

FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CLIFFORD W. COLWELL, JR.; JOHN
BROFMAN; LYNN I. DEMARCO;
PROENGLISH, a nonprofit
organization; THE ASSOCIATION OF
AMERICAN PHYSICIANS & SURGEONS,
a nonprofit organization,

Plaintiffs-Appellants,

v.

DEPARTMENT OF HEALTH AND
HUMAN SERVICES; MICHAEL O.
LEAVITT Secretary of Dept. of
Health and Human Services, in his
official capacity,

Defendants-Appellees.

No. 05-55450

D.C. No.

CV-04-01748-BTM

OPINION

Appeal from the United States District Court
for the Southern District of California
Barry T. Moskowitz, District Judge, Presiding

Argued and Submitted
February 13, 2007—Pasadena, California

Filed March 18, 2009

Before: Harry Pregerson, William A. Fletcher and
Marsha S. Berzon, Circuit Judges.

Opinion by Judge William A. Fletcher

3482

COLWELL v. HHS

COUNSEL

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OPINION

W. FLETCHER, Circuit Judge:

Plaintiffs-Appellants bring a pre-enforcement challenge to Policy Guidance issued by the Department of Health and Human Services (“HHS”) in August 2003 (“2003 Policy Guidance” or “Policy Guidance”). The stated purpose of the Policy Guidance is to clarify the legal obligation of recipients of federal funds to provide meaningful access for individuals with limited English proficiency (“LEP”) to programs supported by those funds. The district court dismissed Plaintiffs’ suit under Federal Rule of Civil Procedure 12(b)(1), holding under Article III that Plaintiffs lacked standing and that their suit was unripe. We hold that Plaintiffs have standing and that their suit is ripe under Article III, but that their suit should be dismissed as unripe under the prudential criteria articulated in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). We therefore affirm the district court’s dismissal.

I. Statutory and Regulatory Background

Section 601 of Title VI of the Civil Rights Act of 1964 mandates, “No 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. Section 602 requires that a federal agency providing financial assistance to a federal program implement the statutory mandate “by issu-

ing rules, regulations, or orders of general applicability which shall be consistent with achievement of general objectives of the statute authorizing the financial assistance in connection with which the action is taken.” *Id.* § 2000d-1.

There is an almost forty-year regulatory history leading up to the 2003 Policy Guidance challenged in this case. The Department of Health, Education, and Welfare (“HEW”) — the predecessor to HHS and the Department of Education — promulgated general implementing regulations almost immediately after the passage of Title VI. A 1964 regulation prohibits recipients of federal financial assistance from “utiliz[ing] criteria or methods of administration which have the effect of 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 individuals of a particular race, color, or national origin.” 45 C.F.R. § 80.3(b)(2); *see* Final Rule, 29 Fed. Reg. 16,298 (Dec. 4, 1964).

Beginning in the late 1960s, HEW interpreted the prohibition against discrimination based on national origin as including discrimination against LEP individuals. In 1968, HEW issued a guidance document providing that “(s)chool systems are responsible for assuring that students of a particular race, color, or national origin are not denied the opportunity to obtain the education generally obtained by other students in the system.” Notice, 33 Fed. Reg. 4955 (Mar. 23, 1968). In 1970, HEW made the guidance more specific, providing that federally funded school districts were required “to rectify the language deficiency in order to open the instruction to students who had ‘linguistic deficiencies.’ ” Notice, 35 Fed. Reg. 11,595 (July 18, 1970). Four years later, the Supreme Court in *Lau v. Nichols*, 414 U.S. 563 (1974), agreed with HEW that discrimination against LEP individuals was discrimination based on national origin in violation of Title VI, holding that the denial to LEP students of Chinese ancestry of a “meaning-

ful opportunity to participate in the educational program” of the San Francisco public schools violated § 601. *Id.* at 567-68.

In 1976, after following the formal notice-and-comment procedures of the Administrative Procedure Act (“APA”), 5 U.S.C. § 553, the Department of Justice (“DOJ”) promulgated regulations governing “the respective obligations of federal agencies [including HHS] regarding enforcement of Title VI.” 28 C.F.R. § 42.401. The DOJ regulations require that

[w]here 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.

Id. § 42.405(d)(1). The DOJ regulations do not mention oral translation.

In 1980, HHS issued a Notice of Decision to Develop Regulations (“NDDR”) that stated that HHS 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.” Proposed Rules, 45 Fed. Reg. 82,972, 82,972-73 (Dec. 17, 1980). The purpose of the NDDR

was to solicit public comments before the issuance of a Notice of Proposed Rulemaking (“NPRM”). *Id.* An NPRM, however, was never issued, and the proposed regulations were never promulgated.

In 1998, the Office for Civil Rights (“OCR”) of HHS issued an internal guidance memorandum “intended to insure consistent application of Title VI standards in assessing the compliance of HHS recipients with respect to the provision of health and social services to LEP persons.” OCR LEP Guidance Memorandum (Jan. 29, 1998), <http://www.hhs.gov/ocr/lepfinal.htm>. The guidance memorandum sets out multiple “factors for OCR staff to consider in determining whether federally-assigned providers of medical care or social services are taking steps to overcome language barriers to health care and social services encountered by LEP persons.” *Id.* The factors to be considered included “[the provider’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 the hours of operation, and the proficiency of available staff members or volunteers available to provide the needed services.” *Id.* at 8.7

In 2000, President Clinton issued an Executive Order “to improve access to federally conducted and federally assisted programs and activities for persons who, as a result of national origin, are limited in their English proficiency (‘LEP’).” Exec. Order No. 13,166, 65 Fed. Reg. 50,121 (Aug. 11, 2000). The Order provided:

[E]ach Federal agency shall examine the services it provides and develop and implement a system by which LEP persons can meaningfully access those services consistent with, and without unduly burdening, the fundamental mission of the agency. Each Federal agency shall also work to ensure that recipients of Federal financial assistance . . . provide

meaningful access to their LEP applicants and beneficiaries.

Id. The Order incorporated by reference a contemporaneously issued DOJ Policy Guidance addressed to “Executive Agency Civil Rights Officers.” *See* Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons With Limited English Proficiency; Policy Guidance, 65 Fed. Reg. 50,123 (Aug. 16, 2000).

The DOJ Policy Guidance begins, “This policy guidance does not create new obligations but, rather, clarifies existing Title VI responsibilities.” *Id.* at 50,123. It then provides that

[r]ecipients who fail to provide services to LEP applicants and beneficiaries in their federally assisted programs and activities may be discriminating on the basis of national origin in violation of Title VI and its implementing regulations. 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. Among the factors to be considered are 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 compliance with the Executive Order, HHS issued its own Policy Guidance in 2000. *See* Policy Guidance on the Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency, 65 Fed. Reg. 52,762 (Aug. 30, 2000). The 2000 Policy Guidance was

republished for public comment a year and a half later, resulting in a 2002 version of the Policy Guidance. Policy Guidance on the Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency, 67 Fed. Reg. 4968 (Feb. 1, 2002). The 2002 Policy Guidance was again republished and reopened for public comment. After receipt of almost 200 comments, and an extensive question and answer session, the HHS revised and republished it as a “Policy Guidance Document” in 2003. Notice, Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47,311, 47,312 (Aug. 8, 2003).

The stated purpose of the 2003 Policy Guidance “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.” *Id.* at 47,313. Like the documents that preceded it, the 2003 Policy Guidance provides a several-factor test that recipients of HHS financial assistance can use to determine the nature and extent of their obligation under Title VI to provide LEP individuals with meaningful access to HHS funded programs and activities. The factors described in the 2003 Policy Guidance 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* Policy Guidance, 68 Fed. Reg. at 47,322.

The non-discrimination requirements of Title VI may be enforced either through termination of federal financial assistance or “by any other means authorized by law.” 42 U.S.C.

§ 2000d-1. The first enforcement step is normally an investigation by HHS, often instigated by private complainants. If the investigation shows that a recipient of HHS funds is not in compliance with Title VI, HHS must attempt to bring the recipient into compliance by informal or voluntary means. *Id.* § 2000d-1; 45 C.F.R. §§ 80.7(d)(1), 80.8(d). The 2003 Policy Guidance provides that if an investigation results in “a finding of noncompliance, HHS must inform the recipient of the noncompliance through a Letter of Findings that sets out the areas of noncompliance and the steps that must be taken to correct the noncompliance.” Policy Guidance, 68 Fed. Reg. at 47,321.

If a recipient’s compliance cannot be achieved voluntarily, HHS is authorized to discontinue federal financial assistance, 45 C.F.R. § 80.8(a), but no such discontinuance can take effect until

(1) the responsible Department official has advised the applicant or recipient of his failure to comply and has determined that compliance cannot be secured by voluntary means, (2) there has been an express finding on the record, after opportunity for hearing, of a failure by the applicant or recipient to comply with a requirement imposed by or pursuant to this part, (3) the expiration of 30 days after the Secretary has filed with the committee of the House and the committee of the Senate having legislative jurisdiction over the program involved, a full written report of the circumstances and the grounds for such action.

Id. § 80.8(c); *see also* 42 U.S.C. § 2000d-1. Recipients of HHS funds are entitled to judicial review of a funding termination decision. *Id.* § 2000d-2; 45 C.F.R. § 80.11.

HHS spends less than \$500,000 annually on enforcement of LEP-related compliance with Title VI. At oral argument before the district court Defendants advised that “HHS has never moved beyond the voluntary compliance stage with any

HHS Recipient.” Plaintiffs have submitted the voluntary compliance agreements to which Defendants refer and have submitted no evidence that any proceeding extended beyond the voluntary compliance stage. None of the voluntary compliance agreements submitted involve any of the plaintiffs before this Court. So far as the record shows, no recipient has ever had its HHS federal funding terminated for violating Title VI’s prohibition against national origin discrimination in its treatment of LEP individuals.

II. Procedural Background

Plaintiffs-Appellants Clifford W. Colwell, Jr., M.D., John Brofman, M.D., and Lynn I. DeMarco, M.D. (collectively “Physician Plaintiffs”) and two nonprofit organizations, ProEnglish and the Association of American Physicians and Surgeons (collectively “Organizational Plaintiffs”), filed a complaint in federal district court against Defendants HHS and the Secretary of HHS seeking declaratory and injunctive relief against the 2003 Policy Guidance. Plaintiffs allege that “Defendants are threatening to enforce and are enforcing this Policy Guidance that orders medical service providers and others to provide free translation services to limited English proficient (LEP) persons, ensures the competency of the translation, and exposes these providers to liability under both federal law and malpractice claims.”

Plaintiff Colwell is licensed to practice medicine in California, with a specialty in orthopedics. He has recently retired from a position as head of the Division of Orthopedic Surgery at the Scripps Clinic. Dr. Colwell alleges that the 2003 Policy Guidance “interferes with his one-on-one physician patient relationship by eliminating his professional judgment on how best to communicate with his patients,” “compels him to speak in a specific manner not of his choosing,” and “forces him to translate his own English words into an language other than English at his own cost.” Dr. Colwell alleges that com-

plying with the “translation requirement is extremely onerous and the cost will be prohibitive.”

Plaintiff Brofman practices pulmonary medicine, inpatient and outpatient and consultative and primary care in Illinois. Dr. Brofman alleges that the Policy Guidance “has a direct financial impact on his practice.” He alleges that before the issuance of the 2003 Policy Guidance he determined at the initial appointment of an LEP patient whether a translator was necessary. If he determined that a translator was necessary, he encouraged the patient to bring a translator to subsequent appointments. Dr. Brofman alleges that if the 2003 Policy Guidance requires that he pay a translator for an LEP patient, the cost will be “at least \$75 an hour.” He alleges that this additional cost “may force [him] to reduce his access to LEP patients.”

Plaintiff DeMarco is a partially retired Professor of Medicine at Truman Memorial Hospital in Missouri. He alleges that prior to the issuance of the 2003 Policy Guidance he used his professional judgment to decide “whether an interpreter or translator was required when treating LEP patients.” He alleges that “[n]ow he must provide an interpreter and translator even when he does not believe it is necessary or face the threat of being reported to the HHS Office of Civil Rights.” Dr. DeMarco alleges that he believes “it would be appropriate to use a family member for translation when treating an LEP patient if the family member is fluent in English and the illness is not serious.” He alleges that under the Policy Guidance he “may not request that the LEP patient use a family member[.]” Dr. DeMarco provides the following example: “In June 2003, I saw a Hispanic patient with a ten-year old daughter who was fluent in English and could have easily translated what her mother was saying to me. However, because of the HHS Policy Guidance I was not able to use her.”

Plaintiff ProEnglish is a nonprofit advocacy organization “dedicated to the preservation and promotion of a common

language — English — in American political and governmental life.” ProEnglish alleges that some of its members are medical doctors who are subject to the 2003 Policy Guidance. Plaintiff Colwell alleges that he is a member of ProEnglish. ProEnglish alleges that the Policy Guidance “undermines or nullifies the English language goals and programs that ProEnglish has conducted in recent years, is currently conducting, and expects to undertake in the future.” ProEnglish alleges that the “adoption and enforcement” of the Policy Guidance will make its “activities far more difficult, if not impossible, to attain.” ProEnglish asserts that some of its members “fear that they will now be the target of complaints filed with the HHS Office of Civil Rights” and that its members “will face, at a minimum, emotional strain, inconvenience, and disruption of their professional life, economic costs, possible harm to their professional reputation, and distraction from their professional duties.” ProEnglish also alleges that its members’ speech is being “unconstitutionally chilled.”

Plaintiff Association of American Physicians and Surgeons (“AAPS”) is a national nonprofit organization of “medical doctors with over 5,000 members” that is “dedicated to preserving freedom in the practice of ethical medicine and opposes government interference in the one-on-one patient-physician relationship.” AAPS alleges that many of its members are medical professionals subject to the 2003 Policy Guidance. Plaintiffs Colwell and DeMarco allege that they are members of AAPS. AAPS alleges that the Policy Guidance “forces physicians to make significant financial outlays for expanded translation and interpreter services or face the likelihood of civil rights complaints.” AAPS alleges that the Policy Guidance “requires physicians to be responsible for the competency of the medical translation and interpreter service they provide,” thus exposing “physicians to increased risk from medical errors and omissions which will escalate insurance costs.” As a result, according to AAPS, its members “may be forced to limit their exposure by not accepting LEP patients.”

The district court dismissed Plaintiffs' complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1). It held under Article III that Plaintiffs lacked standing and their suit was unripe. Plaintiffs timely appealed.

III. Standard of Review

"A complaint should not be dismissed unless it appears beyond doubt that the plaintiff can prove no set of facts in support of the claim that would entitle it to relief." *Daniel v. County of Santa Barbara*, 288 F.3d 375, 380 (9th Cir. 2002) (quoting *Williamson v. Gen. Dynamics Corp.*, 208 F.3d 1144, 1149 (9th Cir. 2000)). At the pleading stage, "general allegations embrace the specific facts that are necessary to support the claim." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (internal citation omitted). The burden of establishing ripeness and standing rests on the party asserting the claim. *Renne v. Geary*, 501 U.S. 312, 316 (1991). In support of a motion to dismiss under Rule 12(b)(1), the moving party may submit "affidavits or any other evidence properly before the court It then becomes necessary for the party opposing the motion to present affidavits or any other evidence necessary to satisfy its burden of establishing that the court, in fact, possesses subject matter jurisdiction." *St. Clair v. City of Chico*, 880 F.2d 199, 201 (9th Cir. 1989) (citations omitted).

We review *de novo* a district court's dismissal for lack of standing, construing all material allegations in favor of the plaintiff. *Schmier v. U.S. Court of Appeals for the Ninth Cir.*, 279 F.3d 817, 820 (9th Cir. 2002). We also review *de novo* a district court's dismissal for lack of ripeness. See *Manufactured Home Cmtys. Inc. v. City of San Jose*, 420 F.3d 1022, 1025 (9th Cir. 2005).

IV. Discussion

Plaintiffs' suit challenges only the 2003 Policy Guidance. For the reasons that follow, we hold that their suit satisfies the

case or controversy requirement of Article III for both standing and ripeness. However, we hold that it does not satisfy the criteria for prudential ripeness.

A. Case or Controversy Requirement of Article III

[1] Article III federal courts are limited to deciding “cases” and “controversies.” U.S. Const. art. III, § 2. Two components of the Article III case or controversy requirement are standing and ripeness.

1. Article III Standing

[2] The “irreducible constitutional minimum” of Article III standing has three “elements,” *Lujan*, 504 U.S. at 560:

First, the plaintiff must have suffered an “injury in fact” — an invasion of a legally protected interest which is (a) concrete and particularized, . . . and (b) “actual or imminent, not ‘conjectural’ or ‘hypothetical,’ ” Second, there must be a causal connection between the injury and conduct complained of — the injury has to be “fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.” . . . Third, it must be “likely,” as opposed to merely “speculative,” that the injury will be “redressed by a favorable decision.”

Id. at 560-61 (alterations in original).

[3] Reading the complaint generously, as we must under Federal Rule of Civil Procedure 8(a), the Physician Plaintiffs have satisfied all three elements. First, they have alleged that they have suffered, or will suffer, “injury in fact” as a result of Defendants’ issuance of the Policy Guidance. Plaintiff Colwell alleges that the Policy Guidance interferes with his relationship with his patients and with the exercise of his

“professional judgment,” and that it forces him to hire translators that he would not otherwise hire “at his own cost.” Plaintiff Brofman alleges that the Policy Guidance has a direct adverse impact on his practice, and that if he needs an interpreter for an LEP patient the cost will be at least \$75 per hour. Plaintiff DeMarco alleges that the Policy Guidance has already obliged him to discontinue his prior practice of using family members to translate for his patients, and will oblige him to do so in the future.

[4] Second, the Physician Plaintiffs have alleged a causal connection between the actions of the Defendants and their injury. Defendants are responsible for the issuance of the Policy Guidance that has allegedly caused injury to Plaintiffs. Their actions are not the result of the “independent action of some third party not before the court.” *Lujan*, 504 U.S. at 560-61.

[5] Third, the Physician Plaintiffs have alleged that their injury will be “redressed by a favorable decision.” *Id.* at 561. If the Policy Guidance is withdrawn, the injury of which the Plaintiffs complain will be redressed.

There are three related but distinct Article III standing requirements for associations. “An association has standing to bring suit on behalf of its members when [1] its members would otherwise have standing to sue in their own right, [2] the interests at stake are germane to the organization’s purpose, and [3] neither the claim nor the relief requested requires the participation of individual members in the lawsuit.” *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000) (bracketed numbers added) (citing *Hunt v. Wash. State Apple Adver. Comm’n*, 432 U.S. 333, 343 (1977)).

[6] The Organizational Plaintiffs have adequately alleged compliance with the three requirements for associational standing. First, Plaintiff Colwell alleges that he is a member

of Plaintiff ProEnglish, and Plaintiffs Colwell and DeMarco allege that they are members of Plaintiff AAPS. As we have just discussed, Plaintiffs Colwell and DeMarco have standing in their own right.

[7] Second, the interests at stake in this suit are “germane” to the purposes of the two associations. Plaintiff ProEnglish alleges that it is “dedicated to the preservation and promotion of a common language — English,” and that the Policy Guidance will interfere with the achievement of its goals. Plaintiff AAPS alleges that it is “dedicated to preserving freedom in the practice of ethical medicine,” and that the Policy Guidance will interfere with the “one-on-one patient-physician relationship.”

[8] Third, although members of the Organizational Plaintiffs are individual plaintiffs in the suit before us, the claim and relief sought in this suit does not require their presence. Stated another way, the claims and relief sought in this suit could be pursued even if the Organizational Plaintiffs were the only plaintiffs.

2. Article III Ripeness

[9] Standing and ripeness under Article III are closely related. For a suit to be ripe within the meaning of Article III, it must present “‘concrete legal issues, presented in actual cases, not abstractions.’” *United Pub. Workers v. Mitchell*, 330 U.S. 75, 89 (1947) (quoting *Elec. Bond & Share Co. v. Sec. & Exch. Comm’n*, 303 U.S. 419, 443 (1938)). But whereas “standing is primarily concerned with *who* is a proper party to litigate a particular matter, ripeness addresses *when* that litigation may occur.” *Lee v. Oregon*, 107 F.3d 1382, 1387 (9th Cir. 1997); *see also Sacks v. Office of Foreign Assets Control*, 466 F.3d 764, 773 (9th Cir. 2006) (“‘[T]he constitutional component of the ripeness inquiry . . . , in many cases, . . . coincides squarely with standing’s injury in fact prong.’”) (internal citation omitted); *Thomas v.*

Anchorage Equal Rights Comm’n, 220 F.3d 1134, 1138 (9th Cir. 2000) (“The constitutional component of the ripeness inquiry is often treated under the rubric of standing and, in many cases, ripeness coincides squarely with standing’s injury in fact prong.”). As is apparent from our description above, Plaintiffs’ stake in the legal issues is concrete rather than abstract. *Mitchell*, 330 U.S. at 89. Even in its present form, Plaintiffs’ suit is a concrete challenge to the 2003 Policy Guidance. Therefore, we hold that the ripeness requirement of Article III is satisfied.

However, that does not end the ripeness inquiry, for ripeness doctrine reflects both constitutional and prudential considerations. “The ripeness doctrine is ‘drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction.’ ” *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803, 808 (2003). The next part of the inquiry, to which we now turn, is whether Plaintiffs’ suit satisfies the prudential criteria for ripeness articulated in *Abbott Laboratories v. Gardner*.

B. Prudential Ripeness

Plaintiffs allege three claims. First, they claim that the 2003 Policy Guidance should not have been issued without following the notice-and-comment procedure required by the APA, 5 U.S.C. § 553. Second, they claim that the prohibition in Title VI against discrimination based on national origin does not include a prohibition against discrimination based on limited English proficiency, and that the 2003 Policy Guidance therefore exceeds the authority delegated to the Secretary of HHS by Title VI. Third, they claim that the Policy Guidance infringes on their First Amendment rights.

As will appear, whether we should reach Plaintiffs’ second and third claims depends on whether we can decide their first claim. For the reasons that follow, we hold, under the criteria for prudential ripeness, that Plaintiffs’ first claim is not ripe.

Because it is not ripe, we do not reach their second and third claims. We therefore affirm the district court's dismissal of Plaintiffs' suit.

[10] The question of prudential ripeness “is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.” *Abbott Labs.*, 387 U.S. at 149; *see also Nat'l Park Hospitality Ass'n*, 538 U.S. at 808. “[A] regulation is not ordinarily considered the type of agency action ‘ripe’ for judicial review under the APA until the scope of the controversy has been reduced to more manageable proportions, and its factual components fleshed out, by some concrete action applying the regulation to the claimant’s situation in a fashion that harms or threatens to harm him.” *Lujan*, 497 U.S. at 891.

1. Fitness of the Issue for Judicial Decision

[11] Plaintiffs’ first claim turns on whether the 2003 Policy Guidance is a substantive rule or a general statement of policy. Under the APA, a federal administrative agency is required to follow prescribed notice-and-comment procedures before promulgating substantive rules. *See* 5 U.S.C. § 553. However, notice-and-comment is not required prior to issuance of “interpretive rules, general statements of policy, or rules of agency organization, procedure or practice.” *Id.* § 553(b)(A). Plaintiffs contend that the 2003 Policy Guidance is a substantive rule. Defendants contend that it is a “general statement of policy” and thus not subject to the notice-and-comment requirement. Defendants do not contend that the Guidance Policy is an “interpretive rule.”

In *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006 (9th Cir. 1987), we distinguished a substantive rule from a general statement of policy:

The critical factor to determine whether a directive announcing a new policy constitutes a rule or a gen-

eral statement of policy is “the extent to which the challenged [directive] leaves the agency, or its implementing official free to exercise discretion to follow, or not to follow, the [announced] policy in an individual case

To the extent that the directive merely provides *guidance* to agency officials in exercising their discretionary power while preserving their flexibility and their opportunity to make “individualized determination[s],” it constitutes a general statement of policy In contrast, to the extent that the directive “narrowly limits administrative discretion” or establishes a “*binding norm*” that “so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule’s criterion,” it effectively replaces agency discretion with a new “binding rule of substantial law.”

Id. at 1013-14 (emphasis in original); *see also Municipality of Anchorage v. United States*, 980 F.2d 1320, 1324-25 (9th Cir. 1992).

The D.C. Circuit distinguishes a substantive rule from a general statement of policy in much the same way. In *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317 (D.C. Cir. 1988), that court wrote:

A policy statement is one that first, does not have “a present-day binding effect,” that is, it does not “impose any rights and obligations,” and second, “genuinely leaves the agency and its decision-makers free to exercise discretion.” . . . The question for purposes of § 533 is whether a statement is a rule of present binding effect; the answer depends on whether the statement constrains the agency’s discretion.

3500

COLWELL v. HHS

Id. at 1320; *see also* *Cement Kiln Recycling Coal. v. Env'tl. Prot. Agency*, 493 F.3d 207, 226-27 (D.C. Cir. 2007) (applying the distinction articulated in *McLouth Steel* to the analogous issue under the Resource Conservation and Recovery Act).

The 2003 Policy Guidance purports to be a general statement of policy not subject to the APA's notice-and-comment requirement. On its first page, it provides, "It has been determined that this revised HHS LEP Guidance does not constitute a regulation subject to the rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. § 553." Policy Guidance, 68 Fed. Reg. at 47,311. However, we need not accept an agency's characterization "at face value." *Hemp Indus. Ass'n v. Drug Enforcement Admin.*, 333 F.3d 1082, 1087 (9th Cir. 2003).

[12] Plaintiffs contend that the Policy Guidance imposes obligations on them and limits the discretion of HHS to such a degree that it constitutes a binding norm of substantive law. If Plaintiffs are correct, notice and comment were required under § 553. Defendants, on the other hand, contend that the Policy Guidance is mere guidance to HHS in the exercise of its discretion and has no binding effect. If Defendants are correct, notice and comment were not required. Neither position is entirely borne out by the text of the 2003 Policy Guidance. As we read the Policy Guidance, it is ambiguous.

Much of the Policy Guidance is written in non-mandatory terms. It begins by stating that "failure of a recipient of Federal financial assistance from HHS 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." Guidance, 68 Fed. Reg. at 47,313 (emphasis added). It then states that the "purpose of this policy guidance is to *assist* recipients in fulfilling their responsibilities to provide meaningful access to LEP persons under existing law" and that the "policy guid-

ance *clarifies* existing legal requirements for LEP persons by providing a description of the factors recipients should consider in fulfilling their responsibilities to LEP persons.” *Id.* (emphasis added). A footnote immediately thereafter adds the following:

The policy guidance is not a regulation but rather a guide. Title VI and its implementing regulations require that recipients take reasonable steps to ensure meaningful access by LEP persons. This guidance 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 (emphasis added).

[13] The Policy Guidance is riddled with words and phrases that, if read alone, would indicate that the guidance is not mandatory and that it imposes no new obligations — “suggest,” “should,” “encouraged,” “may be helpful,” and “clarifies.” *See, e.g., id.* at 47,314 (“As indicated above, the intent of this guidance is to *suggest* a balance that ensures meaningful access by LEP persons to critical services while not imposing undue burdens on small business, small local government, or small nonprofits.”) (emphasis added); *id.* (“The correct mix *should* be based on what is both necessary and reasonable in light of the four-factor analysis.”) (emphasis added); *id.* at 47,315 (“Recipients have substantial flexibility in determining the appropriate mix.”); *id.* (“[T]he use of certified interpreters is strongly *encouraged*.”) (emphasis added); *id.* at 47,720 (“For the recipient who decides to develop a written implementation plan, the following five steps *may be helpful* in designing such a plan; they are typically part of effective implementation plans.”) (emphasis

added); *id.* at 47,322 (in the Q & A section noting that the guidance document “[c]larifies that failure to take one or more of these steps does not necessarily mean noncompliance with Title VI”) (emphasis added).

[14] On the other hand, the Policy Guidance contains a great deal of language suggesting that its directions are mandatory. For example, in the Appendix to the Policy Guidance, a Question and Answer provide: “Q. Does the guidance impose new *requirements* on recipients? A. No This guidance synthesizes the *legal requirements that [the Office of Civil Rights of HHS] has been enforcing* for over three decades.” *Id.* at 47,322 (emphasis added). Earlier in the Policy Guidance, immediately after the notation that recipients “should” consider the four factors, the Policy Guidance states that the four factors “are the same criteria HHS *will* use in evaluating whether recipients are in compliance with Title VI and the Title VI regulations.” *Id.* at 47,313 (emphasis added). The Policy Guidance also states that “a recipient *may not* require an LEP person to use a family member or friend as an interpreter.” *Id.* at 47,317 (emphasis added); *see id.* at 47,323. It goes on to note that “quality and accuracy of [language] services is critical to avoid serious consequences to the LEP person and to the recipient.” *Id.* at 47,316.

Other provisions in the Policy Guidance also suggest that they are mandatory. *See id.* at 47,314 (the guidance document notes that “[w]hile designed to be a flexible and fact-dependant standard, the *starting point is* an individualized assessment that balances” the factors contained in the four-factor balancing test) (emphasis added); *id.* at 47,315 (“[Q]uality and accuracy of language services is nonetheless part of the *appropriate mix of LEP services required.*”) (emphasis added); *id.* at 47,319 (“[T]he extent of the recipient’s *obligation* to provide written translations of documents *should be determined by* the recipient on a case-by-case basis, looking at the totality of the circumstances *in light of* the four-factor analysis.”) (emphasis added); *id.* at 47,322 (in the Q &

A section noting that “OCR will determine compliance on a case by case basis, in light of” the four-factor balancing test) (emphasis added); *id.* at 47,322-23 (“Some large documents may contain no vital information, and others will contain vital information that will have to be translated. Again, the obligation to translate will depend on application of the four factors.”) (emphasis added).

Finally, Plaintiffs point out that the Policy Guidance contains a safe harbor provision. *Id.* at 47,319. The Policy Guidance notes that a “‘safe harbor’ means that if a recipient provides written translations under these circumstances, such action will be considered strong evidence of compliance with the recipient’s obligations.” It goes on to state that the “safe harbor provisions apply to the translation of written documents,” and that the safe harbor provisions therefore “do not affect the requirement to provide oral interpreters where an application of the four factor test leads to the determination that oral language services are needed and are reasonable.” *Id.* (emphasis added). Because one can ensure that one is in compliance by using the safe harbor, the existence of the safe harbor implies there are obligations for which compliance is mandatory. *See Gen. Elec. Co. v. Env’tl. Prot. Agency*, 290 F.3d 377, 384 (D.C. Cir. 2002). That argument, however, is not applicable in this case because any requirement of written translation is mandated not by the 2003 Policy Guidance, but rather by the 1976 DOJ regulation promulgated after notice and comment. *See* 28 C.F.R. § 42.405(d)(1). Plaintiffs do not challenge that regulation in this suit. As for oral translations, as to which the Policy Guidance arguably provides new requirements, the safe harbor provision, by its own terms, does not apply. Guidance, 68 Fed. Reg. at 47,319. Thus, the presence of the safe harbor provision does not imply that the Policy Guidance provides binding norms that HHS must follow.

In *Toilet Goods Association, Inc. v. Gardner*, 387 U.S. 158 (1967), the Court applied the two-part prudential ripeness test

3504

COLWELL v. HHS

it had articulated the same day in *Abbott Laboratories*. Plaintiff in *Toilet Goods Association* was an association of cosmetics manufacturers and distributors that brought a pre-enforcement challenge to regulations promulgated under the Federal Food, Drug, and Cosmetic Act. Plaintiff in *Toilet Goods Association* alleged that the regulations exceeded the authority granted under the Act. The Court held that promulgation of the regulations was final agency action within the meaning of the APA and that plaintiff's suit was a case or controversy under Article III. But the Court nonetheless held the suit unripe as a prudential matter. The regulations allowed inspection of manufacturing premises but were unclear in important respects.

The Court wrote:

At this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order. The statutory authority asserted for the regulation is the power to promulgate regulations 'for the efficient enforcement' of the Act, § 701(a). Whether the regulation is justified thus depends not only, as petitioners appear to suggest, on whether Congress refused to include a specific section of the Act authorizing such inspections, although this factor is to be sure a highly relevant one, but also on whether the statutory scheme as a whole justified promulgation of the regulation. . . . This will depend not merely on an inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets We believe that judicial appraisal of these factors is likely to stand on a much surer footing in the context of a specific application of this regulation than could be the case

in the framework of the generalized challenge made here.

Id. at 163-64. The Court's analysis in *Toilet Goods Association* strongly suggests that we should hold Plaintiffs' suit unripe because of the ambiguity in the Policy Guidance, and because of the likelihood that this ambiguity will be reduced or resolved based on the enforcement activities HHS may undertake in the future.

A case from our own circuit suggests even more strongly that we should hold Plaintiffs' suit unripe. In *Municipality of Anchorage*, the question was precisely the same as in our case, and the facts were remarkably similar. 980 F.2d at 1320. Plaintiffs contended that a Memorandum of Agreement ("MOA") between the Environmental Protection Agency and the Army Corps of Engineers was a substantive rule subject to the APA's notice and comment requirement. *See* 5 U.S.C. § 553. Defendants, on the other hand, contended that the MOA was a general policy statement not subject to the requirement. Plaintiffs pointed to seemingly mandatory language in the MOA. *See, e.g., Municipality of Anchorage*, 980 F.2d at 1324 ("Plaintiffs point to language in the MOA stating that it 'must be adhered to' and that it 'will [be] use[d] . . . when making . . . determination[s] of compliance with the Guidelines'") (emphasis and alterations in original). Defendants pointed to language in the MOA suggesting that the document contained no more than discretionary policy guidance. *See, e.g., id.* ("[Defendants] direct our attention to the following excerpt from the MOA: 'This MOA . . . is written to provide guidance for agency field personnel The MOA does not change the substantive requirements of the Guidelines. It is intended to provide guidance regarding the exercise of discretion under the Guidelines.'" (emphasis in original)).

We held the suit unripe under the prudential ripeness criteria of *Abbott Laboratories*. We wrote:

3506

COLWELL v. HHS

Examining the language of the MOA, it is not at all clear that the EPA and the Corps intend to be bound by the document. On the other hand, one cannot state without reservation that the agencies do not intend to be bound. The MOA seems to send mixed messages as to the binding intent of the agencies in its adoption. In a situation such as this, we are convinced that the better course is to withhold court review Thus, we conclude that only agency action under the MOA “can make the issue determinable and thus fit for review.” . . . It is clear to this court that the judicial process will clearly gain by waiting for a concrete application of the MOA.

Id. at 1325.

[15] We therefore conclude in the case before us that the issue is not now fit for decision. If and when the parties are able to provide examples of the manner in which the HHS has used the Policy Guidance — as, for example, in an enforcement proceeding against one of them — we will be in a better position to determine whether the 2003 Policy Guidance functions as a substantive rule or as a general statement of policy. If and when the case is presented to us in that posture, we will be able “to stand on a much surer footing.” *Toilet Goods Ass’n*, 387 U.S. at 164.

2. Hardship to the Parties of Withholding Court Consideration

[16] Plaintiffs contend that they will suffer hardship if we do not decide their suit in its current posture. Hardship in this context “does not mean just anything that makes life harder; it means hardship of a legal kind, or something that imposes a significant practical harm upon the plaintiff.” *Natural Res. Def. Council v. Abraham*, 388 F.3d 701, 706 (9th Cir. 2004). “The rule in *Abbott Laboratories* has been carefully circumscribed to regulations that pose an immediate dilemma.”

Ass'n of Am. Med. Colls. v. United States, 217 F.3d 770, 783 (9th Cir. 2000). Plaintiffs must show that postponing review imposes a hardship on them “that is immediate, direct, and significant.” *Municipality of Anchorage*, 980 F.2d at 1326.

[17] Plaintiffs contend that if they cannot pursue a pre-enforcement challenge to the 2003 Policy Guidance they will be exposed to liability under both federal law and state malpractice law. However, Plaintiffs acknowledge that HHS “has not threatened any direct action against” them. Nor do Plaintiffs allege that HHS has requested that they comply with the Policy Guidance. Moreover, under Title VI’s regulatory framework, Plaintiffs are several steps removed from any termination of their federal funding. *See* 45 C.F.R. §§ 80.7(d)(1), 80.8(d). Before Plaintiffs’ Title VI funding can be terminated there must be an effort to achieve informal or voluntary compliance, an administrative hearing, and notice to congressional committees. Judicial review is available in an Article III court of any funding termination. If HHS initiates compliance proceedings against Plaintiffs based on the 2003 Policy Guidance, Plaintiffs will have an opportunity to challenge the Policy Guidance on the same legal bases on which it relies in the suit now before us. *Cf. Croplife Am. v. Env’tl. Prot. Agency*, 329 F.3d 876, 882 (D.C. Cir. 2003) (“In this case, by contrast, EPA has enacted a firm rule with legal consequences that are binding on both petitioners and the agency, and petitioners will be afforded no additional opportunity to make the arguments to the agency that they now present in this petition.”).

[18] Finally, there is no indication that Plaintiffs may be subject to any fines by HHS or to financial liability to private parties. The regulations do not contemplate any kind of financial sanction other than termination of federal funding. *See* 45 C.F.R. § 80.8; *Gebser v. Lago Vista Ind. Sch. Dist.*, 524 U.S. 274, 288-89 (1998) (describing administrative enforcement provisions of Title IX, which are nearly identical to those of Title VI, and stating that “the regulations do not appear to

contemplate a condition ordering payment of monetary damages”). Plaintiffs are not potentially liable to their LEP patients under Title VI, for the Supreme Court has held that there is no private right of action for disparate impact discrimination under Title VI. *See Alexander v. Sandoval*, 532 U.S. 275, 285 (2001); *see also Barnes v. Gorman*, 536 U.S. 181 (2000) (no punitive damages under Title VI). Plaintiffs’ suggestion that they could be subjected to malpractice liability, is entirely speculative and would depend on state law that they have neither presented nor explained in this suit.

[19] We agree with Plaintiffs that they may be affected by the 2003 Policy Guidance, for they have alleged that they are spending money on language assistance and have altered their conduct as a result of the 2003 Policy Guidance. However, this hardship is insufficient to overcome the uncertainty of the legal issue presented in the case in its current posture. “Simply stated, plaintiffs have failed to demonstrate any hardship that outweighs our and the agencies’ interest in delaying review.” *Municipality of Anchorage*, 980 F.2d at 1326.

[20] Since Plaintiffs’ first claim is not ripe, we think it inadvisable to proceed to their second and third claims. The questions presented in those claims are potentially difficult, and we do not wish to decide them unnecessarily or on an undeveloped record. If and when Plaintiffs’ first claim becomes ripe, a court will be able to decide whether the 2003 Policy Guidance is invalid because it was not issued after notice and comment. If the Policy Guidance is invalid, Plaintiffs’ second and third claims will become moot. Further, many of the considerations that counsel against deciding the first claim at this juncture under the prudential ripeness criteria apply as well to the second and third claims. Most prominently, if we were to decide Plaintiffs’ second and third claims now, we would do so without knowing the manner in which HHS will apply the 2003 Policy Guidance. The manner of enforcement might make an important difference to the merits of Plaintiffs’ second claim, and would certainly make

such a difference to the merits of their third claim. Also, and critically, the hardship considerations we have just surveyed apply equally to the second and third claims, so there is no imperative to proceed now. We therefore apply the prudential ripeness doctrine to the case as a whole and decline to proceed on the current record.

Conclusion

We hold under Article III that Plaintiffs have standing to bring their pre-enforcement challenge to the 2003 Policy Guidance, and that their suit is ripe. However, we hold under the criteria for prudential ripeness articulated by the Supreme Court in *Abbott Laboratories*, that Plaintiffs' first claim is not ripe. Because Plaintiffs' first claim is not ripe, we do not reach their second and third claims. We affirm the judgment of the district court dismissing the suit.

AFFIRMED.