way, because both an enforceable right and a mechanism to remedy an alleged violation of that right are required to sue the sovereign, the possibility that the APA may provide a remedy means nothing where the IQA does not provide the underlying right. See Gonzaga Univ. v. Doe, 536 U.S. 273, 283-84 (2002); Alexander v. Sandoval, 532 U.S. 275, 286 (2001).

In evaluating whether a statute creates a judicially enforceable right, a court examines the text and structure of the statute to determine whether it displays an intent to create such a right. See Gonzaga Univ., 536 U.S. at 286; Alexander, 532 U.S. at 288. Here, the IQA lacks evidence of a congressional intent to create a judicially enforceable right. Indeed, plaintiff is forced to rely on the generic APA cause of action since the IQA itself provides no private right of action. See Alexander v. Sandoval, 532 U.S. 275, 286 (2001) (finding that "private rights of action to enforce federal law must be created by Congress"); Touche Ross & Co. v. Redington, 442 U.S. 560, 578 (1979) (remedies available are those "that Congress enacted into law"). Nothing in the IQA provides anyone a right of action in a court of law for an alleged violation of any of its provisions. Rather, the IQA requires each federal agency to establish "*administrative mechanisms* allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued [by OMB]." Id. at § 515(b)(2)(B) (emphasis added). Thus, nothing in the text of the statute indicates that Congress intended for the *federal courts* to serve as ongoing monitors of the "quality" of information maintained and disseminated by federal agencies; to the contrary, the language and

structure of the IQA reflects Congress's intent that any challenge to the quality of information disseminated by a federal agency should take place in administrative proceedings before federal agencies. See Kissinger v. Reporters Committee For Freedom of the Press, 445 U.S. 136, 148-49 (1980) (The Federal Records Act "expressly provides administrative remedies for violations of the duties it imposes, implicating our conclusion in [Transamerica Mortgage Advisors, Inc. v. Lewis, 444 U.S. 11, 19 (1979)] that it is 'an elemental canon of statutory construction that where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it.'"); In re: Operation of the Missouri River Sys. Litig., No. 03-MD-1555 at 49 (D. Minn. June 21, 2004) (order granting motions for summary judgment). Fully consistent with Congress's intent that IQA challenges be resolved administratively, the statute contains no language that would create a judicially enforceable right as would be "critical to showing the requisite congressional intent" to do so. Gonzaga Univ., 536 U.S. at 287.

Nor can an "implied" private right of action be inferred from some source of congressional intent other than the Act's text. For example, the IQA's legislative history is completely silent with respect to the particular question of judicial relief. See Touche Ross & Co., 442 U.S. at 571 (concluding that, where "the plain language of the provision weighs against implication of a private remedy," silence in the legislative history "reinforces our decision not to find such a right of action implicit within the section"). And "[i]t is an 'elemental canon' of statutory construction that where a statute expressly provides a remedy, courts must be especially reluctant to provide additional remedies." Karahalios v. National Federation of Federal Employees, 489 U.S. 527, 533 (1989).

Consistent with this conclusion, every court to consider whether the IQA creates a legal right to production or correction of information has concluded that the IQA creates no such right. See Salt Inst. v. Leavitt, 440 F.3d 156, 159 (4th Cir. 2006); Salt Inst. v. Thompson, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004); In re Operation of the Missouri River Sys., 363 F. Supp. 2d 1145, 1174-75 (D. Minn. 2004), vacated in part and aff'd in part on other grounds, 421 F.3d 618 (8th Cir. 2005). As the Fourth Circuit summarized, the IQA "does not create a legal right to access to

information or to correctness" enforceable in federal court. Salt Inst., 440 F.3d at 159. It therefore confers no legal rights to a private entity such as plaintiff that plaintiff can use as a basis for an APA challenge in this Court.[12]

D. HHS's Response to Plaintiff's IQA Request for Correction is Committed to the Agency's Discretion.

Judicial review is also foreclosed in this case under the APA, 5 U.S.C. § 701(a)(2), because the agency's response to plaintiff's Request for Correction was "committed to agency discretion by law." Agency action is committed to the agency's discretion by law when there is "no meaningful standard against which to judge the agency's exercise of discretion." Heckler v. Chaney, 470 U.S. 821, 830 (1984). See also Helgeson v. Bureau of Indian Affairs, 153 F.3d 1000, 1003 (9th Cir. 1998).

In addition, and especially pertinent to this case, "courts have been especially inclined to regard as unreviewable those aspects of agency decisions that involve a considerable degree of expertise or experience[.]" Local 2855, AFGE (AFL-CIO) v. United States, 602 F.2d 574, 579 (3rd Cir. 1979). Here, plaintiff is asking this Court to second-guess the 2001 judgment of HHS that marijuana has no currently accepted medical use in treatment in the United States. As explained above, Congress vested in HHS the responsibility to make these recommendations to DEA under the CSA, and the CSA itself provides the exclusive mechanism for review of DEA's eventual determination. See Gettman, 290 F.3d at 432 (citing 21 U.S.C. § 811(a), (b)).

Furthermore, the language of the IQA confirms that Congress did not intend to enlist the judicial branch in policing agencies' discretion in communicating information. The statute does not impose its own standard of "quality" on agency information; instead, it requires 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 those agencies. Pub. L. No. 106-554, § 1(a)(3) [Title V, § 515(a)], 114 Stat.

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12 For this reason, plaintiff also cannot satisfy the injury in fact requirement for Article III standing. See Salt Inst., 440 F.3d at 159.

2763, 2763A-153 (Dec. 21, 2000). And – of special importance in this case – Congress's decision not to specify when information should be corrected by agencies indicates that Congress did not intend that federal courts would take control over the flow information among federal agencies. See Salt Inst. v. Thompson, 345 F. Supp. 2d at 602-03; In re Operation of the Missouri River Sys., 363 F. Supp. 2d at 1175. Nor, as explained above, do the OMB or HHS IQA guidelines create a right to judicial review of an agency's response to a request for correction.

In promulgating its IQA guidelines, OMB eschewed "detailed, prescriptive, 'one-size-fits-all' government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner," and underscored the "flexibility" that its guidelines gave the agencies. 67 Fed. Reg. at 8452. In particular, OMB stressed that agencies, "in making their determination whether or not to correct information, may reject claims made in bad faith or without justification, and 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 (emphasis added); see also OMB Guidelines § III(3) (agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, "where appropriate," correction of agency information).[13] The HHS guidelines likewise counsel flexibility, indicating that the

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13 The HHS guidelines also afford agencies considerable deference in determining correction requests. For instance, the HHS guidelines counsel its agencies to consider "the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction." www.hhs.gov/infoquality § E (emphases added). The reference to "resource requirements" should make courts particularly cautious, as the Supreme Court has found agency resource allocation determinations (and determinations that rest on discretionary resource allocations) committed to agency discretion by law. See, e.g., Lincoln v. Vigil, 508 U.S. 182 (1993) (agency decision based on resource constraints held committed to agency discretion by law; "Like the decision against instituting enforcement proceedings, . . . an agency's allocation of funds from a lump-sum appropriation requires 'a complicated balancing of a number of factors which are peculiarly within its expertise': whether its 'resources are best spent' on one program or another; whether it 'is likely to succeed' in fulfilling its statutory mandate; whether a particular program 'best fits the agency's overall policies'; and, 'indeed, (continued...)

discretionary determination whether to "correct" prior agency speech will depend upon the agency's evaluation of, among other things, "the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction." www.hhs.gov/infoquality § E.

Thus, in this case HHS's response to plaintiff's correction request regarding the agency's scientific and medical judgment was "committed to agency discretion by law." 5 U.S.C. § 701(a)(2).[14]

Moreover, even assuming *arguendo* that HHS's decision on how to respond to plaintiff's administrative request for correction could be deemed reviewable, the agency's decision was certainly not arbitrary, capricious, or an abuse of discretion. See 5 U.S.C. § 706 (2)(A). The agency acted well within its discretion under its own and OMB's information quality guidelines in concluding that it could "appropriately" review the merits of plaintiff's request as part of the administrative process already in place for considering whether marijuana has a currently accepted medical use in the United States as HHS makes recommendations to DEA concerning the separately-pending petition (filed by an organization that includes plaintiff) to reschedule marijuana under the CSA.

For all of these reasons, the complaint should also be dismissed under the APA, 5 U.S.C. § 701(a)(2).[15]

13(...continued)
whether the agency has enough resources to fund a program 'at all.'" (quoting Heckler v. Chaney, 470 U.S. 821 (1984))).

14 A different question might be presented in a case in which a plaintiff challenges an agency's dissemination of information in connection with its formal rules or regulations.

15 The non-justiciability of plaintiff's demand for correction of HHS's correspondence with DEA is perhaps best understood in the context of the allegations of the complaint, which call on the Court to delve deeply into disputed questions of medical judgment, and thereafter assume an executive editing function in conforming the agency's speech to the Court's scientific conclusions. See, e.g., Compl. Part VII ("Relief Sought") (seeking an injunction "requiring HHS (continued...)

VI. Plaintiff's Complaint Fails to State a Claim Upon Which Relief May Be Granted

Plaintiff's Complaint fails to state a claim upon which relief may be granted against defendants because the HHS statement in question was not "disseminated" by HHS within the meaning of the IQA. The OMB guidelines[16] which plaintiff alleges defendants HHS and FDA have violated apply to "information" that is "disseminated" by a federal agency. 67 Fed. Reg. at 8458. "Dissemination" means "*agency initiated* or sponsored distribution of information to the public," but "does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." Id. at 8460 (emphasis added). Similarly, the HHS guidelines define dissemination as "*agency initiated* or sponsored distribution of information to the public," specifically not including, inter alia, "intra- or inter-agency use or sharing of government information" as well as the other OMB guideline exclusions. See www.hhs.gov/infoquality § D(h) (emphasis added). Indeed, plaintiff recognizes this when it states that under the IQA "HHS has an obligation to consider requests from the public to correct . . . statements that *it has disseminated*." Comp. ¶ 2. While plaintiff alleges that "HHS continues to disseminate" its statement that marijuana "'has no currently accepted medical use in treatment in the United States," id. ¶ 9 (citation omitted), the only "disseminations" that plaintiff alleges are those plainly initiated by *DEA*, not defendants. In particular, the only "dissemination" identified or alleged by plaintiff is DEA's publication in the Federal Register of correspondence from the Surgeon General to the DEA Administrator and secondary re-publication of that Federal Register information on the internet by DEA or the Government

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15(...continued)
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"). In the language of the HHS IQA guidelines, it is simply not clear how this this Court could determine whether correction of HHS's statement is "appropriate" in light of "the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction." www.hhs.gov/infoquality § E.

16 The IQA itself does not define "disseminate."

Printing Office. Id., citing 66 Fed. Reg. 20038. To the extent this qualifies at all as a "dissemination" under the IQA, it was not a dissemination by defendants but rather by another federal agency.[17] Indeed, plaintiff has identified no acts *by defendants* whatsoever to disseminate the underlying document to the public. For that reason, on the face of plaintiff's Complaint and materials referenced therein, plaintiff has failed to state a claim upon which relief may be granted based on any right plaintiff may claim pursuant to the IQA and agency guidelines thereunder.

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17 Although HHS did not directly articulate this fact, there is no need for remand to the agency to consider the question under the doctrine of SEC v. Chenery Corp., 318 U.S. 80, 87 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."), and SEC v. Chenery Corp., 332 U.S. 194, 196 (1947) (same). As numerous courts have noted, "the Chenery doctrine is not applied inflexibly." See Fleshman v. West, 138 F.3d 1429, 1433 (Fed. Cir. 1998) (citing, inter alia, Arkansas AFL-CIO v. FCC, 11 F.3d 1430, 1439-40 (8th Cir. 1993); NLRB v. American Geri-Care, Inc., 697 F.2d 56, 64 (2nd Cir. 1982); Chae-Sik Lee v. Kennedy, 294 F.2d 231, 233-34 (D.C. Cir. 1961)); RNS Services, Inc. v. Secretary of Labor, 115 F.3d 182, 184 n.1 (3rd Cir. 1997). Of particular relevance here, the Chenery "doctrine does not require a remand to the agency" where it is clear that the agency "'would have reached the same ultimate result' had it considered the new ground." Fleshman, 138 F.3d at 1433, quoting Ward v. MSPB, 981 F.2d 521, 528 (Fed. Cir. 1992); Vista Hill Found., Inc. v. Heckler, 767 F.2d 556, 566 n.9 (9th Cir. 1985) ("A remand is not required when it 'would be an idle and useless formality.'" (quoting NLRB v. Wyman-Gordon Co., 394 U.S. 759, 766 n.6 (1969) (also stating "Chenery does not require that we convert judicial review of agency action into a ping-pong game.")). Remand is also not necessary where the new ground does *not* call for "a determination or judgment which an administrative agency alone is authorized to make." Koyo Seiko, 95 F.3d at 1101; cf. Railway Labor Executives' Ass'n v. Interstate Commerce Comm'n, 784 F.2d 959, 969 (9th Cir. 1986) (Chenery doctrine does not bind courts on matters of statutory interpretation). To the extent this Court has jurisdiction over plaintiff's claims at all, any such jurisdiction includes the ability to rule that defendants did not "disseminate" the statement in question pursuant to the IQA. If the Court reaches this ground, yet believes it cannot affirm on this ground under Chenery, however, then the proper course would be remand to the agency to consider it. See Florida Power & Light Co. v. Lorion, 470 U.S. 729, 744 (1985).

CONCLUSION

Accordingly, for all of the foregoing reasons, this Court should grant defendants' Motion to Dismiss Plaintiff's Complaint.

Dated May 25, 2007

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