



# Bodily Differences and Collective Identities: The Politics of Gender and Race in Biomedical Research in the United States

STEVEN EPSTEIN

Patricia Schroeder keeps a framed photo of former President Bill Clinton on the wall of her Washington, DC, office. The photo shows Clinton signing the NIH Revitalization Act of 1993, and Schroeder, who at the time served in the US House of Representatives, is one of several female members of Congress appearing at his side. Schroeder considers this legislation one of her most significant accomplishments – not because of its primary intent, which was to renew federal funding for the National Institutes of Health (NIH), but because of several paragraphs inserted into the legislation at the insistence of the Congressional Caucus on Women's Issues.

In addition to mandating an Office of Research on Women's Health and an Office of Research on Minority Health at the NIH, the Act contained two important and controversial provisions. First, the NIH, the world's largest funder of medical research, was required to ensure that women and members of racial and ethnic minority groups be 'included as subjects' in each clinical study

funded by the agency from 1995 onward. Second, the legislation stipulated that every NIH-funded clinical trial be 'designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial'. As supporters of the law in Congress and elsewhere vigorously affirmed, no longer would it be acceptable to spend tax dollars only on the health research priorities of white men. Neither could biomedical researchers take white males as the norm, and then extrapolate findings from studies done on the bodies of white men to other social groups (Interview with Schroeder; National Institutes of Health, 1993; Weisman, 1998, 2000).<sup>1</sup>

The same year in which the NIH Revitalization Act was signed into law, the Food and Drug Administration (FDA), the government agency responsible for the licensing of pharmaceutical drugs and medical devices, issued new guidelines governing the participation of women in the clinical trials sponsored by drug companies to test the safety and efficacy of new drugs. Since 1977, women 'of childbearing potential' had been routinely excluded from many such trials, whether they were pregnant or not, or had any intention of becoming so, out of concern that an experimental drug might bring harm to a fetus. (In intent, this restriction applied only to early, so-called Phase 1 and Phase 2 trials of new drugs, whose potential for causing birth defects was still unknown; and it was not supposed to apply to trials of drugs for life-threatening conditions. In practice, the broad and automatic exclusion of pre-menopausal women from new drug development had become commonplace.) After members of Congress expressed concern about the exclusion of women from drug testing, and after the HIV Law Project, an activist legal organization in New York City, filed a 'citizen petition' against the FDA (McGovern et al., 1992), the agency removed the 1977 restriction and issued new guidelines. Published in 1993, these guidelines permitted the inclusion of women even in the early phases of drug testing, provided that female subjects used some form of birth control, and also called for drug companies to submit data on the effects of new drugs in both men and women (Food and Drug Administration, 1993). In subsequent years, the FDA increasingly has put the burden on drug manufacturers to present safety and efficacy data by age group, race, and ethnicity, in addition to gender.

It is interesting to observe that formal policies of this sort are almost completely exclusive to the United States. In Canada, a policy requiring the inclusion of women in clinical testing of pharmaceutical drugs was announced by the Health Minister in 1996 ('Official Statement', 1996). However, the policy places less emphasis on the importance of comparing findings between female

and male subgroups than in the US case. Other countries, including the UK, have increasingly come to articulate the good of making research subject populations more inclusive, but without adopting any regulations actually mandating such inclusion.

These changes in US biomedical research policies are interesting for many reasons, and they raise important questions of ethics, equity, and social justice (Baird, 1998; Mastroianni et al., 1994; Sherwin, 1994). In this article I focus attention on debates that underlie these policy shifts and that concern the medical management of bodies, groups, identities, and differences. My concern here is with how the bodily character and social location of the 'research material' is understood to affect the credibility of medical findings (Clarke, 1995). Whose bodies are we obliged to include when we conduct the experiments that establish our standards of care? When can results from the study of specific individuals or groups be extrapolated credibly to the broader population of patients? When do physicians, researchers, and patients believe that, in effect, 'bodies are bodies', and that medical knowledge generated from one group of patients is transferable to other groups? Alternatively, under what circumstances is it believed that sex/gender<sup>2</sup> and racial and ethnic differences matter in medicine? And in such cases, are these differences conceptualized in biological terms or in social terms, or in some distinctive combination of the two? Finally, are sex/gender, race, and ethnicity treated as medically comparable varieties of differentiation among patients or research subjects, or do actors point to differences among types of difference?

Since debates about how to conceptualize 'the body' are manifold, I should be clear that this article does not propose to resolve them. Instead, my strategy is to take questions of bodily and social differences as topics for empirical investigation in the sociology of knowledge. On the basis of interview data as well as analysis of other documentary evidence,<sup>3</sup> I ask: what do people mean when they make claims about the medical consequences of sex, gender, race, and ethnicity? How are ideas about bodies and social groups mobilized in the pursuit of various social, political, economic, scientific, and medical agendas?

I begin by briefly reconstructing the history of the recent political and bureaucratic remedies that have been adopted with the goal of redressing past inequities in biomedical knowledge-making. I consider how the underlying arguments about difference are – in complicated and ironic ways – both continuous with, and in contrast to, earlier medical emphases on sexual, gender, racial, and ethnic distinctiveness. Much of the present uncertainty surrounding these policies, I suggest, stems from the fact that various groups of researchers, physicians, policy makers, and health advocates have adopted competing, and often murky,

understandings of the nature of sex/gender, racial, and ethnic differences, and of the relation of the biological to the social in the manifestation of bodily illness.

### Background: A Revolution in Common Sense

In the late 1980s and early 1990s, the 'under-representation' of women and racial and ethnic minorities as subjects in clinical research emerged as a recognized social problem in the United States (Dresser, 1992; Mastroianni et al., 1994). In fact there continues to be debate about whether or to what degree women or minorities had been under-represented previously, and even what 'under-representation' means. In the absence of any systematic record-keeping or reporting of the demographics of research subjects by the NIH, the FDA or medical journals, a range of empirical studies of research demographics, using different samples and methodologies, have arrived at opposing conclusions (Bird, 1994; Kadar, 1994; Kinney et al., 1981; Mastroianni et al., 1994; Meinert et al., 2000).

However, at least in some research domains, such as heart disease, as well as in new drug development, it was not difficult to make a claim that women had been understudied. In addition to the FDA's restrictions, the reliance of many researchers on Veterans' Administration hospital patients as research subjects had lessened the likelihood that women would be included in studies. Many anecdotal reports further suggested that biomedical researchers sometimes considered women to be 'complicated' research subjects because of monthly fluctuations in hormone levels that could confound the effects of the medical regimes or therapies under investigation. Men's bodies, by this reasoning, were simpler to study: there were fewer 'variables' to control for (Mastroianni et al., 1994: 80). Implicitly, men were conceived of as prototypical humans; women were perceived as opposite, deviant, or other (Tavris, 1992; see also Waldby, 1996), and thus as problematic objects of biomedical research.

In the case of racial and ethnic minorities, no one had specifically argued that they should be kept out of the subject populations of clinical research. However – despite many findings of racial and ethnic differences in the extent and course of disease, and despite reports in the medical literature of 'racial differences' or 'ethnic differences' in the effects of treatments such as antihypertensive drugs and antidepressants (Cotton, 1990; Levy, 1993; Polednak, 1989) – few experts had called for ensuring racial and ethnic representation in subject populations across the board. Racial minorities were often considered to be 'hard to recruit' – especially African-Americans, who were said to reject the role of medical 'guinea pig' out of suspicion of the long history of medical experimentation on black

people that dates back to slavery and includes the infamous 'Tuskegee Syphilis Study' (Corbie-Smith, 1999).

Beginning in the late 1980s, research policies and practices that had seemed uncontroversial and even ethically advisable suddenly began to appear ludicrous, offensive, and unscientific. In short order, a new 'common sense' emerged and replaced a prior, discredited one. Certainly a crucial player in the forging of a new common sense was the women's health movement, which, by the late 1980s, enjoyed support not only at the grassroots but also at elite levels within medicine and government. Women scientists at NIH, such as Florence Haseltine, the director of the Center for Population Research at the National Institute of Child Health and Human Development, worked behind the scenes to call attention to the low profile of women's health issues at the agency (Interview with Haseltine). (One of her favorite 'sound bites' was that the NIH had 39 full-time veterinarians but only 3 gynecologists.) At the same time, the broad issue of women's health became a galvanizing one for women in Congress, even as the topic of health reform moved to the top of the policy agenda in Washington (Weisman, 1998, 2000). 'Every time you picked up the paper, there was something', recalled Pat Schroeder, thinking of the news reports in the 1980s that trumpeted the findings of medical researchers conducting clinical studies – reports about 'men eating fish, men riding bikes, men drinking coffee, men taking aspirin. And we were just wondering whether "men" was an all-encompassing word, or whether it was truly just men' (Interview with Schroeder).

'American women have been put at risk', Schroeder concluded, at a June 1990 House subcommittee meeting at which the issue was bruited. Schroeder cited the NIH-funded Physician's Health Study begun in 1981, which had investigated the role of aspirin use in preventing heart attacks: the study had enrolled 22,000 male doctors. Olympia Snowe, co-chair with Schroeder of the Congressional Caucus on Women's Issues, described for reporters a federally funded study on the relation between obesity and cancer of the breast and uterus; the pilot study had used only men. Commented Snowe, whose mother died of breast cancer: 'Somehow I find it hard to imagine that the male-dominated medical community would tolerate a study of prostate cancer that used only women as research subjects' (Jaschik, 1990).

Female members of Congress began pressing for legislation that would force the NIH to change its ways. That the NIH budget was due for re-authorization provided them with a perfect opportunity to inject their concerns into an existing bill. Meanwhile, NIH's Florence Haseltine worked with a lobbying agency called Bass and Howes that specialized in women's issues to found a new, Washington, DC-based advocacy group called the Society for the Advancement of Women's

Health Research (SAWHR). SAWHR explicitly took up the cause of inclusion of women in clinical research as its priority issue and began pressing for passage of the NIH Revitalization Act (Interview with Haseltine; Interview with Bass).

As legislators and their staff began work on new language to be added to the NIH Revitalization Act, almost immediately, the phrase 'and minorities' was added to the wording about inclusion of women in research. This seemed to its sponsors and to others in Congress to be a logical, and politically desirable, extension of the legislative intent: after all, if the NIH was parceling out federal tax dollars, then the research that it sponsored should be of benefit to the whole population. And if whites were already reaping the benefits of better health while men and women of color suffered from higher levels of morbidity and mortality, then it seemed particularly problematic for the government to be investing at higher rates in the health issues affecting white people.

While Congressional arguments about NIH-funded research emphasized the equitable use of tax dollars, public attention to FDA policies crystallized around issues of autonomy and risk. Here, however, the emphasis on inclusion marks a partial break with a particular way of thinking about medical and research ethics that is itself of fairly recent invention. Although the Nuremberg trials after the Second World War had provided graphic evidence of the horrific uses to which medical experimentation could be put, only in the 1960s, with the publication of reports of widespread abuses of patients in high-profile US medical experiments, did many policy makers begin to assert that stricter measures were needed to safeguard human subjects in the United States (Rothman, 1991: 70–84). Bolstered by publicity surrounding the Tuskegee study of 'untreated syphilis in the Negro male' (Jones, 1981), this wave of concern culminated in the enactment of formal, legal protection of the rights of experimental subjects, along with a new conception of participation in research as a burden which, therefore, must be distributed as equitably as possible in society.

A distinguishing feature of this reform wave was its emphasis on the protection of 'vulnerable populations' – children, fetuses, prisoners, the poor, and the mentally infirm – from harm at the hands of the research enterprise (National Commission, 1979). However, by the 1980s, patients began to decry governmental paternalism and insist on their right to assume risks – indeed, their right to serve as 'guinea pigs' (Edgar and Rothman, 1990; Epstein, 1996; Feenberg, 1992). Some of the same groups that had been singled out for protection in the earlier era, including women and children, were now portrayed as victims of substandard care – at risk both because of researcher indifference to the particular manifestations of illness among them and because of their inadequate access to potentially lifesaving drugs. Drawing explicit comparisons with recent legal

debates about whether women could be excluded from occupations that presented a risk of fetal exposure to environmental hazards, advocates for women emphasized how ‘protectionism’ often served to consign women to second-class citizenship (McGovern et al., 1992).

The AIDS activist movement proved to be an especially significant source of pressure for change – both away from the ‘white male model’ and away from a protectionist or paternalistic emphasis in the approach toward human subjects and research risks (Epstein, 1996). Activists demanded the inclusion of more women and racial minorities in clinical trials of experimental drugs, arguing that clinical trials served as an important means of access to otherwise unobtainable and theoretically helpful new therapies. At the same time, activists noted that, since AIDS had different clinical manifestations in women, it made good scientific sense to study the disease separately in women and not to assume that therapies would have the same efficacy or toxicity across groups.

### Histories of Difference

In addition to the changes in attitudes governing medical ethics, the new perceptions regarding the advisability of including diverse groups in clinical research reflect another noteworthy shift or reversal in what might be called the medical management of patient differences: all of a sudden, in the 1990s, taking account of difference had come to seem like a good thing. After all, over the course of several centuries, many physicians and researchers had been interested in differences, but they conceived of them as instances of ‘embodied deviance’ (Urla and Terry, 1995) which both presumed and reinforced a social hierarchy that placed heterosexual European men at the pinnacle.

Medical theorizing about differences between men and women have a long history – Galen, notes Londa Schiebinger (1987: 46), ‘believed that women are cold and moist while men are warm and dry; men are active, women are indolent’. Yet for Galen the female body was essentially a variation on the theme of man: female sex organs were just male organs ‘turned inward’ (Lacquer, 1987: 5). In 18th-century Europe, however, while ideas about male and female sameness did not disappear, strong notions of fundamental medical differences between men and women – of men and women as ‘opposites’ – were used by some medical authorities to breathe new life into claims that women were destined to be socially subordinate to men (Lacquer, 1987; Schiebinger, 1987, 1993). Whenever Enlightenment ideas about democracy and equality threatened to erode the old distinctions between men’s and women’s places in society, ‘arguments for fundamental sexual differences were shoved into the breach’ (Lacquer,

1987: 18). From a biological and anatomical standpoint, women were often understood to be inalterably different and were portrayed as dissimilar from men in essential and thoroughgoing ways. 'The essence of sex', argued the French physician Pierre Roussel in 1775, 'is not confined to a single organ but extends, through more or less perceptible nuances, into every part.' By the 19th century, measurements of European women's skulls and pelvises had led some scientists to conclude that women ranked below men in terms of evolutionary development (Schiebinger, 1987: 51, 63; see also Jordanova, 1989).

Of course, similar sorts of arguments were invoked in 19th-century Europe and the United States to justify racial hierarchies in general and the practice of slavery in particular (Gould, 1981). Samuel Cartwright, chairman of a committee appointed by the Medical Association of Louisiana to report on the 'diseases and physical peculiarities of the Negro race', described in a medical journal in 1851 how not only the black man's skin but also 'his bile . . . his blood . . . the brain and nerves, the chyle and all the humors' were all 'tinctured with a shade of the pervading darkness'. Cartwright argued further that blacks suffered from a deficiency of red blood caused by 'defective atmospherization'; but since hard exercise could cure this condition, it followed that slavery improved black people 'in body, mind and morals' (Tucker, 1994: 13–14). Thus, not only did medical beliefs reflect social preoccupations with racial difference, but medicine also played an active role in constructing those very notions of racial character and of the boundaries between races.

To be sure, the tendency to emphasize differences between groups of patients on ethnic, racial, sexual or other bases has lost ground in the past century. Generally speaking, 19th-century US physicians were committed to the 'principle of specificity' – the belief that medical therapy 'was to be sensitively gauged not to a disease entity but to such distinctive features of the patient as age, gender, ethnicity, socioeconomic position, and moral status, and to attributes of place like climate, topography, and population density' (Warner, 1986: 58; see also Berg and Harterink, this issue). In the latter part of the 19th century, with the increasing adoption of European theories of scientific medicine, physicians gradually abandoned the notion that treatments should be tailored to the idiosyncratic constitutions of patients, in favor of the idea that each specific kind of illness required a distinctive treatment that might be applied universally to sufferers (Warner, 1986: 248–9). Presumptions of difference did not vanish in the 20th century – for example, the Tuskegee Syphilis Study was premised on the notion that syphilis took a different course in blacks than in whites (King, 1992: 35). Nevertheless, it can be argued that the recent protests against 'one-size-fits-all' medicine, and the calls in the 1990s to study differences in the effects of therapies across social

groups, reflect not so much a new trend in medicine as a recovery of a therapeutic tradition that largely fell out of favor a century ago.

Thus, even while the new discourse of medical difference in the 1990s seemed to mark a dramatic reversal in thinking about medical ethics, in other respects this discourse suggested strong, if ironic, historical continuities, or even full-circle movements back to old views that seemed to have been superseded. Of course, that there are echoes of the past does not mean that history simply repeats itself: most present-day defenders of difference offer their arguments in ostensibly non-judgmental fashion and would repudiate any explicit understanding of sex, gender, race or ethnicity in evolutionary or hierarchical terms. If, for example, men and women metabolize certain medications at different rates, few would use this fact to argue for ranking men as more 'advanced' than women, or vice versa, or for placing men and women in different locations in the Great Chain of Being. But surely it is inadequate or incorrect to claim that, until recent years, medicine 'ignored' difference. The real questions, at each historical moment, have less to do with *whether* differences are recognized than with *precisely how* they are imagined and taken into account and *where* differences are understood to be located.

Put another way, the issue is how uncertainty about difference is to be incorporated into biomedical practice, and how plausible provisional solutions to practical dilemmas are arrived at by the various actors who play roles in these debates. However, I would like to argue that consensus in this case is hampered by debates and confusions that underlie the question of whether and how different groups in society actually differ from one another in medically relevant ways. These debates and confusions, which concern the nature of sex/gender, racial, and ethnic categories, and the relation between the biological and the social, do not simply divide the professional communities from outsiders but cut across both groups.

### Bodies and Categories

There is, of course, an extensive literature on sex/gender, racial, and ethnic differences and inequalities in disease prevalence, health outcomes, and health care provision. Epidemiologists, health services researchers, and health policy analysts are used to worrying about these sorts of differences with regard to such phenomena as morbidity and mortality rates, access to affordable care, the dynamics of the patient-provider relationship, and the composition of the health professions. Furthermore, as I have indicated, researchers have observed various sex/gender, racial, and ethnic differences in the course and symptomatology of

illness, as well as in responses to medications. Sex/gender and race and ethnicity have been treated as relevant health indicators in the US for most of this century, in large measure, as social epidemiologist Nancy Krieger explains, because they are typically (though not always properly) treated as self-evident, immutable, and easily recordable characteristics of individuals (Krieger and Fee, 1996; see also Hanson, 1997). (Socioeconomic status, by contrast, is viewed in the US as hard to define and as varying over the course of the individual's life; Krieger and Fee, 1994.) The everyday political relevance of gender and racial identification in the US only increases the likelihood that these categories will be emphasized in biomedical classification.

How are these sociodemographic categories made medically relevant? To begin with, it is important to note the differences between kinds of difference. While the NIH and FDA guidelines mandating the diversification of clinical research effectively treat gender and minority group status as equivalent and commensurable varieties of classification, in western societies these categories stand in for different sorts of political constituencies (though with overlapping membership), and there is also a tendency to think of them as having quite different kinds of grounding in the body. Let me consider the two cases in turn.

*Sex/gender* is typically treated as if it were a simple dichotomous variable: one is either male or female, and the correct designation is not hard to determine – it can, in effect, be ‘read off’ the body. But sex differences, like all differences in nature, lie on a continuum, and they become evident through statistical aggregation: there is no unambiguous dividing line between the two sexes, and every criterion of differentiation that might be invoked, from genitalia to hormones to chromosomes, fails to perform a strict demarcating function. Various authorities, from doctors who perform surgery on intersexed newborns to Olympic committees which debate how athletes with XY chromosomes and female genitalia ought to compete, perform the cultural work of fitting individuals into categories; yet the active labor that goes into making sex appear dichotomous is generally invisible to the broader society, or at least, rarely remarked upon. Despite the recent political agitation on the part of people calling themselves intersexuals or transgendered, this notion of clear and reliable sex differences endures (Fausto-Sterling, 1993; Hirschauer, 1998; Hirschauer and Mol, 1995; Kessler, 1998; Kessler and McKenna, 1978; Lorber, 1996; Oudshoorn, 1994).

In modern medicine, the reliance on sharply defined notions of sex or gender differences in some quarters has alternated with a tendency simply to ignore women in other quarters. From her vantage point as director of the Boston site of the Women's Health Initiative (an enormous clinical study conducted across the United States), JoAnn Manson, a professor of medicine at Harvard Medical

School, reflected, ‘the medical model, when I was in medical school in the late 1970s, was the 70 kilogram man’ (Interview with Manson). According to that thinking, men’s bodies were perceived as the universal, and women’s, when considered at all, were the deviant exception – hence the presumption that monthly hormonal fluctuations in women posed an additional layer of complexity that could confound the results of clinical research. Thus, in the hand-waving logic that prevailed until the recent debates, women’s differences meant that they were unsuitable research subjects; yet their membership within the universal category of ‘Man’ meant that results, once obtained from experiments on men, could presumably be extrapolated to women.

Manson argued that we ought ‘not to assume that we can just extrapolate results from men to women’. She was quick to point to a variety of medical differences: in the case of heart disease, she noted that lipid profiles may have different predictive values in men and women, that men and women ‘present differently’ in terms of the symptoms of heart disease, and that ‘women may not do as well with certain interventions, such as bypass surgery and angioplasty’. On the other hand, Manson also believed there are many situations in which extrapolation is quite reasonable. Pointing to a research area that she herself has explored, Manson noted that if a study finds that exercise is beneficial to men’s health, ‘I don’t think the public health message should be, “Men should exercise,” I think the public health recommendation is that exercise is protective against cardiovascular disease.’ What distinguishes the latter case, in Manson’s view, is that ‘there is no a priori basis for believing there might be a difference’ between men and women with regard to the effects of exercise – or, in a phrase that appeared to be interchangeable in her vocabulary, ‘there’s . . . no *biological* basis for believing there’s a difference’ (Interview with Manson; emphasis added). The recourse to biology is equally evident in the discourse surrounding pharmaceutical drug development. Ruth Merkatz, the former director of the FDA’s Office of Women’s Health (now working with the drug company Pfizer), spoke of pharmacokinetic differences between men and women (that is, differences in the rates of absorption of drugs by bodily tissues), and Leslie Benet, a professor of pharmacology at UCSF and an expert on sex/gender differences in response to pharmaceutical drugs, explained these pharmacokinetic differences with reference to his research showing that men and women have different levels of the enzymes that metabolize medications (Interview with Benet; Interview with Merkatz).<sup>4</sup>

Sometimes these kinds of biological differences are presented as self-evidently locating women and men in wholly separate medical camps. ‘Everyone knows men and women have different shapes, hormones, and psyches’, observed one

author, writing in the journal *American Health for Women*: 'It seems obvious then that illnesses and medications would affect us differently too' (Shaw, 1998: 42). According to Dr Mary Flack, director of endocrinology and diabetes for Parke-Davis, a pharmaceutical company seeking to play a leading role in 'gender-specific' research, 'By the next century, gender may be the most important factor affecting your health' (Shelton, 1997). In recent years, the emphasis on biological difference has also been promoted by advocacy groups such as the Society for the Advancement of Women's Health Research, which heralds the new field of 'gender-specific biology' – a term invented by Florence Haseltine and defined as 'the field of scientific inquiry committed to identifying the biological and physiological differences between men and women' ('10 Differences', 1998; Interview with Haseltine). The Society's web site catalogues these differences, including findings that women awaken from anesthesia more quickly than men; experience greater pain relief than men from kappa-opiate pain medications; and have a higher blood alcohol content than men after drinking alcoholic beverages, even after adjusting for size differences ('10 Differences', 1998).

The reliance in many quarters on a strong biological conception of sex/gender differences suggests one answer to the extrapolation problem: namely, that extrapolation is a bad idea, and that it makes sense to test for differences in medical outcomes between men and women because, and to the extent that, men and women are biologically different. As critics have noted, such an emphasis on biological sex as 'the foundational truth from which women's health research should start' has the effect of eliding questions about the very 'construction of sexual difference as a category of analysis within research' (Eckman, 1998: 149). At the same time, most researchers and clinicians are cognizant of the role of social factors (or, at least, 'lifestyle' factors) in the production of sex/gender differences in health outcomes – Manson, for example, spoke readily of the 'complex interaction' among estrogen levels, smoking, and stress in determining the risk of heart disease in women. This acknowledgment of the social immediately complicates the extrapolation debate, for while differences in lifestyle practices may often correlate with gender, they are typically not understood as doing so in a clear-cut and universal way. That is, when differences are presumed to be biological in origin, researchers may feel confident in assuming that 'all women' differ from 'all men', and physicians may write their prescriptions accordingly – despite the fact that such differences are observable only through statistical aggregation and may not apply to every man or woman (Hirschauer and Mol, 1995: 377). But when differences are seen as social in origin, then the sense of certainty about when extrapolation is legitimate or illegitimate, or how experimental results apply to individual patients, may diminish rapidly.

In the absence of adequate theorization of the *relation* between the biological and the social (Bird and Rieker, 1999) – theories, for example, about how social inequalities come to be embodied (Krieger, 1996) – uncertainty about extrapolation is magnified. Thus, confusion about the relation between the biological and the social has the effect of destabilizing consensus about the drawing of generalizations within and across the sex/gender divide. At the same time, health professionals and researchers are likely to resolve such confusion by falling back on reductionist assumptions: first, that socially salient markers of difference, such as sex/gender, are invariably the ones that matter most in medicine (Hanson, 1997); and, second, that medical differences between men and women, once discovered, require no further explanation, because they simply reflect the fact that men and women are biologically different.

Similar quandaries surface more explicitly in discussions of *racial and ethnic* differences in biomedicine, the meaning of which are more visibly and vigorously contested than are sex/gender differences. Indeed, the debates about whether race and ethnicity are scientifically legitimate and medically relevant categories have directly influenced discussions over whether the NIH and FDA policy changes constitute medically beneficial reforms. Here what I have called the ‘differences between kinds of difference’ clearly matter. While sex/gender categories are generally (if problematically) seen in our society as binary and dichotomous, racial and ethnic categories are at least somewhat more often understood to pose definitional difficulties: How many racial and ethnic categories are there? What about people who are multiracial or multiethnic? Are ‘races’ and ‘ethnicities’ the same thing, or are they different modes of classification (Cornell and Hartmann, 1998)? Furthermore, while our notions of gender difference ‘rest on’ anatomical and biological differences that are taken to be obvious and are rarely questioned, the anatomical or biological basis of race and ethnicity is very much disputed. From a genotypic standpoint, population geneticists have concluded that racial categorization has no basis in biology; that there is more genetic variation within the so-called races than between them; and that genetic markers such as the sickle cell trait have nothing to do with race per se, but are the product of geography and of socially enforced endogamous mating practices (Duster, 1990; Gould, 1981; Lock, 1993; Marks, 1995). But from a phenotypic standpoint, and in everyday life, race retains an aura of self-evident naturalness and, to be sure, a profound political salience. That racial categories are culturally variable and change over time, and that many of today’s ‘white ethnics’ were considered in the 19th century to belong to different races (Jacobson, 1998), does little to disturb the common-sense understanding of racial difference.

In the domain of health research, debates about the legitimate application of

categories of race and ethnicity have been most evident in public health and epidemiology (Cooper, 1994; Hahn, 1992; Williams et al., 1994). Indeed, a 1998 manifesto in the *American Journal of Public Health* called openly for the 'abandonment' of race as a variable in public health research (Fullilove, 1998). Until very recently, however, these debates penetrated much less fully into clinical medicine. Many medical textbooks continued to provide definitions of 'race' that assume underlying genetic homogeneity within races and distinctiveness between races (Williams, 1997). US medical and public health journals have been called unsystematic in their utilization of racial and ethnic categories (Bennett and Bhopal, 1998).

In its implementation of the NIH Revitalization Act's directive concerning 'minorities', the NIH could not entirely evade these definitional dilemmas. One bureaucratic solution was simply to follow the path of other government agencies by adopting 'Statistical Policy Directive No. 15' of the Office of Management and the Budget ('Race and Ethnic Standards for Federal Statistics and Administrative Reporting'). Published in 1977 and recently revised, Directive 15 specifies the racial and ethnic categories used in the US census. It identifies 'five minimum categories for data on race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or other Pacific Islander, and White'. It also specifies two categories for data on ethnicity: 'Hispanic or Latino' and 'Not Hispanic or Latino'.

This way of operationalizing race and ethnicity has provided the basis for the coding scheme used by the NIH in determining compliance with the Act. In its own words, 'NIH has chosen to use these definitions because they allow comparisons to many national databases, especially national health databases' ('US Public Health Service', 1998). Needless to say, however, census categories are determined in response to a particular set of political needs and pressures, and they have changed with regular frequency since the initiation of the US census in 1790 (Goldberg, 1997: 27–58; Wright, 1994). In 1890, the US census included racial categories such as 'quadroon' and 'octoroon' to designate people who were one quarter and one eighth (or less) black (Goldberg, 1997: 36–7). More recently, a heated debate about whether the category 'multiracial' should be added to the census in the year 2000 ended with the decision to instead allow people to check more than one box in the list of races. Debates over the years have also focused on whether 'Hispanics' constitute a distinct race or an ethnicity or language group that cuts across races. In 1993, when Congress held hearings on the proposed revisions to the census categories, a host of groups lobbied for the inclusion or reclassification of their identities on the census forms, in large part because the census results establish membership at the table of 'a smorgasbord of

set-asides and entitlements and affirmative-action programs' administered by the federal governmental (Wright, 1994: 47).

Since the specification of racial and ethnic categories in Directive 15 is understood to be highly politicized, the adoption of these categories by the NIH can hardly resolve debates about legitimate generalizability across categories in biomedicine. Among clinicians, a range of positions with regard to racial differences can be observed. Many, if not most, researchers and physicians, while not necessarily insensitive to the problematic nature of racial classification, have been relatively untouched by the critiques of the concept of race made by geneticists and anthropologists, and therefore proceed as if the categories are trustworthy markers of difference that yield reliable medical maxims: blacks with hypertension do better on diuretics than on beta blockers. On the other side are researchers, many of them African-Americans, who argue (in the words of Harold Freeman of Harlem Hospital in a recent report to President Clinton from the President's Cancer Panel, which he chaired): 'The biologic concept of race is no longer tenable and . . . race should no longer be considered a valid biologic classification. Race is a product of the Nation's social and political history – it is a social construct' (Freeman, 1998: 220). Or, as Newton G. Osborne and Marvin D. Feit argued in a 1992 commentary in the *Journal of the American Medical Association*:

When race is used as a variable in research, there is a tendency to assume that the results obtained are a manifestation of the biology of racial differences; race as a variable implies that a genetic reason may explain differences in incidence, severity, or outcome of medical conditions. Researchers, without saying so, lead readers to assume that certain racial groups have a special predisposition, risk, or susceptibility to the illness studied. Since this presupposition is seldom warranted, this kind of comparison may be taken to represent a subtle form of racism. (Osborne and Feit, 1992: 275)

Criticisms of this sort have attracted increasing attention in recent years in the US, especially after an editor of the *New England Journal of Medicine* decried what he referred to as 'racial profiling' in the prescribing of medications (Schwartz, 2001).

Such considerations have led some researchers – even some who are heavily invested in promoting the health needs of racial minority groups – to suggest that the NIH Revitalization Act has pernicious, perhaps even racist, effects. For example, Dr Otis Brawley, an African-American who headed the National Cancer Institute's Office of Special Populations Research, argued in the journal *Controlled Clinical Trials* in 1995 that 'the legislation's emphasis on potential racial differences fosters the racism that its creators want to abrogate by establishing government-sponsored research on the basis of the belief that there are significant biological differences among the races' (Brawley, 1995: 293). Brawley,

and the cluster of African-American oncologists who share his views, are acutely conscious of the invidious history of racialized thinking in medicine. They tend to emphasize the fundamental biological sameness of human beings across racial categories and to regret the lack of 'understanding that discoveries about disease in one race are applicable to persons of other races' (Brawley, quoted in Freeman, 1998: 220). Furthermore, they tend to attribute differences in health outcomes to social, cultural, and lifestyle factors, including poverty, diet, differences in the consumption of medications, and access to state-of-the-art care.

On one level, these debates in the biomedical community about how best to apprehend and deploy racial and ethnic labels concern disagreements about how seriously medical researchers and practicing physicians need to take these categories: might researchers and physicians simply employ them in a heuristic or pragmatic fashion, as a way of gesturing at socially recognized distinctions between groups? Or is it medically advisable for the profession to be self-conscious about the socially constructed nature of these categories and to be vigilant against reification? At a different level, as critiques of the NIH Revitalization Act and the NIH guidelines suggest, the debate also, at times, reflects ambivalence about the role of the state in the administration of a racial order (Goldberg, 1997: 27–58; Omi and Winant, 1986), at least as applied to medicine. Criticisms like Brawley's reveal concerns about the power of the state to 'racialize' medicine – to impose particular sets of racial meanings that both reflect and reproduce racial politics as currently practiced, and racial identities as currently experienced.

### Implications for the Study of Medical Bodies

In this article I have not attempted to provide a full accounting or a thorough evaluation of recent attempts in the US to improve the health of women and racial and ethnic minorities by including them in greater numbers as subjects in biomedical research and drug development. My goal has been 'simply' to reveal some of what lurks beneath this health policy debate: a vexed history of attending to, or ignoring, differences in medicine; and confused understandings about how sex/gender, racial, and ethnic categories should be employed in medical research and practice, and whether or when these categories have biological relevance.

Finally, the debate reflects a particular dualism that underlies clinical research. Medical knowledge is always produced in relation to particular groups of people. How social and medical categories are constructed beforehand is an ineliminable feature of that knowledge, but clinical trials, and the politics surrounding their

conduct, may also transform such constructions. It is therefore important to view modern-day medical 'subject populations' as 'subjects' in both senses – they are subjected to medical experimentation that is orchestrated by expert authorities, and they are also acting, thinking subjects with goals, desires, and intentions. Subpopulation descriptors – 'black men', 'Asian-American women', and so on – have a similarly dual character: they pinpoint locations on a reified and static map of social positions and biological properties, but they also designate embodied collective actors engaged in reflexive processes of organizing for political ends, contesting social meanings, and thereby remaking the map. The new policies at the NIH and the FDA emerged out of collective action of this sort – they demonstrate how 'subjects' can sometimes change the way that biomedicine does its work.<sup>5</sup> But the controversy surrounding these policies suggests the difficulties that ensue as a result of the dual nature of categories, as various actors seek either to emphasize the duality, or to ignore it, or to declare it out of existence by bureaucratic fiat.

## Notes

This article is part of a larger research project and thus indirectly benefits from the advice of many more people than I can acknowledge here. Neither am I able to reference in the bibliography the many works that have influenced my thinking in this project. An early version of this essay was presented at a workshop on 'Theorizing Bodies in Medical Practice', held in Paris in September 1998. I am grateful to the workshop organizers, Madeleine Akrich and Marc Berg, for their suggestions with regard to revisions; and I would like to thank Meira Weiss, Ingunn Moser, and the other workshop participants for many more useful suggestions and criticisms than I was able to incorporate here. I also benefited from helpful comments on earlier versions from Chloe Bird, Charles Briggs, Peter Conrad, Steve Cornell, Anne Figert, Sandra Harding, Mark Jones, Margaret Lock, Dorothy Nelkin, Steve Shapin, Janet Shim, John Skrentny, Marisa Smith, Paula Treichler, Jonathan Warren, Carol Weisman, and Howard Winant.

This material is based upon work supported by the National Science Foundation under Grant No. SRB-9710423. Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author and do not necessarily reflect the views of the National Science Foundation. The work on which this article was based was also supported by an Investigator Award in Health Policy Research from the Robert Wood Johnson Foundation. Finally, this work was supported by funding from the University of California, San Diego. I am grateful to my research assistants, Nielan Barnes, Rampaul Chamba, Christine deMaria, Josh Dunsby, Mark Jones, David Ribes, and Marisa Smith, for their contributions to the project.

1. Congress granted the NIH some leeway in interpreting these unprecedented requirements and in deciding when they might not apply; and in practice the requirement for subgroup analysis has not been extended to all clinical trials.

2. The categorical terms used in this article are meant to represent the terms employed by the actors I studied, in all the ambiguity of everyday usage. Throughout much of the period under consideration here, policymakers and commentators tended to use the term 'gender' to refer to both biological and cultural aspects of the relation between both men and women – indeed, principally, to the former –

and tended to avoid the term 'sex', often out of fear of confusion with sexuality. In recent years, however, NIH documents have begun using the term 'sex/gender' in an attempt to invoke both the biological and the cultural. I will employ the hybrid term 'sex/gender' as a way of indicating that actors mostly avoided any precision in their definitions or usage. Somewhat similarly, I will sometimes use 'race/ethnicity' as a placeholder to refer to a set of categories whose relation to biological, cultural, social, geographical, or linguistic differences was often left opaque by actors.

In this paper I focus on sex/gender, race, and ethnicity because those were the first social categories to be singled out in recent NIH and FDA policies on 'inclusion' in clinical research. A fair amount of debate has also focused the variable of age (both children and the elderly), and a lesser amount on sexual orientation (Epstein, 2003b). There has been comparatively little emphasis on social class. On the history of the biomedical reliance on age, sex, and race categories, (see also Hanson, 1997).

3. Data for this study have been obtained from 72 semi-structured, in-person interviews in and around Boston, New Haven, New York, Baltimore, Washington, Atlanta, Ann Arbor, Chicago, Denver, Boulder, San Francisco, Los Angeles, and San Diego. Those interviewed included past and present NIH, FDA, and other government officials; clinical researchers; pharmacology researchers; biostatisticians; medical journal editors; drug company scientists; women's health advocates and activists; bioethicists; members of Congress; Congressional aides; lawyers; representatives of pharmaceutical company trade associations; experts in public health; and social scientists. Additional primary data sources include documents and reports from the NIH, the FDA, the CDC, other government agencies, and the U.S. Congress; archival materials from health advocacy organizations; materials from pharmaceutical companies and their trade organizations; articles, letters, editorials, and news reports published in medical, scientific, and public health journals; and articles, editorials, letters, and reports appearing in the mass media.

4. However, Benet argues that these pharmacokinetic differences rarely translate into meaningful clinical differences in the effect of drugs in different groups (Interview with Benet).

5. Of course, my point is not that actual participants in clinical trials speak in unmediated fashion in policy debates. On processes of delegation and representation by which spokespersons speak on behalf of (and thereby help to constitute) such constituencies as 'women' and 'people of color' in these debates, (see Epstein, 2003a).

## References

### *Interviews*

Bass, Marie. Bass and Howes. Interviewed in Washington, DC, 12 April 1999.

Benet, Leslie, MD. Department of Pharmacy, University of California, San Francisco. Interviewed in San Francisco, CA, 15 May 1998.

Haseltine, Florence, MD, PhD. Center for Population Research at the National Institute of Child Health and Human Development, NIH. Interviewed in Rockville, MD, 19 April 1999.

Manson, JoAnn, MD. Harvard Medical School. Interviewed in Boston, MA, 22 April 1998.

Merkatz, Ruth, PhD, RN. Pfizer (formerly with Office of Women's Health, FDA). Interviewed in New York, NY, 9 March 1998.

Schroeder, Patricia. Former US Representative (D-Colorado). Interviewed in Washington, DC, 18 March 1998.

### *Published sources*

'10 Differences between Men and Women That Make a Difference in Women's Health' (1998) Society for the Advancement of Women's Health Research. <http://www.womens-health.org/insertB.htm>.

Baird, K.L. (1998) *Gender Justice and the Health Care System*. New York and London: Garland.

- Bennett, T. and R. Bhopal (1998) 'US Health Journal Editors' Opinions and Policies on Research in Race, Ethnicity and Health', *Journal of the National Medical Association* 90(7): 401–8.
- Bird, C.E. (1994) 'Women's Representation as Subjects in Clinical Studies: A Pilot Study of Research Published in *JAMA* in 1990 and 1992', pp. 151–73 in A.C. Mastroianni, R. Faden and D. Federman (eds) *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*. Washington, DC: National Academy Press.
- Bird, C.E. and P.P. Rieker (1999) 'Gender Matters: An Integrated Model for Understanding Men's and Women's Health', *Social Science and Medicine* 48(6): 745–55.
- Brawley, O.W. (1995) 'Response to "Inclusion of Women and Minorities in Clinical Trials and the NIH Revitalization Act of 1993 – The Perspective of NIH Clinical Trialists"', *Controlled Clinical Trials* 16(5): 293–5.
- Clarke, A.E. (1995) 'Human Materials as Contested Objects: Problematics of Subjects Who Speak', Unpublished manuscript, University of California, San Francisco.
- Cooper, R.S. (1994) 'A Case Study in the Use of Race and Ethnicity in Public Health Surveillance', *Public Health Reports* 109(1): 46–52.
- Corbie-Smith, G. (1999) 'The Continuing Legacy of the Tuskegee Syphilis Study: Considerations for Clinical Investigation', *American Journal of the Medical Sciences* 317: 5–8.
- Cornell, S. and D. Hartmann (1998) *Ethnicity and Race: Making Identities in a Changing World*. Thousand Oaks, CA: Pine Forge Press.
- Cotton, P. (1990) 'Is There Still Too Much Extrapolation from Data on Middle-aged White Men?', *Journal of the American Medical Association* 263(8): 1049–50.
- Dresser, R. (1992) 'Wanted: Single White Male for Medical Research', *Hastings Center Report* January–February: 24–9.
- Duster, T. (1990) *Backdoor to Eugenics*. New York and London: Routledge.
- Eckman, A.K. (1998) 'Beyond "The Yentl Syndrome": Making Women Visible in Post-1990 Women's Health Discourse', pp. 130–68 in P.A. Treichler, L. Cartwright and C. Penley (eds) *The Visible Woman: Imaging Technologies, Gender, and Science*. New York: New York University Press.
- Edgar, H. and D.J. Rothman (1990) 'New Rules for New Drugs: The Challenge of AIDS to the Regulatory Process', *Milbank Quarterly* 68(Supplement 1): 111–42.
- Epstein, S. (1996) *Impure Science: AIDS, Activism, and the Politics of Knowledge*. Berkeley: University of California Press.
- Epstein, S. (2003a) 'Inclusion, Diversity, and Biomedical Knowledge-making: The Multiple Politics of Representation', pp. 173–90 in N. Oudshoorn and T. Pinch (eds) *How Users Matter: The Co-construction of Users and Technology*. Cambridge, MA: MIT Press.
- Epstein, S. (2003b) 'Sexualizing Governance and Medicalizing Identities: The Emergence of "State-Centred" LGBT Health Politics in the United States', *Sexualities* 6(2): 131–71.
- Fausto-Sterling, A. (1993) 'The Five Sexes: Why Male and Female Are Not Enough', *The Sciences* 33(2): 20–6.
- Feenberg, A. (1992) 'On Being a Human Subject: Interest and Obligation in the Experimental Treatment of Incurable Disease', *Philosophical Forum* 23(3): 213–30.
- Food and Drug Administration, US Department of Health and Human Services (1993) 'Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs', *Federal Register* 58(139): 39406–16.
- Freeman, H.P. (1998) 'The Meaning of Race in Science – Considerations for Cancer Research: Concerns of Special Populations in the National Cancer Program', *Cancer* 82(1): 219–25.
- Fullilove, M.T. (1998) 'Comment: Abandoning "Race" as a Variable in Public Health Research – An Idea Whose Time Has Come', *American Journal of Public Health* 88(9): 1297–8.

- Goldberg, D.T. (1997) *Racial Subjects: Writing on Race in America*. New York: Routledge.
- Gould, S.J. (1981) *The Mismeasure of Man*. New York: W.W. Norton.
- Hahn, R.A. (1992) 'The State of Federal Health Statistics on Racial and Ethnic Groups', *Journal of the American Medical Association* 267(2): 268–71.
- Hanson, B. (1997) *Social Assumptions, Medical Categories*. Greenwich, CT: JAI Press.
- Hirschauer, S. (1998) 'Performing Sexes and Genders in Medical Practices', pp. 13–27 in M. Berg and A. Mol (eds) *Differences in Medicine: Unraveling Practices, Techniques, and Bodies*. Durham, NC: Duke University Press.
- Hirschauer, S. and A. Mol (1995) 'Shifting Sexes, Moving Stories: Feminist/Constructivist Dialogues', *Science, Technology, & Human Values* 20(3): 368–85.
- Jacobson, M.F. (1998) *Whiteness of a Different Color: European Immigrants and the Alchemy of Race*. Cambridge, MA: Harvard University Press.
- Jaschik, S. (1990) 'Report Says NIH Ignores Own Rules on Including Women in Its Research', *Chronicle of Higher Education* 27 June: A-27.
- Jones, J.H. (1981) *Bad Blood: The Tuskegee Syphilis Experiment*. New York: Free Press.
- Jordanova, L. (1989) *Sexual Visions: Images of Gender in Science and Medicine between the Eighteenth and Twentieth Centuries*. Madison: University of Wisconsin Press.
- Kadar, A.G. (1994) 'The Sex-bias Myth in Medicine', *Atlantic Monthly* August: 66–70.
- Kessler, S.J. (1998) *Lessons from the Intersexed*. New Brunswick, NJ: Rutgers University Press.
- Kessler, S.J. and W. McKenna (1978) *Gender: An Ethnomethodological Approach*. Chicago: University of Chicago Press.
- King, P.A. (1992) 'The Dangers of Difference', *Hastings Center Report* 22(6): 35–8.
- Kinney, E.L., J. Trautmann, J.A. Gold, E.S. Vesell and R. Zelis (1981) 'Underrepresentation of Women in New Drug Trials: Ramifications and Remedies', *Annals of Internal Medicine* 95: 495–9.
- Krieger, N. (1996) 'Inequality, Diversity, and Health: Thoughts on "Race/Ethnicity" and "Gender"', *Journal of the American Medical Women's Association* 51: 133–6.
- Krieger, N. and E. Fee (1994) 'Social Class – The Missing Link in US Health Data', *International Journal of Health Services* 24(1): 25–44.
- Krieger, N. and E. Fee (1996) 'Measuring Social Inequalities in Health in the United States: A Historical Review, 1900–1950', *International Journal of Health Services* 26(3): 391–418.
- Lacquer, T. (1987) 'Orgasm, Generation, and the Politics of Reproductive Biology', pp. 1–41 in C. Gallagher and T. Lacquer (eds) *The Making of the Modern Body: Sexuality and Society in the Nineteenth Century*. Berkeley: University of California Press.
- Levy, R.A. (1993) *Ethnic and Racial Differences in Responses to Medicines: Preserving Individualized Therapy in Managed Pharmaceutical Programs*. Reston, VA: National Pharmaceutical Council.
- Lock, M. (1993) 'The Concept of Race: An Ideological Construct', *Transcultural Psychiatric Research Review* 30: 203–27.
- Lorber, J. (1996) 'Beyond the Binaries: Depolarizing the Categories of Sex, Sexuality, and Gender', *Sociological Inquiry* 66(2): 143–59.
- McGovern, T.M., M.S. Davis and A.M. Gomez (1992) 'Citizen Petition', New York: HIV Law Project of the AIDS Service Center.
- Marks, J. (1995) *Human Biodiversity: Genes, Race, and History*. New York: Aldine de Gruyter.
- Mastroianni, A.C., R. Faden and D. Federman (eds) (1994) *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*. Washington, DC: National Academy Press.
- Meinert, C.L., A.K. Gilpin, A. Ünalp and C. Dawson (2000) 'Gender Representation in Trials', *Controlled Clinical Trials* 21: 462–75.
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- (1979) 'The Belmont Report: Ethical Principles and Guidelines for the Protections of Human Subjects of Research'. Washington, DC: US Department of Health, Education and Welfare.
- National Institutes of Health Revitalization Act of 1993 (1993) Public Law 103-43 [S. 1], 10 June.
- 'Official Statement on the Inclusion of Women in Clinical Trials' (1996) *Canada NewsWire*, 26 September.
- Omi, M. and H. Winant (1986) *Racial Formation in the United States: From the 1960s to the 1980s*. New York: Routledge and Kegan Paul.
- Osborne, N.G. and M. Feit (1992) 'The Use of Race in Medical Research', *Journal of the American Medical Association* 267(2): 275-9.
- Oudshoorn, N. (1994) *Beyond the Natural Body: An Archeology of Sex Hormones*. London: Routledge.
- Polednak, A.P. (1989) *Racial and Ethnic Differences in Disease*. New York: Oxford University Press.
- Rothman, D.J. (1991) *Strangers at the Bedside*. New York: Basic Books.
- Schiebinger, L. (1987) 'Skeletons in the Closet: The First Illustrations of the Female Skeleton in Eighteenth-century Anatomy', pp. 42-82 in C. Gallagher and T. Lacquer (eds) *The Making of the Modern Body: Sexuality and Society in the Nineteenth Century*. Berkeley: University of California Press.
- Schiebinger, L. (1993) *Nature's Body: Gender in the Making of Modern Science*. Boston, MA: Beacon Press.
- Schwartz, R.S. (2001) 'Racial Profiling in Medical Research' (editorial), *New England Journal of Medicine* 344(18): 1392-3.
- Shaw, E. (1998) 'What Your Doctor Didn't Learn in Med School', *American Health for Women* 17(6): 42-5.
- Shelton, D. (1997) 'The New Sexual Revolution', *Los Angeles Times* 16 July: E-2.
- Sherwin, S. (1994) 'Women in Clinical Studies: A Feminist View', pp. 11-17 in A.C. Mastroianni, R. Faden and D. Federman (eds) *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies*. Washington, DC: National Academy Press.
- Tavris, C. (1992) *The Mismeasure of Woman*. New York: Simon and Schuster.
- Tucker, W.H. (1994) *The Science and Politics of Racial Research*. Urbana: University of Illinois Press.
- Urla, J. and J. Terry (1995) 'Introduction: Mapping Embodied Deviance', pp. 1-18 in J. Terry and J. Urla (eds) *Deviant Bodies: Critical Perspectives on Difference in Science and Popular Culture*. Bloomington: Indiana University Press.
- 'US Public Health Service, Grant Application Instructions (PHS 398)' (1998) National Institutes of Health. Available at <http://www.nih.gov/grants/funding/phs398/phs398.html>.
- Waldby, C. (1996) *AIDS and the Body Politic: Biomedicine and Sexual Difference*. London: Routledge.
- Warner, J.H. (1986) *The Therapeutic Perspective: Medical Practice, Knowledge, and Identity in America, 1820-1885*. Cambridge, MA: Harvard University Press.
- Weisman, C.S. (1998) *Women's Health Care: Activist Traditions and Institutional Change*. Baltimore, MD: Johns Hopkins University Press.
- Weisman, C.S. (2000) 'Breast Cancer Policymaking', pp. 213-43 in A.S. Kasper and S.J. Ferguson (eds) *Breast Cancer: Society Shapes an Epidemic*. New York: St Martin's Press.
- Williams, D.R. (1997) 'Race and Health: Basic Questions, Emerging Directions', *Annals of Epidemiology* 7(5): 322-33.
- Williams, D.R., R. Lavizzo-Mourey and R.C. Warren (1994) 'The Concept of Race and Health Status in America', *Public Health Reports* 109(1): 26-41.
- Wright, L. (1994) 'One Drop of Blood', *The New Yorker*, 25 July: 46-55.

**Steven Epstein** is Associate Professor of Sociology at the University of California, San Diego, where he is also an active member of the interdisciplinary Science Studies Program. His research interests include biomedical politics and social movements. He is presently completing a book-length study of the politics of identity and the management of difference in biomedical research in the United States. He teaches classes on medicine, science, social movements, sexuality, and social theory.