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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: July 11, 2007 Time: 8:00 a.m. **REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES, GUIDELINES AND FEDERAL REGISTER MATERIALS

LEGISLATIVE MATERIALS

MISCELLANEOUS

INTRODUCTION

Plaintiff Americans for Safe Access, a California advocacy organization, asks this Court to rewrite the U.S. Department of Health and Human Services' ("HHS") statement made six years ago that "marijuana ha[d] no currently accepted medical use in treatment in the United States." But "[t]he federal courts . . . were not established to operate the administrative agencies of government," see Kuhl v. Hampton, 451 F.2d 340, 342 (8th Cir. 1971), and there is no basis in law for the Court to grant plaintiff's request. The Court should dismiss plaintiff's Complaint for a host of jurisdictional defects or, in the alternative, for failure to state a claim upon which relief may be granted.

As an initial matter, plaintiff lacks Article III standing to bring its claim because it has not sufficiently alleged a concrete injury beyond that which is merely speculative or a generalized grievance grounded in its disagreement with the government. Moreover, the concreteness of its injury aside, plaintiff has not alleged an invasion of a legally cognizable right since the substantive statute on which it relies, the Information Quality Act ("IQA"), 44 U.S.C. § 3516 note, vests plaintiff with no such rights enforceable in this Court. Even if plaintiff could establish a cognizable injury, it has failed to show the likelihood that such an injury would be redressed by the declaratory and injunctive relief it seeks: "correcting" HHS's 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 and accepted by few physicians; such a change must be made by DEA. It is therefore reasonable to expect it would remain difficult for plaintiff to persuade individuals to obtain and use marijuana regardless of the outcome of this case.

Plaintiff, bringing its claim under the Administrative Procedure Act ("APA"), makes no assertion that the HHS statement in question had any binding legal effect. It is well settled that agency speech lacking the force and effect of law is not subject to judicial review, and the fact that plaintiff has been afforded and has exhausted administrative remedies does not obviate that statutory limitation to this Court's jurisdiction. Plaintiff's attempt to invoke the APA also fails

because an APA cause of action depends on violation of a substantive statute and, again, the IQA does not provide plaintiff with a cognizable right upon which it may rest an APA claim. The APA further bars plaintiff's claim because plaintiff has an adequate remedy to bring that claim under another statute, the exclusive review provisions of the Controlled Substances Act; and the APA further bars plaintiff's claim because the determination as to whether the information in HHS's statement regarding marijuana is appropriate for correction is within the agency's discretion and expertise to resolve.

Finally, even if plaintiff's purported IQA claim could otherwise be reviewed in this Court, plaintiff has failed to state a claim under the IQA because, under the particular facts of thsi case, defendants have not "disseminated" the statement in question – or any statement as to which plaintiff has exhausted its administrative remedies – within the meaning of the statute and administrative guidelines thereunder.

For all of these reasons, as well as those explained in defendants' opening memorandum ("Def. Mem."), the Court should dismiss plaintiff's Complaint for lack of subject matter jurisdiction or, in the alternative, for failure to state a claim upon which relief may be granted.

ARGUMENT

I. Plaintiff Has Failed to State a Case or Controversy Subject to Judicial Resolution.

As defendants have explained, Def. Mem. 11-21, plaintiff has failed its burden to establish this Court's subject matter jurisdiction over its claims because those claims 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). To establish such a case or controversy, plaintiff must "at an irreducible minimum" show: (1) a legally cognizable 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. See, e.g., Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180-81 (2000); Look v. United States, 113 F.3d 1129, 1130 (9th Cir. 1997).

A. Plaintiff Cannot Establish Standing on Its Own Behalf.

Plaintiff has failed to establish that it has standing to sue on its own behalf, based on its interests as an organization.[1] "To invoke the jurisdiction of an Article III court, the plaintiff[] 'must have suffered an injury in fact.' The injury 'required by Art. III may exist solely by virtue of statutes creating legal rights, the invasion of which creates standing.'" Salt Institute v. Leavitt, 440 F.3d 156, 158 (4th Cir. 2006), quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 578 (1992) (internal citations, quotation marks omitted). The injury alleged by plaintiff is "the asserted incorrectness in [HHS's] public statements." Id.; Compl. ¶ 7. That asserted injury is not a legally cognizable one, however, because plaintiff has no enforceable, legal right to the correctness of agency information. See id. at. 159; Def. Mem. 25-28 & n.12.

To the extent HHS's statement causes plaintiff political harm, this is not the proper forum for its claims. As defendants have noted, a plaintiff's policy "'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the

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1 Defendants previously explained that plaintiff lacks "representational" standing to sue on behalf of its members because, inter alia, it has not identified a single member suffering a cognizable injury, and adjudication of such individuals' claims would require their participation. See Def. Mem. 13-15. In opposition plaintiff has largely abandoned its argument in support of representational standing and provides only a conclusory statement in a footnote. Pl. Mem. 14 n.6. Plaintiff's footnote does cite Associated Gen. Contractors of America v. Metropolitan Water Dist. of Southern California, 159 F.3d 1178 (9th Cir. 1998), for the proposition that "[i]ndividualized proof from the members is not needed where, as here, declaratory and injunctive relief is sought rather than monetary damages," but that statement does not relieve plaintiff of its burden to point to individual members who could bring suit on their own. The statement refers to the requirement of representational standing that "neither the *claim asserted* nor the *relief requested* requires the participation of individual members in the lawsuit." Associated Gen. Contractors v. Coalition for Econ. Equity, 950 F.2d 1401, 1406 (9th Cir.1991) (emphasis added; quoted in id.). The sentence quoted by plaintiff refers only to the "relief requested" portion, not the "claim asserted" portion; as defendants have explained, the participation of individual members would be necessary for the Court to determine whether they have stated a cognizable claim, e.g., whether the individual members 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 marijuana would nonetheless remain a schedule I controlled substance under federal law.

problem" is insufficient to create standing. Sierra Club v. Morton, 405 U.S. 727, 739 (1972) (quoted in Def. Mem. 15). By reference to declarations stating that plaintiff has spent money "designing and printing literature" concerning use of marijuana for medical purposes, plaintiff argues that its allegedly increased advocacy expenditures are a sufficiently concrete harm.[2] Pl. Mem. 12-13. As defendants have explained, plaintiff is mistaken. Def. Mem. 16-17. Even if plaintiff had alleged a sufficiently concrete and specific harm fairly traceable to the alleged "incorrectness" of HHS's statement, however, it would not vest this Court with jurisdiction since plaintiff has not been "granted a legal right" to the correctness of such statements: plaintiff "has not alleged an invasion of a legal right and, thus, ha[s] failed to establish an injury in fact sufficient to satisfy Article III." Salt Institute v. Leavitt, 440 F.3d at 159 (noting "appellants confuse two distinct standing inquiries: the concreteness of the alleged injury and the status of the claimed right").

Plaintiff relies on a line of cases that have upheld organizational standing for fair housing groups that complain of illegal discriminatory practices for the proposition that "[t]he gravamen of the standing inquiry for advocacy organizations is whether the organization alleges an injury beyond litigation expenses." Pl. Mem. 14, citing Fair Housing of Marin v. Combs, 285 F.3d 899, 905 (9th Cir. 2002). As an initial matter, plaintiff fails to mention that this line of authority stemming from Havens Realty Corp. v. Coleman, 455 U.S. 363 (1982), is generally limited to fair housing organizations, as the Ninth Circuit recognized. See Fair Housing of Marin, 285 F.3d at 905 (stating the Court was "[f]ollowing the lead of the other circuits which have upheld organizational standing for fair housing groups"). In any event, plaintiff's argument "confuse[s]

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2 When citing to its own declarations, plaintiff invites the Court to convert defendants' Motion to Dismiss into a summary judgment motion under Fed. R. Civ. P. 12(b). Pl. Mem. 12 n.5. Rule 12 permits conversion of a Rule 12 motion to a Rule 56 motion when the *movant* relies on materials outside the pleadings, so plaintiff's argument is misplaced. It is also unnecessary: plaintiff provides its declarations in an attempt to establish subject matter jurisdiction, and the Court may generally look outside the pleadings to resolve whether it has subject matter jurisdiction under Rule 12. Dreier v. United States, 106 F.3d 844, 847 (9th Cir. 1996); Thornhill Publ'g v Gen. Tel. & Elecs. Corp., 594 F.2d 730, 733 (9th Cir. 1979) (citing cases).

two distinct standing inquiries: the concreteness of the alleged injury and the status of the claimed right." Salt Institute v. Leavitt, 440 F.3d at 159. The fair housing organizations' injuries were legally cognizable because the underlying discriminatory conduct that they challenged, itself, invaded a legal right. As then-Judge Ruth Bader Ginsburg explained, "Havens makes clear . . . that an organization establishes Article III injury if it alleges that purportedly *illegal action* increases the resources the group must devote to programs independent of its suit challenging the action." Spann v. Colonial Village, Inc., 899 F.2d 24, 27-29 (D.C. Cir. 1990) (emphasis added; explaining Havens, 455 U.S. at 379), quoted in Fair Housing of Marin, 285 F.3d at 903-4.[3] Plaintiff in this case lacks Article III standing, and the Havens line of cases is inapposite, because plaintiff has not alleged invasion of a legal right.

"The language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts." Salt Institute v. Thompson, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004), aff'd, 440 F.3d 156, supra. If there could be any doubt on that score, the IQA expressly sets out the mechanism by which the agency's handling of correction requests such as plaintiff's should be reviewed. The IQA provides that agencies should be required to "[r]eport periodically to the director [of OMB] - (I) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency; and (ii) how such complaints were handled by the agency." 44 U.S.C. § 3516 note. Thus, "by its terms, this statute creates no legal rights in any third parties. Instead, it orders the Office of Management

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3 El Rescate Legal Services, Inc. v. Executive Office of Immigration Review, 959 F.2d 742 (9th Cir. 1991) is similarly distinguishable. In El Rescate, the Court of Appeals found standing based on the claims of individual plaintiffs but proceeded, in dicta, to state that an organization representing Central American refugees in efforts to obtain asylum and avoid deportation in immigration court proceedings would also have organizational standing to proceed in a challenge to a government policy concerning the availability of translation in deportation and exclusion proceedings. The underlying challenge thus included a claim that government policy and/or its application – not merely government speech – violated the constitution. Plaintiff has not (and could not credibly) make such a claim about the government statement that underlies its claim here.

and Budget to draft guidelines concerning information quality and specifies what those guidelines should contain." Salt Institute v. Leavitt, 440 F.3d at 159. Accordingly, "even assuming that concrete interests of the [plaintiff is] affected, there is nothing that can be done by way of judicial review to redress the adverse consequences . . . that they say they are suffering. This is because only [the Executive] can do that" under the IQA.[4] See Guerrero v. Clinton, 157 F.3d 1190, 1194 (9th Cir. 1998) (holding agency statements in statutorily required report to Congress unreviewable because they have no direct legal effect). In such a context, as this Court has recognized before, recognition at law of plaintiff's claim would frustrate the intent of Congress since a "court order dictating compliance along plaintiffs' and the court's [wishes] would be inconsistent with Congress' apparent desire to allow agencies to improve on their own." Center For Biological Diversity v. Abraham, 218 F. Supp. 2d 1143, 1160 (N.D. Cal. 2002) (Alsup, J.), citing Guerrero, 157 F.3d at 1193-94.

Plaintiff has not alleged the invasion of a legally cognizable right and, accordingly, lacks Article III standing. For that reason alone, the Court should dismiss plaintiff's Complaint for lack of subject matter jurisdiction.

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

Plaintiff has also failed to state a case or controversy sufficient for Article III standing because it is "merely 'speculative[]' that its alleged injury will be 'redressed by a favorable decision.'" Lujan, 504 U.S. at 561 (citation omitted). As defendants have explained, and plaintiff does not dispute, even if this Court granted plaintiff the relief it seeks, marijuana would remain a schedule I controlled substance under federal law. See Pl. Mem. 18-21. As a result, plaintiff would still have a difficult time (and would still have to devote considerable resources) convincing people to obtain and use marijuana. Plaintiff adduces nothing beyond further speculation and conclusory statements in response. See Pl. Mem. 15. For example, plaintiff

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4 Similarly, as defendants have explained, plaintiff's interests as an advocacy organization are well outside the zone of interests of the IQA and so plaintiff lacks prudential standing as well. Def. Mem. 17-18.

states that "the reality is that many ill persons who receive truthful information about marijuana's medical efficacy would elect to try it." Id. This statement is supported solely by allegations concerning individuals who apparently have ignored HHS's statements and already use marijuana. Id., citing Compl. ¶ 8. Obviously, plaintiff and others who share plaintiff's views are persuading such individuals to use marijuana regardless of what HHS has or has not said, and the outcome of this litigation will have no discernible impact on them. As for those who choose not to use marijuana, it is pure speculation to argue how they would react if this Court ordered HHS to alter its 2001 statement. Many of them would no doubt listen to their physicians, as they presumably do today. And those physicians, in turn, have and will continue to have their own views of the appropriateness of marijuana use.[5] Plaintiff provides no clue as to how its brochure printing costs may rise or fall depending on the views of doctors. Moreover, as defendants have explained, where, as here,

> [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). Plaintiff cannot meet that burden to establish

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5 In 2001 the American Medical Association ("AMA") adopted a policy recommending that marijuana remain a schedule I controlled substance. See AMA Policy, available at http://www.ama-assn.org/ama/pub/category/13625.html#recomendation (last visited June 26, 2007). That recommendation means, inter alia, that the AMA recognized marijuana as having no currently accepted medical use in treatment in the United States as of 2001. See 21 U.S.C. § 812(b) (characteristics of a schedule I controlled substance); U.S. v. Oakland Cannabis Buyers' Co-op., 532 U.S. 483, 492 (2001). Individual physicians largely appear to agree. According to a Government Accountability Office study of two states that permit certain marijuana use under state law for medical purposes, "As of February 2002, less than one percent of the approximately 5,700 physicians in Hawaii and three percent of Oregon's physicians out of about 12,900 had recommended marijuana to their patients." General Accountability Office, "Marijuana: Early Experiences with Four States' Laws That Allow Use for Medical Purposes" (November 1, 2002), available at http://www.gao.gov/new.items/d03189.pdf (last visited June 26, 2007), at 3; see also id. at 5 ("a continuing debate exists over the medical value of marijuana, but an analysis of the scientific aspects of this debate was beyond the scope of our review.").

its alleged injury would likely be redressed by the relief it seeks.[6] The provides another, independent reason why this Court should dismiss plaintiff's Complaint for lack of subject matter jurisdiction.

II. HHS's Response to Plaintiff's IQA Petition Is Not Reviewable Under the Administrative Procedure Act.

"Federal courts are courts of limited jurisdiction. . . . It is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." Kokkonen v. Guardian Life Ins. Co. of America, 511 U.S. 375, 377 (1994) (citations omitted); see Thornhill Publ'g Co., Inc. v. Gen. Tel. & Elec. Corp., 594 F.2d 730, 733 (9th Cir. 1979) (courts should presume lack of jurisdiction until plaintiff proves otherwise).

Plaintiff attempts to state a cause of action under the APA and seeks to invoke the APA waiver of sovereign immunity. See Compl. ¶ 26. While the Supreme Court has "read the APA as embodying a 'basic presumption of judicial review,'" Lincoln v. Vigil, 508 U.S. 182, 190 (1993) (quoting Abbott Laboratories v. Gardner, 387 U.S. 136, 140 (1967)), the Court has also recognized that "[t]his is 'just' a presumption." Id. (quoting Block v. Community Nutrition Institute, 467 U.S. 340, 349 (1984)). Moreover, the APA waiver of sovereign immunity must be read strictly in favor of the United States. Department of the Army v. Blue Fox, Inc., 525 U.S. 255, 261 (1999); Gallo Cattle Co. v. Department of Agriculture, 159 F.3d 1194, 1198 (9th Cir. 1998). Plaintiff's complaint is, at bottom, a quarrel with agency speech. The agency speech in

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6 It bears mention that this Court could not order the relief plaintiff purports to seek: while plaintiff asks the Court to order defendants to reach a certain conclusion on the merits of their IQA request, plaintiff admits that defendants have not yet responded on the merits. Pl. Mem. 20-21 n.7. The most a Court could do, therefore, is remand to the agency with instructions to reach the merits more quickly. If plaintiffs are interested in such relief, however, they have brought the wrong claim. Compare 5 U.S.C. § 706(2) (basis for claim to set aside arbitrary and capricious agency action, invoked by plaintiff at Compl. ¶ 26) with id. § 706(1) (claim concerning "agency action unlawfully withheld or unreasonably delayed"). Defendants do not concede that any claim by plaintiff under 5 U.S.C. § 706(1) would be properly before the Court or that it would have merit. See Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 64 (2004).

question has no direct legal effect and was made in the course of proceedings under the Controlled Substances Act, 21 U.S.C. § 801, et seq., ("CSA"), which has its own exclusive provision for judicial review. "'Under these circumstances, the presumption of reviewability of agency action is woefully inapposite.'" Guerrero, 157 F.3d at 1196 (quoting Natural Resources Defense Council, Inc. v. Hodel, 865 F.2d 288, 319 (D.C. Cir. 1988)). Plaintiff cannot establish subject matter jurisdiction under the APA for its claim because the action of which it complains is not made reviewable by statute, because it does not qualify as final agency action under the APA, because plaintiff has another adequate remedy under the CSA, and because the agency's response to plaintiff's IQA Request for Correction of the agency's statement is committed to agency discretion by law. See 5 U.S.C. §§ 701(a)(2), 704.

A. Agency Statements Lacking the Force and Effect of Law Are Not Judicially Reviewable Under the APA.

The actions reviewable under the APA are limited to agency "action made reviewable by statute and final agency action for which there is no other adequate remedy in a court ." 5 U.S.C. § 704; see Def. Mem. 22-24. At bottom, plaintiff's claim concerns an agency statement that does not qualify. Indeed, plaintiff makes no attempt to refute the well-settled principle of law that agency statements lacking the force and effect of law, such as the 2001 agency statement at issue here, are not reviewable under the APA. Rather, plaintiff argues that the IQA process somehow converted this agency speech into final and reviewable agency action without grappling with defendants' simple explanation of why that cannot be so. See Pl. Mem. 18-20.

"Agency dissemination of advisory information that has no legal impact has consistently been found inadequate to constitute final agency action and thus is unreviewable by federal courts under the APA." Salt Institute v. Thompson, 345 F. Supp. 2d at 602. That is because, while plaintiff is correct that "the term 'action' under the APA 'is meant to cover comprehensively every manner in which an agency may exercise its power,'" Pl. Mem. 18 (in a parenthetical, quoting Whitman v. American Trucking Associations, 531 U.S. 457, 478 (2001)), courts have long held that agency speech without direct legal consequences does not qualify as an

"exercise" of agency "power" cognizable under the APA. Such speech differs from "the prototypical exercise of agency power" in which the agency is "exercising legislative functions . . . or adjudicatory functions that have been specifically ordained by Congress." Hodel, 865 F.2d at 318 (ruling report to Congress not reviewable). An agency statement, such as that at issue here, that is an "educational undertaking" and does not "impose an obligation, determine a right or liability or fix a legal relationship" is not reviewable agency action, even though plaintiff alleges the statement will cost it money. American Trucking Assoc., Inc. v. United States, 755 F.2d 1292, 1296-97 (7th Cir. 1985). As noted, plaintiff makes no effort to quarrel with this unexceptionable proposition, nor could it. See Dalton v. Specter, 511 U.S. 462, 470 (1994) (base closure recommendations by Secretary of Defense and Defense Base Closure and Realignment Commission to President do not constitute "final agency action"); Franklin v. Massachusetts, 505 U.S. 788, 798-99 (1992) (census report from Secretary of Commerce to President is not "final agency action"); LaFlamme v. FERC, 945 F.2d 1124 (9th Cir. 1991) (Forest Service letter to FERC retracting adverse comments about a FERC order did not constitute final agency action because the letter did not impose any obligation, deny any right, or fix any legal relationship); Kukatush Mining Corp. v. SEC, 309 F.2d 647, 650 (D.C. Cir. 1962) (Bazelon, C.J., dissenting on other grounds) (SEC cautionary list that does not determine legal rights is unreviewable); cf. International Telephone & Telegraph Corp. v. Local 134, 419 U.S. 428, 442-48 (1975) (agency process without binding effect, even if it leads to significant "practical consequences," is not reviewable under 5 U.S.C. § 551); Center For Biological Diversity, 218 F. Supp. 2d at 1162 n.8 (discussing "the principle that reporting-to-Congress obligations are not judicially reviewable") (citing Guerrero, 157 F.3d at 1194-96, and Hodel, 865 F.2d at 316-19).

Contrary to plaintiff's argument, the fact that the IQA affords it with an opportunity to seek *administrative* correction of HHS's statement does not convert the statement into final agency action and permit plaintiff to seek judicial review. The agency's response to plaintiff's request for correction "does not augment the [statement's] legal force or practical effect." FTC v. Standard Oil Co. of California, 449 U.S. 232, 243 (1980). Thus, it is of no moment that "ASA

has reached the end of the line in the IQA administrative process." Pl. Mem. 20. As defendants have noted, "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 v. DEA, 290 F.3d 430, 434 (D.C. Cir. 2002), quoted in Def. Mem. 23. The Supreme Court and this Court have explained that exhaustion of administrative remedies and the need for final agency action are distinct requirements, and the exhaustion of administrative remedies does not transform what is not final agency action into something reviewable under the APA.[7] See Standard Oil Co., 449 U.S. at 243 (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"); Ma v. Reno, 114 F.3d 128, 130 (9th Cir. 1997) ("the doctrine of exhaustion of administrative remedies . . . is conceptually distinct from the doctrine of finality"); see also Regional Management Corp. v. Legal Services Corp., 186 F.3d 457, 462 n.6 (4th Cir. 1999) ("the existence of a right of action and of an exhaustion requirement are separate issues"). Accord Aerosource v. Slater, 142 F.3d 572, 579 (3rd Cir. 1998) ("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).[8]

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7 Moreover, plaintiff's citation to cases where "courts have . . . entertained suits under the APA for denials of administrative petitions" is a red herring: the cases upon which plaintiff relied concerned a petition for review of an agency action that itself had direct legal consequences. See Pl. Mem. 19 (citing cases concerning, e.g., immigration decisions, individuals' military records and HUD debarment).

8 Nor has plaintiff established that the agency's response to its IQA petition is "final." By its terms, HHS's last correspondence with plaintiff stated that it is in the process of considering the validity of HHS's statement in question as part of the CSA rescheduling procedure. See Response to Request for Reconsideration, available at http://aspe.hhs.gov/infoquality/requests.shtml (request no. 20). See City of San Diego v. Whitman, 242 F.3d 1097, 1102 (9th Cir. 2001) (citing Queen in Right of Ontario v. EPA, 912 F.2d 1525, 1532 (D.C. Cir. 1990) (agency action final where it was "unambiguous and devoid of any suggestion that it might be subject to subsequent revision") and Ciba-Geigy Corp. v. EPA, (continued...)

Nor is the agency's response to plaintiff's IQA petition a final agency action because, as plaintiff claims, it "has been deprived of its right under the IQA to seek and obtain the timely correction of incorrect information." Pl. Mem. 20. "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; see also Salt Institute v. Thompson, 345 F. Supp. 2d at 602; In re Operation of the Missouri River System Litigation, 363 F. Supp. 2d 1145, 1174-75 (D. Minn. 2004). Also for that reason, HHS could not be acting arbitrarily, capriciously or contrary to law by not now "correcting" its 2001 statement.

B. The IQA Does Not Create a Judicially Enforceable Right on Which Plaintiff May Base its APA Claim.

"There is no right to sue for a violation of the APA in the absence of a 'relevant statute' whose violation 'forms the legal basis for [the] complaint.'" El Rescate, 959 F.2d at 753 (quoting Lujan, 497 U.S. at 882-83, & citing 5 U.S.C. § 702). As defendants have explained, the IQA creates no such right. See supra 4-6; Def. Mem. 25-28. Rather, while it "creates no legal rights in any third parties," the IQA "orders the Office of Management and Budget to draft guidelines concerning information quality and specifies what those guidelines should contain." Salt Institute v. Leavitt, 440 F.3d at 159. Thus, the "language of the IQA reflects Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts." Salt Institute v. Thompson, 345 F. Supp. 2d at 601. The cases that have considered the IQA, which have uniformly held it provides third parties with no enforceable rights, do not, as plaintiff states, merely establish that the IQA contains no private right of action, although "[i]n a complex

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8(...continued)
801 F.2d 430, 436-37 (D.C. Cir. 1986) (agency action was final where "[n]ot only did the statement of position admit of no ambiguity, but it gave no indication that it was subject to further agency consideration or possible modification.")); Sierra Club v. United States Nuclear Regulatory Comm'n, 825 F.2d 1356, 1362 (9th Cir. 1987) ("We will not entertain a petition where pending administrative proceedings or further agency action might render the case moot and judicial review completely unnecessary").

scheme of this type, the omission of such a provision is sufficient reason to believe that Congress intended to foreclose [third party] participation in the . . . process." Block, 467 U.S. at 347. Those cases (all of which also considered APA claims based alleged IQA violations) also establish that the IQA provides plaintiff with no legal right that can form the basis of its APA claim here. See Salt Inst. v. Leavitt, 440 F.3d at 159; Salt Inst. v. Thompson, 345 F. Supp. 2d at 601;[9] In re Operation of the Missouri River Sys., 363 F. Supp. 2d at 1174-75.

Defendants explained in their opening memorandum that "the IQA's legislative history is completely silent with respect to the particular question of judicial relief." Def. Mem. 27, citing Touche Ross & Co. v. Redington, 442 U.S. 560, 571 (1979) (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"). Plaintiff attempts to refute this obviously true statement by reference to what plaintiff claims is legislative history of the Paperwork Reduction Act ("PRA"),[10] 44 U.S.C. § 3501, et seq., from 1990. See Pl. Mem. 23. Plaintiff's argument is meritless. Putting aside the question of whether a committee report from a decade before Congress enacted the IQA could be of much help to this Court in any event, the committee report relied upon (and mis-cited) by plaintiff refers to legislation that

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9 The Salt Institute cases also considered the same OMB and HHS IQA guidelines upon which plaintiff relies in this Court.

10 The Paperwork Reduction Act establishes requirements for federal agencies that seek to collect information from the public. See generally Dole v. United Steelworkers of America, 494 U.S. 26, 28 (1990), superseded in part by statute, Pub. L. No. 104-13 (May 22, 1995), codified in pertinent part at 44 U.S.C. § 3502(3)(A). It requires federal agencies to submit information collection requests to the Director of OMB for approval, and to publish in the Federal Register a notice advising the public of the need for the information, the estimated burdens of collecting the information, and the right to comment on the proposed information collection. 44 U.S.C. § 3507. The statute bars an agency from "conduct[ing] or sponsor[ing]" the collection of information unless the request has been submitted and approved by OMB. 44 U.S.C. § 3507(a). Among the hortatory purposes of the statute are to "ensure the greatest possible public benefit from and maximize the utility of information . . . disseminated by or for the Federal Government," id. § 3501(2) (cited in Pl. Mem. 17), as well as to "minimize the cost to the Federal Government of the . . . dissemination . . . of information," id. § 3501(5).

Congress did not enact, but *rejected*. Plaintiff asserts:

> the Senate Committee that considered the legislation that resulted in the Paperwork Reduction Act (to which the IQA was added) stated that judicial review would be available for with [*sic*] respect to provisions requiring OMB to issue information dissemination guidance to federal agencies. In 1990, the Senate Committee commented as follows: "One consequence of this change [requiring OMB to issue information dissemination guidance] is to make it clearer that judicial review of agency dissemination decisions is available under the provisions of section 702 of the Administrative Procedure Act."

Pl. Mem. 23 (purporting to quote "S. Rep. No. 927, 101st Cong., 2d Sess. at 37 (Oct. 23, 1990)"). In fact, plaintiff is not quoting a Senate report but H.R. REP. NO. 927, 101st Cong., 2d Sess. 1990, 1990 WL 201562 (October 23, 1990), a House committee report printed to accompany H.R. 3695. The report in question referred to Section 103(d) of the House bill, but neither the provision in question nor the House bill itself was enacted. See Paperwork Reduction and Federal Information Resources Management Act of 1990, H.R. 3695, 101st Cong. § 103(d) (1990) (never enacted). The House committee's views of a provision that Congress rejected in 1990 is obviously of no relevance to this Court's interpretation of the IQA that Congress enacted in 2001.

Plaintiff also offers the maxim *expressio unius est exclusio alterius*[11] to argue that the express preclusion of judicial review in a PRA provision, 44 U.S.C. § 3504, indicates Congress's intent that there be judicial review under the IQA, despite all evidence to the contrary. Pl. Mem. 23. The provision relied upon plaintiff, again, is of no relevance to how the 2001 Congress that enacted the IQA viewed that provision or the PRA, since the provision relied upon by plaintiff was repealed in 1995. See 44 U.S.C. 3504, Historical and Statutory Notes, 1995 Acts.[12]

Because the IQA does not vest plaintiff with any legal right on which it may base its APA claim, that claim should be dismissed. See Oregon Natural Resources Council v. Thomas, 92

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11 "The expression of one thing is the exclusion of another."

12 The provision cited by plaintiff continued to apply to certain information collections under the PRA for a limited time after its effective repeal on September 30, 1995, i.e., until the earlier of the first PRA modification or renewal of such a collection or the expiration of its PRA control number. See Pub. L. 104-13 § 4(c), published at 44 U.S.C. § 3501 note.

F.3d 792, 798-799 (9th Cir. 1996) (there is no general arbitrary and capricious review under the APA independent of the requirements of the underlying, substantive statute).

C. Plaintiff's APA Claim Is Precluded Because it Has An Adequate Remedy in a Court Under the CSA.

For its claim to be reviewable under the APA, plaintiff must establish that it otherwise has no "adequate" remedy in a court. 5 U.S.C. § 704. As defendants have explained, plaintiff's purported APA challenge concerns a statement that HHS made to DEA as part of the CSA rescheduling process. See Def. Mem. 24-25. The CSA itself provides plaintiff with an adequate (and exclusive) remedy to challenge all pertinent "final determinations, findings, and conclusions of the" DEA, including any such conclusions it approved and adopted from HHS. 21 U.S.C. § 877 (quoted in Pl. Mem. 24).

As noted, the CSA review provision is exclusive, see John Doe, Inc. v. DEA, 484 F.3d 561, 568 (D.C. Cir. 2007), and so plaintiff is barred from bringing its claim here under that statute as well as the APA, 5 U.S.C. §§ 701(a), 702, 704. Despite plaintiff's protestation, Pl. Mem. 26, the CSA remedy is "adequate" even though plaintiff may not now exercise it years following the conclusion of the relevant CSA proceeding. See Def. Mem. 25 (citing cases). To the extent plaintiff argues that the exclusive CSA review procedure would not apply to the HHS statement of which plaintiff complains because that statement was not clearly adopted as part of the "final determinations, findings, and conclusions of the" DEA, 21 U.S.C. § 877, plaintiff's argument only underscores another fatal flaw in plaintiff's Complaint, discussed supra: the agency speech that plaintiff seeks to challenge had no direct legal effect, does not qualify as final agency action, and thus is not amenable to judicial review under the APA.

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

As defendants have explained, judicial review is 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." That is the case where, as here, there is "no meaningful standard" against which this Court can "judge the agency's exercise of discretion."

Heckler v. Chaney, 470 U.S. 821, 830 (1984). See also, e.g., Legal Services of Northern California, Inc. v. Arnett, 114 F. 3d 135, 140 (9th Cir. 1997); Rank v. Nimmo, 677 F.2d 692, 699-700 (9th Cir. 1982). The IQA and guidelines thereunder "reflect[] Congress's intent that any challenges to the quality of information disseminated by federal agencies should take place in administrative proceedings before federal agencies and not in the courts." Salt Institute v. Thompson, 345 F. Supp. 2d at 601.[13]

Moreover, "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) (quoted in Def. Mem. 28). Plaintiff is asking this Court to second-guess the 2001 judgment of HHS that, based on HHS's expertise and experience, marijuana has no currently accepted medical use in treatment in the United States. As explained supra, 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.

In opposition, plaintiff nonetheless argues that the terms of the IQA such as "quality" and "objectivity" require the agency to correct its statement in this case. See Pl. Mem. 28-29; but see In re Operation of the Missouri River System Litigation, 363 F. Supp. 2d at 1174-75 . While those terms ought to be meaningful to the agencies charged with applying them, as to a request for correction such as plaintiff's, the OMB guidelines stress that agencies, "in making their determination . . . 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." 67 Fed. Reg. 8452, 8458 (Feb. 22, 2002); see also id. at 8459, § III(3) (agencies shall establish "flexible" administrative mechanisms allowing affected persons to seek

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13 Defendants do not mean to imply that the OMB IQA guidelines, the HHS guidelines approved by OMB, and IQA itself do not provide meaningful standards for the *agency* to apply and, if necessary, for OMB to enforce.

and obtain, "where appropriate," correction of agency information). Plaintiff fails to explain how that language provides for review in this Court of the agency's judgment concerning complex medical and scientific questions. Rather, plaintiff's request for correction of a statement that lacks the force and effect of law is *not* reviewable in this Court under the APA "because the IQA and [HHS and] OMB guidelines at issue insulate the agency's determinations of when correction of information contained in informal agency statements is warranted" from such judicial (as opposed to administrative) review. See Salt Institute v. Thompson, 345 F. Supp. 2d at 603. 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).

In addition, even if HHS's decision on how to respond to plaintiff's administrative request for correction could be deemed reviewable, that 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 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. See Def. Mem. 4 (citing 67 Fed. Reg. at 8460), 7 (citing www.hhs.gov/infoquality § E), 20 (discussing CSA rescheduling procedure), 30.

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

As defendants explained, plaintiff has failed to state a claim upon which relief may be granted under the IQA, even assuming *arguendo* that such a claim could be reviewed, because the HHS statements of which plaintiff has complained administratively and now in this Court were not "disseminated" by HHS within the meaning of the IQA, under the particular facts of this case. Def. Mem. 31-32. Rather, the only disseminations alleged by plaintiff in its Complaint or complained of administratively are those initiated by DEA, not HHS. Faced with this irrefutable fact, plaintiff argues that its Complaint is sufficiently vague to encompass other

agency statements that allegedly reference the 2001 HHS statement in question. Pl. Mem. 32. The statements now cited by plaintiff in this Court, for the first time, include subsequent reference to the historical fact of HHS's 2001 conclusion; they are not identical to the original conclusion itself, which was disseminated only by DEA.

Even if (again *arguendo*) these statements could be subject to a meritorious IQA request of HHS, they have not been: plaintiff has alleged that it has utilized and exhausted its administrative remedies as to these newly-identified statements. Thus, it is not dispositive if plaintiff's Complaint *could* encompass such statements under Rule 8; because they have been raised for the first time in this Court, they do not cure the Complaint of its fatal defect under Rule 12(b)(6). See, e.g., United States v. L.A. Tucker Truck Lines, Inc., 344 U.S. 33, 37 (1952) (discussing the "general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice"); Unemployment Compensation Com. v. Aragon, 329 U.S.143, 155 (1946) (a "reviewing court usurps the agency's function when it sets aside the administrative determination upon a ground not theretofore presented and deprives the [agency] of an opportunity to consider the matter, make its ruling, and state the reasons for its action"). For this reason, as well, the Court should dismiss plaintiff's Complaint.

CONCLUSION

Accordingly, for all of the foregoing reasons and those stated in defendants' opening memorandum, this Court should grant defendants' Motion to Dismiss Plaintiff's Complaint.

Dated June 28, 2007

Respectfully Submitted,

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