

1 SHARON L. BROWNE, No. 119246
2 ARTHUR B. MARK III, No. 220865
3 Pacific Legal Foundation
3900 Lennane Drive, Suite 200
4 Sacramento, California 95834
Telephone: (916) 419-7111
Facsimile: (916) 419-7747

5 Attorneys for Plaintiffs

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7
8 IN THE UNITED STATES DISTRICT COURT
9 FOR THE SOUTHERN DISTRICT OF CALIFORNIA
10

11 CLIFFORD W. COLWELL, JR., M.D.; JOHN)
12 BROFMAN, M.D.; CHRISTOPHER B. COLWELL,)
13 M.D.; PAUL C. LEHMULLER, M.D.; LYNN I.)
DeMARCO, M.D.; PROENGLISH, a nonprofit)
14 organization; and THE ASSOCIATION OF)
AMERICAN PHYSICIANS & SURGEONS, a)
nonprofit organization,)

15 Plaintiffs,)

16 v.)

17 UNITED STATES DEPARTMENT OF HEALTH)
AND HUMAN SERVICES; and TOMMY G.)
18 THOMPSON, Secretary of the United States)
Department of Health and Human Services, in his)
19 official capacity,)

20 Defendants.)
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No. 04CV1748

**REPLY IN SUPPORT OF
PLAINTIFFS' MOTION FOR
PRELIMINARY INJUNCTION**

Judge: Hon. Barry T. Moskowitz
Date: October 29, 2004
Time: 11:00 a.m.
Place: Courtroom 15, 5th Floor

**NO ORAL ARGUMENT UNLESS
REQUESTED BY THE COURT**

PACIFIC LEGAL FOUNDATION
3900 Lennane Drive, Suite 200
Sacramento, CA 95834
(916) 419-7111 FAX (916) 419-7747

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
I. PLAINTIFFS HAVE A STRONG PROBABILITY OF SUCCESS ON THE MERITS	1
A. HHS’s Language Rule Violates the Administrative Procedure Act	1
1. The Language Rule Is Not a “General Statement of Policy”	1
2. HHS’s Language Rule Is Not An Interpretive Rule	2
3. Considering Comments as a Matter of Grace Does Not Cure HHS’s APA Violation	4
B. HHS Has No Authority to Equate Language with National Origin	4
C. HHS’s Language Rule Violates the First Amendment	5
1. The Language Rule Is an Impermissible Content Regulation	5
2. The Language Rule Is Not Narrowly Tailored	7
3. The Language Rule Is Unconstitutionally Overbroad	7
4. The Language Rule Is Unconstitutionally Vague	8
II. PLAINTIFFS HAVE SHOWN THE POSSIBILITY OF IRREPARABLE INJURY	8
III. NO BOND SHOULD BE REQUIRED	10
CONCLUSION	10

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3900 Lennane Drive, Suite 200
Sacramento, CA 95834
(916) 419-7111 FAX (916) 419-7747

TABLE OF AUTHORITIES

	Page
Cases	
<i>Am. Mining Cong. v. Mine Safety & Health Admin.</i> , 995 F.2d 1106 (D.C. Cir. 1993)	2
<i>Cnty. Nutrition Inst. v. Young</i> , 818 F.2d 943 (D.C. Cir. 1987)	3
<i>Conn. Gen. Life Ins. Co. v. New Images of Beverly Hills</i> , 321 F.3d 878 (9th Cir. 2003)	8
<i>Elrod v. Burns</i> , 427 U.S. 347 (1976)	10
<i>Erringer v. Thompson</i> , 371 F.3d 625 (9th Cir. 2004)	2
<i>Gorbach v. Reno</i> , 219 F.3d 1087 (9th Cir. 2000)	10
<i>Hemp Indus. Ass’n. v. DEA</i> , 333 F.3d 1082 (9th Cir. 2003)	3
<i>La.-Pac. Corp. v. Block</i> , 694 F.2d 1205 (9th Cir. 1982)	3
<i>Mada-Luna v. Fitzpatrick</i> , 813 F.2d 1006 (9th Cir. 1987)	1
<i>McLouth Steel Products Corp. v. Thomas</i> , 838 F.2d 1317 (D.C. Cir. 1988)	4
<i>Nunez v. City of San Diego</i> , 114 F.3d 935 (9th Cir. 1997)	8
<i>Ross-Whitney Corp. v. Smith Kline & French Laboratories</i> , 207 F.2d 190 (9th Cir. 1953)	4
<i>Rust v. Sullivan</i> , 500 U.S. 173 (1991)	6-7
<i>San Diego Air Sports Ctr., Inc. v. FAA</i> , 887 F.2d 966 (9th Cir. 1989)	4
<i>Ward v. Rock Against Racism</i> , 491 U.S. 781 (1989)	8
<i>Williams v. San Francisco Unified Sch. Dist.</i> , 340 F. Supp. 438 (N.D. Cal. 1972)	4
Federal Constitution	
U.S. Const. amend. I	5, 9-10
Federal Statutes	
5 U.S.C. § 553	1
42 U.S.C. § 2000d-1	4
Federal Rule & Regulations	
Fed. R. Civ. P. 65(c)	10
28 C.F.R. § 42.405(d)(1)	5

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Sacramento, CA 95834
(916) 419-7111 FAX (916) 419-7747

1		Page
2	45 C.F.R. § 80.3	3-5
3		
	Miscellaneous	
4	Anthony, Robert A., “Interpretive” Rules, “Legislative” Rules and “Spurious” Rules: Lifting the Smog, 8 Admin. L.J. Am. U. 1 (1994)	2
5		
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7		
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1 Plaintiffs submit the following points and authorities in reply to Defendants' opposition to
2 Plaintiffs' motion for preliminary injunction.

3 I

4 **PLAINTIFFS HAVE A STRONG**
5 **PROBABILITY OF SUCCESS ON THE MERITS**

6 **A. HHS's Language Rule Violates the Administrative Procedure Act**

7 **1. The Language Rule Is Not a "General Statement of Policy"**

8 HHS's Guidance to Federal Financial Assistance Recipient (Language Rule) at issue here,
9 is not a "general statement of policy" as Defendants contend. Defendants' Memorandum of Points
10 and Authorities in Opposition to Plaintiffs' Motion for a Preliminary Injunction (Defs' Mem.) at 8:1-
11 11:9. The Language Rule establishes a binding norm, the four-factor compliance model, which
12 HHS must use. Plaintiffs' Memorandum of Points and Authorities in Support of Plaintiffs' Motion
13 for a Preliminary Injunction (Pltfs' Mem.) at 10:21-20:10. The authority Defendants cite is not to
14 the contrary. *See* Defs' Mem. at 8:3-27.

15 In *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1014 (9th Cir. 1987), the Court stressed that
16 where a rule establishes a binding norm, it is subject to 5 U.S.C. § 553. Unlike the Language Rule
17 which mandates the regulated community to take specific actions; the rule challenged in *Fitzpatrick*
18 only applied to the district director of the Immigration and Naturalization Service. *Fitzpatrick*, 813
19 F.2d at 1008, n.1. The court found the rule was a general statement of policy because it did not
20 announce any standards governing the regulated community, but only how INS was to adjudicate
21 a particular deportation rule. *Id.*

22 By contrast, HHS's Language Rule expressly applies to all recipients of HHS federal funds,
23 including physicians who receive no funds directly, but are employed by an entity that receives
24 federal funds. Pltfs' Mem., Exh. 1 at 6-7. The binding norm is the four-part model: HHS's
25 "starting point [in] an individualized assessment that balances the following four-factors." Pltfs'
26 Mem., Exh. 1 at 8. Defendants fail to refute the plain commands from the Department of Justice
27 that the four-factor model is mandatory and no deviation is permitted without the DOJ's approval.
28 Pltfs' Mem., Exh. 6 at 118; Exh. 7 at 123; Exhs. 11-12; Pltfs' Mem. at 13:5-15:9. While the four-

1 factor model itself is vague (indeed unconstitutionally so), the fact remains that it is a binding
2 standard HHS has established for determining compliance with its Language Rule. Because the
3 four-factor model is the criteria used by HHS to determine compliance, it is a binding norm and the
4 type of rule that must be issued pursuant to the notice and comment provisions of the APA. Pltfs'
5 Mem. at 15:10-16:12.

6 **2. HHS's Language Rule Is Not An Interpretive Rule**

7 Defendants contend that the Language Rule "does not have the force of law" and is an
8 interpretive rule. Defs' Mem. at 6:1-7:27. Ignoring to the broad legal authority and detailed
9 examination of both the current version of the Language Rule and its regulatory history provided
10 by Plaintiffs, Defendants rely on one case, *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004).

11 *Erringer* applies the same basic rule that is used in D.C. Circuit cases cited by Plaintiffs in
12 support of their arguments that the Language Rule is a spurious rule. *See* Pltfs' Mem., at 7:2-16:12.
13 *Erringer* applies three factors to determine whether a rule is interpretive or requires notice and
14 comment: "(1) when, in the absence of the rule, there would not be an adequate legislative basis
15 for enforcement action; (2) when the agency has explicitly invoked its general legislative authority;
16 or (3) when the rule effectively amends a prior legislative rule." *See Erringer*, 371 F.3d at 630
17 (relying on *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993).
18 This inquiry is in accord with the cases relied on by Plaintiffs: "whether the purported interpretive
19 rule has 'legal effect.'" *Am. Mining*, 995 F.2d at 1112. *See Erringer*, 317 F.3d at 630 (discussing
20 *Am. Mining's* basic inquiry as whether the challenged agency rule has the "force of law.") *Am.*
21 *Mining* uses "the term 'legal effect' to mean 'practical binding effect' rather than a legally binding
22 effect, which a nonlegislatively issued document [such as the Language Rule] by definition cannot
23 possess." Robert A. Anthony, "Interpretive" Rules, "Legislative" Rules and "Spurious" Rules:
24 Lifting the Smog, 8 Admin. L.J. Am. U. 1, 20 (1994). The *Am. Mining/Erringer* categories add
25 nothing to the basic inquiry. *Id.* Indeed, the three factors are simply alternative ways of asking
26 whether the rule has the force of law, and "[i]f the answer to any of these questions is affirmative,
27 we have a legislative, not an interpretive rule." *Am. Mining*, 995 F.2d at 1112. Thus, Ninth Circuit
28 cases and D.C. Circuit cases are in accord.

1 First, Title VI and HHS's Title VI regulation, 45 C.F.R. § 80.3 are not an "adequate
2 legislative basis" for the Language Rule. *Cf.* Defs' Mem. at 6:17-27. Defendants fail to examine
3 the text or history of Title VI or 45 C.F.R. § 80.3 and cite no legal authority to counter Plaintiffs'
4 authority that Title VI and 45 C.F.R. § 80.3 simply do not equate language with national origin.
5 Pltfs' Mem. at 21:9-23:23. Nor, do they rebut Plaintiffs' evidence that as a matter of both legal and
6 scientific authority language is not, and has never been, a proxy for national origin. Pltfs' Mem. at
7 23:25-27:16. In light of this strong showing by Plaintiffs that language is not within the scope of
8 Title VI or 45 C.F.R. § 80.3, HHS's Language Rule lacks an adequate legislative basis.

9 Second, HHS's contention that its own treatment of the law is dispositive, Defs' Mem. at
10 7:1-2 is entitled to no weight. *Hemp Indus. Ass'n. v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003);
11 *La.-Pac. Corp. v. Block*, 694 F.2d 1205, 1210 (9th Cir. 1982). The dispositive question is whether
12 HHS treats the Language Rule as having a practical binding effect. Here, the Language Rule
13 mandates that physicians must provide professional language assistance to LEP persons to avoid
14 civil rights charges. Pltfs' Mem., Exhs. 1-4; Pltfs' Mem. at 7:1-10:19 (discussing and analyzing the
15 regulatory development of the Language Rule from 1998-present). To comply means hiring of
16 bilingual staff, staff interpreters, contract interpreters, and telephone translator lines. Pltfs' Mem.,
17 Exh. 1 at 15-18. Defendants offer no counter-evidence to Plaintiffs' supporting declarations that
18 the Language Rule imposes binding obligations on physicians and other federal funds recipients.
19 *See* Pltfs' Mem. at 10:14-19 (citing declarations of Jane M. Orient, M.D.; Clifford W. Colwell, Jr.
20 M.D.; Christopher Colwell, M.D., and John Brofman, M.D.). *See also* Pltfs' Mem., Exh. 16; Pltfs'
21 Mem. at 18:16-21; 19:1-20.

22 In addition, the Language Rule contains a safe harbor, which authoritatively indicates that
23 the Language Rule is treated as binding by HHS. *Cf.* Defs' Mem. at 9:26-10:9. A safe harbor does
24 not provide another standard for HHS federal funds recipients, instead it effectively binds HHS.
25 *See Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 948 (D.C. Cir. 1987) (finding "it would be
26 daunting indeed to try to convince a court that the agency could appropriately prosecute a
27 [regulated community member that abided by the agency's safe harbor provision]"). Claiming the
28 discretion to prosecute those falling within the safe harbor, smacks of unfairness.

1 **3. Considering Comments as a Matter of**
2 **Grace Does Not Cure HHS’s APA Violation**

3 HHS points out that it periodically invited “comments” on its Language Rule. Defs’ Mem.
4 at 3:2-6. To the extent Defendants raise this point to justify their failure to pass the Language Rule
5 via the APA’s notice and comment provisions, their reliance is misplaced. “Consideration of
6 comments as a matter of grace is not enough” to cure an agency’s failure to follow notice and
7 comment procedures. *McLouth Steel Products Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir.
8 1988). *See San Diego Air Sports Ctr., Inc. v. FAA*, 887 F.2d 966, 969 (9th Cir. 1989) (finding
9 principal purpose of the APA is to “provide that the legislative functions of administrative agencies
10 shall so far as possible be exercised *only upon* public participation”) (emphasis added). In this case,
11 the consideration of comments followed the implementation of the Language Rule, which was
12 effective upon its issuance, without public participation. Pltfs’ Mem., Exh. 3 at 73.

13 **B. HHS Has No Authority to Equate Language with National Origin**

14 Title VI and HHS’s implementing regulations limit Defendants’ authority to legislate with
15 respect to intentional discrimination based on race, sex, and national origin. Pltfs. Mem. at 20:14-
16 27:16. Defendants would have this Court believe that ‘national origin’ includes language, but fail
17 to cite even a single case to support their position and simply ignore the broad authority cited by
18 Plaintiffs to the contrary. Defs’ Mem. at 11:13-12:20.

19 Neither Title VI nor HHS’s implementing regulations have ever equated language with
20 national origin. 42 U.S.C. § 2000d-1; 45 C.F.R. § 80.3. Neither mention language, and as Plaintiffs’
21 un rebutted expert testimony demonstrates, language is not a proxy for national origin. *See* Glynn
22 Custred Decl. ¶¶ 8, 11-20; Pltfs. Mem. at 23:24-27:16. Thus, Dr. Custred’s declaration must be
23 taken as true and the Court should conclude that language is not, and has never been, a proxy for
24 national origin. *See Ross-Whitney Corp. v. Smith Kline & French Laboratories*, 207 F.2d 190, 198
25 (9th Cir. 1953) (finding grant of injunction proper where defendants failed to dispute basic facts in
26 Plaintiffs’ affidavits); *Williams v. San Francisco Unified Sch. Dist.*, 340 F. Supp. 438, 442 (N.D.
27 Cal. 1972) (undisputed affidavits taken as true).

28 ///

1 Defendants' reliance on 28 C.F.R. § 42.405(d)(1) is misplaced. *See* Defs' Mem. at 10:20-
2 11:3. That regulation is not even cited as authority by any version of the Language Rule and is
3 inapplicable here. *See* Pltfs' Mem., Exh. 1 at 2-3. Even if it could form a kind of shadow basis for
4 HHS's Language Rule, the Language Rule itself greatly exceeds the narrow language of 28 C.F.R.
5 § 42.405(d)(1).

6 First, the Language Rule applies to *all* LEP individuals a physician may encounter, not just
7 to those who happen to be part of the majority foreign language group in a recipient's service area.
8 HHS stresses that it was attempting to "ensure that federally assisted programs aimed at the
9 American public do not leave some behind simply because they face challenges communicating in
10 English." Pltfs' Mem., Exh. 1 at 5. "*Individuals* who do not speak English as their primary
11 language and who have a limited ability to read, write, speak or understand English may be limited
12 English proficient [LEP]." Pltfs' Mem., Exh. 1 at 7.

13 Second, the Language Rule applies beyond "written material . . . ordinarily distributed to
14 the public." 28 C.F.R. § 42.405(d)(1). It applies to all "vital written materials" which includes
15 documents reflecting information that is not "ordinarily public." For example, the Language Rule
16 counts as "vital" documents such as "consent and complaint forms, intake forms, [and] written
17 notices of eligibility criteria, rights, denial, loss or decrease in benefits or services, actions affecting
18 parental custody or child, and other hearings." Pltfs' Mem., Exh. 1 at 19.

19 Third, the Language Rule mandates that federal funds recipients provide free, professional
20 oral interpretation services for all LEP patients. *See* Pltfs' Mem. at 8:16-10:19 (demonstrating how
21 the Language Rule obligates physicians to contract for such services, regardless of whether any one
22 particular LEP person actually uses those services). Simply put, 28 C.F.R. § 42.405(d)(1), Title VI,
23 or 45 C.F.R. § 80.3, cannot be read to give a federal agency the authority to impose mandatory
24 language assistance requirements on federal funds recipients.

25 **C. HHS's Language Rule Violates the First Amendment**

26 **1. The Language Rule Is an Impermissible Content Regulation**

27 The Language Rule commands physicians to communicate a specific message and employ
28 methods of communications with patients not of the physician's choosing. Pltfs' Mem. at 28:6-

1 29:2. To contend that the Language Rule leaves physicians “free to speak in any manner of their
2 choosing” ignores the text and purpose of the Language Rule. *See* Defs’ Mem. at 13:17. The core
3 of the Language Rule is to compel physicians to communicate with LEP patients in the LEP’s
4 language. This is the preferred method of the United States government. Pltfs’ Mem. at 5:22-
5 20:10. Defendants admit this when they state that HHS “require[s] recipients to provide an
6 appropriate means of interpreting the message from the manner chosen by the recipients to one that
7 can be understood by LEP persons.” Defs’ Mem. at 13:18-20. This is another way of saying that
8 the government has mandated the language in which physicians are to communicate with their LEP
9 patients. As such, the Court should find the Language Rule unconstitutional.

10 Defendants’ claim that *Rust v. Sullivan*, 500 U.S. 173 (1991), insulates the Language Rule
11 from unconstitutionality. Defs’ Mem. at 13:21-14:8. In *Rust*, however, there was direct statutory
12 authority prohibiting the use of federal family planning funds for abortion. 500 U.S. at 178. The
13 regulations at issue implemented the government’s choice not to fund certain speech. *Id.* at 192-93.
14 The direct relationship between the federal funding and the speech restriction in *Rust* and the
15 narrowness of the statute and regulations argue against it controlling this case.

16 First, the federal government does not even provide funding for the language services
17 mandated by the Rule. Physicians are required to provide paid, professional language translation
18 and interpretation services free of charge and without reimbursement. Pltfs Mem. at 9:3-18;
19 Clifford Colwell Decl. ¶¶ 6, 11, 22-23; Brofman Decl. ¶ 8. Thus, to the extent *Rust* can be read to
20 require a direct relationship between conditions on funds and the funds received, it does not apply
21 here.

22 Second, to the extent the federal funds physicians receive for providing Medicare and
23 Medicaid services require adherence to the Language Rule, the Language Rule controls far too
24 much speech to be constitutional. Government-funded projects cannot invariably use funding as a
25 condition to control speech. *Rust*, 500 U.S. at 199-200. Limiting its holding in *Rust*, the Court
26 stated: “It could be argued . . . that traditional relationships such as that between doctor and patient
27 should enjoy protection under the First Amendment from Government regulation, even when
28 subsidized by the Government. We need not resolve that question here, however, because the

1 Title X program regulations do not significantly impinge upon the doctor-patient relationship.”
2 500 U.S. at 200.

3 In contrast to *Rust*, the Language Rule significantly impinges upon the physician-patient
4 relationship. Orient Decl. ¶ 7; Chris Colwell Decl. ¶¶ 4-12; Brofman Decl. ¶ 7; Clifford Colwell
5 Decl. ¶¶ 11-20. Unlike the narrow restriction of *Rust*, here the Language Rule covers the entire
6 physician-patient relationship. Thus, to the extent the federal funds received require adherence to
7 the Language Rule, the government is unconstitutionally conditioning those funds on physicians’
8 forfeiting their right to speak in the language of their choice in practicing their profession. *See Rust*,
9 500 U.S. at 199-200 (suggesting broad government interference in physician-patient relationship
10 cannot be justified simply because the government subsidizes patient care).

11 **2. The Language Rule Is Not Narrowly Tailored**

12 Defendants attempt to portray the Language Rule as “narrowly tailored” ignores the very
13 test they cite: “narrow tailoring is satisfied so long as . . . the regulation promotes a substantial
14 government interest that would be achieved less effectively absent the regulation.” Defs’ Mem. at
15 14:21-23. Plaintiffs’ unrebutted evidence on this point shows that absent the Language Rule the
16 government’s interest in assuring accurate communication would be achieved *more* effectively
17 because the methods preferred by HHS are the ones doctors least prefer to employ with their LEP
18 patients. Pltfs’ Mem. at 29:16-30:4 (discussing the declarations of Doctors Colwell, DeMarco,
19 Orient, and Brofman). Thus, the Language is not “narrowly tailored.”

20 **3. The Language Rule Is Unconstitutionally Overbroad**

21 Defendants claim the four-factor model saves a regulation that they admit applies to
22 substantial amount of constitutionally protected speech. Defs’ Mem. 15:25-26 (“The Policy
23 Guidance does consider all communication a medical service provider who receives federal funding
24 makes to LEP patients.”). However, they ignore the fact that the Language Rule regulates all
25 speech a physician makes to an LEP patient, regardless of the four-factor model’s outcome. Pltfs’
26 Mem. at 5-16. No amount of case-by-case analysis excuses physicians from the mandate to speak
27 to LEP patients in the way the government directs. *See* Pltfs’ Mem., Exh. 1 at 11 (“Recipients have
28 two main ways to provide language services: oral interpretation . . . and written translation.”).

1 Plaintiffs demonstrate the possibility of irreparable injury on five fronts: (1) professional
2 reputation; (2) interference with patient-physician relationships; (3) unreasonable financial burden;
3 (4) increased liability for medical malpractice and (5) interference with First Amendment rights. Dr.
4 Jane Orient, on behalf of the physician members of the Association of American Physicians and
5 Surgeons (AAPS), as well as Dr. Clifford Colwell, testified that being branded a civil rights violator
6 by HHS in the course of investigation will do irreparable damage to physicians' good names. Orient
7 Decl. ¶ 13; Clifford Colwell Decl. ¶ 5, 7-8. This injury is not "speculative." HHS is regularly
8 enforcing the LEP Guidance nationwide. *See* Pltfs' Mem., Exh. 14 (HHS's OCR case summaries);
9 Orient Decl. ¶ 6. As physicians subject to the guidance, the individual Plaintiffs, and the
10 approximately 5,000 members of AAPS are threatened with this injury.

11 The interference with the patient-physician relationship and effective treatment by HHS's
12 Language Rule is occurring daily, as Plaintiffs' unrebutted evidence demonstrates. Pltfs' Mem. at
13 34:3-21 (citing Declarations of Clifford Colwell, M.D., Jane Orient, M.D., Lynn DeMarco, M.D.,
14 John Brofman, M.D., and Christopher Colwell, M.D.). These declarations all relate factually to how
15 HHS's Language Rule adversely affects the patient-physician relationship. Defendants fail to submit
16 any evidence rebutting these facts.

17 Increased financial liability is a burden imposed on Plaintiffs that Defendants cannot refute.
18 The Language Rule requires physicians to provide language services free of charge. Pltfs' Mem.,
19 Exh. 1 at 23-24; 30. Additional financial burden is imposed by the "competence" requirement of
20 the Language Rule. Pltfs' Mem. at 17:27-18:7. As Dr. Clifford Colwell states: "Lawsuits will be
21 filed under these rules, because they create a new standard of care for physicians. These suits will
22 allege that there was an adverse medical result from a translation failure, or from a physician's not
23 providing adequate translation." Clifford Colwell Decl. ¶ 25. This will cause malpractice premiums,
24 already high to rise even higher. *Id.* ¶ 26.

25 Defendants point out that defenses are available to physicians in malpractice actions. Defs'
26 Mem. at 20:14-27. In doing so, they misunderstand the gravamen of the injury to Plaintiffs.
27 Liability insurance costs rise, regardless of the merits of the lawsuits filed, because the lawsuit is

28 ///

1 filed and must be defended. No defense will change that fact, nor will it reduce the medical
2 insurance premiums once raised. Clifford Colwell Decl. ¶¶ 25-26.

3 Finally, Defendants do not dispute that even a minimal loss of First Amendment freedom
4 “unquestionably constitutes irreparable injury.” *Elrod v. Burns*, 427 U.S. 347, 373 (1976). The
5 threat to Plaintiffs’ and/or their members’ First Amendment freedoms comes from both the
6 Language Rule’s unconstitutional conditioning of federal funds, its vagueness, overbreadth, and its
7 lack of narrow tailoring. *See infra* at 5-8; Pltfs’ Mem. at 27:20-33:5 (discussing First Amendment
8 violations). In the face of Plaintiffs’ strong showing on the merits of their complaint, the possibility
9 of injury Plaintiffs face is sufficient for this Court to grant a preliminary injunction.

10 **III**

11 **NO BOND SHOULD BE REQUIRED**

12 Plaintiffs should not be required to post a bond in the absence of a showing by the
13 Defendants that they will suffer costs or damages due to an injunction. Fed. R. Civ. P. 65(c). *See*
14 *Gorbach v. Reno*, 219 F.3d 1087, 1091-92 (9th Cir. 2000) (finding bond not required under Rule 65
15 as government failed to show it would suffer costs or damages because of preliminary injunction
16 against immigration regulations).

17 **CONCLUSION**

18 For all the foregoing reasons Plaintiffs respectfully request this Court to grant their motion
19 for preliminary injunction.

20 DATED: October 21, 2004.

21 Respectfully submitted,

22 SHARON L. BROWNE
23 ARTHUR B. MARK III

24 By _____
25 ARTHUR B. MARK III

26 Attorneys for Plaintiffs
27
28

