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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: November 15, 2007
Time: 8:00 a.m.

**REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT**

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## INTRODUCTION

This Court already dismissed the bulk of plaintiff's claims under the Administrative Procedure Act ("APA") because they do not meet the bedrock APA requirement that they concern "final agency action," i.e., action with direct legal consequences. Plaintiff has not cured this defect in its Amended Complaint. Instead, it has added a claim for mandamus under the APA that suffers from the same fatal flaw: the action plaintiff seeks to compel would likewise not qualify as final agency action and, therefore, is not subject to an APA mandamus order. Moreover, such a claim to compel agency action requires that the agency be withholding final agency action it has a non-discretionary, legal duty to take. Yet the Information Quality Act, 44 U.S.C. § 3516 note, ("IQA") and the administrative guidelines thereunder – the sole sources of substantive law on which plaintiff relies – vest federal agencies with considerable discretion in determining how they will respond to an IQA request for correction. Here, defendants acted well within that discretion when they chose to consider plaintiff's medical and scientific arguments as they make recommendations to the Drug Enforcement Administration concerning a pending petition (brought by plaintiff, among others) to reschedule marijuana under the Controlled Substances Act ("CSA"). Thus, plaintiff's APA claims do not concern the type of agency action that is reviewable under the APA, and the agency's action in question was well within its discretion.

Unable to refute these clear principles, plaintiff ultimately resorts to unfounded attacks on defendants' good faith. Plaintiff's accusations are baseless; they are also irrelevant to the threshold questions raised by defendants' pending Motion to Dismiss. For these reasons, as well as the additional reasons set forth in defendants' previous memoranda, the Court should dismiss plaintiff's Amended Complaint.

## ARGUMENT

### I. Plaintiff Has Failed To State A Claim To Compel Agency Action Under The APA Because The "Action" In Question Is Not Final Agency Action Cognizable Under The APA.

As defendants have explained, plaintiff has again failed to state a claim upon which relief may be granted (or to establish that the APA waiver of sovereign immunity applies to its claim)

because plaintiff's claim is not cognizable under the APA. See Defendants' Memorandum in Support of Motion to Dismiss Plaintiff's Amended Complaint, Docket Entry No. 45 ("Def. Mem.") at 12-15. In particular, plaintiff cannot raise a claim seeking either compulsion or review of agency action that does not qualify as "final agency action." As this Court has held and the pleadings reveal, however, the agency action in question would be non-final;[1] that fact alone compels dismissal of plaintiff's Amended Complaint.

As the Supreme Court stated, where, as here, "no other statute provides a private right of action," the agency action in question – whether to be reviewed *ex post* or compelled *ex ante* – "must be '*final* agency action.'" Norton v. Southern Utah Wilderness Alliance ("SUWA"), 542 U.S. 55, 61-62 (2004), quoting 5 U.S.C. § 704 (emphasis as in SUWA). Thus, plaintiff is mistaken to argue that a court may compel action under § 706(1) that it could never review, once taken, under the APA. "[S]imply complaining that an agency failed to act is not enough to bring a claim under Section 706(1). . . . the 'agency action complained of must be "final agency action."'" Elhaouat v. Mueller, --- F. Supp. 2d ----, Civ. No. 07-632, 2007 WL 2332488, *3 (E.D. Pa. August 9, 2007) (Joyner, J.) (quoting SUWA, 542 U.S. at 61). Or, as another court in this Circuit has explained, "[s]uits under the APA challenging both agency action under section 706(2), and agency inaction under section 706(1), require that the action or inaction being challenged be a 'final agency action.'" High Sierra Hikers Ass'n v. U.S. Forest Service, 436 F. Supp. 2d 1117, 1140 (E.D. Cal. 2006) (Ishii, J.) (citing SUWA, 542 U.S. at 62, and explaining in a parenthetical that an "action under section 706(1) demands final agency action"); see also Friends of Yosemite Valley v. Scarlett, 439 F. Supp. 2d 1074, 1086 (E.D. Cal. 2006) (same).

The "final agency action" requirement applies because plaintiff invokes the APA's waiver of sovereign immunity, see Am. Compl. ¶ 1, but that waiver "contains several limitations. Of relevance here is 5 U.S.C. § 704, which provides that only '[a]gency action made reviewable

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1 See Def. Mem. 13-15 (citing cases establishing that agency speech lacking the force and effect of law, such as the statement allegedly disseminated by defendants that marijuana has no currently accepted medical use in the United States, does not qualify as "final agency action" and is not subject to judicial review).

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) (emphasis added). This Court has already held that the IQA provides no private right of action and, thus, plaintiff has identified no statute that makes an agency's action, or a decision not to act under the IQA subject to judicial review. Americans for Safe Access v. Dep't of Health and Human Services, Civ. No. 07-1049-WHA, 2007 WL 2141289 (N.D. Cal. July 24, 2007), Docket Entry No. 41 ("Opinion") at 4-6 (following the "courts in other circuits [that] have unanimously and persuasively rejected a right of judicial review under the Information Quality Act" and holding that "[t]he IQA provided only an administrative remedy.").

Because the act plaintiff seeks to compel is not "made reviewable by statute," the APA finality requirement in Section 704 applies. See SUWA, 542 U.S. at 61-62. Section 704 provides that finality is a condition of "judicial review" under the APA, without distinguishing between review under §§ 706(1) and 706(2) of an agency's failures to act (a form of "agency action" under the APA, 5 U.S.C. § 551(13)). Thus, § 706(1) authorizes a court to compel only final agency action, i.e., action that is conclusive and that carries legal consequences, see Bennett, 520 U.S. at 177-78, and that, if taken by the agency rather than withheld, would be reviewable under § 706(2).[2]

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2 This conclusion is further supported by the Attorney General's Manual on the Administrative Procedure Act (1947), to which the Supreme Court has "repeatedly given great weight" in the interpretation of the APA. Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 218 (1988) (Scalia, J., concurring) (citing cases). In describing § 706(1) (Clause (A) of Section 10(e) of the APA as enacted in 1946), the Attorney General's Manual states:

> Clause (A) authorizing a reviewing court to "compel agency action unlawfully withheld or unreasonably delayed", appears to be a particularized restatement of existing judicial practice under section 262 of the Judicial Code (28 U.S.C. 377). Safeway Stores, Inc. v. Brown, 138 F.2d 278 (E.C.A., 1943), certiorari denied, 320 U.S. 797. The power thus stated is vested in "the reviewing court", which, in this context, would seem to be the court which has or would have jurisdiction to review the final agency action. See Roche v. Evaporated Milk Ass'n., 319 U.S. 21, 25 (1943).

(continued...)

Plaintiff's citation to cases where "courts have . . . entertained suits under the APA for denials of administrative petitions" does not save plaintiff's claim. See Plaintiff's Memorandum in Opposition to Defendants' Motion to Dismiss the Amended Complaint, Docket Entry No. 51 ("Pl. Mem.") at 11-12. The APA certainly applies to denials of administrative petitions where the denial is a *final agency action* or is made reviewable by another statute, and where the petitioner lacks another adequate remedy in a court. 5 U.S.C. § 704. It is therefore unsurprising that the cases upon which plaintiff relies concerned a petition for review of a final agency action, i.e., action that itself had direct legal consequences. See Pl. Mem. 11-12 (citing cases concerning, e.g., petitions for rulemaking, immigration decisions, individuals' military records and HUD debarment).

Here, in contrast, the action for which plaintiff seeks an order of mandamus is agency speech lacking any direct legal consequence. "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 589, 602 (E.D. Va. 2004) (Lee, J.), aff'd, 440 F.3d 156 (4th Cir. 2006). See also Def. Mem. 13-14 (same; citing cases). As this Court held when dismissing plaintiff's original Complaint, plaintiff has failed "to allege any facts that suggest that defendants' failure to correct their allegedly erroneous statements has any legal consequences, or that it determines any rights or obligations."[3] Opinion at 6-7 (citing Bennett, 520 U.S. at 178). Plaintiff has not cured that

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2(...continued)
Attorney General's Manual at 108. The "existing judicial practice" described in Safeway Stores permitted a court to compel an agency or official to take a discrete "final action." 138 F.2d at 280. The Safeway court thus made clear that it could grant mandamus to compel an agency to take action on a discrete matter that had been unreasonably delayed, but only in aid of the court's power to review the "final action" of the agency when it ultimately was issued, not based on some broader, free-ranging power to oversee agency conduct.

3 For this reason, plaintiff's conclusory statement that the Court "implicitly" indicated plaintiff has standing when the Court dismissed plaintiff's first Complaint with leave to amend is mistaken. See Pl. Mem. 9. To the contrary, the Court found persuasive and relied upon the Fourth Circuit's holding in Salt Institute v. Leavitt that the IQA/APA plaintiff there "'failed to (continued...)

pleading defect, and the IQA itself "'does not create any legal right to information or its correctness'" enforceable in this Court. Id. at 8, quoting Salt Institute v. Leavitt, 440 F.3d 156, 159 (4th Cir. 2006); see also In re Operation of the Missouri River System Litigation, 363 F. Supp. 2d 1145, 1174-75 (D. Minn. 2004) (Magnuson, J.), vacated in part and aff'd in part on other grounds, 421 F.3d 618 (8th Cir. 2005).

In short, plaintiff's complaint does not concern any final agency action or inaction cognizable under the APA. For that reason alone, it should be dismissed.

## II. Plaintiff's Mandamus Claim Also Fails Because The Agency Has Acted Within Its Statutory Discretion.

Under § 706(1), a claim "can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required* to take." SUWA, 542 U.S. at 64 (emphasis in original). But plaintiff has not identified a source of law that requires HHS to take the action plaintiff asks this Court to compel – a "substantive" response (Am. Compl. ¶ 22) to plaintiff's IQA request for correction. Indeed, the IQA itself "creates no legal rights in any third parties," Salt Institute v. Leavitt, 440 F.3d at 159, and an agency's delay in acting or failure to act "cannot be unreasonable with respect to action that is not required," SUWA, 542 U.S. at 63 n.1. Plaintiff's claim fails for this reason as well.

As the Supreme Court explained, this limitation on claims under § 706(1) was carried forward from the use of writs of mandamus under the All Writs Act, 28 U.S.C. § 1651, prior to the APA's enactment. Id. The "mandamus remedy was normally limited to enforcement of 'a specific, unequivocal command,' the ordering of a 'precise, definite act ... about which [an

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3(...continued)
establish an injury in fact sufficient to satisfy Article III'" standing requirements since the IQA itself creates no rights enforceable in district court. Opinion at 5 (quoting Salt Institute v. Leavitt, 440 F.3d at 159); see also id. at 6-7 ("[P]laintiff has failed to plead that the IQA grants any legal right to the correction of information. Plaintiff has identified no other legal consequences flowing from defendants' response to their IQA information correction request."); Def. Mem. 9-10 (explaining plaintiff's Amended Complaint fails to establish standing).

official] had no discretion whatever.'" Id. (citations omitted).[4] Accordingly, to state a claim under § 706(1) plaintiffs "must identify a statutory provision mandating agency action," not one vesting an agency with discretion. Center for Biological Diversity v. Veneman, 335 F.3d 849, 854 (9th Cir. 2003). Here, however, the agency maintains a great deal of discretion concerning its response to plaintiff's IQA request for correction.

In its effort to "identify a statutory provision mandating agency action," id., plaintiff cites to language in the IQA directing that OMB issue guidelines that "[r]equire that each Federal agency to which the [OMB] guidelines apply– . . . 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. See Pub.L. 106-554, § 1(a)(3) [Title V, § 515], Dec. 21, 2000, 114 Stat. 2763, 2763A-153 (quoted in part in Pl. Mem. 12; italicized portion omitted there by plaintiff). Plaintiff appears to contend the terms "require" and "obtain" amount to a statutory mandate that HHS provide plaintiff the sort of response to plaintiff's IQA request for correction that plaintiff seeks: a "substantive" response, as opposed to the agency's response that it will consider plaintiff's arguments as part of the government's consideration of a pending petition to reschedule marijuana under the Controlled Substances Act. See Pl. Mem. 13; see also Def. Mem. 8 (discussing the agency's response to plaintiff's administrative IQA request and appeal). Plaintiff fails to note that these terms are not a self-

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4 Plaintiff is therefore mistaken when it argues defendants "mischaracterize[] a plaintiff's burden to obtain compulsion of agency action under the APA" as akin to the burden of a petitioner for mandamus relief. Pl. Mem. 10. Defendants do not argue that plaintiff must go beyond the requirement under SUWA that a § 706(1) petitioner must show "that an agency failed to take a *discrete* agency action that it is *required* to take," 542 U.S. at 64, to also "demonstrate . . . a ministerial duty and a clear and certain claim," Pl. Mem. 10. Rather, defendants cite cases showing that these modes of analysis are two sides of the same coin. See, e.g., Independence Min. Co., Inc. v. Babbitt, 105 F.3d 502, 507 (9th Cir. 1997) (cited in pl. mem. 10-11) ("Although the exact interplay between these two statutory schemes has not been thoroughly examined by the courts, the Supreme Court has construed a claim seeking mandamus under the [Mandamus Act], 'in essence,' as one for relief under § 706 of the APA." (quoting Japan Whaling Ass'n v. American Cetacean Soc'y, 478 U.S. 221, 230 n.4. (1986)); Xin Liu v. Chertoff, --- F. Supp. 2d ---, No. Civ. S-06-2808 RRB EFB, 2007 WL 2433337, *3 (E.D. Cal. August 22, 2007) (Beistline, J.) (describing a 5 U.S.C. § 706(1) claim as a "petition for a writ of mandamus compelling an agency to perform an 'action unlawfully withheld or unreasonably delayed.'").

executing or free-standing mandate, but rather reference the OMB's IQA guidelines. And those guidelines, in turn, instruct agencies to issue their own guidelines allowing IQA requesters "to seek and obtain, where appropriate," correction of information. See 67 Fed. Reg. 8452, 8458-59 (February 22, 2002). Thus, the OMB guidelines make it clear 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. at 8459. As explained in the preamble to the OMB guidelines, "[a]gencies, in making their determination of whether or not to correct information, . . . are required to undertake *only the degree of correction that they conclude is appropriate* for the nature and timeliness of the information involved[.]." Id. at 8458 (emphasis added). Thus, far from a statutory mandate that involves no discretion, the IQA and OMB guidelines instruct agencies to act as they conclude is appropriate. Such language plainly vests the agency with discretion. See Steenholdt v. FAA, 314 F.3d 633, 638 (D.C. Cir. 2003) (regulation that authorizes an agency official to take an action for a reason the official "considers appropriate" confers considerable discretion on the agency); Legal Services of Northern California, Inc. v. Arnett, 114 F. 3d 135, 140 (9th Cir. 1997) (statute's terms that legal services be provided to senior citizens "to the maximum extent feasible" in accord with their need left federal court "ill-equipped" to determine how that could be accomplished); Rank v. Nimmo, 677 F.2d 692, 699-700 (9th Cir. 1982) (statute providing the administrator "may" take action "at [his] option" vested the "widest discretion possible" in the administrator). Here, 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. Mandamus is, accordingly, inappropriate. Cf. Local 2855, AFGE (AFL-CIO) v. United States, 602 F.2d 574, 579 (3rd Cir. 1979) ("courts have been especially inclined to regard as unreviewable those aspects of agency decisions that involve a considerable degree of expertise or experience"); In re Operation of the

Missouri River System Litigation, 363 F. Supp. 2d at 1174-75 (finding response to IQA petitions committed to agency discretion by law) (relied upon as persuasive by this Court, see Opinion at 5).

**III. Plaintiff's Merits Arguments And Attacks On Defendants Are Unfounded And Irrelevant.**

As discussed above and in defendants' opening brief, plaintiff has failed its burden to establish that it has any claim reviewable in this Court. Toward the close of its brief, plaintiff relies on strident rhetoric to try to establish the merits of its (non-existent) claim. In particular, plaintiff asserts without foundation that HHS has "acted in bad faith" in a "cynical" and "offensive" matter as it has "dragg[ed] the process out intentionally solely for the purpose of delay." See Pl. Mem. 14-20. Plaintiff's accusations do nothing to address the threshold legal arguments at issue raised by defendants' Motion to Dismiss, which plaintiff would apparently prefer to avoid. Plaintiff's statements also run contrary to the well-recognized principle that "'[t]he presumption of regularity supports'" government agency decisions, and "'in the absence of clear evidence to the contrary, courts presume that [public officials] have properly discharged their official duties.'" See United States v. Armstrong, 517 U.S. 456, 464 (1996) (quoting United States v. Chemical Found., Inc., 272 U.S. 1, 14-15 (1926)); Akiak Native Cmty. v. USPS, 213 F.3d 1140, 1146 (9th Cir. 2000) (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415 (1971)) (Government decision-making process "is accorded a 'presumption of regularity.'"); Red Top Mercury Mines, Inc. v. United States, 887 F.2d 198, 202-03 (9th Cir. 1989) ("There is a presumption of regularity in the performance of their duties by government officials.").

The Court should accord no weight to plaintiff's baseless assertions, which are irrelevant to the legal questions at issue in any event.

## CONCLUSION

Accordingly, for all of the foregoing reasons, this Court should dismiss plaintiff's Amended Complaint with prejudice.

Dated November 1, 2007

Respectfully Submitted,

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