INTRODUCTION

Health Research and the Remaking of Common Sense

The orthodoxy of sameness and the orthodoxy of the mean, which has dominated much of the thinking in medical science . . . often impaired our attitude toward clinical research in those days—we tended to want to reduce the human to that 60 kilogram white male, 35 years of age, and make that the normative standard—and have everything extrapolated from that tidy, neat mean, "the average American male."

Dr. Bernadine Healy, former director of the
National Institutes of Health

Since the mid-1980s, specific ideas about what it means for humans to differ have refashioned medical research and practice in the United States. Two decades of reform—reflected in policies about who gets studied and how they are studied—have placed group identity and group difference squarely in view within the biomedical arena.[1] Socially significant categories and characteristics such as sex and gender, race and ethnicity, and age,[2] used routinely when people assert their belonging or are classified by others, have taken on a new salience within modern medicine.

That these socially meaningful aspects of personhood divide humanity into medically distinguishable populations has become a commonplace assertion, even a cliché:

- "Men and Women Are Different," declared the title of an editorial in a medical journal in 2004. "Sex differences have been noted in most major cardiovascular diseases," the author observed, and "medicine is not exempt from the basic biological fact that men and women are indeed different, and may need to be treated therapeutically as such." According to the *New York Times*, researchers "have found that men and women sometimes report different symptoms of the same disease, and that certain drugs are more effective in one sex than the other, or produce more severe side effects in one sex."[3]
- Television news broadcaster Peter Jennings reported in 2002 that hundreds of children die each year from reactions to medications. Because the drugs have not been tested in pediatric

populations, these children have become the victims of "guesswork" in the determination of proper dosages.[4]

- In an article about how medical researchers were seeking members of racial minority groups to participate in clinical trials, the *Charleston Post and Courier* quoted a registered nurse and oncology research coordinator in 2005: "When you do a randomized trial with an all-white population, you can only extrapolate to the white population. . . . You don't know if it actually works in African-American or Hispanic populations."[5]
- In 2005, the U.S. Food and Drug Administration (FDA) licensed a pharmaceutical drug called BiDil for treatment of heart failure in African American patients only. Having failed to demonstrate the drug's efficacy in the overall population, BiDil's manufacturers reinvented it as an "ethnic drug" and tested it only on African Americans.[6]

Characteristic of this way of thinking is the assumption that social identities correspond to relatively distinct kinds of bodies—female bodies, Asian bodies, elderly Hispanic male bodies, and so on—and that these various embodied states are medically incommensurable. Knowledge doesn't travel across categories of identity—at least, we can't presume that it does. We are obliged always to consider the possibility that the validity of a medical knowledge claim stops dead when it runs up against the brick wall of difference. While some experts, policymakers, and health advocates have embraced this way of thinking about bodies, groups, and health as obviously valuable, and others have dismissed it as pernicious or silly, my goal is to do neither of the above. I seek to understand, first, how a particular way of thinking about medical difference in the United States helped give rise to an important strategy to improve medical research by making it more inclusive. Second, I intend to show how this strategy gained supporters, took institutional form, and became converted into common sense. Third, I want to shed light on its various consequences for government agencies, biomedical researchers, and pharmaceutical companies, as well as for the social groups targeted by new policies. And finally, by comparing this approach to other ways of thinking about the meanings of identities, differences, and inequalities in biomedical contexts, I aim to understand the extent to which the new common sense might lead to better health and a more just society, as well as the extent to which it either falls short or takes a wrong turn.

An evaluation of the merits of this emphasis on bodily difference might begin by considering a second set of recent claims:

- According to the U.S. National Center for Health Statistics, out of every 1,000 babies born to U.S. mothers whose race was identified as “White” or “Asian or Pacific Islander” or whose ethnicity was “Hispanic or Latino,” fewer than 6 died within the first year of life. By contrast, the infant mortality rate (the number of deaths per 1,000 live births) was 8.6 for “American Indian or Alaska Native” mothers, and 13.8 for “Black or African American” mothers.[7]
- According to the same source, a white woman born in the United States in the early twenty-first century could expect, on average, to live 11.5 years longer than an African American man.[8]
- On the basis of a public opinion poll, researchers from Harvard University reported in 2003 that two-thirds of black people in the United States believe that the health care they receive is inferior to that of whites. One in five white respondents agreed with them. Eight out of ten blacks in the study attributed the substandard care to bias, intended or otherwise, on the part of physicians. Only one in five white respondents thought this was the case.[9]

Reports of health disparities—inequalities with regard to health status, access to health care, or experiences within the health care system, measured according to factors such as race, class, gender, geographic location, and sexual identity—have become ubiquitous in recent years.[10] While there is a general sentiment that they constitute a significant social problem, the precise meaning of these disparities has been a matter of some debate.[11] Concern over these disparities also coincides with growing frustration about other problems: the plight of the more than 40 million Americans who lack health insurance (a problem unique to the United States among countries within the so-called developed world), the high price of pharmaceutical drugs, and the quality and character of health care as organized and rationed under the system known as managed care.[12]

Will the new focus on embodied difference lead to the elimination of health disparities? To some extent, the new emphasis that takes categories of human difference as basic units of analysis in medical research and medical treatment has coincided and cooperated with research on these disparities. But in other respects, this way of attending to difference—equating group identities with medically distinct bodily subtypes—has precluded direct attention to reducing inequalities in the domain of health, while encouraging the misleading notion that better health for all can best be pursued through study of the biology of race and sex.[13]

ONE SIZE FITS ALL?

Today's pronouncements about medical differences are often accompanied by self-conscious reflection on social change within biomedical institutions—indeed, by strenuous criticism of past deficiencies. For years, a range of health activists from outside the establishment have issued stinging critiques of neglect by researchers of women, racial and ethnic minorities, and others who have fallen beneath the radar screen.

Well-established biomedical insiders also have had their say. Bernadine Healy, who served as the first (and so far only) female director of the National Institutes of Health (NIH) from 1991 to 1993, commented in 2003 on the worldview that prevailed until relatively recently among medical researchers. When Healy denounced "the orthodoxy of sameness and the orthodoxy of the mean" (see the epigraph at the start of this chapter),[14] she targeted a double whammy of biomedical insensitivity: not only were groups such as women, children, the elderly, and racial and ethnic minorities routinely under-studied in clinical research,[15] but it was assumed that the absence of these groups didn't matter much, because the findings from studying the "normative standard"—middle-aged white men—could simply be generalized to the entire population. Yet the more that researchers have included distinct groups among research subjects, critics have argued, the more it has become apparent that differences do matter and that we cannot just extrapolate medical conclusions from white people to people of color, from men to women, or from middle-aged adults to children or the elderly.

These are not isolated sentiments. Since the mid-1980s, an eclectic assortment of reformers has argued that expert knowledge about human health is dangerously flawed—and health research practices are fundamentally unjust—because of inadequate representation of groups within research populations in studies of a wide range of diseases. The critics have included prominent elected officials, like former member of Congress Patricia Schroeder, who, as cochair of the Congressional Caucus for Women's Issues, asked "Why would NIH ignore half the nation's taxpayers?"[16] Voices calling for change also have come from the ranks of grassroots advocacy groups, clinicians, scientists, professional organizations, and government health officials.

Collectively, reformers have pointed to numerous culprits in the general failure to attend to biomedical difference, but in their bid to change them, they primarily have targeted the state. Reformers have trained their attention on the U.S. cabinet-level Department of Health and

Human Services (DHHS) and especially two of its component agencies: the NIH, the world's largest funder of biomedical research, currently providing about $27 billion annually in research grants;[17] and the Food and Drug Administration (FDA), the gatekeeper for the licensing of new therapies for sale.[18] Under pressure from within and without, these federal agencies have ratified a new consensus that biomedical research—now a $94 billion industry in the United States[19]—must become routinely sensitive to human differences, especially sex and gender, race and ethnicity, and age. Academic researchers receiving federal funds, and pharmaceutical manufacturers hoping to win regulatory approval for their company's products, are now enjoined to include women, racial and ethnic minorities, children, and the elderly as research subjects in many forms of clinical research; measure whether research findings apply equally well to research subjects regardless of their categorical identities; and question the presumption that findings derived from the study of any single group, such as middle-aged white men, might be generalized to other populations.

These expectations are codified in a series of federal laws, policies, and guidelines issued between 1986 and the present that require or encourage research inclusiveness and the measurement of difference. The new mandate is reflected, as well, in the establishment, from the early 1980s forward, of a series of new offices within the federal health bureaucracy; these include offices of women's health and offices of minority health that support research initiatives focused on specific populations. Versions of the inclusionary policies also have been adopted by the "institutional review boards" (IRBs) located at universities and hospitals across the United States—the committees that review the ethics of proposals to conduct research on human subjects. As a result, these policies affect not just those researchers seeking federal support or those companies seeking to market pharmaceuticals; they may apply, in some fashion or another, to nearly every researcher in the natural or social sciences performing research involving human beings.

In other words, if indeed we are witnessing a repudiation of so-called one-size-fits-all medicine in favor of group specificity, then the shift is apparent not just in the realm of free-floating ideas. It is anchored to institutional changes—new policies, guidelines, laws, procedures, bureaucratic offices, and mechanisms of surveillance and enforcement—that are the products of collective action. These changes matter for those who carry out medical research on humans: researchers are obliged to alter their work practices to comply with new requirements if they want to get funding, and so must pharmaceutical companies, if they seek to get their

products on the market. But the changes also matter downstream: they may affect any person who, now or in the future, becomes obliged to claim the status of "patient." More diffusely, but importantly, they also matter insofar as they alter social understandings of what qualities such as race and gender are taken fundamentally to be.

Yet this redefinition of U.S. biomedical research practice has been little remarked upon by social scientists. Several scholars have provided excellent accounts or analyses of recent attempts to include greater numbers of women in biomedical research.[20] In addition, an important and growing body of literature by science studies scholars, while not precisely focused on questions of research inclusion, is analyzing how concepts of race are used in biomedicine—especially, new scientific attempts to take findings from the genetic study of populations and use them to make claims about the medical meaning of race.[21] However, there has been almost no scholarly attention to the broad-scale attempt to dethrone the "standard human" and mandate a group-specific approach to biomedical knowledge production—an identity-centered redefinition of U.S. biomedical research practice that encompasses multiple social categories.[22]

I call this set of changes in research policies, ideologies, and practices, and the accompanying creation of bureaucratic offices, procedures, and monitoring systems, the "inclusion-and-difference paradigm."[23] The name reflects two substantive goals: the inclusion of members of various groups generally considered to have been underrepresented previously as subjects in clinical studies; and the measurement, within those studies, of differences across groups with regard to treatment effects, disease progression, or biological processes.

This way of thinking and doing is by no means the only, or the most important, way in which biomedical research has changed in recent decades. During those same years, as the sociologist Adele Clarke and her coauthors have noted, medicine itself has been remade "from the inside out"—through innovations in molecular biology, genomics, bioinformatics, and new medical technologies; through vast increases in public and private funding for biomedical research; through the ascendance of evidence-based medicine; through the rapid expansion of a global pharmaceutical industry constantly searching for new markets and engaging in new ways with consumers; and through the resurgence of dreams of human enhancement or perfectibility by means of biotechnologies.[24] The point, then, is not to understand how the inclusion-and-

difference paradigm has changed "medicine," as if the latter were a fixed target, but rather to consider how this particular emphasis has intersected with the other transformations that have taken place in the domain of biomedical research and the health care sector generally.

The Time and Place of Difference

Although a shift away from the inclusion-and-difference paradigm could certainly occur, at present this model is reasonably well institutionalized within DHHS agencies. Unlike policies that depend for their survival on the support of a particular politician, bureaucrat, or political party in power, the inclusion-and-difference paradigm has sunk roots and seems to have developed its own staying power. It grew up in the Republican administrations of the 1980s and early 1990s, flourished under the Democratic administration of President Bill Clinton, and mostly has survived—despite some explicit attempts to roll it back and halt its expansion—under Republican President George W. Bush.

Interestingly, formal policies concerning inclusion and difference in biomedicine are mostly restricted to the United States—at least so far. Biomedical research and pharmaceutical drug development are increasingly global industries that crisscross national borders, and it is not unreasonable to imagine that policies promoted by a dominant player will diffuse gradually to other countries or that those countries, on their own, will adopt similar institutional responses. To date this has happened to a limited extent, and not without resistance. This peculiarity explains why I focus on the United States, a narrowing of gaze that otherwise might seem surprising when tracking a global industry. I argue that the nation-state, as well as national political struggles, remain powerful contributors to the definitions of medical and social policies, categories, and identities.[25] Many of the policies that I consider are, if not specific to the United States, then applicable only to those persons or firms seeking U.S. federal funding or regulatory approval. However, given the prominence of the United States in this arena—organizations headquartered in the United States account for about 70 percent of the global drug development pipeline[26]—the consequences of U.S. policies for the rest of the world are not insubstantial. And the general questions concerning the medical management of difference have implications for every country that engages in social and technological practices of differentiation and difference-making across human subgroups—that is to say, all of them.

The nation-specific character of this response to difference also has important implications for the framing of the analysis. To the extent that these concerns appear at present to have a special resonance in the United States, then it would not make sense to attribute their emergence into public debate to any inexorable law of scientific or social progress. Instead, the approach will be to look closely at U.S. culture, politics, and history and the particularities of U.S. biomedical and political institutions to explain why debates about identity and difference have left such a distinctive and indelible mark on biomedicine in this country in the late twentieth and early twenty-first centuries. Rather than treating the inclusion-and-difference paradigm as an obvious scientific development, this analysis examines why new understandings about research and human differences have emerged in the United States and supplanted the common sense that prevailed previously.

Of course, it is not hard to imagine why appeals to include women, minorities, and other groups in biomedical research might acquire traction in the United States in recent years. In the wake of what has been called the "minority rights revolution,"[27] U.S. political culture now typically promotes equality of opportunity and diversity as worthy social goals, though remedies such as affirmative action have been under increasing attack. And the idea of the United States as a multicultural society has become much more taken for granted, even in the face of resistance.[28] Compared to other countries, the United States is also typically seen as a place where "identity politics"—the assertion of political claims in relation to social identities such as "woman," "Latino," or "Native American"—looms large.[29] Even though the phenomenon that the sociologist John Lie has called "modern peoplehood"—the formation of "an inclusionary and involuntary group identity with a putatively shared history and a distinct way of life"—is everywhere present, certain countries, such as the United States, are more likely to establish policies with respect to these categories, while others seek instead to subsume difference under a broader conception of national citizenship.[30] Finally, given the particular prominence and cultural authority of the biosciences in the United States, it seems not unlikely that this country would witness the emergence of what might be called "bio-multiculturalism."[31]

Yet this program for the medical recognition of difference has gone against the grain of powerful trends toward standardization within biomedicine during the same recent decades in the United States—universalizing tendencies reflected in the movement to develop uniform, evidence-based guidelines for patient care, as well as efforts by both the FDA and the pharmaceutical industry to standardize the drug approval process across national borders.[32] And

conversely, the focus on broad social categories, such as women, also has contrasted with the alternative ideology of personalized medicine, the plan to target therapies at the individual. [33] Thus, when viewed against the backdrop of dominant tendencies within biomedicine—emphases on the universal and the individual—the group-based inclusion-and-difference paradigm would seem to lie betwixt and between.

Moreover, the implementation of new inclusionary policies and practices encountered concrete resistance on multiple fronts. Some critics rejected the empirical claim that groups such as women in fact had been under-studied. Defenders of scientific autonomy opposed the politicizing of research and argued that it should be up to scientists, not policymakers, to determine the best ways to conduct medical experiments. Conservatives decried the intrusion of "affirmative action," "quotas," and "political correctness" into medical research. Ethicists and health activists expressed concern about the risks of subjecting certain groups, such as children, to the risks of medical experimentation in large numbers. Statisticians and experts on the methodology of the randomized clinical trial argued that requiring comparisons of population subgroups was not only scientifically unsound but also fiscally unmanageable and that it might bankrupt the research enterprise. And many proponents of medical universalism argued that biological differences are less medically relevant than fundamental human similarities: when it comes right down to it, they insisted, people are people. Claims about racial differences, in particular, seemed to sit poorly alongside well-publicized findings by geneticists that, on average, genetic differences within the groups commonly called races are actually greater than the genetic differences between those groups.[34] If racial classifications are biologically dubious, why were legislators and health policymakers calling for labeling research participants by race and testing for racial difference in clinical studies? Some critics went further, charging that the new medical understandings of race and sex differences were eerie echoes of social prejudices from the past, when scientific reports of bodily differences had provided a veneer of respectability to claims that both women and people of color were not just socially, but biologically, inferior.

Given these varied arguments against the new policies and the logic behind them, we should not take for granted the rise of inclusion and the measurement of difference—still less the particular forms these have taken. The birth and maturation of this paradigm require explanation. Indeed, the more we examine the new inclusionary policies, the less obvious they appear—and hence the more we can learn by studying them in depth.

For example, the whole premise of the reforms is to reverse a past history of exclusion and inequality—but, as is so often the case, "history" here is a contestable matter. To what degree can it be established that medical research used to focus on middle-aged, white men and took them to be the norm or standard? And how much have research practices really changed in response to the new policies? Has there been a revolution in medical knowledge-making? Another set of questions concerns the unexamined choices embedded within the inclusionary remedy: Out of all the ways by which people differ from one another, why should it be assumed that sex and gender, race and ethnicity, and age are the attributes of identity that are most *medically* meaningful? Why these markers of identity and not others? And are there differences among these types of difference, such that the same policy remedies may not be appropriate for each case? In the most general sense, how can we know when to assume that any particular way of differing might have medical consequences? And when is it proper to invoke the unity of the human species—to assert that a body is a body is a body?

Pros and Cons

At least in part, this wave of reform offers an important and valuable corrective to past medical shortsightedness. It exemplifies the more general point, made by feminist theorists and theorists of multicultural citizenship, that sometimes the pursuit of genuine social equality requires policies that *do not* treat everyone the same—policies that affirm group rights and establish new practices of group representation.[35] These reforms also are broadly consistent with the important perception, expressed variously by feminist theorists and science studies scholars, that the formal knowledge of experts sometimes may be improved through the contributions or redirections introduced by those who have been made marginal to the knowledge production enterprise.[36]

But an emphasis on difference-making also rightly invokes concern when difference essentially is taken to be a biological attribute of a group. These, too, are very contemporary preoccupations: in 2005, Lawrence Summers, the president of Harvard University, ignited a fiery debate when he wondered aloud whether the underrepresentation of women in science and engineering professions might actually reflect innate differences between the sexes.[37] Attempts to treat racial differences as biologically based—as in, for example, the claim that I.Q. tests or other standardized tests track natural differences in mental ability between racial groups—likewise have proven resilient, though they, too, have been the subject of much criticism.[38] To

the degree that the inclusion-and-difference paradigm also suggests—albeit in a nonpejorative way—that biology is fundamental in distinguishing races and genders, its logic appears consistent with these other rhetorical moves.

How then, should the inclusion-and-difference paradigm be evaluated? If it were a simple matter of declaring these changes "good" or "bad," the case would be far less interesting than it turns out to be. My strategy will be to link an investigation of the causes and consequences of these new policies and practices with a detailed analysis of their associated cultural and political logic, including ways of standardizing and classifying human beings, beliefs about the meaning of difference, and possibilities for establishing "biopolitical citizenship." On the basis of that analysis, I will argue that although reformers' characterizations of the biomedical *status quo ante* were not entirely accurate, they nonetheless did bring attention to a real and important problem. And the solutions that have fallen into place, while imperfectly designed, have in some respects been positive and praiseworthy from the standpoint of both improved health and social justice—even if a formalistic emphasis on compliance with rules sometimes has obscured or interfered with the substantive goals that originally animated the reforms.[39]

However, I also will argue that these reforms have unintended consequences that merit especially close study. By approaching health from the vantage point of categorical identity, they ignore other ways in which health risks are distributed in society. By valorizing certain categories of identity, they conceal others from view. By focusing on groups, they obscure individual-level differences, raising the risk of improper "racial profiling" or "sex profiling" in health care. By treating each of the recognized categories in a consistent fashion, they often ignore important differences across them. And by emphasizing the biology of difference, they encourage the belief that qualities such as race and gender are biological in their essence, as well as the mistaken conclusion that social inequalities are best remedied by attending to those biological particularities. While the inclusion-and-difference paradigm is certainly preferable to any narrow biomedical practice of exclusion, and while it may generate useful knowledge for specific purposes, the net effect of these unintended consequences is to make it a problematic tool for eliminating health disparities. Rather than tackle the problem of health disparities head on, we have adopted an oblique strategy that brings with it a new set of difficulties.

EXPLAINING CHANGE IN BIOMEDICAL POLICY

Many different sorts of people helped promote the new inclusionary policies described in this book, or worked to implement them, or opposed them, or have had to grapple with their implications. To research this book, I interviewed past and present DHHS officials, clinical researchers, experts on pharmacology, biostatisticians, medical journal editors, drug company scientists, health advocates and activists, bioethicists, members of Congress, congressional aides, lawyers, representatives of pharmaceutical company trade associations, experts in public health, and social scientists.[40] I also analyzed an enormous number of print and electronic materials in which notions of inclusion and difference have been discussed or debated. These included government documents and reports; 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. Finally, I attended conferences at which issues of inclusion and difference were discussed. Juxtaposing different kinds of evidence coming from different occupational groups and "social worlds" concerned with these issues has helped me to acquire the depth and breadth needed for an informed historical account and a fair analysis.[41]

Analyzing the many issues raised in this book also obliged me to delve deeply into a wide range of academic literatures and develop new approaches from their intersections. In chapter 1, I build the theoretical foundations for this book by drawing on various fields, including science studies, political sociology, and critical studies of gender and race. This fruitful mix of approaches, and the hybrid concepts that arise from it, provide me with the tools I need to piece together the story—which begins in earnest in chapter 2.[42]

In terms of their goals, the empirical chapters then divide roughly into two. Chapters 2 through 7 trace the making of the inclusion-and-difference paradigm. They consider how an unlikely set of reforms made their way into common sense, despite heated opposition from those who saw them as political correctness run amok, and how abstract ideas about bodies, truth, and equity were "operationalized" and took institutional form. Chapters 8 through 12 take the story further by exploring the various social and medical consequences of the adoption of these reforms—for government agencies charged with enforcing them, for medical researchers and pharmaceutical companies who have to comply with them, and for the social groups under study, such as racial minorities and women. More specifically, in telling the story, I proceed by addressing the following questions:

To what degree was there a "standard human" in biomedical research, prior to the recent reform wave (*chapter 2*)? This chapter argues that the recent debates over who gets studied in biomedical research must be located within a longer history of the selection of humans as experimental objects in biomedicine. While certain questions—such as the precise demographics of research participation in the past—are not fully answerable given available data, I suggest that we can learn much from that history about changing medical notions of sameness and difference. I examine the variety of ways in which medical researchers have selected their research subjects—often from among those most socially disadvantaged—as well as the shifts over time in the perceived desirability of generalizing conclusions across groups. I emphasize the point that, until recently, medical emphases on differences—such as those between women and men or between black people and white people—were closely linked with social notions of superiority and inferiority. In other words, there is a deep irony in the current attempts to use claims about biomedical difference as the basis of a liberal and egalitarian social policy.

What was the nature of the reform coalition that developed to challenge a reliance on the "standard human"? What were the distinctive ways in which reformers framed their arguments (*chapter 3*)? Here I analyze the ways in which critics of the medical reliance on the "standard human" launched a loosely related series of "antistandardization resistance movements" that insisted on the importance of differences. This chapter analyzes the political rhetoric of a diverse group of reformers—health advocacy organizations, health professionals, grassroots social movements, members of Congress, insiders within the DHHS, and others. I trace how these reformers questioned the legitimacy of current biomedical practice and how they brought political and ethical arguments about representation and citizenship together with scientific arguments about the importance of studying difference.

How did reformers achieve their first successes? What accounted for the potency of their critiques (*chapter 4*)? In this chapter I tell the story of how reformers targeted two key state agencies, the NIH and the FDA, and how they achieved their first important victories in the early 1990s. I present the concept of "categorical alignment"—the merging of social categories from the worlds of medicine, social movements, and state administration—to shed additional light on reformers' successes. I also examine the special characteristics of the reformers' political alliances, their complex "multirepresentational" work, and their claims for a new kind of citizenship as manifested by biomedical inclusion.

How did controversy develop around the proposed reforms, and how was this controversy settled (*chapter 5*)? Having tracked the reformers' actions and arguments, I next examine the claims of opponents of the new policies mandating inclusion and the measurement of difference. In addition to researchers, politicians, and pharmaceutical companies, these opponents included statisticians and experts on clinical trial design, who maintained that the policies made no medical sense and that reformers simply failed to comprehend the logic of scientific generalization as employed in the arena of clinical research. I then analyze the roles of DHHS employees in finding creative ways of institutionalizing the reform mandate and, to a substantial degree, settling the controversy. These officials performed crucial "boundary work"—reestablishing an accepted divide between the realms of science and politics, with the new policies located on the "science" side of the boundary.[43] This work was critical not only for the legitimacy of science, but also for the ability of DHHS agencies to defend their jurisdiction and autonomy.

What is the nature of the "new regime"? And what has become of the "standard human" (*chapters 6 and 7*)? The inclusion-and-difference paradigm is no abstract idea; it is undergirded by an infrastructure of procedural standards, encoded in regulations, and enforced and overseen by new bureaucratic offices. Here I sketch the various policies that came to constitute the inclusion-and-difference paradigm over the course of the 1990s and into the twenty-first century, and I analyze how the paradigm has become institutionalized within the DHHS. I also examine the new standard operating procedures that govern biomedical knowledge production.

I then extend my analysis of the workings of the inclusion-and-difference paradigm by considering the abstract debate between universal, standardized approaches to medicine and policy (treating everyone the same as everyone else) and individualized approaches (recognizing the uniqueness of each person). I argue that the inclusion-and-difference paradigm is a form of what I call "niche standardization" that bypasses this polar opposition between universalism and individualism in order to standardize at the level of the social group.[44] I describe how DHHS officials developed policies, procedures, and classification schemes that have shored up this niche standardization. These officials, along with researchers, played a central role in "operationalizing" sex, gender, race, ethnicity, and age for biomedical purposes—transforming these dimensions of social reality into "variables" whose effects can be measured in quantitative

terms. However, this work of formalizing, standardizing, and operationalizing has not been able to paper over the extraordinary difficulties that may sometimes arise when researchers or federal health officials attempt to sort human beings into categorical boxes.

How has the work of government agencies been affected by the new policies? How successful have officials been in monitoring and enforcing the policies? To what degree has enforcement brought about real changes in medical research practices (*chapter 8*)? In this chapter I examine how DHHS agencies such as the FDA and the NIH have trained their attention on ensuring compliance with inclusionary policies. At the same time, I use the debates about the success of these enforcement efforts to investigate some of the real-world effects of the paradigm. I examine various measurable effects of the paradigm on academic research and pharmaceutical drug development, and I consider the complaints both of those who think the changes have gone too far and those who think they have not gone far enough. In examining the mixed success of reform, I explain why neither of these sets of critics is likely to be satisfied. However, I also consider some of the other—direct and indirect—ways in which the new policies have affected the world of biomedicine, including medical journals, medical education, and the pharmaceutical industry.

What are the implications of the inclusion-and-difference paradigm for the task of recruiting people to serve as research subjects (*chapter 9*)? Because the new policies create strong pressures for researchers to diversify their study populations, they have prompted a renewed interest in the practical problem of finding and convincing different sorts of people to participate in medical experiments. Not only must researchers find willing subjects, not only must those subjects be diverse, but the groups which researchers must represent include those, such as African Americans, that routinely are considered among the most difficult of all to convince to participate. The historical ironies are also profound. The new mandates enjoin researchers to study groups that, in some cases, were horribly exploited by medical researchers in the not-so-distant past—for example, in the infamous Tuskegee study of "untreated syphilis in the Negro male."[45] In this chapter I trace the origins of what might be considered a new field of empirical study—I call it "recruitmentology"—that seeks to develop scientific evidence about the best ways successfully to enroll so-called hard-to-recruit populations for clinical studies. In evaluating the success of recruitmentology, I consider the inability of the inclusion-and-

difference paradigm to resolve the tension between the increased pressure to recruit and the longtime, vexing problem of establishing trust in the relationship between researchers and research subjects.

What are the implications of this reform wave for how difference is understood within biomedicine? What, therefore, are the effects of reform on those most directly targeted by it, such as women and racial and ethnic minority groups (*chapters 10 and 11*)? In these two chapters, I argue that biomedical research does not, in neutral fashion, simply absorb and reflect ideas about sex, gender, race, and ethnicity that are prevalent in society. Rather, biomedicine is a domain in which conceptions of identity and difference actively get worked out in practice. In this sense, the policies that make up the inclusion-and-difference paradigm play a role in refashioning and redefining the very meanings of social categories and attributes. In chapter 10, I advance this argument by examining the heated debates over "racial profiling" in medicine—prescribing treatments to patients on the basis of their racial membership—and I argue that this practice may work to the detriment of the health of individual patients.

Then, in chapter 11, I examine the case of sex and gender, analyzing the emerging philosophy known as "sex-based biology" or "gender-specific medicine." Here I present a double argument: On one hand, sex/gender is a different case from race/ethnicity, because the biological and the social intertwine in different ways, and that means that the tendency for various forms of difference to be "handled" in the same ways by the inclusionary policies may be problematic. But on the other hand, much of the critique directed at racial profiling may also apply to sex profiling—which raises interesting questions about why the former has been the subject of much debate while the latter has not.

What is the trajectory of the paradigm? What other groups may "qualify" for inclusion? Will the paradigm be extended or rolled back (*chapter 12*)? In this chapter I raise questions about where the paradigm may be heading, including whether it will be extended to encompass other identities. A primary case that I consider in this chapter is the attempt by lesbian, gay, bisexual, and transgender health advocates to include sexual orientation and gender identity as dimensions of difference whose salience is authorized by federal health policy. I also examine how well the paradigm holds up in hostile political climates, as well as to what degree it is creeping into the discourse and practice of nations other than the United States.

Finally, in the conclusion, I summarize my findings on the meanings of these reforms and their consequences, both intended and unintended, as well as the implications of this case for the

study of biomedical politics. I then consider alternative pathways: How might things be otherwise? What are other ways of conceiving of the problem and its solutions? I address the issue of alternatives with reference to conceptions of clinical research, notions of public participation in biomedical debates, debates over identity politics, and the fundamental issue of inequality in the domain of health.