No. 05-55450

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CLIFFORD W. COLWELL, JR., M.D., *et al*.,

Plaintiffs-Appellants

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.

Defendants-Appellees

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

SUPPLEMENTAL BRIEF FOR THE FEDERAL DEFENDANTS AS APPELLEES

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TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

CASES: **PAGE**

STATUTES:

REGULATIONS:

REGULATIONS (continued): **PAGE**

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Pursuant to the Court's order issued on February 15, 2007, the federal defendants-appellees file this supplemental brief. In its order, the Court propounded three questions, which are set forth and answered in sequence below.

1. **What regulations, guidance, other administrative authority, or practices regarding federal funding recipients' obligations to limited English proficient (LEP) persons were in effect prior to the 2003 Guidance in this case? Please discuss, among any other authorities, the 2000 and 2002 predecessors to the 2003 Guidance, Executive Order 13166, and the related Department of Justice general guidance**

documents, the internal guidance issued by DHHS's Office of Civil Rights in 1998, 28 C.F.R. § 42.405(d)(1), and the 1970 regulation referenced at oral argument. *See* Title VI of the Civil Rights Act of 1964; Policy Guidance on the Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency, 65 Fed. Reg. 52,762, 52,764-65 (Aug. 30, 2000) (describing regulatory history).

All regulations and other administrative authority regarding federal funding recipients' obligations to limited English proficient (LEP) persons relevant to this litigation derive from Title VI of the Civil Rights Act of 1964, which provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." 42 U.S.C. 2000d. Title VI requires each federal grant agency to implement this principle of non-discrimination "by issuing rules, regulations, or orders of general applicability." 42 U.S.C. 2000d-1.

On December 4, 1964, just five months after Title VI was signed into law, the Department of Health, Education, and Welfare (HEW)[1] promulgated implementing regulations that, *inter alia*, prohibit their funding recipients from employing in their programs "methods of administration which have the effect of

[1] HEW is the predecessor to the current Departments of Health and Human Services and Education.

subjecting individuals to discrimination, because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect to individuals of a particular race, color or national origin." 29 Fed. Reg. 16,298, 16,299 (1964). This regulation has remained in effect and unchanged since 1964. It is currently codified at 45 C.F.R. 80.3(b)(2).

On July 18, 1970, HEW issued an interpretive guideline clarifying that, under Title VI and the agency's regulations, school districts have the responsibility "to provide equal education opportunity to national origin-minority group children deficient in English language skills." 35 Fed. Reg. 11,595. The guideline advised that, "[w]here the inability to speak and understand the English language excludes national origin-minority children from effective participation in the education program offered by a school district, the district must take affirmative steps to rectify the language deficiency in order to open its instructional program to these students." *Ibid.* The guideline further informed school districts that they "should examine current practices which exist in their districts in order to assess compliance with the matters set forth [in the guideline]"

and inform HEW of the steps they are taking to remedy any compliance problems.[2] *Ibid.*

In 1976, the Department of Justice (DOJ) promulgated regulations governing "the respective obligations of federal agencies regarding enforcement of Title VI," including the Department of Health and Human Services (HHS). 28 C.F.R. 42.401. The DOJ regulations included the following provision, currently codified at 28 C.F.R. 42.405(d)(1):

> Where a significant number or proportion of the population eligible to be served or likely to be directly affected by a federally assisted program (*e.g.*, affected by relocation) needs service or information in a language other than English in order effectively to be informed of or to participate in the program, *the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in appropriate languages to such persons*. This requirement applies with regard to written material of the type which is ordinarily distributed to the public.

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[2] In *Lau* v. *Nichols*, 414 U.S. 563 (1974), the Supreme Court affirmed the 1970 HEW guideline to hold that a public school system's failure to provide English language instruction to students of Chinese ancestry who did not speak English denied the students a meaningful opportunity to participate in a public educational program in violation of Title VI and the statute's disparate impact regulations. Although the Court in *Alexander* v. *Sandoval*, 532 U.S. 275 (2001), held that there is no private right of action for private parties to enforce those regulations, the Court expressly assumed that the regulations were valid for purposes of deciding the case, see *id.* at 281.

41 Fed. Reg. 52,669, 52,670-71 (1976) (emphasis added).

In 1979, HEW issued guidelines to recipients of federal funding for the elimination of discrimination, including national origin discrimination, in vocational education programs. The guidelines stated that they "derive from and provide guidance supplementary to Title VI * * * and the implementing departmental regulation." 44 Fed. Reg. 17,162. The guidelines were issued in response to compliance reviews conducted by HEW from 1973 to 1978, which consistently found civil rights violations in vocational schools. Among those violations, the agency found that "[n]ational origin minorities with limited proficiency in English are denied equal opportunity to participate in vocational programs." *Id*. at 17,163. Accordingly, the guidelines reminded recipients that they "may not restrict an applicant's admission to vocational education programs because the applicant, as a member of a national origin minority with limited English language skills, cannot participate in and benefit from vocational instruction to the same extent as a student whose primary language is English," and that they "must take steps to open all vocational programs to these national origin minority students." *Id.* at 17,166. Additionally, the guidelines stated that if a recipient's service area contained a community of national origin minority persons with limited English language skills, the recipient must provide outreach

materials and disseminate information about vocational opportunities and student financial assistance to that community in the appropriate language. See *id.* at 17,166-67. Finally, the guidelines provided that "[r]ecipients must insure that counselors can effectively communicate with national origin minority students with limited English language skills," and that such requirement "may be satisfied by having interpreters available." *Id.* at 17,167. These guidelines are currently codified at 45 C.F.R. Part 80, App. B.[3]

In 1998, HHS's Office for Civil Rights (OCR) issued an internal guidance to its staff to ensure consistency in OCR's investigation of LEP cases. An accompanying memorandum explained that the guidance "does not * * * impose any requirements on recipients nor does it articulate specific substantive standards

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[3] In 1980, HHS issued a notice of decision to develop regulations, stating that, in response to continuing complaints of national origin discrimination resulting from the inability of recipients to communicate effectively with LEP beneficiaries, the agency was "considering requiring certain classes of recipients to conduct self-evaluations of the extent to which their beneficiary population is of limited English proficiency and the extent to which the services provided are accessible to such persons," as well as "steps that recipients should be required to take to comply with Title VI in this area," including "the use of interpreters and bilingual employees and the translation of forms and informational materials." 45 Fed. Reg. 82,972-73. The notice explained that it did not intend to change the legal standard for determining compliance under Title VI. See *ibid*. The purpose of the notice was to solicit public comment before issuance of a notice of proposed rulemaking (NPRM). See *ibid.* No NPRM, however, was ever issued, and HHS did not promulgate regulations expressly requiring any recipients to undertake specific steps to comply with Title VI with respect to their LEP beneficiaries.

for compliance or the formulation of voluntary compliance remedies. Because there are many novel circumstances which will present difficult questions in the future, we do not believe that we can anticipate them sufficiently to warrant a 'one size fits all' guidance." OCR LEP Guidance Memorandum (Jan. 29, 1998), at 1.[4] Similarly, the guidance stated that it "stresses flexibility, particularly for small providers, in choosing methods to meet their responsibilities to LEP persons" and that it "is intended to clarify standards consistent with case law and well established legal principles that have developed under Title VI." *Id.* at 3. The guidance recommended a number of ways in which a recipient could accommodate the needs of LEP beneficiaries, but emphasized that the kind of services required would likely depend on a number of factors, including "[the recipient's] size, the size of the LEP population it serves, the setting in which interpreter services are needed, the availability of staff members and/or volunteers to provide interpreter services during its hours of operation, and the proficiency of available staff members or volunteers available to provide the needed services." *Id.* at 8.

On August 11, 2000, President Clinton issued Executive Order 13,166 "to improve access to federally conducted and federally assisted programs and

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[4] The 1998 OCR LEP Guidance Memorandum is attached as Exhibit A.

activities for persons who, as a result of national origin, are limited in their English proficiency." 65 Fed. Reg. 50,121 (2000). The Executive Order directed federal agencies, after consulting with appropriate program and activity participants, to develop agency-specific guidance for its recipients to help ensure that LEP persons have meaningful access to federally assisted services. See 65 Fed. Reg. 50,121 (2000). To assist agencies in developing LEP guidance, the Executive Order incorporated by reference a contemporaneously issued DOJ General Policy Guidance and instructed each agency to issue LEP guidance consistent with that policy document. *Ibid*.

The DOJ General Policy Guidance stated that it was intended to clarify pre-existing Title VI responsibilities, not to create new obligations beyond those already established by the statute or prior implementing regulations. 65 Fed. Reg. 50,123 (2000). It also stated that, while the guidance might help agencies shape overall standards, the specific application of Title VI regulations would vary on a case-by-case basis:

> Title VI and its regulations require recipients to take reasonable steps to ensure "meaningful" access to the information and services they provide. What constitutes reasonable steps to ensure meaningful access will be contingent on a number of factors * * * [including] the number or proportion of LEP persons in the eligible service population, the frequency with which LEP individuals come in contact with the program, the importance of the service provided by

> the program, and the resources available to the recipient.

Id. at 50,124.

In accordance with the Executive Order, HHS published its own LEP guidance to recipients of HHS financial assistance on August 30, 2000. See 65 Fed. Reg. 52,762 (2000). Like the 1998 internal OCR guidance and the DOJ General Policy Guidance, the 2000 HHS guidance reiterated that:

> The type of language assistance a recipient/covered entity provides to ensure meaningful access will depend on a variety of factors, including the size of the recipient/covered entity, the size of the eligible LEP population it serves, the nature of the program or service, the objectives of the program, the total resources available to the recipient/covered entity, the frequency with which particular languages are encountered, and the frequency with which LEP persons come into contact with the program.

Id. at 52,765. The guidance explained that "[t]here is no 'one size fits all' solution for Title VI compliance with respect to LEP persons. OCR will make its assessment of the language assistance needed to ensure meaningful access on a case by case basis, and a recipient/covered entity will have considerable flexibility in determining precisely how to fulfill this obligation." *Ibid.* The guidance also set forth several elements usually found in programs that OCR has found to be effective in ensuring meaningful access to LEP persons, but made clear that failure to implement one or more of those elements would not necessarily mean

noncompliance with Title VI, and that OCR would review the totality of the circumstances in each case. See *ibid.*

On October 26, 2001, Assistant Attorney General Ralph F. Boyd, Jr., issued a memorandum to all federal agencies clarifying the requirements of Executive Order 13,166. See 67 Fed. Reg. 4,968, 4,980 (Feb. 1, 2002). The memorandum explained that the Executive Order simply "requires each Federal Agency providing federal financial assistance to explain to recipients of federal funds their obligations under the Title VI disparate impact regulations," and reminded agencies that any action they take to implement the Executive Order "must not impose new obligations on recipients of federal funds, but should instead help recipients to understand their existing obligations." *Id.* at 4,981. The memorandum emphasized that, "[i]n developing [its] own LEP guidance for recipients of federal funds, an agency should balance the factors set forth in the DOJ [General Policy] Guidance." *Ibid.* The memorandum directed agencies that had already published LEP guidance to obtain public comment on the guidance documents they had issued. See *ibid.* Accordingly, HHS republished its 2000 LEP guidance for public comment on February 1, 2002. See 67 Fed. Reg. 4,968 (2002).

On July 8, 2002, Assistant Attorney General Boyd issued another

memorandum expressing the need for legal consistency in federal agency LEP guidance documents. See Boyd Memorandum (July 8, 2002), at 2.[5] The memorandum requested that federal agencies use as a model the LEP guidance DOJ issued to its own recipients on June 18, 2002. See *ibid*. The memorandum instructed agencies to revise and republish their guidance documents based on the DOJ model for public comment. See *id.* at 3. Pursuant to the two memoranda, and after receipt of public comments, HHS revised its LEP guidance and republished it on August 8, 2003. 68 Fed. Reg. 47,311 (2003).

2. What are the differences between the 2003 Guidance and those earlier authorities, in terms of (a) the requirements imposed on recipients like the appellants in this case; and (b) their legal authority and enforceability?

As explained in our opening brief, the only authorities at issue in this litigation that impose any legal requirements on HHS recipients with respect to LEP persons are Title VI and that statute's implementing regulations.[6] There is no

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[5] The 2002 Boyd Memorandum is attached as Exhibit B.

[6] Indeed, some of the authorities discussed above, such as the HHS's 1998 internal guidance to OCR staff, Executive Order 13,166, the DOJ General Policy Guidance, and Assistant Attorney General Boyd's memoranda, have no applicability at all to recipients of federal financial assistance, as those documents were addressed to federal agencies and intended only to improve the internal management of the Executive Branch with respect to Title VI enforcement and implementation. See, *e.g.*, 65 Fed. Reg. 50,122.

difference between the 2003 Guidance and the authorities discussed above in terms of the requirements imposed on recipients such as plaintiffs. The 2000, 2002, and 2003 HHS Guidance documents are substantively identical and the slight variations between them result only from a shift in format, focus and emphasis. The 2000 and 2002 Guidance focused on explaining Title VI, its implementing regulations and the obligations that flow from them. In contrast, the 2003 Guidance focused on offering technical assistance to recipients that might want the Department's help with their compliance efforts, and explained additional plans to meet their technical assistance needs. The 2003 Guidance also provided more guidance as to who is covered, and who is not a recipient of HHS federal financial assistance. See 68 Fed. Reg. 47,313.

The 2003 Guidance, like prior DOJ and HHS/HEW guidances, simply reminds recipients that "the failure * * * to take reasonable steps to provide LEP persons with meaningful opportunity to participate in HHS-funded programs may constitute a violation of Title VI and HHS's implementing regulations." *Id.* at 47,313. The Guidance states that its purpose "is to assist recipients in fulfilling their responsibilities to provide meaningful access to LEP persons under existing law" and to "clarif[y] existing legal requirements for LEP persons by providing a description of the factors recipients should consider in fulfilling their

responsibilities to LEP persons." *Ibid.* Thus, the "policy guidance is not a regulation but rather a guide," which "provides an analytical framework that recipients may use to determine how best to comply with statutory and regulatory obligations to provide meaningful access to the benefits, services, information, and other important portions of their programs and activities for individuals who are limited English proficient." *Id.* at 47,313 n.2.

Like prior DOJ and HHS/HEW guidances, the 2003 HHS Guidance sets forth factors to help recipients of federal financial assistance assess their existing obligation under Title VI and its implementing regulations to take reasonable steps to provide meaningful access to federally assisted programs to LEP persons. *Id.* at 47,314. Pursuant to the 2002 Boyd Memorandum, the 2003 Guidance adopts the four-factor analysis set forth in the DOJ model.[7] This analysis, however, is not new. The factors derive from DOJ's coordination regulation, 42 C.F.R. 405(d)(1), in effect since 1976, and have appeared in slightly different form in the 2000 and 2002 predecessors to the 2003 Guidance.

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[7] The four factors are: (1) the number or proportion of LEP persons eligible to be served or likely to be encountered by the program, activity, or service provided by the recipient; (2) the frequency with which LEP individuals come into contact with the recipient's program, activity, or service; (3) the nature and importance of the recipient's program, activity, or service; and (4) the resources available to the recipient and costs. See 68 Fed. Reg. 47,322.

The Guidance does not require that recipients apply the four-factor analysis to assess their obligations. Indeed, the Guidance itself states that the analysis is a tool intended "to suggest a balance that ensures meaningful access by LEP persons to critical services while not imposing undue burdens on small business, small local governments, or small nonprofits." *Id.* at 47,314. Accordingly, the 2003 Guidance, including the four-factor analysis, does not impose any new legal obligations on recipients, but merely reiterates the longstanding requirement that "[r]ecipients * * * take reasonable steps to ensure meaningful access to their programs and activities by LEP persons." 68 Fed. Reg. 47,314. This requirement, interpreted as "a flexible and fact-dependent standard," *ibid*., derives not from the Guidance, but from the HHS's implementation of the statute and regulation informed by DOJ's coordination regulation, 28 C.F.R. 42.405(d)(1). Accordingly, neither the 2003 Guidance nor any prior guidance document imposes any new or different legal requirements on HHS recipients.

Similarly, only Title VI and its implementing regulations are legally enforceable. See 42 U.S.C. 2000d-1; 45 C.F.R. 80.8 (setting forth HHS's administrative enforcement procedures for noncompliance with the regulations' nondiscrimination mandate). Although the 2003 Guidance and prior guidance documents encourage recipients to conduct individualized assessments of their

obligation, if any, to provide meaningful program access to LEP persons by considering certain factors, such assessments are not legally required and a recipient's failure to conduct such an assessment cannot constitute grounds for an enforcement action.[8] See 45 C.F.R. 80.8.[9]

3. What is the impact of those differences on (a) whether the plaintiffs have alleged an injury-in-fact due to the promulgation of the 2003 Guidance; (b) when any such injury arose; (c) whether such an injury is redressable by the plaintiffs' requested relief? In connection with this question, the parties may wish to discuss *Nat'l Park Hospitality Assoc. v. Dept. of the Interior*, 538 U.S. 803 (2003), and *Takhar v. Kessler*, 76 F.3d 995 (9th Cir. 1996).

As explained above, there are no differences between the 2003 Guidance and the earlier authorities in terms of the requirements imposed on recipients, and their legal authority and enforceability. The 2003 Guidance and the other administrative authorities discussed above do not create any new legal obligations, but rather reiterate and clarify plaintiffs' existing obligations to LEP patients under Title VI and its implementing regulations. Since no legally significant

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[8] Indeed, in 1980, HHS considered promulgating a legally enforceable regulation that would have expressly required recipients to conduct self-evaluations and, where necessary, provide language services to its LEP beneficiaries. See 45 Fed. Reg. 82,972-73. As discussed above, *supra* note 3, however, HHS never promulgated such a regulation.

[9] Indeed, all of HHS's LEP-related enforcement activities summarized in Exhibit 6 of plaintiffs' complaint predate promulgation of the 2003 Guidance. See E.R. V. I 81-89.

differences exist between the 2003 Guidance and the prior authorities, those authorities have no bearing on the question whether plaintiffs have suffered an injury-in-fact due to the promulgation of the 2003 Guidance. Any alleged injury plaintiffs may have suffered as a result of their obligations to LEP patients derives from Title VI and its implementing regulations, not the 2003 Guidance or any of the other administrative authorities discussed above. See Brief for the Federal Defendants as Appellees at 18-27. Moreover, any alleged injury is not redressable by plaintiffs' requested relief, as they seek only invalidation of the 2003 Guidance – not the statute and regulations. See *id.* at 27-28. The cases this Court cites in the Order fully support the conclusion that plaintiffs lack standing.

In *Takhar* v. *Kessler*, 76 F.3d 995, 1003 (9th Cir. 1996), this Court held that a veterinarian lacked standing to challenge two Compliance Policy Guides (CPGs) issued by the Food and Drug Administration (FDA). The CPGs set forth criteria and precautions for "extra-label" use of animal drugs and use of human drugs on animals pursuant to the Food, Drug and Cosmetic Act (FDCA). See *id.* at 997-998. The veterinarian challenged the CPGs as exceeding Congress's grant of agency authority under the FDCA and violating the Administrative Procedure Act (APA). See *id.* at 997. This Court rejected each of the veterinarian's allegations of injury as insufficient to confer standing. See *id.* at 1000. For all of the same

reasons this Court provided in *Takhar*, plaintiffs' alleged injuries in the instant case are also insufficient to confer standing.

In *Takhar*, the veterinarian alleged injury based upon a fear of prosecution by the FDA, claiming that if he were to use certain drugs proscribed by the CPGs he could be prosecuted for extra-label drug use and subject to stiff criminal penalties. See *ibid*. This Court, however, concluded that such allegations were based on conjecture and "do not set forth any concrete or actual threat of prosecution." *Ibid.* This Court further concluded that, "[e]ven if Takhar's allegations of fear of prosecution stated sufficient injuries in fact for standing purposes, those injuries are not caused by the CPGs that he challenges." *Ibid.* The Court explained that it is the FDCA, not the CPGs – which merely set forth the FDA's enforcement policy – that regulate what sort of drugs can be used on animals. See *ibid*.

Plaintiffs' allegations in the instant case of "threatened enforcement" by HHS (E.R. V. I 13) are also insufficient to confer standing because, like the veterinarian, plaintiffs fail to set forth any claims of concrete or actual threat of enforcement. In fact, plaintiffs' allegations of injury are even more tenuous than those of the veterinarian, who alleged a desire to prescribe drugs that, if used, could subject him to stiff criminal penalties and fines. See *Takhar*, 76 F.3d at

1000. Here, however, plaintiffs do not allege that they have even applied the four-factor analysis set forth in the 2003 Guidance to determine whether they are obligated to provide language assistance to LEP persons in the first place,[10] or that they desire to engage in conduct that could violate Title VI or the regulations. Rather, as counsel for plaintiffs stated at oral argument, plaintiffs' allegations of injury stem from a subjective belief or fear that they could be found to be engaging in unlawful discriminatory behavior. Like the veterinarian's allegations in *Takhar*, however, plaintiffs' allegations of fear, even if sufficient to constitute injury-in-fact, are not caused by the Guidance, but rather by the statute and regulations, which are the only legally enforceable Title VI authority with respect to recipients' obligations to LEP beneficiaries.[11] Moreover, even if plaintiffs failed to comply with the requirements of Title VI or its implementing regulations, they would not be subject to the sort of penalties at issue in *Takhar*. On the

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[10] Even if plaintiffs had alleged that they applied the four-factor analysis to assess their obligations, such allegation would still be insufficient to confer standing under *Takhar*.

[11] *Cf. National Wrestling Coaches Ass'n* v. *Department of Educ.*, 366 F.3d 930, 939-940 (D.C. Cir. 2004), cert. denied, 545 U.S. 1104 (2005) (concluding that plaintiffs' requested relief that court invalidate two agency policy documents would not redress alleged injuries because the applicable statute, Title IX of the Education Amendments of 1972, and its implementing regulations would still be in place).

contrary, HHS regulations prohibit the agency from taking any immediate action against a recipient who is found to be noncompliant with the regulations' nondiscrimination mandate.[12] See 45 C.F.R. 80.8.

The veterinarian in *Takhar* also alleged that, in response to the CPGs' proscription of certain drugs he regularly used in his practice, he was forced to substitute different drugs that were more expensive and less effective in his treatment of animals. See 76 F.3d at 1001. This Court agreed that this allegation supported a cognizable injury, but concluded that the cause of the injury was again the FDCA and not the CPGs since "the statute prohibits extra-label use and Takhar would be liable for statutory violations even in the absence of the CPG." *Ibid*.

In this case, plaintiffs have alleged that the 2003 Guidance could force them to change their daily medical practices and incur additional costs on interpretation and translation services (E.R. V. I 3-6), but they do not allege, as the veterinarian

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[12] Under HHS regulations, OCR must first seek to achieve Title VI compliance through voluntary or informal means, 45 C.F.R. 80.8(a), (d), and may not initiate enforcement proceedings unless voluntary compliance fails. 45 C.F.R. 80.8(d). In addition, HHS must satisfy several procedural requirements before terminating federal funding, including, *inter alia*, providing an administrative hearing, receiving approval from the Secretary to terminate funding, and filing a report with the House and Senate legislative committees having jurisdiction over the programs involved. 45 C.F.R. 80.8(c). A recipient may seek judicial review of a final decision by HHS to terminate federal aid. 42 U.S.C. 2000d-2; 45 C.F.R. 80.11.

in *Takhar* did, that they have actually incurred any such costs as a result of the Guidance. Accordingly, unlike the veterinarian, they have not alleged sufficient injury-in-fact to confer standing. Moreover, as this Court held in *Takhar*, such an injury, even if properly alleged, is caused by the statute and regulations, not by the Guidance. See *id*. at 1001.

Finally, this Court held that the veterinarian's claim that the FDA failed to comply with the APA's notice-and-comment procedure in issuing the CPGs did not constitute a legally cognizable injury because the CPGs are interpretive rules and policy statements not subject to the notice-and-comment procedure. See *id.* at 1002. This Court explained:

> The CPGs that Takhar challenges are interpretive rules because they do not create any obligations or rights with respect to extra-label veterinary drug use. It is the FDCA itself that makes such use illegal. The challenged CPGs merely set forth which instances of such illegal use the FDA is likely to view as requiring it to take enforcement action and which instances, while technically violative of the statute, will not ordinarily be subject to enforcement action.

Accordingly, the Court concluded, "Takhar was not injured by denial of notice and the opportunity to comment." *Ibid.*

Plaintiffs in this case also allege injury based on their claim that HHS failed to adhere to the APA's notice-and-comment procedures in issuing the 2003 Guidance (E.R. V. I 13-14). Like the CPGs in *Takhar*, however, the Guidance is

an interpretive rule exempt from the APA's notice-and-comment procedure. See 68 Fed. Reg. 47,311. Thus, plaintiffs' APA claim also fails to state a legally cognizable injury. Again, plaintiffs' allegation of injury is even more tenuous than that of the veterinarian because, despite the Guidance's exemption under the APA, HHS solicited comments from the public and even provided an extended comment period to encourage comment from recipients. See *ibid.* Thus, unlike the veterinarian, plaintiffs in this case had an opportunity to comment.[13] Accordingly, this Court's decision in *Takhar* fully supports the conclusion that the plaintiffs in this case lack standing.

The Supreme Court's decision in *National Park Hospitality Association* v. *Department of the Interior*, 538 U.S. 803 (2003), also supports this conclusion. In that case, the Court concluded that a challenge to a National Park Service (NPS) regulation interpreting the Contracts Disputes Act (CDA) to exclude concession contracts was not ripe for review. See *id.* at 808. The Court concluded that the regulation – which the Court considered to be nothing more than an interpretive rule because the NPS lacked rulemaking authority – failed to create "adverse effects of a strictly legal kind," which the Court had previously required for a

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[13] In fact, the associational plaintiffs in this case submitted comments responding to the 2003 Guidance. See E.R. V. I 55-66.

showing of hardship under the ripeness doctrine. *Id.* at 809 (citing *Ohio Forestry Association, Inc*. v. *Sierra Club*, 523 U.S. 726, 732-733 (1998)). The Court explained that the petitioner would not be harmed if judicial review were withheld because the regulation did not command anyone to do anything or otherwise affect a concessioner's conduct. See *id.* at 810. Rather, it leaves "a concessioner free to conduct its business as it sees fit." *Ibid.*[14] For these same reasons, Justice Stevens concluded in a concurring opinion that the petitioner failed to allege a sufficient injury to establish standing. See *id.* at 815 (Stevens, J., concurring). Justice Stevens explained:

> [Petitioner failed to identify] a specific incident in which the regulation caused a concessionaire to refuse to bid on a contract, to modify its bid, or to suffer any other specific injury. Rather, petitioner has focused entirely on the importance of knowing whether the Park Service's position is valid. While it is no doubt important for petitioner and its members to know as much as possible about the future of their business transactions, importance does not necessarily establish injury.

Id. at 816.

Similarly, in this case, the Guidance does not create any adverse legal

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[14] The Court also concluded that the issues were not fit for review, the second prong of the ripeness inquiry, because "further factual development would significantly advance [the Court's] ability to deal with the legal issues present." *National Park Hospitality Ass'n*, 538 U.S. at 812 (quoting *Duke Power Co.* v. *Carolina Environmental Study Group, Inc.*, 438 U.S. 59, 82 (1978)).

effects or command plaintiffs to do anything. As previously explained, the Guidance merely reiterates and clarifies plaintiffs' existing legal obligations under Title VI and that statute's implementing regulations. The Guidance is a tool that plaintiffs may use to assess whether they have any obligations to LEP persons, but it does not require them to apply the four-factor assessment analysis or otherwise do anything. Like the interpretive rule in *National Park Hospitality Association*, the Guidance does not affect their daily medical practices, but rather leaves plaintiffs free to conduct their business as they see fit. Moreover, as Justice Stevens explained in his concurring opinion, plaintiffs cannot establish injury by their "desire," as expressed by counsel at oral argument, to know whether HHS's interpretation of Title VI and its implementing regulations is valid. See *ibid.*

CONCLUSION

For the foregoing reasons, and the reasons set forth in our opening brief, this Court should affirm the judgment of the district court.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify, pursuant to Fed. R. App. P. 32(a)(7)(C), that the attached SUPPLEMENTAL BRIEF FOR THE FEDERAL DEFENDANTS AS APPELLEES is proportionally spaced, has a typeface of 14 points, and complies with this Court's order issued on February 15, 2007.

_____

TOVAH R. CALDERON
Attorney

Date: February 23, 2007

CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2007, one copy of the foregoing SUPPLEMENTAL BRIEF FOR THE FEDERAL DEFENDANTS AS APPELLEES was served by overnight delivery on the following counsel of record:

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