

UNCONSTITUTIONAL CONDITIONS, GERMANENESS, AND INSTITUTIONAL REVIEW BOARDS

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INTRODUCTION

Mention to colleagues that you are writing about the doctrine of unconstitutional conditions, and their eyes widen with a mixture of pity and alarm. You, and they, are well aware that you are stepping into a doctrinal and scholarly morass. As one scholar notably put it, “Supreme Court decisions on challenges to unconstitutional conditions seem a minefield to be traversed gingerly.”¹ Unfortunately, the subject is unavoidable. So expansive has government largesse become that the question of what sorts of conditions the federal government may constitutionally put on those who accept its money or other benefits is ever more vital.

This Paper will explore the doctrine of unconstitutional conditions in the context of Institutional Review Boards (IRBs). The IRB regime, based on federal statutes and regulations, conditions federal funding of academic research on human subjects at universities on pre-approval of the research projects by IRBs created at each institution.² The goal of requiring IRB approval is to make sure that the research meets certain ethical standards. Certain requirements extend beyond federally funded research to include all research on human subjects done at a university.

The paper focuses particularly on an aspect of unconstitutional conditions doctrine called germaneness. In a number of U.S. Supreme Court cases dealing with unconstitutional conditions, the Court has examined the nexus between the condition and the government’s purpose in making the expenditure, known as germaneness. If the nexus is attenuated or nonexistent, the Court has held that the condition is improper. In the IRB context, the paper addresses two issues related to germaneness: how to determine the purpose of a government program, and how to assess the fit between the government purpose and the condition.

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¹ Kathleen M. Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413, 1415 (1989).

² See 45 C.F.R. § 46.101(a) (2006).

In discussing how to determine the purpose of the program, this Paper explores the distinctions the Court has made between conditions that affect only particular federally funded programs and those that affect an entire organization receiving federal funding. (I call these program restrictions and organization-wide restrictions.) I then apply those distinctions to the IRB regime. I further suggest that courts examine the alleged government purpose carefully to make sure that it is the actual government purpose, similar to what has been done in cases involving sex-based distinctions under the Equal Protection Clause. In considering how courts should assess the fit between the government purpose and the condition, I again borrow from intermediate scrutiny Equal Protection analysis.

IRB review of academic research raises a question about whether the condition is unconstitutional because of First Amendment implications. Other participants in this symposium have explained how, if Congress were to impose Institutional Review Boards directly, serious First Amendment concerns would be raised, at least in certain applications. Philip Hamburger suggests that the entire IRB scheme is unconstitutional because it imposes a licensing requirement that requires people to get permission before they speak or publish, and the First Amendment absolutely prohibits licensing schemes.³ James Weinstein argues that, if the requirements were imposed directly and not as a spending condition, IRBs would be problematic under the First Amendment in their attempt to address “‘soft’ psychological harms arising from communication with the subjects,” such as embarrassment. Attempts to address such harms, he says, invite viewpoint-oriented discrimination.⁴

As a number of scholars have suggested, in a world in which the Supreme Court has permitted Congress a broad spending power, the unconstitutional conditions doctrine functions as a necessary check.⁵ Since the judicially-created federal spending power is not clearly limited either by Congress’s enumerated powers or by enumerated rights such as freedom of speech or the press under the First Amendment,⁶ unconstitutional conditions doctrine is needed to restore some sort of constitutional balance.

³ Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 S. CT. REV. 271, 281–313.

⁴ See James Weinstein, *Institutional Review Boards and the Constitution*, 101 NW. U. L. REV. 493 (2007).

⁵ See, e.g., Hamburger, *supra* note 3, at 315 n.110, 317–18.

⁶ See Hamburger, *supra* note 3, at 317–18. Analyzing the work of Jeffrey Renz, Hamburger points out that the “so-called Spending Clause” was in fact intended as a check on the taxing power and that it was deliberately drafted to avoid a general spending power. See *id.* at 317 & n.112 (citing Jeffrey T. Renz, *What Spending Clause? (Or the President’s Paramour): An Examination of the Views of Hamilton, Madison, and Story on Article I, Section 8, Clause 1 of the United States Constitution*, 33 J. MARSHALL L. REV. 81 (1999)).

How exactly should the doctrine restore that balance?⁷ This Paper takes as its starting point several scholars' emphasis on the distinction between purchases and regulation,⁸ building on Justice O'Connor's dissent in *South Dakota v. Dole*.⁹ If the government is acting as a purchaser, that is, is spending for a good or service, it may put certain conditions on those purchases. Those conditions may include limitations on speech or the press.¹⁰ On the other hand, if the government is in fact acting as a regulator, that is, using the condition as a substitute for the constraining force of law, the limitations of the Bill of Rights apply.¹¹

Germaneness is relevant to the purchase–regulation distinction. As Professor Hamburger suggests, one indicia of regulation as opposed to simple purchase is germaneness.¹² The more tenuous the connection between the condition and the purchase, and the more disproportionate, the more likely the condition is to be a regulation. Drawing on Equal Protection doctrine, the germaneness inquiry may be honed to make these distinctions

⁷ Scholars have given many answers to this question. For example, Epstein, coming from a public choice perspective, is concerned about reducing rent-seeking associated with public funding. He suggests that at least germaneness limits the scope of bargaining between government and others, and therefore to some extent limits rent-seeking. See Richard A. Epstein, *The Supreme Court, 1987 Term—Foreword: Unconstitutional Conditions, State Power, and the Limits of Consent*, 102 HARV. L. REV. 4, 17–22 (1988).

⁸ See, e.g., Thomas R. McCoy & Barry Friedman, *Conditional Spending: Federalism's Trojan Horse*, 1988 S. CT. REV. 85, 103; see also Lynn A. Baker, *Conditional Federal Spending After Lopez*, 95 COLUM. L. REV. 1911, 1962–63 (1995) (calling the distinction one of “reimbursement spending” versus “regulatory spending”); Hamburger, *supra* note 3, at 315–16 & 318–19.

⁹ 483 U.S. 203, 212–18 (1987) (O'Connor, J., dissenting). Justice O'Connor's dissent, in turn, built on the Court's analysis in *United States v. Butler*, 297 U.S. 1, 73 (1936). For analysis of the relationship of *Butler* to the *Dole* opinions and the implications of Chief Justice Rehnquist's opinion for the Court in *Dole*, see McCoy & Friedman, *supra* note 8, at 123:

If the direct purchase of voluntary conduct is spending—something separate and apart from regulation—there is no constitutional problem of Congress exceeding its delegated regulatory powers. Indeed, if Congress can purchase conduct, why go to the trouble of purchasing some goods and services and then attaching the purchase of conduct to the purchase of the goods and services as in *Dole*? Congress simply could pay states a flat fee to enact laws Congress desires, but which are outside the scope of Congress' regulatory power.

Id.

¹⁰ But even when acting as a purchaser, Congress could not buy a right that the Constitution allocates elsewhere. (This last caveat is not because of a broad federal spending power, but simply because of the constitutional scheme of limited legislative powers.) Nonetheless, if the government is acting as a purchaser, it can reach a more modest agreement with a person to waive a particular exercise of a right. For example, the government could condition federal employment on the employee not revealing information he has learned on the job. But it could not have a condition that he never speak in public on a matter unrelated to the job. See Hamburger, *supra* note 3, at 319–21.

¹¹ See Hamburger, *supra* note 3, at 319. This is an appropriate recasting of Seth Kreimer's distinction between threats and offers. See Seth Kreimer, *Allocational Sanctions: The Problem of Negative Rights in a Positive State*, 132 U. PA. L. REV. 1293, 1301 (1984).

¹² See Hamburger, *supra* note 3, at 326 n.130.

more precise.¹³ Equal Protection doctrine is helpful to the germaneness inquiry because it deals with the similar question of fit between government purpose and a distinction made by law. Equal Protection doctrine also closely resembles First Amendment substantive law in some areas, and therefore has a connection with the underlying constitutional provision of special concern in the IRB regime.

In Part I, I will address two major difficulties with the germaneness approach: the lack of any substantive limitation on government purpose and the difficulty involved in defining the scope of the government purpose. The first problem is in part solved by distinctions the Court has drawn between program- and organization-wide speech restrictions in unconstitutional conditions cases. The second problem, defining the scope of the government purpose, requires courts to delve deeply into the asserted purposes, often from a historical perspective, similar to what has been done in equal protection cases involving sex-based classifications.

In Part II, I examine how close the fit between purpose and condition must be. Some Supreme Court cases have required only a loose connection, but others, particularly those that touch on First Amendment rights, have required a closer fit. Borrowing again from Equal Protection scrutiny, it would be appropriate to adopt a stricter test than rational basis if the condition touches on First Amendment rights. Using an intermediate-scrutiny or strict-scrutiny test leads naturally to the question whether there are less restrictive alternatives, with implications particularly for organization-wide restrictions found in the IRB regime. With some refinements of the germaneness inquiry already conducted by the Court, one can move fairly far toward a purchase–regulation distinction in unconstitutional conditions cases.

I. PROBLEMS WITH GERMANENESS: LIMITING, DEFINING GOVERNMENT PURPOSE

Two important problems with the germaneness inquiry as a cure for the ills of unconstitutional conditions doctrine center on the government's purpose in conditioning federal funds. First, a germaneness inquiry does not formally put any limit on conceivable government purposes. There are, however, other limits on government purposes that courts have recognized in unconstitutional conditions cases involving speech rights. While the government may in many instances limit speech associated with particular federally funded programs, the government generally may not limit speech by a federal grantee funded entirely by private sources (program restrictions

¹³ Kathleen Sullivan has suggested using an Equal Protection approach to unconstitutional conditions in a much more sweeping way. Sullivan, *supra* note 1, at 1499–1500. The incorporation of Equal Protection principles suggested here would be more targeted, and used to hone an approach the Court has already taken, the germaneness inquiry. Sullivan rejects the germaneness inquiry as inadequate and unworkable. *Id.* at 1474–76.

vs. organization-wide restrictions). This distinction has implications for the purchase–regulation distinction. The second problem is the difficulty in defining the scope of government purpose. Borrowing certain aspects from the Court’s approach in equal protection cases involving sex discrimination could help resolve the second problem. As in sex-discrimination cases, courts should dig deep into the history of a program to see if the government’s stated purpose is the actual one. Such a thorough examination helps to reveal whether the government is acting as a purchaser or regulator.

A. Limits on Government Purposes

One notable difficulty with the germaneness inquiry is that it does not, of itself, put any limit on government purposes. If the government purpose were to ensure the dominance of the Aryan race, for example, then a government program conditioning a benefit offered to the rest of the population—free room and board, say—on enslavement would indeed be germane to the purpose. A bit closer (not to say more germane) to our exploration here, the government purpose might be to censor any research on humans it deemed to be politically unacceptable. In that case, government funding of research conditioned on the creation of IRBs would undoubtedly be germane.

The problem of improper government purposes can be handled through various provisions of the U.S. Constitution, especially through equal protection analysis with its suspect classifications and categorization of purposes: legitimate, substantial, or compelling. Unfortunately these categories may be manipulated, but they provide some protection. Kathleen Sullivan has proposed a way to deal with the problem of controlling purposes: her preferred test would subject “to strict review any government benefit whose primary purpose or effect is to pressure recipients to alter a choice about exercise of a preferred constitutional liberty in a direction favored by government.”¹⁴ Of course, one solution to the problem of improper purposes would be to cabin the judicially-created spending power for the “general welfare” and return to serious limitations on Congress’s spending power based on other powers or rights enumerated in the Constitution.

Though no major overhaul of the “spending power” is in sight, the Court has restricted Congress’s ability to purchase a right as a whole in cases involving speech-related conditions. In a line of cases, the Court has held that the government can, as a condition of receiving government money, require a person or organization to waive the right to say certain things in some instances, but the government cannot restrict the right entirely.¹⁵ This is perhaps the best way of conceiving of the distinction the Court has repeatedly drawn between program speech restrictions—which

¹⁴ *Id.* at 1499–1500. Unfortunately, as Sullivan points out, this formulation does not define what the scope of the right should be.

¹⁵ See Hamburger, *supra* note 3, at 320–21 & n.119.

prevent specified speech acts in certain instances only—and organization-wide speech restrictions. Where restrictions are limited to use of program funds, the condition tends to be upheld, but where the restriction operates organization-wide, the condition tends to be struck down.¹⁶

Beginning with *Regan v. Taxation with Representation* (“*TWR*”) in 1983, the Court emphasized that restrictions on speech were more likely to be upheld if they were limited to federally funded programs and not applied to the organization as a whole. In *TWR*, the Court upheld § 501(c)(3) in its denial of a tax exemption—a subsidy analogous to a “cash grant,” the Court said¹⁷—for nonprofit organizations conducting substantial lobbying.¹⁸ The Court noted that *TWR* could use a “dual structure” to get the § 501(c)(3) subsidy for their non-lobbying activities, but then use a § 501(c)(4) structure for lobbying.¹⁹ Justice Blackmun’s concurrence stated that the constitutionality of § 501(c)(3) “depends entirely upon” the ability to create a separate affiliate for lobbying.²⁰ The following year, the Court struck down a restriction that operated organization-wide in *FCC v. League of Women Voters*.²¹ The law in *League of Women Voters* conditioned noncommercial broadcasters’ receipt of federal grants on their agreement not to “engage in editorializing,”²² even with private money. The Court treated this difference from *Taxation with Representation* as dispositive, and stated that if stations were allowed to establish affiliates that could editorialize with nonfederal funds, the restriction would be constitutional.²³ Likewise, in *Rust v. Sullivan*,²⁴ the Court emphasized that “[t]he Secretary’s regulations do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities.”²⁵

The IRB regime, unlike the scheme in *Rust*, extends beyond projects with federal funding to include all research on humans conducted at grantee institutions, and thus does not keep the grantee and the project fully distinct. The regime puts on grantee institutions a condition of maintaining “ethical principles” for all research involving human subjects.²⁶ The government defines appropriate “ethical principles” as either those laid out in the *Bel-*

¹⁶ The Court in some cases characterizes the distinction as one turning on whether a right must be “subsidized,” and declares that Congress need not subsidize exercise of a right. See *Regan v. Taxation with Representation*, 461 U.S. 540, 546 (1983).

¹⁷ See *id.* at 544.

¹⁸ See *id.* at 551.

¹⁹ See *id.* at 544.

²⁰ See *id.* at 552.

²¹ 468 U.S. 364 (1984).

²² See *id.* at 366.

²³ See *id.* at 400–01.

²⁴ 500 U.S. 173 (1991).

²⁵ *Id.* at 196.

²⁶ See 45 C.F.R. § 46.103(b)(1) (2006).

mont Report,²⁷ or described in some other document negotiated between the institution and the government.²⁸ (It seems very few institutions have chosen to negotiate a separate set of principles.)²⁹ These organization-wide restrictions suggest that the government is not simply defining how its money can be spent, but attempting to broadly regulate.

Essentially, the Court has moved far toward a purchase–regulation distinction in unconstitutional conditions cases involving speech, by allowing the government to restrict certain rights associated with purchase (directly associated with the program) but not all (by the entire organization). Although this distinction does not proceed from the germaneness inquiry itself, it helps to limit permissible government purposes and therefore helps solve one of the main difficulties with germaneness analysis. The IRB regime runs afoul of this distinction by imposing restrictions organization-wide.

B. Defining the Government Purpose

Even though the germaneness inquiry by itself puts no formal limits on government purposes, at least it forces courts to seriously inquire into government purpose, and to explicitly assign one. In the course of deciding whether a condition is appropriately related to the purpose of a government program, a necessary first step is determining that purpose. It is not always easy to figure out precisely what the government purpose is,³⁰ and some have considered this malleability of government purpose to be a fatal weakness of the germaneness approach.³¹

In unconstitutional conditions cases, similar to equal protection cases, the government asserts a purpose. It then becomes the task of the court to probe that asserted purpose to determine if it is the actual one, or simply pretextual. In the area of conditions involving speech restrictions, courts should be particularly wary of accepting government assertions of purpose.

²⁷ See NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (DHEW Publication No. 78-0012, 1979); see also U.S. DEP'T OF HEALTH AND HUMAN SERVS., OFFICE FOR HUMAN RESEARCH PROTS., FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS 1 (2005) [hereinafter FEDERALWIDE ASSURANCE], available at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>.

²⁸ See FEDERALWIDE ASSURANCE, *supra* note 27, at 1.

²⁹ See Hamburger, *supra* note 3, at 322 n.122.

³⁰ There is, of course, substantial literature devoted to that question. See, e.g., Paul Brest, Palmer v. Thompson: *An Approach to the Problem of Unconstitutional Legislative Motive*, 1971 S. CT. REV. 95, 101–46; John Hart Ely, *Legislative and Administrative Motivation in Constitutional Law*, 79 YALE L.J. 1205 (1970). A large number of cases addressing the problem of determining government purpose are cited in the various opinions in *Kassel v. Consolidated Freightways*. 450 U.S. 662, 682 n.3 (1981) (Brennan, J., concurring in the judgment); *id.* at 702–03 (Rehnquist, J., dissenting).

³¹ See Sullivan, *supra* note 1, at 1474.

To this end, courts should pay attention to the detailed probing courts have given to asserted purposes in the context of sex-discrimination cases.³²

Difficulties in determining government purpose have come up in unconstitutional conditions cases. Courts may, of course, define purposes broadly or narrowly.³³ Logically, the more broadly a purpose is defined, the more likely the condition is germane to that purpose. For example, in *South Dakota v. Dole*, Chief Justice Rehnquist's opinion for the majority defined the federal program's purpose broadly—to promote highway safety in general—and upheld the drinking-age condition.³⁴ Meanwhile Justice O'Connor's dissent argued that the purpose was more modest—to promote highway safety through sound construction—and would have struck down the condition.³⁵ In *Nollan* the majority and dissent were reversed, with the majority defining the purpose narrowly—the provision of visual access to the sea—and the dissent defining it broadly—encouraging public use and enjoyment of the beach.³⁶ The outcome accordingly was the opposite, and the condition struck down.

One would think, therefore, that the government could ensure a condition would nearly always be found germane simply by defining the purpose of the program as broadly as possible. In the context of IRBs, Congress could simply declare the purpose of the program to be ensuring that all research on humans is conducted “ethically,” rather than ensuring that federal funds are only used to support research that is conducted “ethically.” Congress could also announce that conducting research “ethically” means not just protecting physical safety but also protecting from embarrassment, etc.

However, for the reasons discussed above, where conditions restrict speech and thus touch on First Amendment rights, the Court has taken almost the opposite approach. The narrower the purpose of the program—for example, to control use of government funds rather than to broadly regulate—the more likely the Court is to uphold the condition. This approach prevents the government from winning unconstitutional conditions cases involving speech restrictions simply by declaring a broad program purpose. A restriction that is “frankly aimed at the suppression of dangerous ideas”³⁷ will not pass muster.

³² Sex-discrimination cases are particularly instructive. Racial classifications are almost never upheld, unless members of certain racial groups are benefited in higher education, in which case the U.S. Supreme Court has held equal protection is relatively easy to satisfy. See generally *Grutter v. Bollinger*, 539 U.S. 306 (2003) (upholding the affirmative action program used by the University of Michigan Law School).

³³ See Sullivan, *supra* note 1, at 1474.

³⁴ See *South Dakota v. Dole*, 483 U.S. 203, 208–09 (1987) (Rehnquist, C.J.).

³⁵ See *id.* at 218 (O'Connor, J., dissenting).

³⁶ Compare *Nollan v. Calif. Coastal Comm'n*, 483 U.S. 825, 834–36 (1987), with *Nollan*, 483 U.S. at 843–48 (Brennan, J., dissenting).

³⁷ *Speiser v. Randall*, 357 U.S. 513, 519 (1958) (quoting *Am. Commc'ns Ass'n v. Douds*, 339 U.S. 382, 402 (1950)).

The danger in unconstitutional conditions cases involving speech restrictions, therefore, is not that courts will interpret the government purpose too broadly, but that they will interpret the purpose too narrowly. The government might declare that its purpose is simply to control expenditure of government funds, but in fact it may have a broader agenda. This difficulty came up in *Rust*, where Chief Justice Rehnquist's majority opinion emphasized several times that "advice regarding abortion is simply beyond the scope of the program,"³⁸ since the purpose of the program was to provide preconception services only. The dissent argued that this narrow understanding of the government's purpose "rings hollow," since the program authorized, and indeed in some cases required, grant recipients to refer women to post-conception services such as prenatal care.³⁹ The argument over the purpose of the government program turned out not to be determinative in *Rust*, however, since the regulations covered only use of government funds. The Court emphasized that grant recipients did not wholly give up their speech rights; they could engage in abortion advocacy, as long as they kept such activity distinct from the government funded project: "Title X expressly distinguishes between a Title X *grantee* and a Title X *project*."⁴⁰

As with the Title X program in *Rust*, IRBs present the same danger of an overly-narrow interpretation of the government purpose, but without the saving feature that the conditions are strictly limited to use of program funds. It would be possible to declare, as one commentator has, that "[t]he purpose of the [National Research] Act is to assure that federal research funds support ethically-conducted, useful research involving human subjects."⁴¹ But the organization-wide "ethical principles" condition, discussed above, suggests that the purpose is in fact more broadly regulatory, as does the Act's history, discussed below.

Courts, then, in speech restriction cases have the difficult task of trying to determine the government purpose in the face of government incentives to claim that the purpose is quite narrow. Certain conditions may not fit a narrow stated purpose, and would therefore indicate that the purpose is in fact broader than claimed. But it may also be useful, in the germaneness

³⁸ *Rust v. Sullivan*, 500 U.S. 173, 200 (1991); *see also id.* at 194 (Abortion is "outside of the project's scope."); *id.* at 195 (Abortion activities are "excluded from the scope of the project funded."); *id.* at 200 ("The program does not provide post conception medical care, and therefore a doctor's silence with regard to abortion cannot reasonably be thought to mislead a client into thinking that the doctor does not think abortion an appropriate option for her."). The Court stated that, because the government program was to provide preconception services, all post-conception services were simply outside its scope. *Id.* at 179 ("Because Title X is limited to preconceptional services, the program does not furnish services related to childbirth."); *id.* at 193 ("The Title X program is designed not for prenatal care, but to encourage family planning. . . . [P]renatal care . . . is outside the scope of the federally funded program.").

³⁹ *See Rust*, 500 U.S. at 210 (Blackmun, J, dissenting).

⁴⁰ *Rust*, 500 U.S. at 196 (emphasis original).

⁴¹ John A. Robertson, *The Law of Institutional Review Boards*, 26 UCLA L. REV. 484, 500 (1978).

context, to examine purposes closely through other types of analysis, such as historical. A model for this is found in sex-discrimination cases under the Equal Protection Clause.

In cases involving government programs making sex-based distinctions, the Court has put the burden on the government to show “at least that the classification serves ‘important governmental objectives and that the discriminatory means employed’ are ‘substantially related to the achievement of those objectives.’”⁴² The Court has shown that it is willing to probe the asserted important governmental objectives; the government’s assertions “will not be accepted automatically; a tenable justification must describe actual state purposes, not rationalizations for actions in fact differently grounded.”⁴³ In a number of cases in this area, the Court has delved deep into legislative and other history to discredit asserted government purposes.⁴⁴ The Court’s historical analysis of purposes has been especially intense in cases involving higher education.⁴⁵

Applying this standard of digging deep into the history of laws to discover their true purposes, and not simply accepting the government’s asserted purpose, analysis of the history of IRB statutes and regulations clearly shows the government’s intent to regulate broadly. The 1974 Committee Report on the National Research Act stated that the creation of a National Commission for the Protection of Human Subjects was “essential to the development of a system where human subjects of biomedical and behavioral research are adequately protected.”⁴⁶ The scope of this national commission “should cover all biomedical and behavioral research involving human subjects.”⁴⁷ A report from the National Commission for the Protection of Human Subjects in 1978 recommended that Congress give the Department of Health, Education, and Welfare (“HEW”) authority “to promulgate regulations governing ethical review of all research involving

⁴² *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 724 (1982) (quoting *Wengler v. Druggists Mut. Ins. Co.*, 446 U.S. 142, 150 (1980)).

⁴³ *United States v. Virginia*, 518 U.S. 515, 535–36 (1996).

⁴⁴ *See, e.g., Weinberger v. Wiesenfeld*, 420 U.S. 636, 650 (1975) (examining in detail legislative history going back to the origin of the program in 1939 to determine that, in a provision of the Social Security Act, “Congress was not concerned . . . with the employment problems of women generally but with the principle that children of covered employees are entitled to the personal attention of the surviving parent if that parent chooses not to work”); *Califano v. Goldfarb*, 430 U.S. 199, 216–17 (1977) (conducting similar examination: “We conclude, therefore, that the differential treatment of nondependent widows and widowers results not, as appellant asserts, from a deliberate congressional intention to remedy the arguably greater needs of the former, but rather from an intention to aid the dependent spouses of deceased wage earners, coupled with the presumption that wives are usually dependent.”).

⁴⁵ *See Virginia*, 518 U.S. at 535–40; *Hogan*, 458 U.S. at 727–30.

⁴⁶ COMMITTEE REPORT ON THE NATIONAL RESEARCH ACT, Pub. L. No. 93-348, S. REP. NO. 93-381 (1974), as reprinted in 1974 U.S.C.C.A.N. 3634, 3653. For an account of the historical genesis of IRB regulations, see Hamburger, *supra* note 3, at 325 & n.127.

⁴⁷ *Id.*

human subjects that is subject to federal regulation.⁷⁴⁸ Given this background, it is hardly surprising that HEW published in 1979 regulations that “require[d] IRB review and approval of research involving human subjects, even if it is not supported by Department funds.”⁷⁴⁹ In the face of academic protests against these sweeping regulations,⁷⁵⁰ HEW simply adopted the current approach to regulations concerning IRBs, in effect accomplishing the same thing through different means.

It is therefore possible to overcome two significant difficulties with the germaneness inquiry related to government purpose: the problem of limiting the government purpose, and the problem of defining it. In unconstitutional conditions cases touching First Amendment rights, the Supreme Court has created a program- versus organization-wide distinction that in effect limits the government purpose and somewhat tracks the purchase–regulation distinction. The organization-wide restrictions in the IRB regime are thus highly suspect. By borrowing from searching equal protection analysis to determine the government purpose in sex-discrimination cases, courts can more accurately define the government purpose in unconstitutional conditions cases and help to reveal whether the government is acting as a purchaser or a regulator. Applying this analysis to the IRB regime reveals a government purpose to regulate broadly.

II. DETERMINING CLOSENESS OF FIT BETWEEN PURPOSE AND CONDITION

The central feature of the germaneness inquiry is deciding how close the fit between government purpose and condition has to be. As noted above, this consideration of fit can help to reveal whether the government is acting as a purchaser or a regulator. Some of the cases, most notably *South Dakota v. Dole*, require only a loose connection between purpose and condition, holding that any sort of rational basis is sufficient. But in cases touching on First Amendment rights, the Court has required a somewhat closer fit. Again borrowing from equal protection (and First Amendment) analysis, at a minimum any organization-wide restriction should satisfy heightened scrutiny, meaning that it is narrowly tailored to achieve the government purpose.

The opinions in *South Dakota v. Dole* lay out different possibilities for how close the fit must be between purpose and condition. At issue in *Dole* was a federal statute conditioning states’ receipt of part of federal funds for highway construction and maintenance on their adoption of a minimum

⁴⁸ NAT’L RESEARCH COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: INSTITUTIONAL REVIEW BOARDS 3 (DHEW Publication No. 78-0008) (1978).

⁴⁹ Proposed Regulations Amending Basic HEW Policy for Protection of Human Research Subjects, 44 Fed. Reg. 47,688 (proposed Aug. 14, 1979).

⁵⁰ Hamburger, *supra* note 3, at 325.

drinking age of twenty-one. Chief Justice Rehnquist's opinion for the Court stated that the condition "is directly related to one of the main purposes for which highway funds are expended—safe interstate travel."⁵¹ As noted above, one of the areas of disagreement between the majority and the dissent was the scope of the purpose. Justice O'Connor, in contrast to the majority, defined the purpose as funding safe "interstate highway construction."⁵² But that very definition of the purpose's scope proceeded from her understanding of the necessary relationship between the purpose and the condition.

Justice O'Connor heavily emphasized the purchase–regulation distinction in arguing there should be a close fit between the purpose and condition. The federal government could not insist that the State change regulations in other areas because of an "attenuated or tangential relationship to highway use or safety."⁵³ Otherwise, Congress could in effect regulate almost any area through the states on the theory that highway use or safety would somehow be affected.⁵⁴ Justice O'Connor argued that "Congress has no power under the Spending Clause to impose requirements on a grant that go beyond specifying how the money should be spent."⁵⁵ If Congress went beyond this limit, it was not imposing a condition but rather regulating. Given the federal government's vast resources, such regulation would entirely upset the U.S. constitutional scheme.

Although in a case involving federalism such as *Dole* the Supreme Court was willing to allow restrictions that clearly went beyond "specifying how the money should be spent," in cases that touch on First Amendment rights the Court has hewed closer to that line, and in the process insisted more rigorously on the fit between purpose and condition. *FCC v. League of Women Voters* provides the best example of this. *League of Women Voters* concerned a federal statute that forbade any noncommercial educational broadcasting station which received a grant from the federal Corporation for Public Broadcasting to "engage in editorializing." As noted above, the Court stressed that Congress provided no way for broadcasters to segregate funds so that other funds could be used to finance editorializing. This undermined the government's contention that Congress simply decided it would not subsidize public broadcasting station editorials.⁵⁶ Under the stat-

⁵¹ *South Dakota v. Dole*, 483 U.S. 203, 208 (1987).

⁵² *Id.* at 214 (O'Connor, J. dissenting).

⁵³ *Id.* at 215.

⁵⁴ *Id.*

⁵⁵ *Id.* at 216 (quoting Brief for the National Conference of State Legislatures et al. as Amici Curiae).

⁵⁶ *FCC v. League of Women Voters*, 468 U.S. 364, 399 (1984). The government had argued this narrow definition of purpose in the unconstitutional conditions context to accord with the Court's then-recent case *Taxation with Representation*, which upheld the lobbying restrictions on 501(c)(3) organizations in part because they could form affiliates to engage in lobbying. See *Regan v. Taxation with Representation*, 461 U.S. 540, 551 (1983).

ute, “a noncommercial educational station that receives only 1% of its overall income from CPB grants is barred absolutely from all editorializing.”⁵⁷

Elsewhere in the opinion, discussing the First Amendment proper, the Court made clear that the restriction did not further the government’s broader asserted purpose of protecting the independence of noncommercial broadcast stations. In determining the closeness of the fit, the Court used an intermediate scrutiny test: the restriction must be “narrowly tailored to further a substantial government interest.”⁵⁸ The Court determined that the restriction in question was not necessary because there was already in place an elaborate and effective web of requirements to ensure station independence from government influence.⁵⁹ Even if these did not exist, the Court decided, the particular ban on editorials was both underinclusive and overinclusive: underinclusive because it did not cover non-editorial programming, which would likely be more subject to influence, and overinclusive, among other reasons, because many editorials would be unlikely to provoke Congress’s ire and because the restriction in no way addressed the influence of state and local governments.⁶⁰ The restriction was therefore not “narrowly tailored” to achieve a substantial government interest.

At a minimum, given Supreme Court precedents, restrictions on speech or the press that go beyond federally funded projects to affect an entire organization should be subject to more intense scrutiny than rational basis. This is assuming such restrictions are constitutionally permissible at all. Cases such as *League of Women Voters* suggest that the proper standard for determining the fit between purpose and condition is at least intermediate scrutiny, and more likely strict scrutiny, if allowed at all.

Whether a rational basis test or a heightened scrutiny test is used would likely have a decisive effect on the constitutionality of organization-wide IRB regulations. The main—indeed, apparently the sole—constitutional argument for extending the scope of IRBs beyond federally funded projects has to do with hypothesized spillover effects of research methods. The argument runs as follows: The government purpose is simply to ensure that *federally funded* research is conducted ethically. (As we have seen, Supreme Court precedents have strongly suggested that control of federal funds is the only constitutionally permissible government purpose in the case of restrictions that trench on First Amendment rights.) Restrictions on research funded by other sources, however, may be helpful in furthering this purpose because these broader restrictions accustom both institutions

⁵⁷ *League of Women Voters*, 468 U.S. at 400.

⁵⁸ *Id.* at 380. The Court did not adopt a strict scrutiny test in that case because it involved broadcast media. *Id.* at 374–81.

⁵⁹ *Id.* at 388–90.

⁶⁰ *Id.* at 390–99.

and researchers to IRB oversight and requirements, which in turn would encourage greater compliance concerning federally funded research.⁶¹

While it is conceivable that such an argument would pass a rational basis test, it is unlikely it would be viewed as narrowly tailored under an intermediate or strict scrutiny test. It is entirely possible that institutions and researchers would be able to accurately follow different procedures for federally funded and otherwise funded research. Government contractors in a variety of fields have successfully met federal requirements that are different from those of their other customers; they are generally quite sensitive to the special requirements of the federal government and the need to follow distinctive procedures. Even if imposing requirements on all research might marginally aid compliance in federally funded research, the high burden imposed⁶² would likely be found to outweigh any conceivable benefit. It would therefore not be narrowly tailored under intermediate or strict scrutiny.

The question of how close the fit has to be leads naturally into the question whether there are less restrictive alternatives that would accomplish the same or similar goals. In discussing unconstitutional conditions, in *League of Women Voters* the Court noted that, unlike in Hatch Act cases, here the government's restriction "is not grounded in any prior governmental experience with less restrictive means."⁶³ In the case of IRBs, less restrictive means are readily conceivable. Philip Hamburger has pointed out that the potential harms caused in research are quite similar to potential harms from journalism and medical treatment. Yet both those enterprises are regulated not by requiring prior permission for activity, but by imposing liability for harm after the fact through tort law.⁶⁴

Equal protection heightened scrutiny analysis therefore has much to offer in unconstitutional conditions cases touching on First Amendment rights. Germaneness and equal protection both address the question of fit between government purpose and a distinction made by law. Heightened scrutiny is also used in the substantive First Amendment context. Applying

⁶¹ See Robertson, *supra* note 41, at 500. Robertson emphasizes the institution's role as well as the researcher's in phrasing the argument this way: "Requiring the same rules for all research with human subjects might sensitize the institution to problems of protecting subjects; stimulate oversight of research; and induce greater awareness, commitment, and consistency in ethical concerns among investigators, thereby promoting ethical conduct in federally funded research." Robertson, *supra* note 41, at 500. The National Science Foundation has lent support to this connection in its answer to the question: "What are the overall goals of the federal policy? . . . Institutions engaged in research should foster a culture of ethical research." Hamburger, *supra* note 3, at 325 n.127.

⁶² Many participants in this Symposium have discussed the burdens IRBs impose. These include research delays, expenditure of considerable time and effort to comply, and suppression of speech and the press. See also Hamburger, *supra* note 3, at 343–50.

⁶³ *League of Women Voters*, 468 U.S. at 401 n.27.

⁶⁴ See Hamburger, *supra* note 3, at 339–43.

heightened scrutiny to the IRB regime, it seems doubtful that the organization-wide restrictions would pass constitutional muster.

CONCLUSION

Although the germaneness inquiry does not solve all difficulties with unconstitutional conditions doctrine, it is capable of moving a fair distance toward the purchase–regulation distinction. Incremental changes in the doctrine, building on past precedent, that might be palatable to courts could move doctrine in a more wholesome direction. Particularly with borrowings from aspects of equal protection jurisprudence, it can help uncover improper government purposes and ensure a close fit between conditions and purposes. It therefore has a useful role to play in limiting the damage done to constitutional limitations on the federal government by the Court’s spending jurisprudence.

A germaneness analysis influenced by equal protection doctrine reveals that the government purpose in creating the IRB regime was to regulate broadly research on human subjects, whether federally funded or not. The regime is not narrowly tailored to promote a more limited purpose. The IRB regime is a notable example of the precise problem that unconstitutional conditions doctrine needs to address. The borrowings from equal protection analysis this Paper suggests would allow the problem to be addressed more thoroughly and help to limit the federal government to its proper sphere under the Constitution.

