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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. **DEFENDANTS' NOTICE OF MOTION AND MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT**

Notice of Motion and Motion to Dismiss Plaintiff's Complaint, set for hearing on November 15, 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 October 11, 2007

Respectfully Submitted,

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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." The Court, holding that plaintiff failed to state a claim upon which relief may be granted, has already dismissed plaintiff's claim once with leave to amend. Plaintiff's Amended Complaint failed to cure the defects of its original claims under the Administrative Procedure Act ("APA"), and its one new claim a request for mandamus under the APA similarly fails to establish jurisdiction or state a claim that would entitle plaintiff to relief in this Court.

First, plaintiff lacks Article III standing to bring its claim because it 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 the plaintiff had standing to raise its APA claim, it makes no assertion that the HHS statement in question has or had any binding legal effect. And, as the Court recognized in its opinion dismissing plaintiff's first Complaint, agency acts (such as agency speech) lacking the force and effect of law are not subject to judicial review. Because the APA cannot be used to compel action that the APA doesn't otherwise cover, plaintiff's request for mandamus should, therefore, be denied. 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.

At bottom, plaintiff's claims whether couched as review of final agency action or a request for mandamus to compel final agency action do not concern the type of agency action

that is reviewable under the APA. Because the IQA also does not provide for judicial review of plaintiff's claims, this Court should dismiss them.

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 September 28, 2001, 66 Fed. Reg. 49718 (Sept. 28, 2001). Following another period for

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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).

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

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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.

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).

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.

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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.

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 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

5 The DEA Administrator has applied a "five-part test for determining whether a drug is in (continued...)

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).

The CSA 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

5(...continued)
'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)).

(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, sent a letter and attached analysis to the DEA Administrator. Id. at 20039. DEA chose to publish the Assistant Secretary's letter and accompanying analysis in the Federal Register. Id. The Assistant Secretary'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 Assistant Secretary's letter to the DEA

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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

(continued...)

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 resolved 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 (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. On July 24, 2007, this Court dismissed plaintiff's Complaint but provided plaintiff leave to amend to add a claim under 5 U.S.C. § 706(1). See 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"). The Court held that plaintiff's claims failed because "the IQA does not subject

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6(...continued)
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.).

agency IQA decisions to judicial review. Nor is there any final agency action on the present record" that would permit review under the APA. Id. at 4.

ARGUMENT

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

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 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.; see Am. 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; 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 5-6. Accordingly, 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").

"The IQA provided only an administrative remedy." Opinion at 5; see also Salt Institute v. Thompson, 345 F. Supp. 2d 589, 601 (E.D. Va. 2004) ("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."), aff'd, 440 F.3d 156, supra. Indeed, the IQA expressly sets out the non-judicial 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 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.[7] 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.

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

This Court has already dismissed plaintiff's claims under the APA, 5 U.S.C. § 706(2)(A) & (C), "alleging that defendants' response to their petition constituted final agency action in violation of the IQA." Opinion at 7. The Court granted plaintiff leave to amend its Complaint to state a claim it raised at oral argument that the Court should "compel agency action unlawfully withheld or unreasonably delayed" under the APA, 5 U.S.C. § 706(1). Plaintiff has done so, but

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7 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.

its new claim suffers from the same flaws.

Plaintiff's complaint is, at bottom, a quarrel with agency speech. The agency speech in 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)).[8]

As this Court has held, 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 and because it does not qualify as final agency action under the APA. Opinion at 4. In addition, plaintiff has another adequate remedy under the CSA and 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. The agency did not, therefore, violate any clear statutory duty when it determined how to respond to plaintiff's IQA request.

A. Plaintiff Fails To Plead A Claim Under 5 U.S.C. § 706(1) That Would Entitle Plaintiff To The Mandamus Order It Seeks .

This Court's review of plaintiff's claim under 5 U.S.C. § 706(1) is similar to review of a claim for mandamus relief. See Independence Mining Co. v. Babbitt, 105 F.3d 502, 506-507 (9th Cir. 1997).[9] Under the Mandamus Act or the APA, mandamus relief may be granted only when (1) the plaintiff's claim is clear and certain; (2) the duty is "ministerial and so plainly prescribed as to be free from doubt;" and (3) no other adequate remedy is available. See Oregon Natural

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8 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).

9 See also Japan Whaling Ass'n v. American Cetacean Soc., 478 U.S. 221, 230 n.4 (1986) (a claim for mandamus under 28 U.S.C. § 1361 is "in essence" a claim for relief under 5 U.S.C. § 706).

Resources Council v. Harrell, 52 F.3d 1499, 1508 (9th Cir. 1995). Thus, as the Supreme Court has held, "a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required* to take." Norton v. Southern Utah Wilderness Alliance ("SUWA"), 542 U.S. 55, 64 (2004) (emphasis in original). "These limitations rule out several kinds of challenges," id., including plaintiff's.

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

First, plaintiff's new claim fails because the APA does not waive sovereign immunity for a claim that seeks only to compel non-binding agency speech. The "action" plaintiff seeks to compel would not be "final agency action," or "agency action" at all, under the terms of the APA. As the Supreme Court noted, where, as here, "no other statute provides a private right of action," the agency action a plaintiff challenges "must be '*final* agency action.'" SUWA, 542 U.S. at 61-62, quoting 5 U.S.C. § 704 (emphasis as in SUWA). "The APA provides relief for a failure to act in" the provision now invoked by plaintiff, "§ 706(1): 'The reviewing court shall . . . compel agency action unlawfully withheld or unreasonably delayed." Id. at 62. Thus, to state a claim under the APA and invoke its waiver of sovereign immunity, plaintiff must identify "an 'agency action,' either as the action complained of (in §§ 702 and 704) or as the action to be compelled (in § 706(1))." Id.

Moreover, the "agency action" sought to be compelled must qualify as "final agency action." Section 706(1) has been described as a "limited exception to the finality doctrine" that permits jurisdiction "only when there has been a genuine failure to act." Ecology Center v. United States Forest Service, 192 F.3d 922, 926 (9th Cir. 1999). That is because the inaction itself may be seen as depriving the underlying action of sufficient finality. See id. Put another way, "[i]n certain circumstances, agency inaction may be sufficiently final to make judicial review appropriate." Sierra Club v. Peterson, 228 F.3d 559, 568 (5th Cir. 2000), cert. denied, 532 U.S. 1051 (2001). Under 5 U.S.C. § 704, however, the action sought to be compelled by an APA claim must itself qualify as "final agency action," i.e., action that is conclusive and that carries legal consequences, see Bennett, 520 U.S. at 177-178, and that, if taken by the agency rather than

withheld, would be reviewable under Section 706(2). Section 704 provides that finality is a condition of "judicial review" under the APA, without distinguishing between review under Section 706(1) of an agency's failures to act (a form of "agency action" under Section 551(13)) and review under Section 706(2) of an agency's affirmative acts. See also Aladjem v. Cuomo, Civ. No. 96-6576, 1997 WL 700511, at *3 n.2 (E.D. Pa. Oct. 30, 1997) (Pollak, J.) (noting that 5 U.S.C. § 704 defines the types of agency actions subject to judicial review while § 706 defines the scope of review over reviewable actions). Accordingly, the Ninth Circuit "has refused to allow plaintiffs to evade the finality requirement with complaints about the sufficiency of an agency action 'dressed up as an agency's failure to act.'" Ecology Ctr., 192 F.3d at 926 (quoting Nevada v. Watkins, 939 F.2d 710, 714 n. 1 (9th Cir. 1991)).

Here, as defendants have previously noted and plaintiff has not refuted, the action sought to be compelled agency speech that lacks any direct legal effect would not qualify as reviewable final agency action. It therefore cannot be compelled under Section 706(1). "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 courts have long held that agency speech without direct legal consequences does not qualify as an "exercise" of agency "power" cognizable under the APA. Cf. Whitman v. American Trucking Associations, 531 U.S. 457, 478 (2001) (construing term "agency action"). 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). See also 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).

The fact that the IQA affords plaintiff with an opportunity to seek *administrative* correction of HHS's statement does not convert the statement into agency action and permit plaintiff to seek judicial review under any portion of the APA. The lack of a "substantive response" to plaintiff's request for correction, like a response, does "not augment the [statement's] legal force or practical effect." FTC v. Standard Oil Co. of California, 449 U.S. 232, 243 (1980). See id. (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).

"[P]laintiff has failed to plead that the IQA grants any legal right to the correction of information." Opinion at 7. Indeed, "'[t]he IQA . . . does not create any legal right to

information or its correctness'" enforceable in this Court. Id. at 8, quoting 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). Similarly, plaintiff "has failed to plead that defendants' response to their administrative appeal constituted final agency action," Opinion at 7, or that the "substantive response" plaintiff seeks *would* constitute such an action. Since the definitive response plaintiff seeks would be agency speech without the force and effect of law, it would not be "final agency action" (or even "agency action") reviewable under the APA. And because the APA does not permit the compulsion of that which could not be reviewed, plaintiff's Section 706(1) claim fails.

2. Plaintiff's Claim Also Fails Because The Agency Speech It Seeks To Compel Is Not Legally Required.

As noted above, the Supreme Court has held that "a claim under § 706(1) 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. Defendants have explained above that the action plaintiff seeks to compel does not qualify because it is not "agency action" cognizable under the APA. Plaintiff's claim also fails because the action is not required by law, and "[t]he limitation to required agency action rules out judicial direction of even discrete agency action that is not demanded by law." Id., 542 U.S. at 63.[10]

Plaintiff has not identified a source of law that required HHS to provide a "substantive" response (Am. Compl. ¶ 22) to plaintiff's IQA request for correction within a time certain. The statute itself provides no such deadlines for agency responses. Indeed, it "creates no legal rights in any third parties." Salt Institute v. Leavitt, 440 F.3d at 159. Rather, the IQA "orders the Office of Management and Budget to draft guidelines concerning information quality and

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10 See also Center for Biological Diversity v. Veneman, 335 F.3d 849, 854 (9th Cir. 2003) (under § 706(1), plaintiffs "must identify a statutory provision mandating agency action"); San Francisco BayKeeper v. Whitman, 287 F.3d 764, 770 (9th Cir. 2002) ("for a claim of unreasonable delay to survive, the agency must have a statutory duty in the first place"); accord, ONRC Action v. Bureau of Land Mgmt., 150 F.3d 1132, 1137 (9th Cir. 1998) (judicial intervention under § 706(1) is warranted "'[w]hen agency recalcitrance is in the face of clear statutory duty or is of such a magnitude that it amounts to an abdication of statutory responsibility'" (citations omitted).

specifies what those guidelines should contain." Id. Specifically, the statute 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. 2763, 2763A-153 (Dec. 21, 2000).[11]

Nor do the OMB guidelines mandate the substantive response that plaintiff seeks to compel. The OMB guidelines eschew "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 underscore the "flexibility" that the guidelines give 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).

The HHS guidelines likewise counsel flexibility and afford the agency considerable deference, indicating that the 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

11 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.

requirements[12] for the correction." www.hhs.gov/infoquality § E.[13] Put another way, defendants have not violated any clear and unmistakable duty since the determination of how to respond to plaintiff's Request for Correction was "committed to agency discretion by law." See, e.g., Heckler v. Chaney, 470 U.S. 821, 830 (1984); 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).

Nor do any of the guidelines impose a strict deadline. The HHS guidelines state that "[t]he agency will respond to all requests for correction within 60 calendar days of receipt. If the request requires more than 60 calendar days to resolve, the agency will inform the complainant that more time is required and indicate the reason why and an estimated decision date." Id.

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12 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).

13 The HHS guidelines also state that "[e]xisting public comment procedures for rulemakings 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." See www.hhs.gov/infoquality § E. As noted above, HHS channeled plaintiff's concerns to an existing and ongoing process: consideration of a related petition to reschedule marijuana under the CSA.

The HHS guidelines further provide that "[i]n cases where the agency disseminates a study, analysis, or other information prior to the final agency action or information product, requests for correction will be considered in those cases where *in the agency's judgment*" two conditions have been met. Id. (emphasis added; quoted in Am. Compl. ¶ 14). Those conditions are that "issuing an earlier response would not unduly delay issuance of the agency action or information product *and* the complainant has shown a reasonable likelihood of suffering actual harm from the agency's dissemination" if the agency does not resolve the IQA petition separately. Id. (emphasis added). As defendants have noted, plaintiff's IQA petition did not challenge any statement that was "disseminated" by HHS or FDA within the meaning of the IQA. See Brief in Support of Defendants' Motion to Dismiss (Docket No. 31) at 31-32; Reply Brief (Docket No. 39) at 17-18. Moreover, plaintiff did not show a reasonable likelihood of suffering actual, cognizable harm from any HHS or FDA dissemination. Cf. generally Brief in Support of Defendants' Motion to Dismiss at 13-17 (explaining plaintiffs have not established any injury in fact); Reply Brief at 3-6 (same). Finally, this language from the HHS guidelines provides neither the kind of firm deadline nor the sort of clear and unmistakable duty on the agency that would be amenable to judicial enforcement on a petition for mandamus.

Similar language addresses HHS's response to and resolution of an appeal on the agency's decision. By their terms, the guidelines do not require that a request be *resolved* within 60 days or any time certain; they require only that there be a response in 60 days, and say nothing about the relative "substance" of such a response. It is undisputed that plaintiff's IQA petition received a response, as did plaintiff's appeal. Am. Compl. ¶¶ 17, 22. Indeed, plaintiff alleges not that it was denied a resolution but that it received a "nonsubstantive final denial" that "mark[ed] the conclusion of the administrative IQA petition process." Id. ¶ 22.

Judicial intervention under § 706(1) is warranted only "'[w]hen agency recalcitrance is in the face of clear statutory duty or is of such a magnitude that it amounts to an abdication of statutory responsibility.'" ONRC, 150 F.3d at 1137 (citations omitted). Plaintiff has identified no such clear and unmistakable duty. For that reason, as well, the Court should dismiss its claim. Cf. 5 U.S.C. § 701(a)(2) (no APA review of actions "committed to agency discretion by law"); 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).

B. 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. 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, 484 F.3d 561, 568 (D.C. Cir. 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, or that the CSA review process may take some time, 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.

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.

C. Plaintiff Has Not Cured The Defects In Its Original APA Claims.

This Court previously dismissed plaintiff's claims under the APA, 5 U.S.C. § 706(2)(A), seeking review in this Court of the purportedly final agency action with regard to plaintiff's IQA request. Plaintiff has done nothing to cure the defects in those claims, including the failure to allege a final agency action cognizable under the APA that injured plaintiff or to point to another statute authorizing judicial review. See Opinion at 4; see also Defendants' Memorandum in Support of Defendants' Motion to Dismiss (Docket Entry No. 31) and Defendants' Reply Memorandum (Docket Entry No. 39) (each explaining why plaintiff's claims fail as a matter of law; incorporated herein by reference).

CONCLUSION

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

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