

Steven Epstein, *Inclusion: The Politics of Difference in Medical Research*.

S Inrig

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Abstract

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The field of Western bioethics was born in an effort to protect vulnerable populations from the exploitations of modern science. Consequently, present concerns to include vulnerable groups in clinical research – in fact to see their exclusion as somehow unethical – cannot help but seem somewhat ironic for those schooled in the history of the field. Still, the “inclusion-and-difference” paradigm represents the ruling interpretive framework in our present era. In his award-winning book, *Inclusion: The Politics of Difference in Medical Research*, Sociologist Stephen Epstein sets out to explore how this ruling paradigm came to ascendancy.

Epstein, Professor of Sociology, and the John C. Shaffer Professor in the Humanities at Northwestern University, is well equipped to take up this subject. His previous book, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (University of California Press, 1996), examined the role of grassroots politics in the production of scientific knowledge and medical research (specifically HIV/AIDS).

This book, then, comes as something of a natural outgrowth of his previous work. In *Inclusion*, Epstein establishes a fourfold purpose: 1) to understand the development of America’s perspective on medical difference and the ensuing strategy, what Epstein calls “the inclusion-and-difference paradigm”; 2) to explain how this strategy institutionalized and became common sense; 3) to explore the consequences of these strategies on researchers, regulators, industry, and affected groups; and 4) to examine the extent to which this paradigm will, or will not, improve health and increase social justice, particularly when compared to other viable

paradigms.

After laying out his methodology for studying a “biopolitical paradigm,” Epstein launches into a historical overview of the complex medical and ethical history of racial and gender differences that existed in American research into the 1970s. The disclosure of several profound ethical breaches combined with new statistical techniques and the burgeoning Freedom Movements of the 60s and 70s to create the exclusionary and protectionistic research paradigm embodied in The Belmont Report (1978) and the FDA’s Women of Childbearing Potential restrictions (1977).

This protectionist paradigm proved temporary, according to Epstein, because “a diverse set of reformers” began in the 1980s to frame this post-Belmont approach as “exclusionary and homogenizing, one-size-fits-all approach to biomedical knowledge-making” (the middle-aged white men as “standard human” model). While Epstein concludes that this claim oversimplified the true history of research, their alternative perspective – an “inclusive but ‘group-specific’” strategy – tapped into common feelings about the biases of biomedical research and the spotty medical history and social theory built upon it.

Epstein then turns to the process by which this paradigm garnered support, institutionalized, and became common sense. The heterogeneous group took advantage, independently, of a common political environment to bring pressure against “standardized” medical research. The reformers, operating both from inside and outside the American research infrastructure, promoted a new “set of meanings” about medical research, what Epstein labels “biomulticulturalism.” This inclusion-and-difference paradigm sought to include members of diverse groups in research and use politically defined subgroups as the metric

of outcomes measurement.

Epstein then addresses the various consequences the new paradigm has had on researchers, regulators, industry, and the affected groups. The attractiveness of the paradigm enabled advocates to superimpose categories in biomedicine, identity politics, and administration for maximum effect, a process Epstein calls “categorical alignment.” These socially constructed categories of biomedical differentiation became incorporated into the federal research infrastructure, obscuring other paradigms (Epstein suggests ones like behavioral practice or social class). He contends that “the question of why the categories of political mobilization and administration should also be viewed as the categories of greatest biomedical relevance was effectively bypassed.” Census categories, social identities, and market niches - “niche standardization” Epstein calls it — became standardized measures of evaluation. Standardizing these units of analysis, he contends, aligned the new approach to the interests of many subgroups.

Accordingly, the paradigm has met with an impressive reception. The US has institutionalized it through numerous laws and rules put in place since the mid-1980s, most notably the NIH Revitalization Act of 1993. The paradigm has spawned a new science of human subject recruitment, which Epstein labels “recruitmentology.” And the paradigm has generated spillover effects in other areas of biomedicine as well as a reconsideration of what constitutes risk and autonomy in clinical trials. Expanding the domain of vulnerable subject groups has met with mixed success, and Epstein points to pregnant women and lesbian, gay, bisexual, and transgender health advocates as examples of this

incomplete expansion. That said, he clearly sees the paradigm spreading across national boundaries, at least to a limited extent, as clinical research globalizes.

Epstein does not consider this all an unparalleled good. The paradigm’s acceptance and institutionalization mask several questions about the consequences of its adoption. The paradigm might institutionalize style over substance, Epstein warns: the formal approach to including diverse groups in clinical research may replace genuine concern for substantive inclusion of excluded populations. The “inclusion-and-difference paradigm” may concentrate on categorical identities as a means of grouping people, to the expense of other legitimate ways, like social behavior or social structure. This, Epstein warns, may distract health advocates from some of the pathways that truly lead to ill health and health disparities. Not only might these subgroup analyses generate findings on racial and gender differences that are unclear, but they might lead to inappropriate care for individuals within those socially-constructed subgroups. They may, in fact, reinforce notions of difference between race and gender groups that previous generations of reformers had worked to erase, occluding other ways of thinking about ill health. In his conclusion, Epstein provides several ideas for how researchers might think differently about some of these issues and their consequences. Readers may not agree with his suggestions or conclusions, but the process of thinking with Epstein about the important role such ideological frameworks have on the process of knowledge-generation cannot help but be beneficial to those seeking to improve health and health research in its modern guise. Highly recommended.

References

Author Information

Stephen J. Inrig, PhD

Assistant Professor of Clinical Sciences (Medical History), Division of Ethics and Health Policy Department of Clinical Sciences UT Southwestern Medical Center