No. 04-1084

IN THE Supreme Court of the United States

ALBERTO R. GONZALES, ATTORNEY GENERAL, ET AL.,

Petitioners,

v.

O CENTRO ESPIRITA BENEFICIENTE UNIAO DO VEGETAL,

ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

BRIEF OF DOUGLAS LAYCOCK AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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QUESTIONS PRESENTEDPRIVATE

1. Whether the courts below properly applied the law of preliminary injunctions with respect to burdens of proof and arguments about the status quo.

2. Whether the Religious Freedom Restoration Act permits government to prohibit religious use of hoasca if the government permits religious use of peyote and has not shown that religious use of the two drugs differs materially with respect to alleged health risks or alleged risks of diversion to recreational markets.

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INTEREST OF THE AMICUS

Amicus Douglas Laycock holds the Alice McKean Young Regents Chair in Law at The University of Texas at Austin. This case arises at the intersection of two fields to which I have devoted the bulk of my scholarly research for nearly thirty years -- the law of religious liberty (including the Religious Freedom Restoration Act (RFRA)) and the law of remedies (including injunctions).

My work on religious liberty may be known to the Court through numerous publications in the law reviews and numerous briefs in this Court on behalf of parties or amici. My work on injunctions is probably less familiar to the Court. I have written a leading casebook on remedies and a prize-winning monograph on injunctions.

This brief speaks in my own voice and offers expertise from both of my scholarly fields. First, I address the intersection of the law of preliminary injunctions with the Religious Freedom Restoration Act; the government's position threatens to do serious doctrinal harm to preliminary injunctions and to effectively delete key provisions of RFRA. Second, I address the relevance of the Congressionally enacted exemption for peyote, both to the RFRA claim on which certiorari was granted and to the Free Exercise Clause claim that is part of the case below.

SUMMARY OF ARGUMENT

The preliminary injunction is reviewable only for abuse of discretion, and the Court of Appeals' affirmance of the preliminary injunction is also entitled to deference.

The District Court properly allocated the burden of proof. The church was required to bear the burden of persuasion on seven issues: all four parts of the traditional standard for preliminary injunctions, including probability of success on the merits, plus all three elements of a prima facie case under the Tenth Circuit's interpretation of RFRA. The government bore the burden of proof only on its affirmative defenses of compelling interest and least restrictive means, a burden that Congress expressly allocated in RFRA.

The church carried its burden of proving probable success on the merits. If plaintiff shows that it can probably prove a prima facie case, and defendant fails to show that it can probably prove its affirmative defenses, it necessarily follows that plaintiff will probably succeed on the merits. The Court adopted this straightforward reasoning in *Ashcroft v. ACLU*, 542 U.S. 656 (2004), and in an analogous context in *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). The lower courts were generally in agreement even before *Ashcroft*. The allegedly contrary cases in the government's brief do not support the government's position.

Arguments about the status quo are irrelevant to this appeal. This Court has never held that preliminary injunctions changing the status quo should be held to anything like the Tenth Circuit's "heightened standard." It should not do so now. The central purpose of preliminary injunctions is to minimize irreparable injury that turns out to be legally unjustified. That purpose specifies the relationship among the four traditional factors. No version of a status quo test adds anything useful.

To the contrary, the status quo is a highly manipulable and contestable concept. It is an accurate *description* to say that preliminary injunctions usually preserve the status quo. But to make that a rule or a test invites litigants and judges into unproductive and unresolvable debates about when and how to define the status quo. All leading commentators reject tests based on the status quo. The Tenth Circuit's heightened standard should be disapproved. But note too that the Tenth Circuit applied its heightened standard, and that the church satisfied it.

The regulatory exception for religious use of peyote defeats the government's claims of compelling interest under RFRA. Religious use of peyote and of hoasca is highly similar, and the government did not prove any differences that support a compelling interest in banning one but not the other. The government's principal argument is the special political status of Indian tribes, but that status is irrelevant to the alleged health effects of hoasca and equally irrelevant to the alleged risk that hoasca will be diverted to recreational markets.

ARGUMENT

I

THE PRELIMINARY INJUNCTION IN THIS CASE IS FULLY CONSISTENT WITH THE LAW OF PRELIMINARY INJUNCTIONS. A

This Court Reviews Preliminary Injunctions for Abuse of Discretion.

This case is here on appeal from a preliminary injunction, issued by the District Court after a two-week hearing, affirmed by the Court of Appeals, and affirmed again by the Court of Appeals en banc. The District Court's fact-finding has also been affirmed by the Court of Appeals and by the Court of Appeals en banc.

The government seems to believe that because preliminary relief is often said to be exceptional, this Court should be more prone to reverse a preliminary injunction than a final judgment. The opposite is true: it is well settled that preliminary injunctions are reviewed for abuse of discretion. "[T]he standard of appellate review is simply whether the issuance of the injunction, in light of the applicable standard, constituted an abuse of discretion." *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931-32 (1975). "`This Court, like other appellate courts, has always applied the abuse of discretion standard on the review of a preliminary injunction.'" *Ashcroft v. ACLU*, 542 U.S. 656, 124 S.Ct. 2783, 2790 (2004) (quoting *Walters v. Nat'l Ass'n of Radiation Survivors*, 473 U.S. 305, 336 (O'Connor, J., concurring)). Moreover, in applying the abuse-of-discretion standard in this Court, "[t]he informed judgment of the Circuit Court of Appeals exercised upon a view of all relevant circumstances is entitled to great weight." *Meccano, Ltd. v. John Wanamaker*, 253 U.S. 136, 141 (1920).

This Court has also said that it reviews "the District Court's legal conclusions *de novo*, and its ultimate conclusion for abuse of discretion." *McCreary County v. ACLU*, 125 S.Ct. 2722, 2737 (2005). This distinction is sound, but it makes sense only with respect to discrete legal conclusions, cleanly presented for review and not embedded in preliminary fact finding or assessment of probabilities. "If the underlying constitutional question is close, therefore, we should uphold the injunction and remand for trial on the merits." *Ashcroft*, 124 S.Ct. at 2790-91 (2004).

B

The District Court Properly Allocated the Burden of Proof.

1. The Basic Reasoning. It is common ground that plaintiffs bear the burden of showing that a preliminary injunction should issue. One of the important factors relevant to whether a preliminary injunction should issue is probability of success on the merits. We may set aside

cases where a strong showing of irreparable injury and balance of harms excuses a weaker showing of probability of success; the church relies on no such theory here. In this case, the church undertook to show, and did show, a probability of success on the merits.

A preliminary determination of probability of success on the merits depends on predictions about what will happen at final adjudication, and thus necessarily depends on the rules applicable at final adjudication, including rules allocating the burden of proof. If plaintiffs carry the burden of showing that they can probably prove a prima facie case, so that defendants are forced to rely on an affirmative defense, *and* if it appears at preliminary hearing that defendants can not carry the burden of proving that affirmative defense, then it necessarily follows that plaintiffs will probably succeed on the merits. On such a set of facts, plaintiffs have carried their burden on the ultimate issue -- they have shown probable success on the merits. The affirmative defense is a subsidiary issue, one step en route to the ultimate determination of probable success. That the District Court properly allocated to defendants the burden of proving their affirmative defense does not mean that the District Court misallocated plaintiffs' ultimate burden of showing probable success on the merits.

The District Court understood each step in this reasoning, and got it exactly right. At the beginning of its opinion, and again at the end, the District Court clearly allocated to the church the burden of proof on all elements of the standard for preliminary injunctions:

"A movant is entitled to a preliminary injunction *if he can establish* the following: (1) a substantial likelihood of success on the merits of the case; (2) irreparable injury to the movant if the preliminary injunction is denied; (3) the threatened injury to the movant outweighs the injury to the other party under the preliminary injunction; and (4) the injunction is not adverse to the public interest."

Pet. App. 182a (emphasis added), quoting *Kikumura v. Hurley*, 242 F.3d 950, 955 (10th Cir. 2001). Later the court repeated that "parties seeking preliminary injunctions *must show*" these four elements of a preliminary injunction claim. *Id.* at 243a (emphasis added).

The principal contested issue at the preliminary injunction hearing went to probability of success on the merits. The District Court held that to make out a prima facie case, "plaintiff *must show*" three elements of a claim under the Religious Freedom Restoration Act: "(1) a substantial burden imposed by the federal government on a (2) sincere (3) exercise of religion." Pet. App. 207a (emphasis added), quoting *Kikumura v. Hurley*, 242 F.3d 950, 960 (10th Cir. 2001). The church carried this burden on all three elements; indeed, the government did not dispute the church's showing on any of these elements. Pet. App. 207a. The government's interpretation of the law would ban the central act of worship of a long-practiced religion; it is therefore no surprise that the case came to focus on the government's affirmative defenses of compelling interest and least restrictive means. "[T]he hearing began with the Government shouldering the weighty load thrust upon it by Congress in passing RFRA." *Id.*

The District Court concluded that the government had failed to prove any of its three alleged compelling interests. *Id.* at 227a, 236a, 242a-243a. The church having carried its burden on the prima facie case, and the government having failed to carry its burden on affirmative defenses, the church had carried the ultimate burden: "The Court has found that *the Plaintiffs have demonstrated* a substantial likelihood of success as to their RFRA claim." *Id.* at 243a (emphasis added).

The District Court also concluded that the church prevailed on the less vigorously contested issues of irreparable injury, balance of harms, and public interest. *Id.* at 244a. "This Court thus concludes that *the Plaintiffs have satisfied the requirements* for preliminary injunction as to their RFRA claim." *Id.* at 245a (emphasis added). At every step, the District Court was clear: the church bore the burden on all four elements of the preliminary injunction test and all three elements of a prima facie case under RFRA; government bore the burden only on its affirmative defenses.

This entirely proper allocation of burdens did not become improper just because the affirmative defenses were the principal contested issues. The hearing focused on affirmative defenses only because the church carried its burden on every other issue arising either under the standard for preliminary injunctions or the standard for a prima facie RFRA claim. The government, no doubt for good reasons, hung its case on the one set of issues where it bears the burden. Its failure to carry that burden does not mean that burdens were misallocated.

2. The Legal Authority. This straightforward reasoning is fully in accord with the cases. This Court addressed the very issue, in a strikingly similar context, in *Ashcroft v. ACLU*, 542 U.S. 656, 124 S.Ct. 2783 (2004). Plaintiffs there showed that the provisions they challenged were "content-based restrictions on speech," 124 S.Ct. at 2791, thus requiring "that the Government bear the burden of showing their constitutionality." *Id.* This allocation of the burden of persuasion on the merits necessarily affected the probability of success on the merits:

As the government bears the burden of proof on the ultimate question of COPA's [the challenged Act's] constitutionality, respondents must be deemed likely to prevail unless the Government has shown that respondents' proposed less restrictive alternatives are less effective than COPA.

Id. at 2791-92. "The Government having failed to carry its burden, it was not an abuse of discretion for the District Court to grant the preliminary injunction." *Id.* at 2793.

The government's attempt to distinguish *Ashcroft* misstates the reasoning of that case. The government says that the allocation of the burden of proof in *Ashcroft* "is just one of a number of special procedural rules required by the First Amendment for adjudicating constitutional free speech claims." Pet. Br. 13, citing a passage about the rule in free speech cases, 124 S.Ct.

at 2788, four pages away from the relevant passage about preliminary injunctions. The rule allocating the burden of proof "on the ultimate question," *id.* at 2791, is indeed a rule of free speech law. But the relevant rule here -- the rule set out in the block quote immediately above -- is a rule of preliminary injunction law: that if a case turns on affirmative defenses on which defendants bear the burden of proof, plaintiffs "must be deemed likely to prevail" unless defendants show that they will probably carry that burden. *Id.* at 2791-92.

In *Ashcroft*, the burden of proof was allocated by this Court's interpretation of the Constitution; here, the burden of proof was allocated by Congress. The Religious Freedom Restoration Act explicitly, and with unusual and emphatic attention to detail, places on government the burden of proving that the challenged application of federal law, on the facts of the individual case, serves a compelling interest by the least restrictive means. "Government may substantially burden a person's exercise of religion *only if it demonstrates* that application of the burden to the person" furthers a compelling interest by the least restrictive means. 42 U.S.C. '2000bb-1(b) (2000). And "demonstrates" is a defined term: "The term `demonstrates' means meets the burdens of going forward with the evidence and of persuasion." 42 U.S.C. '2000bb-2(3) (2000). Exactly as in *Ashcroft*, if the government probably cannot meet those burdens, then the church will probably succeed on the merits.

The government says that *Ashcroft* was a constitutional case and this is not. Pet. Br. 13. The government suggests no reason why that distinction should be relevant, and if anything, it cuts the other way. Constitutional cases are governed by some measure of deference to Congress and by a general presumption of constitutionality. In *Ashcroft*, that presumption was overcome by a showing of content discrimination in the challenged law. The resulting allocation of the burden of proof in *Ashcroft* is a judge-made rule, drawn from judicial precedent and experience in implementing the quite general language of the First Amendment, which certainly says nothing explicit about burdens of proof.

In this case, both sides rely on an Act of Congress; deference to Congress requires taking both statutes seriously and giving meaning to each within its scope. The presumption of constitutionality applies to both statutes, and neither side questions the constitutionality of either Act. One statute regulates drugs in rigorous but quite general terms; the other much more specifically addresses the question of conflicts between general laws and religious practice, enacting a standard for courts to apply and directing courts to base their decisions on the facts of individual cases. The burden of proof is allocated not by judicial inference, but by express statutory provision. There is nothing exceptional about the preliminary injunction rule in *Ashcroft*, but if there were, the policy of that exception would apply to this case a fortiori.

Ultimately, the relevant reasoning in *Ashcroft* depends not on the First Amendment, but on the straightforward logic of preliminary injunctions and the reality of trials: if plaintiffs can probably prove a prima facie case, and defendants probably can not prove an affirmative defense, then plaintiffs will probably succeed on the merits.

This Court applied the same reasoning, at greater length, in the analogous context of motions for summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). A motion for preliminary injunction requires a prediction of whether one side is *likely* to succeed; a motion for summary judgment requires a prediction of whether one side might *possibly* succeed. Either prediction "must be guided by the substantive evidentiary standards that apply to the case." *Id.* at 255. "It makes no sense to say that a jury could reasonably find for either party without some benchmark as to what standards govern its deliberations." *Id.* at 254-55. It makes no more sense to say that one party is likely to succeed apart from the standard that will guide that determination. These standards "are in fact provided by the applicable evidentiary standards." *Id.* at 255.

Anderson is best known for holding that in a defamation case, a plaintiff's evidence in opposition to a motion for summary judgment must be assessed in light of the standard of clear-and-convincing evidence applicable at trial. *Id.* at 252-56. That holding is analogous here. But *Anderson* also addressed a burden-of-proof issue. "The movant has the burden of showing that there is no genuine issue of fact, but the plaintiff is not thereby relieved of his own burden of producing in turn evidence that would support a jury verdict." *Id.* at 256. Similarly here, the church has the burden of showing probability of success on the merits, but the government is not thereby relieved of its own burden of showing probability of success on an affirmative defense that is central to its case.

3. The Lower Court Cases. *Ashcroft* and *Anderson* are clearly controlling on this issue, so lower court cases are of little moment. But the government's string cite of lower court cases, Pet. Br. 12 n.4, cannot be allowed to pass without comment.

The government purports to cite six cases (plus a *see also* case) for the proposition that a "preliminary injunction movant must disprove affirmative defense"). Two of these cases give far more support to the church than to the government. Two are at most ambiguous with respect to the critical distinction between the burden of proving probable success, which plaintiffs bear, and the burden of disproving affirmative defenses, which plaintiffs do not bear. Three say nothing about the burden of proof on affirmative defenses.

Suntrust Bank v. Houghton Mifflin Co., 268 F.3d 1257, 1275 n.31 (11th Cir. 2001), says only that plaintiff bears the burden "to demonstrate the likelihood of success on the merits," including, where a fair use defense is presented, "that the fair use factors are *insufficient to support* such a defense." *Id.* (emphasis added). This formulation is entirely consistent with the church's position; plaintiff was required to show only that the fair use factors were insufficient to carry defendant's burden.

Atari Games Corp. v. Nintendo Inc., 975 F.2d 832, 837 (Fed. Cir. 1992), also supports the church instead of the government. The opinion says that plaintiff must show "a likelihood that it will overcome Atari's copyright misuse defense," *id.*, but this is immediately followed by a

statement that the "entitlement to preliminary injunction `is determined in the context of presumptions and burdens that inhere at trial on the merits," quoting *H.H. Robertson Co. v. United Steel Deck*, 820 F.2d 384, 388-89 (Fed Cir. 1987). Reliance on "the burdens that inhere at trial" is precisely the church's position. The only word in the opinion that gives any color to the government's citation is "overcome." But unlike "burdens," "overcome" has no settled meaning in the law of burden of proof. Plaintiff may overcome a defense by disproving the defense, or by proving a reply that overrides or negates the defense, *or* by simply preventing defendant from proving the defense. Plaintiff may "overcome" a defense by cross-examination or argument, including argument emphasizing defendant's burden of prevasion or failure to prove an essential element of the defense, without offering any evidence of his own.

DSC Communications Corp. v. DGI Technologies, Inc., 81 F.3d 597, 600 (5th Cir. 1996), says only that plaintiff "will have to overcome DGI's affirmative defenses." *Id.* "Overcome" has the same ambiguities here as in *Atari.* On the facts, defendant appears to have carried its burden of proving a probable affirmative defense.

Coastal Fuels, Inc. v. Caribbean Petroleum Corp., 990 F.2d 25, 27 (1st Cir. 1993), merely quoted *Atari's* statement about overcoming defenses, without noting *Atari's* clarification that this was to be "determined in the context of presumptions and burdens that inhere at trial." "Overcome" has the ambiguities already noted. A "*[b]ut cf.*" citation to *Dallas Cowboys Cheerleaders, Inc. v. Scoreboard Posters, Inc.*, 600 F.2d 1184, 1188 (5th Cir. 1979), suggests that the court might have understood "overcome" to mean something like what the government wants it to mean. This uncertain inference from a cryptic citation is the strongest point for the government in any of the seven cases in its footnote. But the opinion in *Coastal Fuels* did not clearly distinguish the burden of proving probability of success from the burden of proving (or disproving) affirmative defenses, and the court plainly doubted whether plaintiff had even shown a probability of proving a prima facie case. *See id.* at 26.

Mova Pharmaceuticals v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998), says nothing about the burden of proof on affirmative defenses. It says only that plaintiff must show the four traditional factors for a preliminary injunction.

Kontes Glass Co. v. Lab Glass, Inc., 373 F.2d 319, 320 (3d Cir. 1967), also says nothing about the burden of proof on affirmative defenses. After summarizing several affirmative defenses, and noting that plaintiff had "sought to answer these defenses," the court said only that "there is not that strong likelihood of success which in the circumstances of this case would alone justify our holding that the court below abused its discretion in refusing to grant a preliminary injunction." *Id.* at 321. The "circumstances" referred to are that plaintiff offered "only slight evidence on the question of irreparable injury." *Id.* at 320.

Lexmark Int'l, Inc. v. Static Control Components, Inc., 387 F.3d 522, 550 (6th Cir. 2004), (the *see also* case) also says nothing about the burden of proof on affirmative defenses. It says

only that plaintiff "bears the burden of proving likelihood of success." *Id.* On the facts, the court plainly believed that defendant had carried the burden of proving probable success on its affirmative defense.

Numerous other lower court cases are consistent with this Court's decisions in *Ashcroft* and *Anderson*, requiring defendant to show a probability of success on affirmative defenses relied on to oppose a preliminary injunction. The church cites many of these cases, including several RFRA cases, in part III of its brief. Unlike the government's cases, the cases cited by the church actually support the proposition for which they are cited.

Even if the lower court cases supported the government's position, they could not overcome the clear and recent authority of *Ashcroft v. ACLU*, 124 S.Ct. 2783, 2791-92 (2004). But the lower court cases do not support the government's position. Most of the cases are entirely consistent with *Ashcroft*. Where probability of success turns on an affirmative defense, plaintiff shows probable success on the merits if defendant fails to show probable success on the defense.

С

Arguments About the Status Quo Are Irrelevant to the Resolution of This Case.

The Court of Appeals heard this case en banc to resolve questions about a Tenth Circuit rule holding certain preliminary injunctions, including those that would change the status quo, to a "heightened standard" of proof. Pet. App. 2a-3a (per curiam). A majority of the Court reaffirmed that standard, with some modifications. *Id.* at 3a (Murphy, J., for the court). A larger majority held that this heightened standard was satisfied. "[E]ven under the heightened standard affirmed by a majority of this court, the district court did not abuse its discretion in granting the injunction to the church." *Id.* at 78a (Seymour, J., for the court). "[C]ourts should issue preliminary injunctions that disturb the status quo only when the traditional balance is strongly in the plaintiff's favor, but on this record, plaintiff UDV satisfied that demanding test." *Id.* at 119a (McConnell, J., concurring). Judges McConnell and Tymkovich, who defended the heightened standard at length, *id.* at 80a-93a, fully joined part II of Judge Seymour's opinion for the court holding that the heightened standard was satisfied. *See id.* at 5a, 53a (listing the judges joining Judge Seymour's opinion); *id.* at 79a-80a n.1 (McConnell, J., concurring).

Because the Tenth Circuit's standard was satisfied, the principal relevance of that heightened standard is to highlight the strength of the church's case as viewed by the Court of Appeals. But there should be no such heightened standard. Heightened standards, and the sometimes metaphysical debates over the meaning of the status quo that are required to implement such standards, are a large distraction from the true functions of preliminary injunction law. No case in this Court requires such a heightened standard. The government does not claim otherwise,

despite its rhetoric about alleged changes in the status quo.

Of course courts commonly say that a purpose, or even the purpose, of preliminary injunctions is to preserve the status quo. *See, e.g., Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). Courts also commonly say that plaintiff in a preliminary injunction case must prove some combination of four factors: probability of success on the merits, irreparable injury, balance of harm, and public interest. *See Hilton v. Braunskill*, 481 U.S. 770, 776-77 (1987); *Camenisch*, 451 U.S. at 392. The relationship between these factors and the status quo is usually left unclear.

No version of a status quo "test" adds anything useful to the traditional four factors. Such a test does add a highly debatable and manipulable concept that prolongs litigation and distracts courts and parties from the real issues at stake. The Court of Appeals should have simply applied the traditional standards for a preliminary injunction, with no talk of heightened standards.

The central problem that gives rise to the need for preliminary injunctions is the risk that plaintiff will be irreparably injured before the slow processes of litigation can reach a final decision. But the solution to this problem has its own central problem: the court is more likely to err when it acts on partial information after a preliminary hearing, and such an error may lead to an order that causes irreparable injury instead of preventing it. In the face of these conflicting risks, "the preliminary injunction standard should aim to minimize the probable irreparable loss of rights caused by errors incident to hasty decision." John Leubsdorf, *The Standard for Preliminary Injunctions*, 91 Harv. L. Rev. 525, 540-41 (1978).

The traditional four factors implement this standard if the relationship among them is properly specified. The risk of irreparable injury to plaintiff is explicitly one of the four factors; the risk of irreparable injury to defendant if the injunction is granted is considered under the balance of harms factor. The effect on the public interest allows consideration of any risk of harm to third parties or the general public. The risk of error is assessed under the probability of success factor.

The key to making the traditional four factors work is to assess the risks of irreparable injury in light of the probability of success on the merits. If plaintiff is highly likely to win on the merits, the irreparable injury threatening plaintiff is more likely to be legally unjustified, and any threatened injury to defendant is more likely to be the justified consequence of the substantive law's allocation of rights. The opposite is true if plaintiff is unlikely to succeed on the merits. The threatened harms to each side should therefore be weighted by -- or more realistically, assessed in light of -- each side's probability of success on the merits.

Professor Leubsdorf illustrated this analytic approach with a numerical example, in which probability of success and threatened irreparable injury to each side were quantified, each side's threatened injury was mathematically discounted for its probability of success, and the

discounted values compared. Leubsdorf, 91 Harv. L. Rev. at 542. Judge Posner expressed Leubsdorf's approach in the form of a mathematical inequality written in algebraic notation. *Am. Hosp. Supply Corp. v. Hosp. Prods., Ltd.*, 780 F.2d 589, 593 (7th Cir. 1986). Of course the prospect of quantification was illusory, and these mathematical formulations drew heavy criticism. Leubsdorf and Posner had no illusions about quantification; their math was intended only as a (probably unfortunate) illustration. But their analytic concept is sound. It is widespread in the cases and supported by leading scholars in the field.

The leading treatise describes the traditional four factors as imperfectly stating the basic point:

[T]he gist of the standards is probably easy to understand in common sense terms even if the expression is imperfect: the judge should grant or deny preliminary relief with the possibility in mind that an error might cause irreparable loss to either party. Consequently the judge should attempt to estimate the magnitude of that loss on each side and also the risk of error.

Dan B. Dobbs, *Law of Remedies: Damages-Equity-Restitution* '2.11(2) at 255 (2d ed. West 1993). Professor Dobbs concludes that the Leubsdorf-Posner formulation brings coherence to this imperfectly expressed standard; it "helps judges by reminding them of the ultimate goal." *Id.* at 260. "What Leubsdorf's formula does is to bring adjudication back to its own best ideals." *Id.* This amicus agreed: the Posner-Leubsdorf model helpfully "focuses attention on the point of the balancing process and specifies the relationship among the factors to be balanced." Laycock, *supra* note 4, at 120. I further elaborated the variables that go into the balance, including the likelihood, severity, and degree of irreparability of threatened irreparable injury; this elaboration further confirms the universally accepted view that the necessary balancing must be qualitative, not quantitative. *See id.* at 120-23.

All or nearly all the federal circuits have adopted some variation of a sliding scale or balancing formulation that incorporates the essential insight of the Leubsdorf-Posner formulation. *See* Thomas R. Lee, *Preliminary Injunctions and the Status Quo*, 58 Wash. & Lee L. Rev. 109, 113 n.7 (2001) (collecting cases from eleven circuits). Professor Lee concludes that the Leubsdorf-Posner model now provides "the dominant conceptual framework for ordering and balancing the traditional factors." *Id.* at 155. Professors Wright, Miller, and Kane do not discuss Leubsdorf by name, but they endorse the sliding scale formulation that integrates the four traditional factors into a single balance:

[T]he degree of likelihood of success is not determinative. Rather it must be considered and balanced with the comparative injuries of the parties. . . . Thus, the balancing which takes place between the two factors is often referred to as a "sliding scale."

11A Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice and Procedure* '2948.3 at 189-95 (2d ed. West 1995) (collecting cases in pages of footnotes).

The basic principle has deep roots in this Court's cases. Consideration of the "comparative injury" to each side was a "settled rule" at least by the time of Russell v. Farley, 105 U.S. 433, 438 (1881). And this injury was already assessed in light of probability of success: "[I]f the legal right is doubtful, either in point of law or of fact, the court is always reluctant to take a course which may result in material injury to either party." Id. The converse of this proposition is that where the legal right is more certain, the court is less reluctant to impose material injury on the party likely to lose. Where the balance of harms strongly favors plaintiff, a serious question for litigation will justify a preliminary injunction even without a determination of probable success. Ohio Oil Co. v. Conway, 279 U.S. 813, 815 (1929); see also Atchison, Topeka, & Santa Fe Ry. v. Wichita Bd. of Trade, 412 U.S. 800, 822 n.15 (1973). Of course many cases say more generally that the court must balance the injuries to each side, or the interests of each side. What is always implicit in the probability of success factor, and is sometimes made explicit, is that "The balance may depend to a large extent upon determination of the State's prospects of success " Hilton v. Braunskill, 481 U.S. 770, 778 (1987). The Leubsdorf-Posner formulation is thus a succinct and precise statement of the basic approach in this Court's cases. The goal of preliminary injunctions is to minimize irreparable injury that turns out to be legally unjustified.

The status quo has nothing to add to this standard. To say that preliminary injunctions preserve the status quo is frequently an apt *description*, but it is not a *test* or a *standard*. In one sense, the status quo formulation is tautological: the infliction of irreparable harm on either side would be a sharp and irretrievable change from the status quo. In this sense, preservation of the status quo is simply another way to say prevention of irreparable injury.

More often, courts use the phrase "status quo" to refer not just to the absence of irreparable injury, but to the existing state of all facts relevant to the case. And they often specify that it is the last peaceable uncontested status quo that counts. *See, e.g., Select Milk Producers, Inc. v. Johanns*, 400 F.3d 939, 948 (D.C. Cir. 2005); Pet. App. 68a (Seymour, J., for the court). It is generally true that a peaceable and uncontested status quo was not inflicting irreparable injury on anyone, so in this sense too, it can generally be said that an order minimizing irreparable injury preserves the status quo. But this is only generally true, not uniformly true. Every circuit has recognized that:

[T]here are cases in which preservation of the status quo may so clearly inflict irreparable harm on the movant, with so little probability of being upheld on the merits, that a preliminary injunction may be appropriate even though it requires a departure from the status quo.

Id. at 83a (McConnell, J., concurring). In those cases, a status quo test is clearly an obstacle to justice rather than an aid. The status quo test points to the wrong result; the "test" must be overcome by the more fundamental factors. Indeed, any time a status quo test changes the result from that indicated by the goal of minimizing unjustified irreparable injury, the effect is to increase unjustified irreparable injury.

A status quo test is an obstacle to justice even when it does not change the result. The status quo is a highly manipulable concept, and a status quo test encourages the parties to argue about competing conceptions of the status quo instead of arguing directly about irreparable injury and probability of success. This case is a good illustration. Part of the status quo was that the church had been using hoasca in its worship for years, in accord with its understanding of RFRA. *Id.* at 69a (Seymour, J., for the court). Part of the status quo was that the government was enforcing its understanding of the Controlled Substances Act (CSA) in cases that came to its attention. *Id.* It was impossible to preserve both parts of this status quo; which part counts? The opinion holding that enforcement of the CSA was the status quo relied not on a determination of the facts that existed before the dispute arose, but on an assignment of blame: because the church worshiped in relative secret, its part of the status quo did not count. *See id.* at 15a (Murphy, J., for the court). Whatever one thinks of this reasoning, it has nothing to do with identifying the status quo in actual fact. And what if the church had been more open, but the government simply didn't know about it? How would Judge Murphy define the status quo then?

Similar conundrums, and worse, abound in the cases. The concept of the "last peaceable uncontested status quo" invites the parties to argue about when the contest began and which date counts as the proper status quo. The court can order recent actions reversed to restore an earlier status quo. See, e.g., Porter v. Lee, 328 U.S. 246, 251 (1946). The status quo may be defined as a condition of ongoing activity, or it may be defined as conditions not yet changed by that activity at the moment the court decides. Thus in Ferry-Morse Seed Co. v. Food Corn, Inc., 729 F.2d 589 (8th Cir. 1984), the court distinguished a status quo "of action" from a status quo "of rest," and preliminarily ordered defendant to deliver 7,000 bags of seed corn. Id. at 593. Another court of appeals has said that "[t]he status quo of daily newspapers is to publish news promptly that editors decide to publish." In re Providence Journal Co., 820 F. 2d 1342, 1351 (1st Cir. 1986) (Wisdom, J., by designation), modified on other grounds, 820 F.2d 1354 (1st Cir. 1987) (en banc). On this view, enjoining publication of private information did not preserve the status quo of privacy but instead disrupted the status quo of continuous publication. Similarly in a dispute over a pipeline company's right to cut trees on plaintiff's land, one court thought the status quo was that the company was at work; another thought the status quo was that some of the trees were still standing. See Rees v. Panhandle Eastern Pipe Line Co., 377 N.E.2d 640 (Ind. App. 1978).

Professor Lee reviews similar examples, 58 Wash. & Lee L. Rev. at 163-66, en route to concluding that "the heightened standard turns on questions that have no objective, determinate answer," *id.* at 165, and thus leads lawyers and judges to expend time and resources on a "hollow inquiry" into a criterion that is "arbitrary and capricious" and "incapable of consistent, reasoned application." *Id.* at 166. Professor Leubsdorf found emphasis on the status quo to be "a habit without a reason." Leubsdorf, 91 Harv. L. Rev. at 546. Wright, Miller, & Kane, erroneously cited below as supporting a status quo rule, Pet. App. 8a-9a (Murphy, J., for the court), in fact reject it:

When there are other adequate grounds for denying the injunction, this [status quo] formula appears to be a harmless makeweight, but it is regrettable if it leads to the denial of an injunction when the important conditions for its issuance have been satisfied. The doctrine has been subject to academic criticism and frequently is ignored or rejected by the courts.

11A Wright, Miller, & Kane, '2948 at 137-38.

Judge McConnell's opinion below, perhaps the only thoughtful defense of a status quo rule ever written, does not grapple with these difficulties. He argues that using the status quo as a partial proxy for the balance of irreparable injury will yield more accurate results than assessing irreparable injury directly. Pet. App. 92a (McConnell, J., concurring). This approach could work only if the status quo were clearly and reliably identifiable -- and plainly it is not.

Judge McConnell's strongest point is that humans feel the loss of long-held assets or entitlements more than they feel the failure to gain some new asset or new entitlement. *Id.* at 87a-89a. But this, like his less forceful observations, has bite only where the parties' preexisting holdings are clear and long settled. In those cases, the status quo will seem relatively clear, but so will the balance of irreparable injury considered in light of the probability of success. Where the identity of the status quo is fairly debatable, the human preference for existing entitlements will be little help. In this case, refusing a preliminary injunction would have taken away an asserted right the church had long enjoyed; granting the preliminary injunction deprived the government of a new found opportunity to prosecute a case never previously prosecuted. The loss of long-held entitlement was plainly greater on the church's side, yet Judge McConnell joined Judge Murphy's opinion holding the status quo to be the government's right to prosecute.

Debates over the status quo do not work as a proxy for the real issues at stake. They divert attention from the real issues and invite endless manipulation by both lawyers and judges. Courts will best minimize irreparable loss of rights if they focus directly on that goal. This Court has never adopted any version of a status quo test, and it should not do so now.

I

Ι

THE EXCEPTION FOR RELIGIOUS USE OF PEYOTE DEFEATS TWO OF THE CLAIMED COMPELLING INTERESTS UNDER RFRA.

As the church explains in part II.A.2 of its brief, with citations to the record, hoasca and peyote are highly similar in their chemistry, in their psychoactive effects, in their Schedule I status, and in their lack of an illicit recreational market. The UDV and the Native American Church (NAC) are similar in their highly controlled ritual use of their respective substances, and in their beneficial effects on their members. Peyote is used, with the government's full

approval, by 250,000 members of the NAC. Yet the government insists it has a compelling interest in refusing any exception for hoasca use by 130 members of the UDV.

"It is established in our strict scrutiny jurisprudence that `a law cannot be regarded as protecting an interest of `the highest order' . . . when it leaves appreciable damage to that supposedly vital interest unprohibited."" *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 547 (1993), quoting *Florida Star v. B.J.F.*, 491 U.S. 524, 541-42 (1989) (Scalia, J., concurring), and citing additional cases. The current law on peyote is a substantial exception to the government's asserted compelling interest in universal enforcement of the Controlled Substances Act. Unless the government can show some controlling difference between peyote and hoasca, its claim of compelling interest is defeated by its own treatment of peyote.

The government's principal response is that Indian tribes have a special political status under *Morton v. Mancari*, 417 U.S. 535 (1974). Pet. Br. 27, 28. *Mancari* may have some relevance to the church's *constitutional* claim of religious discrimination, although even that is far from clear. *Mancari* is nonresponsive to the *RFRA* claim. The government claims a compelling interest in protecting worshipers from the alleged health risks of hoasca and in preventing diversion of hoasca to recreational markets. But the unique political status of Indian tribes neither protects Indians from health risks nor hinders them from selling peyote to drug traffickers. *Mancari* is simply irrelevant to these two claims of compelling interest. What the government must show is that hoasca is dangerous in some way that peyote is not, or that hoasca is likely to be diverted for reasons that do not apply to peyote. It has made no effort to show either of these points; it could not do so if it tried.

Second, the government says that Congress, not the courts, created the peyote exception. Pet. Br. 27. This is partly wrong and totally nonresponsive. *Congress* created the rule that federal law cannot be applied to substantially burden religious practices unless necessary to serve a compelling interest, and *Congress* made that rule enforceable in the courts. The government keeps trying to imply that the courts below are somehow guilty of judicial activism for enforcing RFRA, but this is exactly backwards. Judicial activism would be refusing to enforce RFRA, or removing the substance of RFRA by adopting the government's view that it need not actually "demonstrate" a compelling interest in "application of the burden to the person." 42 U.S.C. "2000bb-2(3) and 2000bb-(1)(b) (2000). Individual Justices may think RFRA wise or foolish, but either way, they will carry out their duty to enforce it according to its terms.

Finally, the government says that the 1994 amendment to the American Indian Religious Freedom Act (AIRFA), 42 U.S.C. '1996a (2000), enacted subsequent to RFRA, implies a Congressional view that RFRA cannot authorize religious exemptions from Schedule I. Pet. Br. 28. This claim is refuted by the structure of the two Acts, by the statutory text of AIRFA, and by the state of the law at the time AIRFA was amended. It is also explicitly rejected in the legislative history of both Acts.

First, RFRA enacts a general standard; AIRFA enacts a specific rule. RFRA's *standard* governs cases adjudicated in the courts where Congress has not enacted a more specific rule; it covers all cases that Congress could not anticipate or investigate or resolve by legislation. By providing a generally applicable standard, RFRA ensures that Congress does not inadvertently discriminate against religions that are unknown, unfamiliar, or unpopular. Individual cases under that standard are left to the courts; for obvious reasons of separation of powers, Congress cannot resolve individual cases under RFRA or tell courts how to decide them.

AIRFA's *rule* covers a specific case that Congress did know about, did investigate, and did resolve by legislation. AIRFA does not tell courts what to do with peyote cases under RFRA, but it enacts a more specific rule that governs cases within its terms independently of RFRA.

Second, by its express terms, AIRFA confirms that RFRA applies to peyote issues not resolved by AIRFA. AIRFA does not prohibit "reasonable traffic safety laws," or federal regulations restricting use of peyote shortly before reporting to work, or regulation of peyote in the military. But laws under these exceptions are expressly made "subject to the provisions of the Religious Freedom Restoration Act." 42 U.S.C. '1996a(b)(4), (6), and (7). As applied to each of these provisions, RFRA would require the government to demonstrate a compelling interest in restricting religious use of a Schedule I drug. These provisions incorporating RFRA are inconsistent with the government's claim that courts should not strictly scrutinize drug laws under RFRA.

Third, the state of the law when AIRFA was amended shows why Congress thought it necessary despite the existence of RFRA. Whatever its own views, Congress could not be confident that the courts would protect peyote under RFRA. The best known judicial opinion was Justice O'Connor's concurring opinion in *Employment Div. v. Smith*, 494 U.S. 872, 903-07 (1990), finding that Oregon had a compelling interest in refusing to permit religious use of peyote. If other judges accepted her reasoning, then courts would find a compelling interest under RFRA, and whatever Congress might have preferred, courts would interpret RFRA not to protect religious use of peyote. This fear was the principal impetus for amending AIRFA, and it certainly does not imply that Congress agreed with Justice O'Connor.

Finally, the history of both Acts expressly confirms this relationship between them. Both the Senate and House Committee Reports on RFRA made clear that RFRA enacted a standard and not any particular rule:

The committee wishes to stress that the act does not express approval or disapproval of the result reached in any particular court decision involving the free exercise of religion, including those cited in the act itself. This bill is not a codification of the result reached in any prior free exercise decision but rather the restoration of the legal standard that was applied in those decisions.

S. Rep. No. 103-111 at 9 (1993), 1993 U.S.C.C.A.N. 1892.

Substantially identical language appears in the House Report, H.R. Rep. No. 103-88, at 7 (1993). The House Report also confirmed that RFRA would apply to peyote:

In terms of the specific issue addressed in *Smith*, this bill would not mandate that all states permit the ceremonial use of peyote, but it would subject any such prohibition to the aforesaid balancing test. The courts would then determine whether the State had a compelling governmental interest in outlawing bona fide religious use by the Native American Church and, if so, whether the State had chosen the least restrictive alternative

Id. (The contrary statement from Senator Biden, Pet. Br. 26, is from 1990, three years before passage and before Congress had investigated religious use of peyote.)

The House Report on the AIRFA amendment (there was no Senate report) made this relationship between the two laws even more explicit. The government quotes the Report's introductory statement that the bill "remains necessary notwithstanding" RFRA. H.R. Rep. 103-675 at 6, 1994 U.S.C.C.A.N. 2404, quoted in Pet. Br. 28 n.14. The government says nothing about the explanation that immediately follows this statement. In the very next sentence, the Committee began its explanation of how Justice O'Connor in Smith found a compelling interest in suppressing religious use of peyote. Id. at 6-7. The Committee expressly disagreed with Justice O'Connor on this question. Accepting instead the findings and reasoning in Justice Blackmun's dissent in Smith, 494 U.S. at 909-21, the Committee said that Oregon's claim of compelling interests "rests on no evidentiary foundation at all" and was "entirely speculative." Report at 7. The Committee made findings, based principally on the judicially-compiled record in Smith, that largely track the issues in this case. The Committee found that "peyote is not injurious," that it "has nothing to do with . . . traffic in illegal narcotics," that "[t]here is virtually no illegal trafficking in peyote," that the "carefully circumscribed religious context in which peyote is used by Indians is far removed from the irresponsible and recreational use of unlawful drugs," that the NAC "forbids the non-religious use of peyote, and also advocates self-reliance, familial responsibility and abstinence from alcohol," and that the church "has been effective in combatting the tragic effects of alcoholism among the Native American population." Id.

Recognizing that "RFRA left open the question of whether the reinstated compelling government interest test would provide adequate legal protection for the traditional religious use of peyote," *id.* at 6, the Committee plainly feared, based on Justice O'Connor's opinion in *Smith*, that courts would answer that question in a way the Committee considered erroneous. Even if the courts got it right, the compelling-interest issue would have to be litigated state by state, "with varying results possible," and this process "would be unduly burdensome, costly and time consuming." *Id.* at 8. The Committee therefore recommended, and Congress enacted, a law to resolve the peyote question with a specific rule, to that extent taking peyote out of the general standard in RFRA.

The Committee also expressly stated that the peyote regulations permitted by AIRFA would remain subject to RFRA and that prison rules on peyote (eventually excepted from AIRFA by 42 U.S.C. '1996a(b)(5) (2000)) would be subject to RFRA. Report at 10.

The Committee also found that a peyote exemption would not "open the floodgates to claims" by other religions, because the courts had "consistently rejected similar arguments in past free exercise cases, having held that the religious use of peyote by American Indians is the sole circumstance warranting claims for a religious exemption for any controlled substance." Id. at 8. Even the reference to "sole circumstance" does not support the government's position, because it must be read in light of the state of the law and Congressional knowledge at the time. The Committee accurately described the then-extant cases rejecting free exercise claims to drugs other than peyote (cited in Pet. Br. 25-26 n.13), none of which were analogous to peyote. Nearly all of these cases involved marijuana, which has a huge recreational market, and they involved groups that did not confine their use of the drug to a tightly controlled ritual. A finding of no compelling interest in restricting religious use of peyote would imply nothing about the government's claim of compelling interest in those cases. The analogy from peyote would not be relevant until government tried to suppress an analogous religion. The record in this case shows that religious use of hoasca is highly analogous; for the same reasons that led Congress to find no compelling interest in regulating religious use of peyote by the NAC, there is no compelling interest in regulating religious use of hoasca by the UDV. Facts matter; exemptions for peyote and hoasca imply nothing about any religion using a recreational drug or lacking similarly tight controls.

AIRFA confirms that RFRA applies to this case. More than that, it confirms a Congressional judgment about the compelling interest arguments in this case. Deference to Congress would defer to that Congressional judgment. Moreover, the Department of Justice and the Drug Enforcement Administration supported the judgment that there was no compelling interest and supported the bill. *See* Letter from David A. Melocik and Statement of Gene R. Haislip, appended to the House Report at 14-16. Justice O'Connor's finding of a compelling interest in *Smith* cannot survive these developments. The government's compelling interest argument is a non-starter unless it proves that the UDV's use of hoasca is somehow dangerous in a way that the NAC's use of peyote is not. And it made no serious effort to prove such a difference.

CONCLUSION

The preliminary injunction should be affirmed.

Respectfully submitted,

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No attorney for any party authored any part of this brief, and no person other than amicus made any financial contribution to preparation or submission of this brief. I file this brief in my personal capacity as a scholar, and of course The University of Texas takes no position on the issues in this case. This brief is filed with consent of the parties. Consent letters are submitted with the brief.

See, e.g., Douglas Laycock, Theology Scholarships, the Pledge of Allegiance, and Religious Liberty: Avoiding the Extremes but Missing the Liberty, 118 Harv. L. Rev. 155 (2004); Douglas Laycock & Oliver Thomas, Interpreting the Religious Freedom Restoration Act, 73 Tex. L. Rev. 209 (1994); Douglas Laycock, Towards a General Theory of the Religion Clauses: The Case of Church Labor Relations and the Right to Church Autonomy, 81 Colum. L. Rev. 1373 (1981).

Douglas Laycock, Modern American Remedies: Cases and Materials (3d. ed. Aspen 2002). For chapters principally devoted to the law of injunctions, see *id.* at 233-510, 775-855.

Douglas Laycock, *The Death of the Irreparable Injury Rule* (Oxford Univ. Press 1991). The thesis of this book, based on a review of more than 1,400 cases, is that the irreparable injury rule does not explain the choice between legal and equitable remedies at final judgment. More relevant to this case, the book argues that a version of the irreparable injury rule is and should be very much alive with respect to preliminary relief, including preliminary injunctions. *See id.* at 110-32.

See also O'Connor v. Bd. of Educ., 449 U.S. 1301 (1980) (Stevens, J., in chambers), reviewing a stay of a preliminary injunction in a sex discrimination case:

I think it is clear that the defendants have the burden of justifying a discrimination of this kind.

Second, since the burden of justification was on the defendants, at this stage of the proceeding the stay entered by the Court of Appeals cannot be upheld on grounds not yet supported by the record \ldots

Id. at 1305.

Additional cases to the same effect include Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997) ("In order to demonstrate that it has a likelihood of success, Genentech must show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove that Novo infringes the '199 patent and (2) its infringement claim will likely withstand Novo's challenges to the validity and enforceability of the '199 patent.") (emphasis added); Abbott Labs v. Mead Johnson & Co., 971 F.2d 6, 20 (7th Cir. 1992) (stating, on appeal from denial of preliminary injunction, that "[t]he third element, functionality, is actually an affirmative defense as to which Mead bears the burden of proof."); Dallas Cowboys Cheerleaders, Inc. v. Scoreboard Posters, Inc., 600 F.2d 1184, 1188 (5th Cir. 1979) (defendant offered fair-use defense based on parody, but "[n]othing beyond an unelaborated invocation of the term `parody' was ever put before the district court, and we cannot fault the court if it found the simple allusion to the concept of parody insufficient to shift the calculus of probabilities in the defendants' favor."); Washington Capitols Basketball Club, Inc. v. Barry, 419 F.2d 472, 477 (9th Cir. 1969) (holding, on appeal from preliminary injunction, that "illegality [of contract] is an affirmative defense and defendants-appellants have the burden of pleading and proof.").

Of course these risks are much reduced in this case, where a year of preparation by the parties, two weeks of trial, and a year of deliberation by the judge were devoted to consideration of the preliminary injunction. *See* J.A. 10-15 (docket entries); Pet. App. 182a (two weeks of trial).

See, e.g., Amoco Prod. Co. v. Gambell, 480 U.S. 531, 542 (1987) ("court must balance the competing claims of injury"); Doran v. Salem Inn, Inc., 422 U.S. 922, 931 (1975) ("district court must weigh carefully the interests on both sides"); Yakus v. United States, 321 U.S. 414, 440 (1944) ("court balances the conveniences of the parties and possible injuries to them").

Cf. DeNoie v. Board of Regents, 609 S.W.2d 601 (Tex. Civ. App.--Austin 1980), holding that open and continuous operation by a sandwich vendor for nine years -- four years without complaint and five more without litigation -- was not a peaceable uncontested status quo where the vendor was found to be a trespasser.

Mancari makes sense as an equal protection case; without it, any provision for a tribe could be characterized as a racial classification. There is much less reason to extend *Mancari* to other constitutional rights. Doing so would allow Congress to grant Indians free speech or free exercise privileges denied to other Americans.

The executive created the peyote exemption at the federal level. 21 C.F.R. 1307.31 (2005). Congress later codified that exemption and preempted contrary state laws. 42 U.S.C. '1996a (2000).

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