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# THE DIMENSIONS OF CONSTITUTIONAL ANALYSIS: A REPLY TO PROFESSOR HAMBURGER

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Professor Hamburger's Response to my main contribution to this Symposium[1] usefully highlights the differences between our perspectives on the constitutionality of Institutional Review Board ("IRB") regulations.[2] He identifies two crucial points of substantive disagreement: (1) whether IRB regulations restrict speech or conduct; and (2) whether these regulations merely constitute funding conditions or instead directly impose legal obligations. In addition, Hamburger describes an important difference in our styles of legal analysis: whereas he focuses on what the law should be, I am much more interested in trying to figure out what the law actually is in several difficult and uncertain areas of constitutional law relevant to this inquiry. But rather than advance his position, Hamburger's Response actually serves to underscore the implausibility of his claim that IRB regulations impose facially unconstitutional restrictions on speech. This brief Reply will address, in turn, the two substantive points as well as this crucial difference in our mode of analysis.

## SPEECH VERSUS CONDUCT

In my article I argued that under the Supreme Court's basic free speech taxonomy IRB regulation of ordinary biomedical research, such as blood draws, PET scans and experimental surgery, would be classified as regulation of "nonexpressive conduct" devoid of First Amendment protection, including the prohibitions against licensing and content discrimination.[3] In his Response, Hamburger insists that, despite appearances, these regulations actually restrict speech because the Common Rule defines research as a "'systematic investigation' in pursuit of 'generalizable knowledge'" and

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[1] James Weinstein, *Institutional Review Boards and the Constitution*, 101 NW. U. L. REV. 493 (2007). In that article, I engaged several arguments against the constitutionality of IRB regulations made in Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271.

[2] Philip Hamburger, *Two-Dimensional Doctrine and Three-Dimensional Law: A Response to Professor Weinstein*, 101 NW. U. L. REV. 563 (2007).

[3] *See* Weinstein, *supra* note 1, at 497–505. In contrast, IRB regulations of ordinary social science interviews and surveys are regulations of speech within the meaning of the First Amendment and thus, funding issues aside, present substantial First Amendment issues. *See id.* at 505–42.

thus, according to Hamburger, in terms of "verbal language."[4] Although the Common Rule's definition of "research" in terms of "generalizable knowledge" is itself devoid of any reference to "verbal language" or other forms of expression, Hamburger points out that the *Belmont Report* (an antecedent to the Common Rule) refers to "generalizable knowledge" as that which is "*expressed* . . . in theories, principles, and statements of relationships."[5] He then attempts to link this reference to expression with IRB regulations by noting that the government requests that institutions receiving federal research funds "acknowledge" this explanation of "generalizable knowledge."[6]

The connection between the incidental reference to expression in the *Belmont Report* and the actual IRB regulations is much too tenuous to convert the regulation of ordinary biomedical research into speech protected by the First Amendment. This effort is especially strained when one recalls that the *Belmont Report*'s explanation of "generalizable knowledge" in this way was not to target expression, as Hamburger implies. Rather, this explanation served to distinguish between "research," which the Report concluded should be subject to review, and "the practice of accepted therapy," which, it concluded, should not be.[7] Nor does Hamburger advance the analysis by arguing that IRB regulations really target speech rather than conduct because "a recent NIH committee, the National Science Foundation and most IRBs recognize that a 'systematic investigation' designed to develop 'generalizable knowledge' means what a researcher 'plans to publish' and often what is 'publishable.'"[8] This argument is merely a variation of the "necessary precondition of speech" argument considered in detail and rejected in Part I.B of my primary article.

## FUNDING CONDITIONS VERSUS DIRECT REGULATION

In my article, I argued that any First Amendment difficulty with IRB regulations might be largely obviated by the fact that these regulations are imposed as funding conditions rather than by force of law. A crucial question is whether these conditions are themselves constitutionally valid or rather impose an "unconstitutional condition." I explored this question in detail in my article and concluded that the funding conditions are most

[4] Hamburger, *supra* note 2, at 565.

[5] *Id.* (emphasis added) (quoting THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, REPORT OF THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, 44 Fed. Reg. 23,192, 23,193 (April 18, 1979) [hereinafter BELMONT REPORT]).

[6] *Id.*

[7] *See* BELMONT REPORT, *supra* note 5, at 23,193.

[8] *See* Hamburger, *supra* note 2, at 565 (quoting Committee on the Role of Institutional Review Boards in Health Services Research Data Privacy Protection, Protecting Privacy in Health Services Research 43, 53 (National Academy Press 2000); National Science Foundation, Frequently Asked Questions and Vignettes, http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp).

likely constitutional. In his Response, Professor Hamburger does not take issue with my analysis on this point but rather seeks to avoid its consequence by arguing that these regulations actually have the obligation of law because the federal government has increasingly relied on the threat of liability under state negligence law to get universities and other institutions to establish IRBs.[9] But the mere fact that the standard of care applied in state negligence law may be influenced by the widespread adoption of IRB regulations cannot possibly render *an otherwise constitutional condition* on spending a violation of the First Amendment. This claim ignores the separate identities of the state and federal governments. A state court judgment penalizing an institution for failing to adopt an IRB regulation that could not be directly imposed consistent with the First Amendment might well be unconstitutional, for such a judgment does indeed impose "the full obligation of law" on a defendant. But the fact that *state* courts, in the development of their negligence law, might unconstitutionally add coercive force to an otherwise valid federal funding condition cannot make the *federal* regulation unconstitutional or otherwise limit the power of federal government. It is most telling that Hamburger cites no authority—be it case law or commentary—to support this novel theory.

A somewhat more plausible variation of this argument posits that in imposing IRB regulation as a condition of federal funding the federal government specifically intended that state courts would look to these regulations as establishing the standard of care in negligence cases. Professor Hamburger seems to be making this argument, charging in his Response that the federal government has "deliberately ma[de] IRB licensing the standard of care" for liability under state tort law. But there are any number of problems with this argument, not the least of which is that Hamburger adduces no evidence of such illicit intent. But even if there was such evidence, the argument would still have to contend with the rule that, in free speech challenges, the Court "will not strike down an otherwise constitutional statute on the basis of an alleged illicit legislative motive."[10]

## DESCRIPTIVE VERSUS NORMATIVE ANALYSIS

Finally, Professor Hamburger correctly states that we have brought very different "styles of analysis" to the question of the constitutionality of IRB regulations. Although no analysis of a practice as normatively rich as

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[9] *See* Hamburger, *supra* note 2, at 564–66. In his Response, Hamburger makes clear that this is an independent argument distinct from his claim that the funding conditions are invalid either because they are beyond Congressional power or because they attach an unconstitutional condition. The independent status of this argument was much less clear in his earlier article. *See* Hamburger, *supra* note 1, at 331 (charging that the federal government "has employed unconstitutional conditions to ensure wide use and acceptance [of IRB regulations], and it has relied upon this wide use and acceptance to trigger liability under state tort law for institutions that do not adopt [the regulations]").

[10] United States v. O'Brien, 391 U.S. 367, 383 (1968).

American constitutional law can be entirely descriptive, Hamburger is right that I have largely tried to analyze the constitutionality of IRB regulations under "the doctrines enunciated by the Supreme Court"[11] rather than focus on what the law should be. But in doing so, I have not, as Hamburger curiously charges, looked only to what can be found on "the mere surface of Supreme Court opinion."[12] To the contrary, in trying to determine what the law is in various areas relevant to the question of the constitutionality of IRB regulations, I have often explained the pattern of decided cases in ways that deviate markedly from the "surface of the [Court's] prose"[13] and have done so, moreover, by examining the values that underlie the Court's free speech doctrine.

In contrast to my primary focus on determining the applicable law, Professor Hamburger is much more interested in criticizing the Court for what he sees as disastrous wrong turns in any number of areas. Hamburger is particularly incensed about what he believes to be the weakening of a historically absolute prohibition against licensing speech and the press by the Court's assimilating this prohibition with a weaker one against injunctions restraining speech.[14] This critique is interesting but largely irrelevant to the constitutionality of IRB regulation: If I am correct that under the best understanding of current doctrine much of what IRB rules regulate is not within the scope of the First Amendment, then even the most ardent rule against licensing speech and press is not implicated, let alone violated, by application of IRB regulations to this conduct. Thus, the crucial issue is not, as Hamburger believes, the *strength* of the prohibition against licensing (which in any event remains quite stringent) but the *scope* of that rule. And this brings us back to the question of whether ordinary biomedical research is speech within the meaning of the First Amendment.

Perhaps Hamburger believes the stark speech–conduct dichotomy that I describe as underlying the Court's free speech doctrine is yet another example of the Court's "irresponsible creation of doctrines that invite censor-

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[11] Hamburger, *supra* note 2, at 566.

[12] *Id.* Also curious is Hamburger's charge that the "threat to liberty" created by the Court's "irresponsible" doctrine is exacerbated by "the tendency of commentators to accept the thinnest surface of doctrine as if it were entirely the law." *Id*. at 567. Whatever problems may exist with First Amendment scholarship, an abundance of uncritical acceptance of Supreme Court doctrine is not among them. More frequent and far more damaging to contemporary First Amendment scholarship are strident critiques by commentators with an all consuming gripe against some regulation but who are not well enough acquainted with the workings and goals of free speech doctrine to realize that the First Amendment has, and should have, no bearing on the matter.

[13] *Id.* at 566.

[14] Professor Hamburger chides me for using the term "prior restraint" rather than "licensing" to refer to the IRB requirement of prior review. But this is purely a semantic quibble: In saying the doctrine against prior restraints on speech is not applicable to the restrictions on biomedical research imposed by IRB regulations, I did not mean to imply that the strength of the prohibition against licensing of the press is or should be the same as that applicable to injunctions.

ship."[15] But such a position would be hard to reconcile with his astute observation that expanding the scope of a right can dilute its strength. Just as Hamburger believes that the Court's combining prohibitions against injunctions and licensing into a single doctrine of "prior restraints" weakened what once was an absolute prohibition against licensing, I fear that if activity such as experimental surgery were mixed into the same pot as criticism of the war in Iraq, the strong protection presently afforded core political speech might be diluted: If the Court were to extend First Amendment protection to ordinary biomedical research, it would doubtless continue to allow the government a relatively free hand to regulate this activity, thus cheapening what it means to have a First Amendment right. The Court's speech–conduct dichotomy is, admittedly, formalistic and somewhat arbitrary. Nonetheless, these drawbacks are, in my view, far preferable to the weakening of free speech protection that might result from a more flexible approach that allows virtually any form of human activity First Amendment shelter.[16]

In sum, it is telling that Professor Hamburger is forced to rely on far-fetched arguments to support the two central pillars of his claim that IRB regulation violates the First Amendment. Perhaps in the fifth dimension, regulation of ordinary biomedical research violates the First Amendment. But in the three-dimensional world that law and legal commentary inhabit, IRB regulations are facially constitutional.

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[15] Hamburger *supra* note 2, at 567.

[16] I should have perhaps been more explicit in my main article about why I think the Court's free speech taxonomy is basically right. I am grateful for the opportunity to briefly do so here.