IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

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 07-01049 WHA

ORDER GRANTING MOTION TO DISMISS

INTRODUCTION

In this Administrative Procedure Act action, plaintiff Americans for Safe Access seeks to compel the United States Department of Health and Human Services to provide a "substantive" response to its petition to correct statements regarding the accepted medical use and efficacy of marijuana. Plaintiff filed its first amended complaint on August 17, 2007.

On motion to dismiss pursuant to Rule 12(b)(6), this order addresses the following two questions: (1) What constitutes an "agency action" under 5 U.S.C. 706(1), the provision of the APA which allows a court to "compel agency action unlawfully withheld or unreasonably delayed," and (2) Is adherence to guidelines promulgated under the requirements of the Information Quality Act legally required? This order finds that it is not necessary to reach a conclusion as to the first question because plaintiff has not shown that the action it seeks to compel is legally required. This order therefore **GRANTS** defendants' motion to dismiss.

STATEMENT

The Information Quality Act of 2000 directed the Office of Management and Budget 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 Federal agencies . . . ." Pub. L. No. 105-554 § 1(1)(3) [Title V. § 515] (Dec. 21, 2000) (published at 44 U.S.C. 3516 note 4(a)). The IQA directed OMB to include the following provisions in its guidelines: (1) that federal agencies issue their own guidelines not more than one year after OMB issues its guidelines; (2) that agencies "establish administrative mechanisms allowing affected person to seek and obtain correction of information maintained and disseminated by the agency that does not comply with [the OMB guidelines];" and (3) that agencies periodically report to the director of OMB the nature and number of complaints and how they were handled. *See* 44 U.S.C. 3516 note 4(b)(2).

The OMB guidelines, finalized on February 22, 2002, stated the following as to information-correction procedures:

> To facilitate public review, agencies shall 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. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.
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> i. Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.
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> ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.

67 Fed. Reg. at 8459.

On October 1, 2002, pursuant to the IQA and the OMB guidelines, the United States Department of Health and Human Services implemented its own guidelines. The HHS guidelines established an information-correction procedure as follows:

> Based on a review of the information provided, the agency will determine whether a correction is warranted and if so, what action to take. The agency will respond to the requestor by letter or e-mail. The agency's response will explain the findings of the review and the actions that the agency will take, if any. The response will consider the nature and timeliness of the information involved and such factors as the significance of the correction on the use of the information, the magnitude of the correction and the resource requirements for the correction. The response will describe how the complainant may request reconsideration. The 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.
>
> If the individual submitting the complaint does not agree with the agency's decision (including the corrective action), the complainant may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal shall state the reasons why the agency response is insufficient or inadequate. Complainants shall attach a copy of their original request and the agency response to it, clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal to the specific agency appeals address.
>
> The agency official who handles the original complaint will not have responsibility for resolving the appeal. The agency will respond to all requests for appeals 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.

http://aspe.hhs.gov/infoquality/Guidelines/index.shtml.

Plaintiff filed an information-correction request with HHS on October 4, 2004, asking HHS to correct information it was disseminating about the medical use of marijuana (Compl. ¶ 15). Specifically, plaintiff disagrees with defendants' statements that marijuana "has no currently accepted medical use in treatment in the United States" (Compl. ¶ 1). HHS responded on December 1, 2004, stating that it needed to consult with the Drug Enforcement Administration, which was contemporaneously reviewing a petition to reschedule marijuana, in order to provide a response. Plaintiff protested this response as inexcusable delay, but HHS

nevertheless continued to state that it needed more time to coordinate agency review (Compl. ¶¶ 18–19). On April 20, 2005, HHS denied plaintiff's information-correct petition, and plaintiff appealed on May 19, 2005. Subsequently, HHS made a series of interim responses noting that the process was still ongoing, and on July 12, 2006, noted that it anticipated providing a response by September 2006 in connection with a marijuana rescheduling petition pending before the DEA. According to plaintiff, this marked the conclusion of the administrative IQA petition process, as plaintiff was left without additional avenues of recourse (Compl. ¶¶ 19–22)).

Plaintiff filed suit on February 21, 2007, seeking declaratory and injunctive relief under the Administrative Procedure Act. On July 24, 2007, this Court granted defendants' motion to dismiss the original complaint for failure to state a claim under Rule 12(b)(6), but granted plaintiff leave to amend to proceed on a theory that defendants unlawfully withheld or delayed agency action by not providing a *substantive* response to plaintiff's information-correction petition. Plaintiff did so amend its complaint, and filed its amended complaint on August 17, 2007. Defendants then filed a second motion to dismiss under Rule 12(b)(6) on October 11, 2007.

ANALYSIS

1. "FINAL" AGENCY ACTION UNDER SECTION 706(1).

The APA allows judicial review of federal agency action that is either "made reviewable by statute [or] final agency action for which there is no other adequate remedy in a court." 5 U.S.C. 704. It also directs the reviewing court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. 706(1). A claim under Section 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*, 542 U.S. 55, 64 (2004).

Plaintiff argues that an action under Section 706(1) only needs to be a "discrete" action, not a "final agency action," stating that "courts have routinely entertained suits under the APA for denials of administrative petitions" (Opp. 11). Plaintiff cites numerous cases on this point, all of which are similarly unhelpful inasmuch as they all address final agency actions.

Defendants, however, note several decisions, including two district court decisions within the Ninth Circuit that have squarely addressed this question and have held that Section 706(1) requires that the action sought to be compelled must be final agency action. *See Elhaouat v. Miller*, 2007 WL 2332488 at *3 (E.D. Penn., Aug. 9, 2007); *High Sierra Hikers Ass'n v. United States Forest Serv.*, 436 F. Supp. 2d 1117, 1140 (E.D. Cal., June 8, 2006); *Friends of Yosemite Valley v. Scarlett*, 439 F. Supp. 2d 1074, 1086 (E.D. Cal., July 19, 2006). Ultimately it is not necessary for this order to rule on the question because plaintiff fails to meet the second requirement under Section 706(1); that the action to be compelled is legally required.

2. ACTION LEGALLY REQUIRED.

"[T]he only action that can be compelled under the APA is action legally *required*." *Norton*, 542 U.S. at 63. In this case, plaintiff argues that defendants have unreasonably delayed in making a substantive response, but a delay "cannot be unreasonable with respect to action that is not required." *Id.* at 63 n.1. Plaintiff argues that the language in the IQA, which directs the OMB to issue guidelines that would "require" agencies to issue their own guidelines that would allow "affected persons to seek and obtain correction of information" creates a legal requirement (Opp. 12) (quoting 67 Fed. Reg. 8452, 8459 (Feb. 22, 2003)). Furthermore, plaintiff notes that the OMB guidelines state that agencies "shall specify appropriate time periods for agency decisions." *Ibid*. As stated above, the HHS guidelines direct the agency to respond to requests for correction and appeals within sixty days.

Defendants rely on *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006), in which the Fourth Circuit held that the IQA "creates no legal rights in any third parties." Defendants further argue that the HHS guidelines do not impose a strict deadline because they only state that "[t]he agency will respond to all requests for correction within 60 calendar days of receipt," and if the requests requires more than 60 days, the agency "will inform the complainant that more time is required and indicate the reason why." http://aspe.hhs.gov/infoquality/Guidelines/index.shtml. Plaintiff does not dispute that defendants *did* respond but, instead, argues that defendants' response amounted to a "nonsubstantive final denial" (Compl. ¶ 22).

Defendants also contend that the OMB guidelines do not *mandate* a substantive response, but instead "underscore the 'flexibility' that the guidelines give the agencies" (Reply 16). Guidelines are by nature advisory, but the Ninth Circuit has recognized that "[a]n agency's regulations *may* create judicially enforceable duties." *Lowry v. Barnhart*, 329 F.3d 1019, 1022 (9th Cir. 2003) (emphasis added). In *Salt Institute v. Thompson*, 345 F. Supp. 2d 589, 602 (E.D. Va., Nov. 15, 2004), however, Judge Gerald Lee considered whether an agency's actions under the IQA and the OMB guidelines were judicially reviewable and stated that "[a]gency 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." That decision held that "neither the IQA nor the OMB Guidelines provide judicially manageable standards that would allow meaningful judicial review to determine whether an agency properly exercised its discretion in deciding a request to correct a prior communication." *Ibid*. The OMB guidelines give discretion to agencies by stating that "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." 67 Fed. Reg. at 8458.

In addition to the holding in *Salt Institute*, other courts have held similar language to allow discretion on the part of agencies, and render action not legally required. *See Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) (regulations allowing rescission of a designation for any reason the administration considers appropriate not judicially reviewable).

This order agrees that the IQA and OMB guidelines do not create a duty to perform legally required actions that are judicially reviewable. Since plaintiff has not shown that the action it seeks to compel is legally required, defendants' motion to dismiss for failure to state a claim must be **GRANTED**.

CONCLUSION

Plaintiff has failed to show that defendants have unreasonably delayed the performance of a legally required duty. For the above reasons, defendants' motion to dismiss for failure to

state a claim pursuant to Rule 12(b)(6) is hereby **GRANTED**. Further leave to amend is unwarranted. The Clerk shall close the file.

IT IS SO ORDERED.

Dated: November 20, 2007.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE