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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

AMERICANS FOR SAFE ACCESS, Plaintiff, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES and FOOD AND DRUG ADMINISTRATION, Defendants.	No. 3:07-cv-01049-WHA **MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO MOTION TO DISMISS** Date: July 12, 2007 Time: 8:00 a.m. Place: Courtroom of the Honorable William H. Alsup

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INTRODUCTION

Defendants have moved to dismiss the complaint for a variety of reasons, but their import can be summarized as follows: Although Congress enacted the Information Quality Act ("IQA") to remedy a serious problem caused by federal agencies disseminating factual information that is inaccurate and then refusing to correct the inaccuracies when called to their attention, the IQA is a legal nullity. According to defendants, no one may sue to enforce the IQA, and agencies are entirely free to disregard its commands, and those of its Guidelines, save perhaps as the Office of Management and Budget ("OMB") may be able to persuade them to comply. According to the Department of Health and Human Services ("HHS"), agencies are free to disregard requests to correct indefinitely, or entirely, and offer legally insufficient reasons for not complying, all without any judicial oversight. Congress did not enact such a meaningless statute, and nothing in the Administrative Procedure Act allows defendants to disregard the mandates of the IQA in the manner that they have done. Accordingly, the motion to dismiss should be denied.

THE INFORMATION QUALITY ACT AND ITS IMPLEMENTING GUIDELINES

Recognizing serious defects in the quality of information disseminated by federal agencies, Congress enacted the Information Quality Act ("IQA") in December of 2000 as a supplement to the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.* ("PRA"). Codified in the Statutory and Historical Notes to the PRA at 44 U.S.C. § 3516, Pub. L. No. 106-554 § 1(a)(3), 114 Stat. 2763 (2000) (hereinafter "Section 515"), the IQA requires federal agencies to "issue guidelines ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by the agency. . . ." Section 515, § (b)(2)(A). In furtherance of this goal, Congress required federal agencies to "establish administrative mechanisms allowing affected persons to seek *and obtain* correction of information maintained

and disseminated by the agency that does not comply with the guidelines. . . ." Section 515, § (b)(2)(B) (emphasis added).

In compliance with the IQA mandate, HHS promulgated Guidelines for seeking and obtaining corrections of information it disseminates.[1] The HHS Guidelines define "quality" as "an encompassing term comprising utility, objectivity, and integrity." HHS Guideline D.2.a. These Guidelines recognize that "objectivity" requires that "disseminated information [be] presented in an accurate, clear, complete, and unbiased manner." HHS Guideline D.2.c. As for "utility," the Guidelines define that term as referring to the "usefulness of the information to its intended users, including the public. . . ." HHS Guideline D.2.b. Furthermore, the HHS Guidelines recognize that agencies responsible for dissemination of "vital health and medical information" have additional responsibilities to "ensur[e] the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public." HHS Guideline D.2.c.2.

To carry out the public participation mandate in the IQA, the HHS Guidelines provide for: (1) an initial "request for correction" of information disseminated by HHS and (2) an administrative appeal, or "Information Quality Appeal." With regard to an initial petition, the 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." HHS Guideline E. If the initial petition is denied by HHS, the HHS Guidelines provide for an administrative appeal, and the "agency will respond to all requests for appeals

[1] The HHS Guidelines are published at 67 Fed. Reg. 61343 (Sept. 30, 2002) and can also be found at http://www.hhs.gov/infoquality/part1.html. Similar Guidelines, with which the HHS Guidelines were required to comply, have been promulgated by the Office of Budget and Management ("OMB") and are published at 67 Fed. Reg. 8452 (Feb. 22, 2002).

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." HHS Guideline E.

STATEMENT OF FACTS

In response to a marijuana rescheduling petition filed in 1995, HHS made statements, which it codified in the *Federal Register* and which it continues to disseminate on government websites to this day, that marijuana has no medical use. 66 Fed. Reg. 20037, 20039 (April 18, 2001). HHS admitted that such statements were not raised by, nor were necessary to, the adjudication of the marijuana rescheduling petition then pending before it, *see* 66 Fed. Reg. 20037, 20038 (April 18, 2001), yet it assigned the Food and Drug Administration Controlled Substances Staff ("FDA") the task of assessing whether marijuana had any medical uses. After four full years, the FDA concluded that marijuana had not met three of the five criteria it employs to determine whether a substance has a "currently accepted medical use." 66 Fed. Reg. 20037, 20051 (April 18, 2001).[2] Specifically, the FDA found:

> [T]here have been no studies that have scientifically assessed the efficacy of marijuana for any medical condition.
>
> A material conflict of opinion among experts precludes a finding that marijuana has been accepted by qualified experts. At this time, it is clear that there is not a consensus of medical opinion concerning medical applications of marijuana.

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[2] These criteria are as follows:

> a. The drug's chemistry is known and reproducible;
> b. There are adequate safety studies;
> c. There are adequate and well-controlled studies proving efficacy;
> d. The drug is accepted by qualified experts;
> e. The scientific evidence is widely available.

Id. (citing *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131, 1135 (D.C. Cir. 1994)).

> [A] complete scientific analysis of all the chemical components found in marijuana has not been conducted. . . .

Based on these findings, HHS determined that marijuana "has no currently accepted medical use in treatment in the United States." 66 Fed. Reg. 20037, 20039 (April 18, 2001).

Plaintiff's Request for Correction of Information under the IQA ("Petition") to HHS contended that these statements are patently false, but that many people believe them. *See* Complaint ¶¶3, 7 & 21. The Complaint further alleges that, as a result, numerous seriously ill persons have foregone the use of marijuana, even though taking it would have dramatically improved their lives. Complaint ¶8. For instance, ASA's founder and Executive Director, Steph Sherer ("Sherer"), suffers from a condition known as torticollis, which causes her to experience inflammation, muscle spasms, and pain throughout her body, and decreased mobility in her neck. Complaint ¶8(a). Until November of 2001, Sherer did not believe that marijuana had any medical use because of statements by the government that it did not; however, after Sherer suffered kidney damage from the large amounts of conventional pain killers she was taking, her physician recommended that she try marijuana. Complaint ¶8(a). Sherer heeded her physician's advice and has successfully used marijuana since November of 2001 to reduce her inflammation, muscle spasms, and pain. Complaint ¶8(a). Sherer founded ASA several months later to share information about the medical benefits of marijuana with others. Complaint ¶8(a).

Since its formation in 2002, ASA's membership has grown to more than twenty thousand, including many seriously ill people who would have benefited from the use of marijuana for medical purposes, but who were deterred from doing so, in part, by HHS's statement that marijuana "has no currently accepted medical use in treatment in the United States." *See* Complaint ¶7. To combat this and the other harmful effects of HHS's false statements, ASA implemented a campaign to educate the public about the true benefits of

marijuana. Complaint ¶7. To this end, ASA has spent more than one hundred thousand dollars and hundreds of hours of staff time producing and disseminating educational materials explaining that scientific studies demonstrate that marijuana is effective in treating symptoms associated with cancer, HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders, and chronic pain. Complaint ¶7. ASA is making headway, but the task of combating HHS's false statements continues to drain its limited resources and impedes ASA's other efforts to improve the access of seriously ill persons to medical marijuana. *See* Complaint ¶7.

Then, ASA discovered a legal remedy. Because the IQA requires federal agencies to disseminate truthful information and provides a mechanism to ensure this, ASA filed with HHS a Petition to correct information disseminated by HHS regarding the medical use of marijuana on October 4, 2004. *See* Complaint ¶15.[3] ASA's Petition sought the correction of the four statements disseminated by HHS about medical marijuana quoted above. *See* Complaint ¶15; Petition at 1-3. The Petition explained in detail why each statement is false and provided an extensive discussion of the numerous peer-reviewed scientific studies proving this. *See* Complaint ¶15; Petition at 5-10. In addition, the Petition details why these statements violate the objectivity and utility requirements of the IQA. *See* Complaint ¶15; Petition at 5-10.

Over the next six months, HHS responded to the Petition with evasion and delay. On December 1, 2004, HHS sent ASA an interim response to its October 4, 2004, petition. Complaint ¶17. HHS stated that it had not yet completed its review of the ASA petition, due to other agency priorities and the need to coordinate agency review. Complaint ¶17. HHS contended that it needed to consult with the Drug Enforcement Administration ("DEA"), which

[3] Copies of the Petition, the initial agency response, ASA's appeal, the final agency response to the appeal, and all agency interim responses can be accessed at http://aspe.hhs.gov/infoquality/requests.shtml, item 20.

was considering a new petition filed on October 9, 2002, to reschedule marijuana, in order to prepare a response to ASA's Petition, and that it hoped to provide a response within the next 60 days. *See* Complaint ¶17. By letter dated December 20, 2004, ASA protested that HHS, by consulting with DEA, was inexcusably expanding its review to include considerations outside the scope of ASA's Petition and that such expansion would unduly delay an administrative response to the requested correction of information. Complaint ¶18. In particular, the rescheduling petition raises the issue of marijuana's relative abuse potential compared to other drugs, which is not at issue in ASA's IQA Petition. Nevertheless, HHS provided a series of interim responses over the next several months stating that it needed additional time to coordinate agency review. Complaint ¶19. Finally, on April 20, 2005, HHS denied ASA's Petition without presenting any evidence that its statements about the lack of medical efficacy of marijuana are justified. Complaint ¶19. HHS made no mention of its IQA Guideline D.2.c.2, which requires it to ensure the "timely flow of vital information from agencies to medical providers, patients, health agencies, and the public." *See* Complaint ¶19.

On May 19, 2005, ASA filed an appeal of the HHS rejection of its October 4, 2004, Petition, pursuant to HHS Guideline E. Complaint ¶20. ASA's appeal protested that: (a) HHS was evading its information quality responsibilities and delaying a response in contravention of its Guidelines, especially by referring the issues raised by the ASA petition to an agency outside HHS; (b) the issues raised by ASA's request for correction under the Information Quality Act are different and more limited than those raised in the DEA rescheduling proceeding, so that merging the proceedings would not permit HHS to consider the information quality issues "on a timely basis," as required by the HHS Guidelines, and (c) HHS had ignored its Guidelines stating that information quality complaints must be acted upon in a timely fashion where there is a

reasonable likelihood that persons were suffering actual harm from the inaccurate information being disseminated by the agency. Complaint ¶21. ASA alleged that "seriously ill persons represented by ASA are suffering from being misled about the medical benefits of marijuana [by HHS]." Complaint ¶21.

Again, commencing on July 28, 2005, HHS sent ASA a series of interim responses to its appeal over a period of more than eleven months, stating that the agency required additional time to coordinate agency review to prepare a response and that its "goal is to have a response to your appeal within 60 days of the date of this letter." Complaint ¶22. After five such letters, on July 12, 2006, HHS sent ASA a final response effectively denying the appeal without addressing the scientific evidence. *See* Complaint ¶22. HHS merely noted that it anticipated providing a response to the marijuana rescheduling petition pending before it since October 9, 2002, by September of 2006. Complaint ¶22. HHS still has not provided such response. ASA, then, filed this action.

To illustrate the impact of HHS's refusal to correct its dissemination of false information about the medical uses of marijuana, ASA identified three individuals in its Complaint, in addition to Sherer, whose lives have been transformed by learning the truth about the medical efficacy of marijuana. Complaint ¶¶8(a)-(d). Victoria Lansford ("Lansford"), for instance, suffers from fibromyalgia, which causes her to suffer severe chronic pain and muscle spasms. Complaint ¶8(b). Until 2002, Lansford used a regimen of pain medications, including a morphine patch and Oxycontin, because she did not believe marijuana had medical use, due to HHS's statements. Complaint ¶8(b). In 2002, however, on the recommendation of her sister, Lansford started using medical marijuana to treat her chronic pain and muscle spasms, which significantly improved her health. Complaint ¶8(b). Because of her transition to marijuana,

Lansford has been able to discontinue her use of the highly addictive Oxycontin. Complaint ¶8(b).

A similar story is told by Shayne Kintzel ("Kintzel"). Like Lansford, Kintzel experiences chronic pain and muscle spasms as a result of a serious back injury. Complaint ¶8(d). Until 2002, Kintzel used conventional prescription pain medications, including morphine, to treat his chronic pain, because he was led to believe that marijuana would not be effective for this purpose from his review of federal government websites. Complaint ¶8(d). In approximately July of 2002, however, Kintzel began using marijuana in place of prescription medications. Complaint ¶8(d). According to progress measured by Kintzel's physician, Dr. Michael McMillan, Kintzel is now completely mobile, has discontinued his use of morphine, and has lost more than fifty pounds that he had gained from taking large amounts of morphine and being unable to exercise. Complaint ¶8(d).

Then, there is Jacqueline Patterson ("Patterson"). Patterson has cerebral palsy, which impairs her speech and causes her to suffer muscle spasticity and pain. Complaint ¶8(c). Until June of 2001, Patterson did not believe that marijuana was medicine because of the federal government's statements that it was not, but her husband eventually convinced her to try it. Complaint ¶8(c). Patterson began using marijuana with great success, and she is now able to speak more clearly and rarely suffers the serious muscle spasms she used to experience in her right arm. Complaint ¶8(c).

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ARGUMENT

I. ASA HAS STANDING TO PURSUE ITS CLAIM UNDER THE APA AND IQA

A. ASA Has Suffered Article III Injury

To avoid adjudication of ASA's claim under the APA and IQA, HHS contends that ASA lacks standing to bring suit either on its own behalf or on behalf of its individual members. *See* Memorandum of Points and Authorities in Support of Motion to Dismiss Plaintiff's Complaint, filed May 25, 2007 ("Motion to Dismiss") at 11-18. In making these contentions, HHS unduly restricts ASA's stated purposes by selectively quoting from the organization's website, while ignoring the more complete description of ASA's objectives as they appear there and in the Complaint.[4] The allegations of the Complaint, not HHS's misleadingly narrow construction of

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[4] The section of ASA's website entitled, "Our Mission," describes ASA's purposes as follows:

> Americans for Safe Access (ASA) is the largest national member-based organization of patients, medical professionals, scientists and concerned citizens promoting safe and legal access to cannabis for therapeutic uses and research.
>
> ASA works in partnership with state, local and national legislators to overcome barriers and create policies that improve access to cannabis for patients and researchers. We have more than 30,000 active members with chapters and affiliates in more than 40 states.
>
> *ASA provides* legal training for and *medical information to patients, attorneys, health and medical professionals and policymakers throughout the United States.* We also organize media support for court cases, rapid response to law enforcement raids, and capacity-building for advocates. Our successful lobbying, media and legal campaigns have resulted in important court precedents, new sentencing standards, and more compassionate community guidelines.
>
> The mission of Americans for Safe Access is to ensure safe and legal access to cannabis (marijuana) for therapeutic uses and research.

See http://www.safeaccessnow.org/article.php?list=type&type=129 (emphasis added). As the Ninth Circuit recognized in *Fair Housing of Marin v. Combs*, 285 F.3d 899 (9th Cir. 2002), it is not uncommon for advocacy organizations to engage in multiple activities to promote a broad purpose. *See id.* at 902. As the Complaint reveals, educating the public about the benefits of

ASA's purposes, are controlling. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) ("At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we "presum[e] that general allegations embrace those specific facts that are necessary to support the claim.") (quotation omitted).

To establish organizational standing to sue on its own behalf under Article III, an organization needs to show that it has suffered an actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision. *See Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.,* 454 U.S. 464, 472 (1982). An organization meets the requisites for Article III injury if it alleges that purportedly illegal action increases the resources the group must devote to its substantive programs, excluding the costs of its suit challenging the defendant's action. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982); *Fair Housing of Marin v. Combs*, 285 F.3d 899, 905 (9th Cir. 2002).

Conspicuously absent from HHS's Motion to Dismiss is any discussion of the Ninth Circuit's decision in *Fair Housing of Marin v. Combs*, 285 F.3d 899 (9th Cir. 2002). In that case, the Court held that a non-profit advocacy organization had first-party standing to sue as an organization based on its claim that the defendant engaged in racial discrimination in housing rentals, which caused the advocacy organization to suffer injuries in the form of diversion of its resources and frustration of its mission in providing accurate information on housing opportunities. *Id.* at 904-05. The Court described the organization's activities as follows:

> Among its many activities to further its mission of promoting equal housing opportunities, Fair Housing [of Marin] investigates allegations of discrimination,

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marijuana increases access for therapeutic uses because it provides seriously ill persons with the information they need to choose whether to use marijuana medicinally. *See* Complaint ¶7.

> conducts tests of housing facilities to determine whether equal opportunity in housing is provided, takes such steps as it deems necessary to assure equal opportunity in housing and to counteract and eliminate unlawful discriminatory housing practices, and *provides outreach and education to the community regarding fair housing.*

Id. at 902 (emphasis added). Relying on the Supreme Court's decision in *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), the Ninth Circuit held that Fair Housing of Marin had direct standing to sue to vindicate its own interests because:

> [O]ne of [Fair Housing's] activities in combating illegal housing discrimination is to provide "outreach and education to the community regarding fair housing." Complaint, ¶ 5. [Fair Housing] alleges that, as a result of defendant's discriminatory practices, it has "suffered injury to its ability to carry out its purposes ... [and] economic losses in staff pay, in funds expended in support of volunteer services, and in the inability to undertake other efforts to end unlawful housing practices." *Id.* Thus, fairly construed, [Fair Housing] complains that defendant's discrimination against African Americans has caused it to suffer injury to its ability to provide outreach and education (i.e., counseling).
>
> The record supports the district court's finding that Fair Housing's resources were diverted to investigating and other efforts to counteract Combs' discrimination above and beyond litigation. Fair Housing itemized its claim of $16,317 for diversion of resources, and the district court granted $14,217. With respect to frustration of mission, the district court found that Fair Housing suffered $10,160 in frustration of mission damages, *namely for design, printing, and dissemination of literature aimed at redressing the impact Combs' discrimination had on the Marin housing market*.
>
> We hold that Fair Housing of Marin has direct standing to sue because it showed a drain on its resources from both a diversion of its resources and frustration of its mission.

Fair Housing, 285 F.3d at 905 (quoting *Fair Housing of Marin v. Combs*, 2000 WL 365029 (N.D. Cal. March 29, 2000) (emphasis added)). The injury suffered by ASA here is nearly identical.

Like the non-profit advocacy organization in *Fair Housing of Marin*, ASA has alleged that it:

> [H]as its primary purpose working to expand and protect the rights of patients to use marijuana for medical purposes, including providing outreach and education to the public regarding the use of marijuana for medical purposes. ASA's members and constituents include seriously ill persons who would have benefited from the use of marijuana for medical purposes, but who were deterred from using marijuana to ease their suffering, in part, by HHS' statement that marijuana "has no currently accepted medical use in treatment in the United States." ASA has devoted significant resources to combat this false statement, including the expenditure of more than one hundred thousand dollars and hundreds of hours of staff time producing and disseminating educational materials explaining that scientific studies demonstrate that marijuana is effective in treating symptoms associated with cancer, HIV/AIDS, multiple sclerosis, arthritis, gastrointestinal disorders, and chronic pain. HHS' failure to correct its false statement that marijuana does not have any currently accepted medical use in treatment in the United States adversely affects the membership and constituency of ASA and causes ASA to suffer injury to its ability to carry out its mission, as well as causing ASA to suffer economic loss in staff pay, funds expended to produce educational materials, and in the inability to undertake other efforts to improve the access of seriously ill persons to medical marijuana.

Complaint ¶7.

As in *Fair Housing of Marin* and *Havens*, these allegations, especially when considered in light of ASA's itemized receipts of $104,345.58 for designing and printing literature to combat HHS's false statements, *see* Declaration of Allayne Steph Sherer in Support of Plaintiff's Motion for Summary Judgment or Summary Adjudication of Issues, filed May 24, 2007, ¶¶9 & 11 & Exhibit 2,[5] are sufficient to establish organizational standing for ASA. ASA has suffered injuries to its organizational interests both in terms of a drain of its resources and frustration of its mission through its efforts to combat HHS's false statements. *Cf. Fair Housing*, 285 F.3d at 905. Correction of these false statements would foster ASA's mission of educating the public about the medical benefits of marijuana and reduce its need to expend funds to combat HHS's statements to the contrary. *Cf. Havens,* 455 U.S. at 379 (finding that advocacy organization

[5] This Court may consider evidence outside the complaint by converting the motion to dismiss to a motion for summary judgment. *See Bank Melli Iran v. Pahlavi*, 58 F.3d 1406, 1408 (9th Cir. 1995) (quoting Fed.R.Civ.P. 12(b)).

suffered injury sufficient to confer standing, since it devoted significant resources to identifying and counteracting defendant's discriminatory steering practices, and this diversion of resources frustrated the organization's counseling and referral services: "Such concrete and demonstrable injury to the organization's activities--with the consequent drain on the organization's resources--constitutes far more than simply a setback to the organization's abstract social interests") (citing *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972)); *Ragin v. Harry Macklowe Real Estate Co.*, 6 F.3d 898, 904 (2d Cir. 1993) (holding that fair housing organization had standing to sue real estate company for placing newspaper advertisements depicting only white people because the fair housing organization was forced to devote significant resources to identify and counteract defendants' advertising practices and did so to the detriment of their efforts to obtain equal access to housing through counseling and other services); *Central Alabama Fair Housing Center, Inc. v. Lowder Realty Co., Inc.*, 236 F.3d 629, 643 (11th Cir. 2000) (holding that fair housing organization has standing to recover in its own right for the diversion of its resources to combat defendant's discrimination); *El Rescate Legal Services, Inc. v. Executive Office of Immigration Review*, 959 F.2d 742, 748 (9th Cir. 1991) ("The allegation that the EOIR's policy frustrates [the advocacy organization's goals and requires the organizations to expend resources in representing clients they otherwise would spend in other ways is enough to establish standing") (citing *Havens*); *see also La. ACORN Fair Hous. v. LeBlanc*, 211 F.3d 298, 305 (5th Cir. 2000) ("an organization could have standing if it had proven a drain on its resources resulting from counteracting the effects of the defendant's actions"); *Alexander v. Riga*, 208 F.3d 419, 427 n.4 (3d Cir. 2000) (holding that plaintiff, a fair housing organization, had standing because it "diverted resources to investigate and to counter [the defendants' discriminatory] conduct.").

HHS contends that *Havens* is distinguishable because it does not apply to challenges to general governmental statements of policy. *See* Motion to Dismiss at 16 n.8. ASA, however, is not challenging general statements of policy, such as the current administration's view that marijuana should remain illegal for all purposes; rather, ASA is challenging scientific statements that are demonstrably false. The gravamen of the standing inquiry for advocacy organizations is whether the organization alleges an injury beyond litigation expenses. *See Fair Housing of Marin*, 285 F.3d at 905. ASA has alleged such injury here. *Cf. Fair Housing of* Marin, 285 F.3d at 904 ("Expenditures . . . to counteract on an ongoing basis public impressions created by defendants' use of print media, are sufficiently tangible to satisfy Article III's injury-in-fact requirement").[6]

B. The Injuries Suffered by ASA Would Be Redressed by a Favorable Decision in This Court

Based on the foregoing, it becomes clear that a ruling in ASA's favor would likely redress the injury to the organization and the persons that it seeks to protect. HHS contends that any benefit to ASA would be only speculative from a ruling in its favor, since the ruling would not require the DEA to reschedule marijuana, *see* Motion to Dismiss at 18-21. However, HHS fails to appreciate what ASA is seeking to achieve through this case. ASA has made clear in its Complaint that its institutional mission of increasing access to medical marijuana by seriously ill persons who need it is impeded by its need to expend resources to combat HHS's false statements. *See* Complaint ¶7. A decision in ASA's favor would have an immediate and long-

[6] ASA also has standing to bring suit on behalf of its constituents who have experienced unnecessary suffering from HHS's false statements. *See* Complaint ¶¶3, 7, 8 & 21; *see generally Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333, 343 (1977) (discussing representational standing); *see also Associated General Contractors of America v. Metropolitan Water District of Southern California*, 159 F.3d 1178, 1181 (9th Cir. 1998) ("Individualized proof from the members is not needed where, as here, declaratory and injunctive relief is sought rather than monetary damages") (citation omitted).

term impact on the organization by allowing it to reduce the resources it expends on printing and distributing educational materials to combat HHS's dissemination of false information about medical uses of marijuana, regardless whether marijuana is rescheduled. Standing alone, this benefit to ASA is sufficient to confer standing. *Cf.* cases cited *supra* at 12-13.

Furthermore, a decision in ASA's favor would help remove informational barriers to the medical use of marijuana by sick persons who would benefit from it, thereby advancing ASA's mission. Whereas HHS contends that it will "remain difficult for plaintiff to effectively convince its members to use marijuana . . . since distribution of the drug outside already-permissible, albeit strictly controlled, circumstances would remain a crime," *see* Motion to Dismiss at 19, the reality is that many ill persons who receive truthful information about marijuana's medical efficacy would elect to try it. Four examples are described in ASA's Complaint, including one person who lives in a state that does not authorize medical marijuana use. *See* Complaint ¶8. The prospect of a federal prosecution for personal medical marijuana use is extremely attenuated, in most districts, "United States Attorneys bring Federal charges only if a marijuana case involves the cultivation of at least 500 plants grown indoors, 1,000 plants grown outdoors, or the possession of more than 1,000 pounds." *Conant v. Walters*, 309 F.3d 629, 646 n.10 (9th Cir. 2002) (Kozinski, J., concurring) (quoting Tim Golden, *Doctors Are Focus of Plan To Fight New Drug Laws: Officials Deal with Narcotics' Medical Use,* N.Y. Times, Dec. 23, 1996, at A10). Knowing this, seriously ill persons for whom marijuana would provide the only effective relief for their suffering would experiment with marijuana, if only they knew it could help them. A decision in ASA's favor will help hundreds, if not thousands, of such persons.

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C. ASA's Petition for Correction Is Within the Zone of Interests to be Protected by the IQA and Its Guidelines

For similar reasons, an organization, like ASA, which files a petition for correction of information under the IQA, has prudential standing to seek judicial review under the APA. The "Right of Review" section of the APA, 5 U.S.C. § 702, provides that "[a] person suffering legal wrong, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." Because "[h]istory associates the word 'aggrieved' with a congressional intent to cast the standing net broadly -- beyond the common-law interests and substantive statutory rights upon which 'prudential' standing traditionally rested," *Federal Election Comm'n v. Akins*, 524 U.S. 11, 19-20 (1998), the "zone of interests" test under the APA "is not intended to impose an onerous burden on the plaintiff and 'is not meant to be especially demanding.'" *Clarke v. Securities Indus. Assoc.*, 479 U.S. 388, 399 (1987) (quoting *National Wildlife Fed'n v. Burford,* 871 F.2d 849, 852 (9th Cir.1989)); *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 940 (9th Cir. 2005) (citation omitted); *Cetacean Community v. Bush*, 386 F.3d 1169, 1177 (9th Cir. 2004); *Central Ariz. Water Conservation Dist. v. EPA,* 990 F.2d 1531, 1538 (9th Cir. 1993). To establish prudential standing under the APA, "plaintiffs need only show that their interests fall within the 'general policy' of the underlying statute, such that interpretations of the statute's provisions or scope could directly affect them." *Graham v. Federal Emerg. Mgmt. Agency*, 149 F.3d 997, 1004 (9th Cir. 1998) (citation omitted); *see also Nat'l Credit Union Admin. v. First Nat'l. Bank & Trust Co*., 522 U.S. 479, 488 (1998) ("For a plaintiff to have prudential standing ... the interest sought to be protected by the complainant must be arguably within the zone of interests to be protected or regulated by the statute ... in question") (internal quotations omitted).

An organization, such as ASA, which files a petition for correction clearly falls within the "general policy" of the IQA of "ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by" federal agencies. *See* Section 515, § (b)(2)(A). ASA is clearly (at the very least "arguably") "aggrieved" within the meaning of the IQA and the agency guidelines implementing it because the statutory zone of interests they seek to protect is the right to "obtain" correction of inaccurate information that they have an interest in correcting. *Cf.* Section 515, § (b)(2)(B) (requiring federal agencies to "establish administrative mechanisms allowing affected persons to seek *and obtain* correction of information maintained and disseminated by the agency that does not comply with the guidelines") (emphasis added).

HHS contends that ASA does not fall within the "zone of interests" protected by the IQA because the Act only expressly places burdens on federal agencies. *See* Motion to Dismiss at 17-18. However, the obvious purpose of the IQA is to enhance the quality of information disseminated by these agencies for the benefit of the public. One of the stated purposes of the Paperwork Reduction Act ("PRA"), which contains the IQA, is to "ensure the greatest possible *public benefit* from and maximize the utility of information . . . disseminated by or for the Federal Government. . . ." 44 U.S.C. § 3501(2) (emphasis added). To achieve this, Congress mandated that administrative agencies create necessary procedures, and HHS has implemented Guidelines that allow affected persons to file a petition for correction of information and, if necessary, an appeal. *See* HHS Guideline E. HHS cannot simply shrug aside its responsibilities under the IQA by claiming they are discretionary. Congress enacted the IQA to improve federal agency disseminations of information for the benefit of the public, not just for the benefit of federal agencies.

II. DEFENDANTS' DENIAL OF ASA'S PETITION FOR CORRECTION OF INFORMATION IS SUBJECT TO JUDICIAL REVIEW

A. HHS's Denial of ASA's Petition for Correction of Information Is a Final Agency Action

Where, as here, the substantive statutes under which plaintiff seeks relief do not provide for a private right of action, the Administrative Procedure Act, 5 U.S.C. §§ 702-706 ("APA") provides for judicial review of a "final agency action for which there is no other adequate remedy in a court. . . ." 5 U.S.C. § 704. The APA's promise of judicial review is generous, liberally construed, and readily available in the absence of powerful authority to the contrary. *See Japan Whaling Ass'n v. American Cetacean Soc.*, 478 U.S. 221, 230 n.4 (1986); *Block v. Community Nutrition Institute*, 467 U.S. 340, 345 (1984); *Inova Alexandria Hospital v. Shalala*, 244 F.3d 342, 346 (4th Cir. 2001). The APA "creates a strong presumption of reviewability that can be rebutted only by a clear showing that judicial review would be inappropriate." *Nat'l Res. Defense Council, Inc. v. S.E.C.*, 606 F.2d 1031, 1043 (D.C. Cir. 1979); *see also Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986) (noting "strong presumption that Congress intends judicial review of administrative action").

The APA expressly provides that the "denial" of, or "failure to act" upon an administrative "application or petition" is an "agency action" covered by the Act. *See* 5 U.S.C. §§ 551(11); 551(13) & 701(2); *see also Whitman v. American Trucking Associations*, 531 U.S. 457, 478 (2001) (noting that the term "action" under the APA "is meant to cover comprehensively every manner in which an agency may exercise its power"); *FTC v. Standard Oil Co. of California*, 449 U.S. 232, 238 n.7 (1980) (noting that term "agency action" is intended "to assure the complete coverage of every form of agency power, proceeding, action, or inaction"). Consequently, courts have routinely entertained suits under the APA for denials of

administrative petitions. *See*, *e.g., Darby v. Cisneros,* 509 U.S. 137 (1993) (APA review of HUD debarment); *Brownell v. We Shung*, 352 U.S. 180 (1956) (APA review of denial of immigration petition); *Spencer Enterprises, Inc., v. United States*, 345 F.3d 683, 688 (9th Cir. 2003) (APA judicial review of denial of petition for immigrant investor visa); *Mendez-Guitierrez v. Ashcroft*, 340 F.3d 865 (9th Cir. 2003) (APA judicial review of denial of immigrant asylum "application"/"request"/"petition"); *Chang v. United States*, 327 F.3d 911 (9th Cir. 2003) (APA review of agency denial of immigration application). In *Barber v. Widnall*, 78 F.3d 1419 (9th Cir. 1996), for instance, the Ninth Circuit reviewed an Air Force denial of a "request for correction" of a military record, which the Court referred to as a "petition." *See id.* at 1421-22; 10 U.S.C. § 1552(b). Notably, neither the Ninth Circuit nor the government had any question about the applicability of the APA in that case. Likewise, in *Miller v. Lehman*, 801 F.2d 492 (D.C. Cir. 1986), the court found reviewable a naval officer's request to correct military records. The court noted that: "Both parties to this appeal agree that the Secretary's denial of an application for correction of naval records is a final agency action subject to review under the standards of the Administrative Procedure Act." *Id.* at 496.

HHS's denial of ASA's IQA Petition is also "final" under the test articulated by the Supreme Court in *Bennett v. Spear*, 520 U.S. 154 (1997), which requires that the action: (1) "mark the consummation of the agency's decisionmaking process" and (2) "be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 178 (internal quotation marks omitted); *accord Oregon Natural Desert Ass'n v. United States Forest Service*, 465 F.3d 977, 982 (9th Cir. 2006). "[T]he core question [to determine finality] is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." *Indus. Customers of NW Utils. v. Bonneville*

Power Admin., 408 F.3d 638, 646 (9th Cir. 2005) (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992)).

After more than twenty months of considering ASA's Petition, including eight different requests for additional time to respond, HHS sent a "response" to ASA's appeal of the denial of its Petition, leaving ASA nowhere else to seek relief from the agency. Ninth Circuit authorities make clear that agency orders are final orders "if they . . . deny a right . . . as a consummation of the administration process." *US West Communications, Inc. v. Hamilton*, 224 F.3d 1049, 1054-55 (9th Cir. 2000); *Ukiah Med. Ctr. v. Fed. Trade Comm'n*, 911 F.2d 261, 264 (9th Cir. 1990); *Sierra Club v. U.S. Nuclear Regulatory Comm'n*, 862 F.2d 222, 225 (9th Cir. 1989). The legal consequence of HHS's final decision denying ASA's Petition and appeal is that ASA has been deprived of its right under the IQA to seek and obtain the timely correction of incorrect information. *See supra* at Part I.C. This, in turn, harms seriously ill persons who are deterred from using marijuana where it might benefit them and will require ASA to continue expending its resources to spread the truth. *Cf. Oregon Natural Desert Ass'n*, 465 F.3d at 982 (noting that consideration in determining whether agency action is "final" is whether it "'has a direct and immediate effect on the day-to-day operations' of the subject party") (quoting *Indus. Customers of NW Utils*, 408 F.3d at 646). ASA has reached the end of the line in the IQA administrative process to the detriment of the organization and its constituents. HHS's rejection of ASA's IQA Petition constitutes a final action that is judicially reviewable.[7]

[7] Although HHS has indicated that the issue of medical efficacy is still being examined in another proceeding under the CSA, the current agency position is definite, and any future change in that position is indefinite in both timing and outcome. Several courts have held that the possibility of future agency action is not sufficient to foreclose review of a definitive action; otherwise, "review could be deferred indefinitely." *Americans Petroleum Inst. v. Envtl. Prot. Agency*, 906 F.2d 729, 739-40 (D.C. Cir. 1990)); *cf. Sierra Club v. U.S. Nuclear Regulatory Comm'n*, 862 F2d 222, 225 (9th Cir. 1988) (holding that the fact that the NRC expressly

B. This Court Has the Power to Review HHS's Denial of ASA's IQA Petition

Nor does this Court lack power to review HHS's denial of ASA's IQA Petition under the APA because Congress did not expressly provide for judicial review when enacting the IQA. Again, there is a strong presumption that final agency actions are judicially reviewable, unless Congress precludes such review. *See* 5 U.S.C. § 701(a) (stating that APA applies "except to the extent that - (1) statutes preclude judicial review"). As the Court explained in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), judicial analysis of whether a statute precludes judicial review begins "with the strong presumption that Congress intends judicial review of administrative action[, which] will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." *Id.* at 670. "The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review." *Id.* at 671 (quoting with approval from the report of the House Committee on the Judiciary). The presumption favoring judicial review can be overcome "only upon a showing of

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maintained its authority to review an Appeals Board decision as a full Commission did not destroy the finality of the Appeals Board decision); *see also Appalachian Power Co. v. U.S. Envtl. Prot. Agency*, 208 F.3d 1015, 1022 (D.C. Cir. 2000) ("The fact that a law may be altered in the future has nothing to do with whether it is subject to judicial review at the moment"). In a provision ignored by HHS, which ASA pointed out in its appeal, its Guidelines require it to act on ASA's Petition before the final resolution of the marijuana rescheduling petition where such 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 complaint prior to the final agency action or information product." HHS Guidelines, Section E; *see also* HHS Guideline E (permitting agency to defer requests for correction of information to"rule-making and other formal agency actions [that] already provide well established procedural safeguards *that allow affected persons to raise information quality issues on a timely basis*") (emphasis added). Here, a prompt response to ASA's Petition would expedite, rather than delay, the DEA's consideration of the pending marijuana rescheduling petition and, in the meantime, seriously ill persons represented by ASA are suffering unnecessarily from being misled about the medical benefits of marijuana. HHS has no credible explanation why it cannot at least respond to ASA's request on the merits, instead of hiding behind the long pending (and irrelevant) DEA rescheduling proceeding.

'clear and convincing evidence' of a contrary legislative intent," and an agency arguing against the presumption has "the heavy burden of overcoming the strong presumption . . . ." *Id.* at 671-72. While the standard of "clear and convincing evidence" is not applied in the strict evidentiary sense, "nevertheless, the standard serves as 'a useful reminder to courts that, where substantial doubt about the congressional intent exists, the general presumption favoring judicial review of administrative action is controlling.'" *Id.* at 672 n.3 (quoting *Block v. Community Nutrition Institute*, 467 U.S. 340, 350-351 (1984)). Thus, HHS has it backwards when it contends that judicial review of agency action is presumed not to exist where Congress has not expressly provided for it by statute. *See* Motion to Dismiss 25-28; *Bowen,* 476 U.S. at 671.

Here, not only does HHS fall far short of meeting its heavy burden of demonstrating Congress' intent to preclude judicial review under the APA, but the text, structure, and legislative history of the IQA all suggest that Congress intended such review. Congress expressly designed the PRA, which contains the IQA, to "(2) ensure the greatest possible public benefit from and maximize the utility of information . . . disseminated by or for the Federal Government" and to "(4) improve the quality and use of Federal information to strengthen decisionmaking, *accountability*, and openness in Government and society. . . ." 44 U.S.C. § 3501 (emphasis added). To this end, Congress mandated that federal agencies "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. . . ." Section 515, § (b)(2)(B) (emphasis added). That data correction efforts are initiated through a petition with the appropriate agency in no way suggests that Congress intended to preclude judicial review of the agency's response. Numerous cases brought under

the APA involve judicial review of final agency action in the form of a denial of an administrative application or petition. *See* cases cited *supra* at 18-19.

Furthermore, contrary to HHS's assertion that "the IQA's legislative history is completely silent with respect to the particular question of judicial relief," Motion to Dismiss at 27, 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 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." S. Rep. No. 927, 101st Cong., 2d Sess. at 37 (Oct. 23, 1990). By sharp contrast, where Congress does not intend for judicial review to be available, as with information *collection* by federal agencies, it has expressly precluded judicial review in the PRA. *See* 44 U.S.C. § 3504, Historical and Statutory Notes (citing former version of section 3504(h)(9) as it existed on Sept. 30, 1995) ("There shall be no judicial review of any kind of the Director's decision to approve and not to act upon a collection of information requirement contained in an agency rule."). No such provision exists, however, with respect to information *dissemination*. Under the doctrine of statutory construction, *expressio unius est exclusio alterius*, this omission evidences Congress' intent that judicial review under the APA not be foreclosed. *Cf. Sanford v. Memberworks, Inc.*, 483 F.3d 956, 965 (9th Cir. 2000) ("Where Congress includes particular language in one section of a statute but omits it in another . . . , it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (quoting *Keane Corp. v. United States*¸ 508 U.S. 200, 208 (1993)).

To distract this Court from this straightforward application of the APA, HHS cites *Salt Institute v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006) and related cases for the proposition that the IQA does not create a private right of action. *See* Motion to Dismiss at 27. This is a complete red herring. The lack of a "private right of action" in no way affects the availability of judicial review under the APA. *See Lujan v. Natl. Wildlife Federation*, 497 U.S. 871, 882 (1990); *Japan Whaling Assn. v. American Cetacean Socy*., 478 U.S. 221, 230 n. 4 (1986); *Chrysler Corp. v. Brown*, 441 U.S. 281, 316-17 (1979); *Ashley Creek Phosphate Co.*, 420 F.3d 934, 939 (9th Cir. 2005); *Cetacean Community v. Bush*, 386 F.3d 1169, 1176-77 (9th Cir. 2004); *San Carlos Apache Tribe v. United States*, 417 F.3d 1091, 1095-96 (9th Cir. 2005); *see also Gros Ventre Tribe v. United States*, 469 F.3d 801, 809 (9th Cir. 2006) ("[B]ecause the statutes that the Tribes cite authorize no private right of action, the Tribes must state their claims within the confines of the APA."); *San Carlos Apache Tribe v. United States*, 417 F.3d 1091, 1096 (9th Cir. 2005) ("An aggrieved party can sue under the APA to force compliance with § 106 [of the National Historic Preservation Act] without having a 'private right of action' under the statute."). The *Salt Institute* case was decided the way it was because the corporate plaintiff in that case was seeking to *obtain* information from the defendant agency under the IQA, not *correct* erroneous information disseminated by that agency. *See* 440 F.3d at 159. The court found that the Salt Institute did not have a "legal right to the information in question," and thus it had not suffered an injury under the IQA sufficient to give it standing to sue because the IQA is not an information access statute, like the Freedom of Information Act, 5 U.S.C. § 552. *See* 440 F.3d at 159. As demonstrated in Part I, *supra*, ASA has demonstrated that it meets the standards for Article III standing. Judicial review is available under the APA, notwithstanding the lack of an explicit private right of action in the IQA.

C. ASA Does Not Otherwise Have an Adequate Remedy in Court

HHS also contends that it is exempt from judicial review under the APA because ASA could have challenged the DEA's denial of the 1995 marijuana rescheduling petition in the Court of Appeals under the Controlled Substances Act ("CSA"). *See* Motion to Dismiss at 24-25 (citing 21 U.S.C. § 877). Again, HHS misconstrues the "final agency action" challenged by this suit by ASA. As ASA has repeatedly told HHS throughout the administrative process, this suit is not seeking to reschedule marijuana, but, instead, asks for a correction of HHS's false statements that marijuana lacks medical use. *See* Complaint ¶18. There is no non-APA remedy in court for the latter agency action, as opposed to the former.

Moreover, the 1995 marijuana rescheduling petition did not even present the issue of the medical efficacy of marijuana; instead, it was based on a claim that marijuana does not have a "high potential for abuse." *See* 21 U.S.C. § 812(B)(1)(a) (defining schedule I substances as having highest abuse potential and lack of currently accepted medical use); 66 Fed. Reg. 20037, 20038 (April 18, 2001) ("You do not assert in your petition that marijuana has a currently accepted medical use in treatment in the United States or that marijuana has an accepted safety for use under medical supervision."). It was on that point that DEA disagreed with the petitioners there. *See* 66 Fed. Reg. 20037, 20038 (April 18, 2001) ("Basis for Denial of Your Petition: The Evidence Demonstrates That Marijuana Does Have A High Potential For Abuse" "For this reason alone, your petition must be denied." "DEA's denial of your petition is based exclusively on the scientific and medical findings of HHS, with which DEA concurs, that lead to the conclusion that marijuana has a high potential for abuse."). The review provision of the CSA, 21 U.S.C. § 877, vests jurisdiction exclusively in the Court of Appeals only for "final decisions" of the DEA. HHS's statements that marijuana lacks medical use are not final

decisions of the DEA, and so section 877, and judicial review under it, have nothing to do with this case. *Cf. Novelty, Inc. v. Tandy*, No. 1:04-cv-1502, 2006 WL 2375485, at *1 (S.D. Ind. Aug. 15, 2006) ("Novelty argues that the letters amount in substance to unilateral rulemaking, without notice and an opportunity for affected parties to comment. . . . Plaintiff has not challenged a final 'determination,' 'finding,' or 'conclusion' by the DEA after formal procedures that develop a record suitable for judicial review, so 21 U.S.C. § 877 does not apply").

Indeed, ASA did not exist in April of 2001 when HHS's statements about marijuana were published in the *Federal Register*, due in large part to HHS's false statements. *See* Complaint ¶¶7 & 8(a). To this day, HHS continues to disseminate its disputed statements regarding marijuana well after the publications of these statements in the *Federal Register,* and these current disseminations are at issue in ASA's IQA Petition. *See infra* at Part III. The IQA seeks to ensure a timely mechanism for the correction of faulty information disseminated by federal agencies, *see* HHS Guideline E, and it is the denial of a petition that seeks such correction, not marijuana rescheduling, that is at issue here. The possibility that some other proceeding may, at some future date, provide a remote possibility of considering the factual claims at issue in this case, does not preclude plaintiff from maintaining this APA action to vindicate its rights under the IQA, rights that continue to be injured every day that HHS does not make the necessary corrections provided for under the IQA. *Cf. Commodity Trend Service, Inc. v. Commodity Futures Trading Comm'n*, 233 F.3d 981, 985 (7th Cir. 2000) ("An administrative determination is ripe for review if (1) it is fit for judicial resolution, and (2) the parties would endure hardship from the withholding of court consideration.") (citation omitted).

D. Judicial Review Is Not Precluded Because Reponses to IQA Petitions Are Not Committed to Agency Discretion By Law

The strong presumption in favor of judicial review and the requirement that Congressional intent to prohibit judicial review be shown by clear and convincing evidence applies to the "committed by agency discretion by law" provision of § 701(a)(2), as it does to §702(a)(1). This exemption from judicial review applies only in those "rare instances" where a statute is drawn "in such broad terms that in a given case there is no law to apply." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). Under the APA, agency action can be reviewed for "abuse of discretion" so long as there are "meaningful" or "manageable" standards available to judge how and when an agency should exercise its discretion and the action has not been committed to agency discretion "absolutely." *Id.*; *see Newman v. Appel*, 223 F.3d 937, 942-43 (9th Cir. 2000). Such standards can be applied by the court even though the statute itself appears to give the agency extremely broad discretion if the standards can be found in agency rules, policy, or practice. *See INS v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1997); *Ana Intl., Inc. v. Way*, 393 F.3d 886, 890 (9th Cir. 2004); *Mendez-Gutierrez v. Ashcroft*, 340 F.3d 865, 868-69 (9th Cir. 2003); *Socop-Gonzales v. INS*, 208 F.3d 838, 843-44 (9th Cir. 2000).

The IQA (and the underlying statute, the Paperwork Reduction Act of 1995) and the IQA guidelines provide readily manageable standards by which to judge whether final agency action denying a petition for correction is arbitrary and capricious or an abuse of discretion. The applicable standard in the statute is "objectivity," and the statutory requirement for administrative mechanism allowing affected parties to seek and obtain "correction" of information necessarily incorporates a standard that information must be "correct." The HHS (and OMB) Guidelines further define "objectivity" as requiring that information be presented in

an "accurate, clear, complete, and unbiased manner," and that the information itself be "accurate, reliable, and unbiased." HHS Guideline D,2,c. These standards are certainly manageable.

Underscoring this point is *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971), where the Court held that the Secretary of Transportation's decision to authorize the use of federal funds to finance construction of an expressway through a public park did not fall within the exception to reviewability for actions "committed to agency discretion." The statutes at issue in that case provided that the Secretary shall not approve a project that requires the use of public parkland, unless there is no "feasible and prudent" alternative. *Id.* at 411 (citing 23 U.S.C. § 138). After noting that the "committed to agency discretion by law" exception is a "very narrow exception," the Court concluded that the terms "feasible" and "prudent" provided meaningful standards for courts to apply to review the Secretary's decision. *Id.* at 410-13. As demonstrated above, the IQA and its implementing guidelines are even clearer.

Furthermore, the information dissemination provisions of the PRA -- the statute which the IQA supplements and implements and incorporates by reference -- also make it clear that compliance with the "objectivity" standard is required and not a matter of unfettered agency discretion. The PRA states that "[t]he head of each agency shall be responsible for . . . complying with the requirements of this subchapter and related policies established by the Director [of OMB]." 44 U.S.C. § 3506(a)(1)(B). In recognition of this, the HHS Guidelines state that "HHS is committed to disseminating information that meets the standards of quality set forth in OMB and the guidelines discussed in this document" and that "the HHS guidelines are intended to assure that all the information that is disseminated meets a basic level of quality and that more important information meets a more rigorous quality standard." HHS Guidelines A & C; *see also* HHS Guideline B ("the OMB Guidelines require agencies to adopt a basic standard

of quality as a performance goal").[8] The OMB Guidelines further clarify that "[i]t is crucial that information Federal agencies disseminate meets these guidelines" and that "it is clear that agencies should not disseminate substantive information that does not meet a basic level of quality." 67 Fed. Reg. 8452, 8453 (Feb. 22, 2003); *see also id.* (referring to guidelines as "requirements"); 67 Fed. Reg. 8452, 8452 (Feb. 22, 2003) ("OMB designed the guidelines so that agencies will meet basic information quality standards [and] . . . it is clear that agencies should not disseminate substantive information that does not meet a basic level of quality." "The more important the information, the higher the quality standards to which it should be held").

In arguing that HHS decisions on whether to correct information that does not meet basic IQA standards of quality (including objectivity) are committed by law to its discretion, the agency selectively focuses on some language that indicates that agencies have discretion in how to fashion a correction and whether the information for which a correction is sought is important enough to merit the effort that would be involved in considering and fashioning a correction. For example, HHS observes that the OMB guidelines require the agencies to "*undertake only the degree of correction they conclude is appropriate*. . . ." *See* Motion to Dismiss at 29 (emphasis in original). This statutory language indicates only that the agency has discretion to judge the exact manner in which to make or word the correction when applying the quality standards; it does not indicate that whether to make a correction at all is completely committed to agency discretion. *Cf. Barber v. Widnall*, 78 F.3d 1419, 1420 (9th Cir. 1996) (holding justiciable under APA the denial of a petition to correct plaintiff's military record where statute at issue required only that "[t]he Secretary of a military department may correct any military record of the

[8] It bears noting that persons submitting a Request for Correction must state the specific reasons for believing the information "does not comply" with the OMB or HHS guidelines. HHS Guideline E.

Secretary's department when the Secretary considers it necessary to correct an error or remove an injustice," according to procedures established by the Secretary) (quoting 10 U.S.C. §§ 1552).

There is one aspect of HHS's conduct in the proceedings on ASA's petition that is clearly not committed to HHS's discretion. Under both the OMB and HHS Guidelines under the IQA, agencies are required to give prompt and substantive responses to IQA petitions to correct, yet HHS did neither. This Court cannot cure the unreasonable delay that has already transpired, but it surely has the authority to order HHS to comply with its non-discretionary duty to answer ASA's petition on the merits, which it has never done. The closest that HHS has come to giving a reason for not correcting its disseminations is that it has no obligation to do so, either because of DEA's 2001 response or because DEA may respond to the rescheduling proceeding that has been pending for almost five years, and ASA can sue DEA or HHS at that time. As we have demonstrated above, those excuses are invalid, and therefore HHS has a duty to provide a substantive response to ASA's petition and explain to ASA and the rest of the world why it contends, in the face of massive evidence to the contrary, that "no sound scientific studies supported medical use of marijuana for treatment in the United States. . . ." *See* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html

III. ASA'S COMPLAINT SUFFICIENTLY STATES THAT HHS CONTINUES TO DISSEMINATE THE DISPUTED STATEMENTS

Without once contesting in the twenty months of administrative proceedings that it continues to disseminate the four false statements at issue, HHS now contends that these statements were disseminated by another federal agency, the DEA. *See* Motion to Dismiss at 31-32. Overlooked by HHS in making this argument is that the FDA's Director of the Office of Drug Evaluation II at the Food and Drug Administration's, Center for Drug Evaluation and Research, Dr. Robert Meyer, testified before Congress on April 1, 2004, about "the merits of

marijuana for medicinal purposes" and concluded his statement of the FDA and HHS position by referencing the portion of the *Federal Register* where the disputed statements appear. *See* http://www.fda.gov/ola/2004/marijuana0401.html ("HHS performed a scientific and medical evaluation of marijuana in 2001 and concluded with a recommendation to DEA that marijuana should remain in Schedule I pursuant to section 201(b) of the CSA. HHS's scientific and medical evaluation and scheduling recommendation can be found at Volume 66, *Federal Register* page 20038 (April 18, 2001)."). This testimony appears on the FDA website under the title and logo of HHS. *See* http://www.fda.gov/ola/2004/marijuana0401.html. Furthermore, on April 20, 2006, the FDA, along with the DEA and the Office of National Drug Control Policy, issued an "Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine," in which it denied that marijuana has medical use and it referred again to HHS's 2001 conclusions. *See* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html ("A past evaluation by several Department of Health and Human Services (HHS) agencies, including the Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and National Institute for Drug Abuse (NIDA), concluded that no sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of marijuana for general medical use."). Like the previous dissemination, this announcement appears on the FDA website under the HHS name and logo. *See* http://www.fda.gov/bbs/topics/NEWS/2006/NEW01362.html. These are clearly "disseminations" of the disputed statements by HHS that are subject to petitions for correction under the IQA. *Cf.* HHS Guideline C ("the HHS guidelines apply to a wide range of government information dissemination activities across HHS and are generic enough to fit all types of media, including print, electronic, and other forms"); HHS Guideline D.2.h ("'Dissemination' means

agency initiated or sponsored distribution of information to the public"); HHS Guideline D.3 ("The administrative mechanism for correction applies to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information").

Under Rule 8 of the Federal Rules of Civil Procedure, a complaint need only provide "fair notice" of what the plaintiff's claim is and the grounds upon which it rests. *Mayle v. Felix*, 545 U.S. 644, 655 (2005) (citing *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Both ASA's Petition and Complaint specifically identified the four disputed statements and alleged that "HHS continues to disseminate these disputed statements to the public through federal government websites. . . ." *See* Petition at 4; Complaint ¶9 ("HHS continues to disseminate this and related statements in its publications and on government websites."). HHS is well aware of the basis for ASA's claim, and it surely knows that it is continuing to disseminate the disputed statements on its own website, which is all that the federal rules of pleading require. *Cf. Sundstrand Corp. v. Standard Kollsman Industries, Inc.*, 488 F.2d 807, 811 (7th Cir. 1973) ("in deciding whether a complaint fairly notifies a defendant of matters sought to be litigated, courts have often looked beyond the pleadings to the pretrial conduct and communications of the parties") (citations omitted); *see also Charfauros v. Board of Elections***,** 249 F.3d 941, 956-57 (9th Cir. 2001) ("we should 'construe pleadings to do substantial justice' and give the plaintiff 'the benefit of the doubt if his pleading makes out any claim for relief'") (quotation omitted). HHS cannot now contend that it does not disseminate the disputed statements, since it does and it failed to claim this in its many responses to ASA's Petition, including the final denial. *Cf. SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."); *SEC v. Chenery Corp.*,

332 U.S. 194, 196 (1947) ("[A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency. If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis."); *NEC Home Electronics, Ltd. v. United States*, 54 F.3d 736, 743 (Fed. Cir. 1995) ("We are powerless to affirm an administrative action on a ground not relied upon by the agency."). HHS's motion to dismiss for failure to state a claim should be rejected.

CONCLUSION

For all of the foregoing reasons, the motion to dismiss should be denied and the Court should direct defendants to respond to plaintiff's motion for summary judgment within 14 days. An order to this effect is submitted with this memorandum.

DATED: June 21, 2007

Respectfully Submitted,

/s/ Joseph D. Elford
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