

TWO-DIMENSIONAL DOCTRINE AND THREE-DIMENSIONAL LAW: A RESPONSE TO PROFESSOR WEINSTEIN

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Professor Weinstein examines how the IRB laws would fare under Supreme Court doctrine, and whereas it is my view that these laws should be considered unconstitutional, he reaches largely the opposite conclusion. His article therefore offers a valuable opportunity for further exploration of the constitutional questions, and although there is not sufficient space here to discuss all of his analysis, it seems important at least to draw attention to the major points on which we take different perspectives.

MY POSITIONS

It is probably best to begin by clarifying my basic constitutional arguments. I had obviously hoped to make my positions clear, but I may perhaps have failed in this regard. Certainly, upon reading Professor Weinstein's article, I cannot help thinking that one can never be clear enough. Therefore, even if at the risk of repetition, it seems necessary to draw attention to some of my positions.

First, rather than concern conduct, my argument is that the IRB laws "target and even specify speech and the press as the object of their licensing."¹ In Professor Weinstein's view, I take the position that the IRB laws are regulations of conduct, and on this basis he answers that such regulations are unlikely to be held unconstitutional.² It may be that my argument should centrally concern conduct, but this is not my focus. On the contrary,

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¹ Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271, 281.

² Incidentally, in pursuit of this point, Professor Weinstein quotes me that "although the IRB regulations appear to be focused on conduct, they discriminate on the basis of content"—his implication being that I share his view that the IRB laws are primarily regulations of conduct. James Weinstein, *Institutional Review Boards and the Constitution*, 101 NW. U. L. REV. 493, 504–05 (2007) (citing Hamburger, *supra* note 1, at 306). My next sentence, however, explains that the regulations which "appear" to be focused on conduct are, in fact, regulations that "candidly require IRBs to license the verbal core of speech and the press." Hamburger, *supra* note 1, at 306. The footnote elaborates that "the IRB regulations expressly define 'research' in terms of speech and the press." *Id.* at 306 n.94.

my argument emphasizes that the IRB laws “candidly require IRBs to license the verbal core of speech and the press.”³

Second, far from relying exclusively on spending conditions, my argument is that the IRB laws have the full obligation of law. Professor Weinstein is under a different impression and says I take the view that the IRB laws are unconstitutional “even though” they “are not directly imposed on research institutions by force of law but rather are adopted . . . as a condition on receiving federal research funds.”⁴ In fact, although I discuss such conditions and argue that they should be considered unconstitutional, my argument concludes that the federal government now primarily relies on state negligence law to give force to the IRB laws. In particular, the government used its conditions to establish IRBs as the standard of care for conducting research, and having thus successfully “elevated IRBs as the standard method of avoiding research injuries, it could rely on state tort law to induce research institutions to use IRBs.”⁵

Third, my argument rests on the concept of licensing rather than the notion of prior restraint. Professor Weinstein assumes it is my view that the IRB laws are unconstitutional as prior restraints. He thus says that my argument is “[s]pecifically . . . that these regulations constitute a content-based prior restraint.”⁶ This is the sort of analysis, however, that I specifically reject. Instead, my argument is that notwithstanding Supreme Court doctrine on prior restraint, the core of the freedom of speech and the press remains a freedom from licensing. On this basis, the IRB laws should be considered unconstitutional because they “set up a system of licensing” and “target and even specify speech and the press as the object of their licensing.”⁷

In short, rather than rest on conduct, conditions, and prior restraint, my argument actually ends up focusing on verbal language, the direct obligation of law, and licensing.

THE IRB LAWS

More significantly, the IRB laws themselves are a matter on which there are different perspectives. It is especially important to examine these differences, for an analysis of the IRB laws must rest on the reality of these laws.

It is possible to take the view that the IRB laws concern conduct rather than speech. Certainly, the IRB laws focus on “research,” and Professor Weinstein therefore assumes that the laws specify a sort of conduct. The

³ Hamburger, *supra* note 1, at 306.

⁴ Weinstein, *supra* note 2, at 493.

⁵ Hamburger, *supra* note 1, at 329.

⁶ Weinstein, *supra* note 2, at 493.

⁷ Hamburger, *supra* note 1, at 281.

Common Rule, however, defines research in terms of verbal language—as a “systematic investigation” in pursuit of “generalizable knowledge.”⁸ This is an allusion to scientific knowledge, and it expressly refers to such knowledge as can be reduced to an hypotheses or general statement. Although Professor Weinstein does not consider this a reference to speech or the press, there are many reasons to understand it as such. Here, it should suffice to observe that the government itself asks universities to acknowledge that “generalizable knowledge” is that which is “expressed . . . in theories, principles, and statements of relationships.”⁹ Moreover, 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.”¹⁰ In these ways, the government and other participants in the licensing system openly concede that the IRB laws license speech and the press.

Professor Weinstein’s distinctive understanding of the IRB laws also becomes apparent when he argues that IRB laws lack legal obligation, for he assumes they are imposed “through a condition on receipt of federal support for research.”¹¹ As already suggested, the federal government began by relying on conditions, but it systematically used its conditions to elevate IRB licensing as the standard of care for human subjects research. To be precise, it “employed unconstitutional conditions to ensure wide use and acceptance” of IRB licensing, thus deliberately making IRB licensing the standard of care for “liability under state tort law.”¹² Negligence law is therefore now the primary legal obligation behind the IRB laws, and far from being a matter of dispute, this is widely recognized by universities.

Constitutional analysis can only be persuasive if it focuses on statutes, regulations, and other laws as they actually exist. To be sure, on the surface, the IRB laws use spending conditions to secure licensing of research,

⁸ 45 C.F.R. § 46.102(d) (2005).

⁹ 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). The request that institutions acknowledge this appears in U.S. DEP’T OF HEALTH & HUMAN SERVS., FEDERALWIDE ASSURANCE (FWA) FOR THE PROTECTION OF HUMAN SUBJECTS FOR INSTITUTIONS WITHIN THE UNITED STATES 3 (2006), available at <http://www.hhs.gov/ohrp/humansubjects/assurance/filasur.rtf>.

¹⁰ For the Committee and the IRBs, see COMM. ON THE ROLE OF INSTITUTIONAL REVIEW BDS. IN HEALTH SERVS. RESEARCH DATA PRIVACY PROT., DIV. OF HEALTH CARE SERVS., INST. OF MED., PROTECTING DATA PRIVACY IN HEALTH SERVICES RESEARCH 53 (2000). The National Science Foundation says that research “includes activities, which are intended to lead to published results, or for example, findings presented at a professional meeting.” National Science Foundation, Frequently Asked Questions and Vignettes, <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp> (last visited Apr. 12, 2007).

¹¹ Weinstein, *supra* note 2, at 550.

¹² Hamburger, *supra* note 1, at 331. Of course, there are also state IRB laws, but negligence law is more significant.

and this would be bad enough. The reality, however, is that the government also uses the obligation of negligence law to secure licensing of what is “expressed” and designed to be “publish[ed],” and if the government and many of those who enforce its licensing admit as much, then so should the academics who study the constitutionality of the licensing.

THE DIMENSIONS OF LAW

Underlying these different perceptions is a deeper problem—a style of analysis in which three-dimensional law gets reduced to doctrine as flat as the pages of Supreme Court opinions. Professor Weinstein argues as if the debate here concerns the constitutionality of the IRB laws under the doctrines enunciated by the Supreme Court. As it happens, the IRB laws are probably unconstitutional under the Court’s doctrines, but this is almost beside the point, for the central question, which must precede any application of doctrine, is the plausibility of the Court’s doctrines as applied to the core freedom from licensing.

Americans once enjoyed the benefit of an absolute prohibition against laws requiring the licensing of speech and the press, but in the twentieth century this old freedom of speech and the press came to be submerged under newer doctrines. In particular, the U.S. Supreme Court developed doctrines on spending and prior restraint that gave the impression that the federal government could impose licensing of speech or the press as long as it did so through conditions on expenditures or with a strong government interest. The Court’s doctrines thus simultaneously emboldened the government to think that it could impose the licensing and deprived academics of any confidence they had a constitutional ground to object.¹³ This was the constitutional disaster that gave rise to the IRB laws, and therefore the central question is not whether the IRBs are constitutional under the Court’s doctrines, but rather whether these doctrines should be understood to obliterate the old, absolute freedom from licensing. The Court’s doctrines created an opening for the government to impose licensing of speech and the press, and once it is recognized that the Court bears responsibility for the censorship, it becomes evident that the Court has a duty to restore the constitutional obstacles against it.

In the end, both IRBs and the Constitution deserve a deeper analysis than can be found on the mere surface of Supreme Court opinions. Even the best constructed judicial doctrine is little more than an attempt to summarize, on a two-dimensional page, a law that must exist in the full three-dimensions of life, and it therefore cannot be assumed that the surface of the prose is a complete account of the ideas that lie below. With respect to spending and prior restraint, moreover, the Court’s doctrines are not at all well constructed. On the contrary, these doctrines have given legitimacy to

¹³ *Id.* at 277–81, 351–54.

three decades of licensing, and thus, as I have written before, “[r]esearchers who oppose IRBs face many difficulties, but none more debilitating than the doctrines of the Supreme Court, for those doctrines give the impression that researchers are without a plausible constitutional claim.”¹⁴ The threat to liberty comes from the Court’s irresponsible creation of doctrines that invite censorship, and this threat is all the greater because of the tendency of commentators to accept the thinnest surface of doctrine as if it were the entirety of the law. What is therefore needed is not an application of two-dimensional doctrines—let alone merely the top surface of such doctrines—but rather, more substantially, an understanding of the three-dimensional law that still can be discerned beneath.

¹⁴ *Id.* at 353.

