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Race Categorization and the Regulation of Business and Science

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Despite the lack of consensus regarding the meaning or significance of race or ethnicity amongst scientists and the lay public, there are legal requirements and guidelines that dictate the collection of racial and ethnic data across a range of institutions. Legal regulations are typically created through a political process and then face varying kinds of resistance when the state tries to implement them. We explore the nature of this opposition by comparing responses from businesses, scientists, and science-oriented businesses (pharmaceutical and biotechnology companies) to U.S. state regulations that used politically derived racial categorizations, originally created to pursue civil rights goals. We argue that insights from cultural sociology regarding institutional and cultural boundaries can aid understanding of the nature of resistance to regulation. The Food and Drug Administration's guidelines for research by pharmaceutical companies imposed race categories on science-based businesses, leading to objections that emphasized the autonomy and validity of science. In contrast, similar race categories regulating first business by the Equal Employment Opportunity Commission (EEOC) and later scientific research sponsored by the National Institutes of Health (NIH) encountered little challenge. We argue that pharmaceutical companies had the motive (profit) that NIH-supported scientists lacked and a legitimate discourse (boundary work of science) that businesses regulated by the EEOC did not have. The study suggests the utility of a comparative cultural sociology of the politics of legal regulation, particularly when understanding race-related regulation and the importance of examining legal regulations for exploring how the meaning of race or ethnicity are contested and constructed in law.

Despite uncertainty and confusion among both social and natural scientists about the meaning, nature, and even reality of "race" and "ethnicity" (Lee 2009), there are *legal* requirements that employers record and report to the government the race of all of their employees, legal requirements that scientists consider and report the race of subjects in their research, and legal guidelines that drug manufacturers record and report the race of subjects in their clinical

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trials. These legal cases have led to varying responses from the regulated and offer an important opportunity to show the dynamics of resistance to progressive racial regulation and the power of civil rights law to transcend institutional boundaries. They show the ability of the federal government to impose politically constructed legal race categories that cross over into the regulation of business, science, and scientific, research-based businesses.

The federal government's official schema is familiar to anyone who has ever filled out an application for school or employment. The Civil Rights Act of 1964 created the Equal Employment Opportunity Commission (EEOC) to enforce civil rights in employment, and in 1965 this agency issued a regulation requiring all businesses with at least 100 employees to fill out a form, the EEO-1, that categorized all employees based on their employer-perceived identities as white, black, "Spanish-American," "Oriental," or "American Indian" (Skrentny 1996, 2002). These categories spread into other areas of civil rights policy, such as set-asides and aid for small businesses (LaNoue & Sullivan 1994). The federal Office of Management and Budget's (OMB) Directive 15 in 1977 standardized these race categories for use by agencies across the government—eventually including those involved in health and biomedicine. Congress's passage of the National Institutes of Health (NIH) Revitalization Act of 1993 required the NIH to establish guidelines for including women and minorities in clinical research—called the Inclusion Mandate, which the agency implemented in 1994. The NIH eventually issued its policy on the reporting of racial and ethnic data in 2001, which specified the use of the OMB Directive 15 categories. In 2005, the U.S. Food and Drug Administration (FDA) announced a new guidance to industry regarding the collection and use of data on race and ethnicity, following the issuance of a draft guidance in 2003. In this guidance, the FDA advised those filing new drug applications to collect data on race and ethnicity, utilizing the OMB Directive 15 categories. Though these were technically only guidelines, with no legal obligation for compliance, the leverage the FDA wields makes them comparable to legal regulations. The FDA thus introduced the use of sociopolitical constructs into the business of biomedical research and health. While businesses in 1965 and NIH-funded scientists in 2001 did not object to the introduction of the official racial scheme, pharmaceutical and biotechnology companies affected by the FDA guidance resisted.[1] For the first time, regulated entities challenged the legal race categories.

In this article, we contribute to debates in the sociology of law, race and ethnicity, science studies, and cultural sociology to ask what

[1] The guidance affected any sponsor of a new drug application, which included pharmaceutical and biotechnology companies. For sake of brevity, we use "pharmaceutical companies" or "drug industry" in some places but refer to all FDA-regulated drug companies.

happens when the state tries to bring politically constructed legal categories to regulate institutions in business and science. Specifically, we use a "method of difference" comparison (Ragin 1987) to compare the responses of different entities to race-counting regulations. We contrast the variable response to the introduction of these racial and ethnic categories into regulations implementing the Civil Rights Act of 1964's prohibition of employment discrimination on businesses, into the reporting of clinical research funded by the NIH, and into new drug applications to the FDA. Employers and NIH-supported scientists did not resist the new race-counting regulations (though some scientists did object to the Inclusion Mandate itself), but companies regulated by the FDA opposed the introduction of racial and ethnic categories. We do not try to explain here why the pharmaceutical companies failed to halt the FDA from issuing its guidance and ultimately acquiesced to the race regulations; our dependent variable is resistance to the race categories themselves. What explains the variation?

On the one hand, we might expect all the regulated entities to resist. Government regulation entails a loss of autonomy, and actions not chosen in the pursuit of profit by definition impose costs in time and/or money. For example, the EEO-1 as well as other civil rights regulations have led in many cases to new burdens on human resource departments or the creation of compliance offices in businesses across the country (Dobbin 2009). Scientists also seek to maximize autonomy and perform "boundary work"—"the discursive attribution of selected qualities to scientists, scientific methods and scientific claims for the purpose of drawing a rhetorical boundary between science and some less authoritative residual non-science" (Gieryn 1999:4)—which preserves their authority and autonomy (Gieryn 1983, 1999). We might expect pharmaceutical companies, which have a desire for profit like other businesses as well as an interest in doing their science without interference, to also resist race classification regulation. This is because race regulations in the pharmaceutical business may require these businesses to look longer and harder at different populations in order to test drugs. Race regulations could force them to search for research subjects whom the government, and not the business, deems appropriate; to worry about whether or not the research will be in compliance; to utilize categories of appropriateness that the government and not the business created; and, inevitably, to spend time on paperwork rather than money-generating endeavors. Put most simply, the race regulations create obstacles and use valuable time.[2]

[2] Sometimes drug companies have a market incentive to seek population-specific, even ethnic-specific, drugs, which was the case with the introduction of BiDil for treating congestive heart failure among African Americans (Kahn 2004). For Nitromed, the company that originally brought BiDil to market, the decision to target and test the drug for a specific ethnic group was made by the company and not required by the government.

At the same time, there are reasons to expect quiet compliance with the race regulations. Though American voters are happy to strike down pro–civil rights initiatives in referenda (Gamble 1997), the mid-1960s marked a new era of overwhelming public support for the *principles* of racial equality and support for general laws guaranteeing nondiscrimination to racial minorities (Schuman et al. 1998). The Civil Rights Act of 1964 itself faced almost no opposition except from Southerners; business interests were split, but few bothered to lobby one way or the other (Burstein 1985:106–7). Since the passage of the Civil Rights Act of 1964, it has been politically perilous, especially for government leaders but also big businesses, to have a reputation of being anti–civil rights (Skrentny 2001). It is not easy to fight civil rights regulations and other regulatory efforts to promote racial equality or address racial disparities. This may be particularly limiting when there is no legitimate, authoritative discourse to frame the resistance to law. This was the case with businesses in 1965, which had a strong profit motive for fighting back but lacked the legitimate discourse to frame their opposition other than self-interest.

On the other hand, NIH-funded scientists had discursive power but did not have similar profit motives to resist. Moreover, the agency assured scientists that their work would not be fundamentally altered. With FDA-regulated businesses, they had both the strong profit motive and the scientific discourse to frame their objection. We show that pharmaceutical and biotechnology companies strongly resisted the FDA's guidance on racial recordkeeping, using boundary work strategies that emphasized primarily the importance of maintaining the autonomy of science. Though they ultimately failed to achieve their goal of blocking the FDA guidance, science provided these businesses with a legitimate and authoritative discourse to resist law.

This analysis can contribute to researchers' growing knowledge on law and race. Studies of discrimination law, business response, and race categories have long been major foci in legal studies. Critical Race theorists working in the area of race categorization have demonstrated a number of points that are central to our framework. In addition to seeing race as a social construction, which is shaped and transformed by social and political pressure, they argue that the meaning of race is constituted in the creation and administration of law (L. Collins 2002; Haney López 1996; Omi & Winant 1994; Sohoni 2007). A study such as this, which examines the issue of resistance to racial regulation, can further build on this work by illustrating how racial categories and the meaning of race itself are open to contestation.

Legal studies of civil rights enforcement and race offer some insight on how regulated groups may react. For example, there has

been much research into how firms responded to civil rights regulations that were often ambiguous, settling on practices that symbolized compliance rather than resisting compliance (Dobbin et al. 1993; Edelman 1992). Compliance itself may have unintended consequences that are contrary to the original goals of regulation. For example, Minow (1990), highlighting the "dilemma of difference," suggests that if one uses law to enforce equal treatment, one tends to ignore the conditions that led to inequality. Yet using law to require special treatment risks reinforcing whatever sense of difference or stigma that led to the inequality. In the regulation of science, this is especially acute because putting the power of the state behind the categories would seem to give scientific basis to them rather than simply "reinforcing" them (Duster 2003). The growing administrative apparatus for promoting civil rights principles in health can naturalize or "biologize" not just racial or ethnic categories but racial or ethnic inequalities themselves. Thus, as legislative responses to social inequalities such as health disparities become increasingly more biological in framework and outlook (Halfmann et al. 2005), how information about group differences, health, and biomedical responses are categorized and captured will have even greater consequences.

We begin our comparative analysis by situating our cases in literatures on business regulation and legal constraints on business and science. Second, we show that the race categories have political origins and were based on civil rights concerns and pressures. They did not have a scientific basis and emerged in the regulatory implementation of employment civil rights, meeting no resistance from businesses. Third, we review the movement of these categories into science at the NIH and the lack of sustained, scientific criticism from its supported scientists. Fourth, as these categories were introduced to the FDA, we show how, despite support from civil rights organizations and physicians' professional associations, pharmaceutical and biotech companies regulated by the FDA strongly resisted the race categories, doing boundary work that emphasized both their scientific and (to a lesser extent) business autonomy. Last, we conclude by considering the power of regulatory law to construct or transcend the meaning of race across varied institutions for the purposes of effecting social or political change.

Cultural Boundaries and the Legal Constraints on Business and Science

A classic question in the sociology of law is whether and how movements or state actors can mobilize or use law to create social

change (Sumner [1906]1959). Cultural and organizational sociologists would conceptualize much of this activity as legal regulation across institutional or cultural boundaries (Lamont & Molnár 2002). Shared meanings create standards of legitimacy, common discourses, and logics of action. Taken-for-granted assumptions and routines allow individuals to "play the game" following an institution's particular logic (Friedland & Alford 1991), furthering their own interests, and excluding actors with illegitimate interests and roles (Lamont & Molnár 2002). These ideas are easily adapted to understanding state regulation. The state creates law through a political process and then seeks to regulate other institutions with sometimes controversial results. Thus, if a state regulation advances particular interests that actors within a given institutional arena view as illegitimate and unwelcome, the nature of their resistance is shaped by the logic of that institution.

Businesses operate under their own institutional rules or logics, standards of legitimacy, and use of distinctive discourses. While cultural sociologists have more often analyzed the ways professions have set themselves off from others by working to maintain cultural boundaries (Lamont & Molnár 2002), the same can be said of business organizations. Business involves economic rationality with freedom to seek profit as a key operating principle. Businesses most basically want, as Weber argued, a predictable legal environment to allow for planning (R. Collins 1980). Regulation—especially if done badly or irrationally —leads to unpredictability. Not surprisingly, much early research on the regulation of business found that business resisted it. This research identified the tendency of businesses to "capture" or control the agencies that were supposed to regulate them (Stigler 1971).

More recent studies, however, have shown that this is by no means an inevitable or even typical pattern (Kagan 2000:7; Kagan & Axelrad 2000). First, Wilson (1980) argues that agencies are risk averse and seek to avoid attacks from constituencies. This would make capture unnecessary. Second, Vogel (1996) as well as Martin (1998) note that big business interests are fragmented and are not a cohesive political force in fighting state actions that affect them. Third, Vogel (2005:20) finds that rather than holding a singular focus on profit, many businesses (70 percent of global chief executives, according to a 2002 study) believe that "corporate social responsibility," or good corporate citizenship, is an important part of their business operations because actions showing commitment to the community improve their reputation, loyalty, and innovation.

In the area of civil rights regulation, as described above, large corporations typically have not resisted and have recently even tended toward the corporate social responsibility stance of promoting diversity. By the 1980s, large businesses sought not to

resist regulation but to find standardized ways to symbolize compliance (Edelman 1992). By the 1990s, many large businesses became supporters and advocates of affirmative action or harbored supporters in their human resources departments (Kelly & Dobbin 2001; Skrentny 2001). A group of Fortune 500 companies, for example, submitted an amicus curiae brief in support of racial diversity considerations in university admissions when the Supreme Court considered that issue in 2003 (Skrentny 2008). Thus, though there is reason to expect large corporations to resist regulation in general, they do not always do that, and in the area of civil rights in particular, the trend has been toward corporate social responsibility in the area of civil rights and race categorizations, as we show below. What remains unexamined is how business has responded to the introduction of politically derived race categories and how this varies with other race regulations across institutional arenas.

Regulations affecting the practice of science may show different dynamics. Science has its own standards of legitimacy, such as those emphasizing technical rationality (Bourdieu 1991). Thus, for example, analytical variables should be consistent and their categories mutually exclusive (Timmermans & Berg 2003), although this may be an ideal type that most research can never achieve (Bowker & Star 1999). Nevertheless, scientists are guided by an edict in science that demands a level of consistency and freedom from political contestation. Thus, regardless of how political the day-to-day work of science really is (Kempner et al. 2005), scientists regularly engage in boundary work. This is not simply the expulsion of junk science but also the expansion of scientists' claims to more practical tasks or—and most germane to the case here—their work to maintain the autonomy of science from outside encroachment. In this sense, political interests are antithetical, at least symbolically, to the logic of scientists and scientific organizations. Thus, when scientists defend their work from political intrusion, they seek to do so on their own terms, avoiding any suggestion that the content of scientific knowledge is tainted by politics (Moore 1996). As we show, however, NIH-funded scientists did *not* resist the agency's policy on the collection of racial and ethnic data.

As a regulatory agency, the FDA is rooted in the logic of science. The FDA has long had great political autonomy established in its expertise, and it has "tremendous power over the pharmaceutical industry" (Carpenter 2001:366). How does business respond when the FDA seeks to impose nonscientific regulations on its scientific research? We show that despite the FDA's power, businesses engaged in science for profit have been the only ones to resist civil rights regulations requiring racial recordkeeping.

Study Design: Method of Difference Comparison

We use a "method of difference" (Ragin 1987) comparative case design to identify factors that help explain the variation. In these types of comparisons, the researcher identifies cases that share many similarities but vary on some outcome. Observing the cases and the outcome variation can help identify which factors lead to the outcome. While all businesses in 1965, scientists in 2001, and drug companies in 2003 might appear to be very different cases, we believe their similarities and differences help us rule out likely explanations for the pharmaceutical companies' resistance to regulation.

First, the comparison suggests that the reason for their resistance does not appear to be the political environment. Both businesses and scientists quietly accepted race categorization regulation in very different eras. Yet the NIH regulation preceded the FDA regulation, which *was* resisted, by only a few years. This suggests that political climate is not a key variable. Nonresistance occurred at the high-water mark of the civil rights movement *and* during its quiet years in the 2000s, and nonresistance occurred during the administration of a liberal Democratic president (Lyndon B. Johnson) and a conservative Republican (George W. Bush). This does not mean that political environment is irrelevant but that if it is an explanatory factor, it works in interaction with some other factor(s).

Second, the comparison gives us reason to believe that the explanation for the variation is not in the nature of the regulation. It is true that the EEOC regulation was targeted at employees, and the FDA regulation was directed at research subjects. However, the NIH regulation also focused on research subjects but was not resisted. The response to the regulations does not follow the specific entities to be categorized by race. Though there are other differences in the regulations that we explain below, there is nevertheless a basic similarity: All the regulations required the regulated to count and categorize by race, using ambiguous categories, thereby imposing a recordkeeping burden that they would not choose on their own.

Third, as stated above, the pattern of response does not follow the nature of the institutions regulated. We have one hybrid case, the pharmaceutical companies, which can be classified as both business and scientific entities. This means that in our three cases, two are involved in business, and two are involved in science. However, we cannot conclude that being a business interest leads to resistance to race regulations, and we cannot conclude that doing science leads to resistance.

Therefore, the logic of the comparative method suggests that there are factors that make the drug industry distinctive. One of

these may be the industry's greater cohesiveness than that of the entire business sector that was the target of the EEOC regulations. Businesses had opportunities to resist the race reporting regulation, but neither acting individually nor through organizations like the National Association of Manufacturers or the U.S. Chamber of Commerce did they mount any significant resistance. In contrast, drug companies acted both together—through industry associations *and* as individual entities—making original arguments against the regulations. This suggests that greater cohesiveness is not the only explanation or the most important explanation.

We argue instead that there are two key factors that distinguish pharmaceutical companies and make them more likely to resist race regulations. Both of these factors can be understood most basically to result from their hybrid institutional identities as organizations that do science for profit. First, their business model requires enormous investment and debt to finance drug development that may not work and, if it does, may not get the green light from the government (Adams & Brantner 2006; DiMasi et al. 2003). This means that they may have more to lose than other businesses and thus will be sensitive to regulatory efforts they fear will hinder profit. Second, and the factor we emphasize here, is that their identity in science has given them a discourse to resist progressive racial regulations, which mainstream businesses have lacked. The boundary work in which scientists engage has provided the pharmaceutical companies with a discourse to resist the regulations that has not depended on self-interest; instead, it has relied on the integrity of science. With the discursive authority afforded by science, pharmaceutical and biotech companies have not had to argue against racial justice with arguments based on their own self-interest for profit—a difficult task in American political culture since the mid-1960s' delegitimation of openly racist discourse (see Table 1).

To empirically evaluate this comparative difference, we carefully examined official documents and policy guidelines and responses from regulated entities. In the business case, we examined congressional hearings, filings with the government, and

Table 1. Response to Race-Counting Regulations by Different Types of Institutions

	Type of Regulation		
Type of Regulation	EEOC/Labor Department Regulation	NIH Policy on Reporting Race and Ethnicity	FDA Guidance on Collection of Race and Ethnicity Data
Regulated Scientific Enterprise	No	Yes	Yes
Regulated Business Enterprise	Yes	No	Yes
Drew Objections	No	No	Yes

individual business and associational responses. For the NIH and FDA cases, we exhausted all available government documents related to the policies and regulations. In addition, we evaluated all submitted comments, which followed the FDA's issuance of the draft guidance in 2003. We also referred to secondary sources to flesh out the organizations' responses.

The Political Development of State Racial Classification

The racial and ethnic categories introduced to the NIH and the FDA developed with no input from scientists. Instead, they originated with civil rights law administrators and mirrored folk categorizations, not scientific claims. That these folk categorizations have been the basis for what has become a massive edifice of thoroughly rationalized government statistical analysis and policymaking is perhaps the greatest irony of America's race classification and data collection—especially as it has been applied to the field of biomedical research.

Business Acceptance of Race Classification in the Civil Rights Era

Though federal agencies such the U.S. Census Bureau, the U.S. Department of Education, and the armed forces have also used racial statistics, civil rights racial categorizations were the most significant for later standardization. Civil rights agencies never defined "race," and they designed their categorizations with the political goals of understanding and combating racial discrimination. Policy makers therefore designed government classifications to mirror what they perceived to be the most pernicious folk categories in American society.

This pattern began in a 1947 report of a special body created by President Harry S. Truman. His President's Committee on Civil Rights (PCCR) studied the need for civil rights legislation in America. It defined "racial minorities" as "groups whose color makes them more easily identified [and] are set apart from the 'dominant majority' much more than are the Caucasian minorities" (PCCR 1947:x), and it focused on blacks, Mexican Americans, Japanese Americans, Chinese Americans, and American Indians (PCCR 1947:54, 60). The PCCR's simple, discrete categories roughly corresponded with what Hollinger (1995) later called America's "ethno-racial pentagon": black, brown, red, white, and yellow.

These basic categories then reappeared in later civil rights enforcement efforts that focused on private business, with political interests weighing in on occasion (Skrentny 2002). The EEOC developed the EEO-1 form for employers to report the race and sex composition of their workforces at various job levels. The goal

was to generate statistics that would indicate the nature and severity of discrimination in various geographic areas or industries. The EEO-1 used the same categories as the ethno-racial pentagon (Blumrosen 1971). Employers had to report their "white," "Negro," "Spanish American," "Oriental," and "American Indian" employees in several different levels and job categories. The regulation offered no clear definitions of these groups and instructed employers that they should count and categorize based on their own "visual survey" of their workforce and not use self-reports from employees. It offered no guidance on how employers should handle persons of ambiguous race. Firms that did not report risked facing a court order to comply (*Federal Register* 30, No. 228, Thursday, November 25, 1965:14,658).

The historical record reveals almost no resistance at all from business regarding the content or logic of the state's racial categories on the form. One EEOC administrator reported that he received letters from South Carolina that complained that years of racial mixing had rendered race especially ambiguous in that state, but this effort was not pursued then or in public hearings on the matter (Interview, Charles Markham, 15 June 1998). Hearings in December 1965 on the EEO-1 showed little resistance from anyone present, including business leaders. The only hints of debate came from competing political interests within the civil rights movement, including both activists and state-level civil rights administrators, who sometimes had conflicting views on whether or not official state race categorization was in contradiction to goals of the movement, which many understood as being race-neutral or "color-blind." General Counsel Bernard Frechtman of the National Employment Association was the only voice of concern from the business field about counting by race. Others at the hearings criticized his resistance, to which he responded following the logic of politics and not business. That is, his concern was not about profit or efficiency but about justice: "I think [the race reporting system] would do nothing more than to initiate and condone a type of discrimination that we are trying to prevent. . . . I would say that this is just not a good idea" (Lawson 1984: "EEOC Hearing on the Proposed Employer Reporting System," 16 Dec. 1965; Part 2, Reel 2, frame 470). Quiet acceptance appeared to have been the norm. The EEOC received EEO-1 reports from more than 118,000 individual units in 1966 (Lawson 1984: "The Role of the EEO-1 Reporting System in Commission Operations," 27 May 1967; Part 2, Reel 2, frame 635).

Businesses had another opportunity to resist race categorization when the U.S. Department of Labor issued affirmative action regulations, first targeted at the construction industry in 1969 in the so-called Philadelphia Plan and for all government contractors

in 1970 in Order No. 4 (Skrentny 1996). Unlike the EEO-1 form, which asked for reports on the makeup of firms' workforces, these regulations required businesses to make good-faith efforts to hire certain percentages of racial minorities into the workforces. The racial categories were the same as on the EEO-1 form. Businesses' response, however, remained the same; they were quiet and accepted the regulation without complaint or resistance.

Standardizing Politically Constructed Categories: OMB Directive 15

By the 1970s, federal agencies regulating employment, loans to small businesses, education, and other fields were using race categorizations. Though most programs and practices used the same standard five categories, there was also some divergence, and an effort to standardize race categories led to OMB Directive 15. The interests here were mostly rooted in an administrative concern with efficiency while balancing political interests in civil rights. OMB Directive 15 developed from activities by the Federal Interagency Committee on Education (FICE), created to coordinate federal education activities, which in 1973 recommended the creation of "common definitions for racial and ethnic groups" (U.S. Congress 1994:218).

The FICE committee's race standardization efforts, according to one official, were based on the political goals and logic of civil rights. The official stated, "In all of these initiatives, special attention was given to disparities between black, Latinos, American Indian and Asian American populations in comparison to the white population . . . . These disparities were in large part due to earlier policies of limited or total exclusion in various areas—such as citizenship, property rights, and immigration—directed to these groups" (U.S. Congress 1994:42; U.S. Congress 1998:66). Not surprisingly, the report suggested the five standard and minimal categories, with modifications for inclusiveness: "American Indian or Alaskan Native, Asian or Pacific Islander, Black/Negro, Caucasian/White and Hispanic." Hispanic was an ethnic category, and in a departure from the civil rights forms of the previous decade the report suggested that categories for whites and blacks should specify "not of Hispanic origin" (U.S. Congress 1998:67–9). After some testing, OMB issued Directive 15 in 1977, stating that its classifications "should not be interpreted as being scientific or anthropological in nature" (see http://wonder.cdc.gov/wonder/help/populations/bridged-race/Directive15.html; accessed 8 July 2010).

By the early 1990s, critics attacked the categories on a political basis—their lack of fit with America's new realities of immigration and interracial marriage (K. Williams 2006). After hearings in the House of Representatives in 1993, OMB agreed to review the

categories.[3] Political interests continued to dominate the process.[4] For example, groups representing Hawaiians moved the OMB with arguments that this group faced discrimination and inequality, which were different from that experienced by Asians. They insisted that their inclusion in the Asian category "overwhelmed" them, as Hawaiians constituted only 3 percent of that broad category of Asians and Pacific Islanders.[5] The final revisions for Directive 15 explained that "the categories represent a social-political construct designed for collecting data on the race and ethnicity of broad population groups in this country, and are not anthropologically or scientifically based."[6] In short, the standardized race categories established in 1997, as before, do not reflect scientific interests on race or even an awareness of any scientific perspective, and instead reflect political interests and understandings of minorityhood.[7]

In stating that the racial categories were not anthropologically or scientifically based but instead sociopolitical constructs, the OMB provided an opening for a scientific critique of the use of categories. Though scientific theories of race have long been repudiated (Gould 1981), by highlighting a distinction between sociopolitical construction and scientific claims, the agency offered the idea that there is indeed a *scientific* way to examine race despite its own understanding of the historically long political, economic, and social basis for its meaning and categorization scheme. In addition, by explaining that the logic or interest for the development and use of the categories rested with the logic and enforcement of civil rights, the OMB indicated that the categories were antithetical to the logic or interest of entities that might not have civil rights as a stated goal.

The Argument for and Against Using Race Categories in Science

Well before the formal introduction of government-defined racial and ethnic categories into scientific research, race and what it means for understanding human difference had a long and sordid past in the history of science and medicine (Gould 1981; Shipman 1994). Given charges of scientific racism and paternalism, scientists

[3] This and other material regarding the 1997 revisions can be found at http://www.whitehouse.gov/omb/fedreg/1997standards.html.

[4] http://www.whitehouse.gov/omb/fedreg/1997standards.html. Also see Edmonston et al. 1996.

[5] See http://www.whitehouse.gov/omb/fedreg/1997standards.html.

[6] See http://www.whitehouse.gov/omb/fedreg/1997standards.html.

[7] The 1997 revised OMB Directive 15's two-part race and ethnicity questions include the following racial and ethnic categories, respectively: American Indian or Alaskan Native, Asian or Pacific Islander, Black, White, Hispanic origin and not of Hispanic origin.

with a range of motives have been questioned about their use of racial or ethnic data and racial or ethnic minority subjects in scientific experiments. Thus, it is no surprise that scientists today remain divided over the meaning and use of race in science (Lee 2009; Reardon 2004). In biomedical research, scientists fall into two main camps: one that refutes a biological basis for race and another that sees race as being potentially biologically meaningful. Researchers who do not see a biological basis to race believe it is a proxy for socio-cultural, economic, and historical experiences. They use it to capture behavioral and structural differences between racialized groups. Advocates for this position state that there is genetic variation amongst humans but insist that they do not overlap with contemporary notions of race. Furthermore, they argue that these differences do not necessarily overlap with modern racial categories used in places like the contemporary United States. Thus, these scientists warn against the biological conceptualization of race while still exploring how lived experiences of a racialized identity shape health outcomes (Cooper et al. 2003; Krieger 1996; Schwartz 2001; Witzig 1996).

Scientists who argue that there is, or may be, a biological basis to race disagree over this significance and the precision of this notion. Some geneticists and biomedical researchers believe that modern constructs of race and racial self-identification are good approximations of ancestral origin (Burchard et al. 2003; Risch et al. 2002; Rosenberg et al. 2002). There are also scientists who accept some biological meaning of race but question its use in research, claiming that race as identified, categorized, and used in the contemporary United States is a bad proxy for continental or ancestral origin and should not be used as a proxy for population genetic variations (Jorde & Wooding 2004; Rotimi 2004).

The conflict over the meaning and use of race or ethnicity arises in part from historical debates regarding racial classification in health data and governmental regulation. Modern public health government agencies and organizations have collected data on health indicators by gender and race and ethnicity since the early twentieth century (Krieger & Fee 1994). Health officials treat these categories as static, self-evident, and easily recordable, helping to make the continued collection of racial or ethnic data and the categories themselves relevant for measures of health and biomedical research. In addition, the women's movement and civil rights movement have served to politicize these categories, making them more significant for shaping political action and ideas about difference. As Epstein argues, "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" (S. Epstein 2004:192). The civil rights movement origins

of these categories frame their meanings and the justification for the introduction into science and medicine, especially as health becomes articulated as a civil rights matter.

Adoption of an Official Racial Classificatory Scheme in Science and Medicine

In formal terms, the relationship between health and civil rights extends back to the passage of the 1964 Civil Rights Act. Title VI regulations of the act forbid intentional discrimination in federally funded programs and activities. Thus, hospitals receiving Medicare payments had to comply with the act and by 1966, all but 2 percent of hospital and health facilities applying for Medicare payments were compliant. Unlike some areas of civil rights, hospital desegregation was "smooth and effective" (Bonastia 2006:363).

However, beyond this area of health care, civil rights legislation and enforcement in health and science remained "half-hearted and ineffective" (Bonastia 2006:362). While the 1960s and 1970s legislative acts that were part of the "minority rights revolution" led to the creation and adoption of a racial classification system and "official minorities" counting (Skrentny 2002:17), no formal effort to introduce "diversity" in medical research occurred until the mid-1980s (S. Epstein 2007). In particular, women's health activists helped draw attention to the scientific and political inadequacies of a system of medical research that ignored women as clinical subjects (Auerbach & Figert 1995). Working with key allies in Congress, feminist activists, health advocacy groups, and medical experts pressured Congress to pass the NIH Revitalization Act in 1993.

Regulating Race and Ethnicity at the NIH

The NIH Revitalization Act set guidelines for including "women and minorities" in NIH-sponsored clinical research, often referred to as the Inclusion Mandate.[8] Though this went beyond the requirement for recordkeeping that the EEOC required of businesses, what is important for our purposes is that it introduced politically derived race categories into science. The Inclusion Mandate requires NIH-supported researchers to include women and minorities in their clinical trials. Many scientists

[8] "Minorities" were tacked on without much debate in Congress, although the NIH did receive comments from groups both for and against the inclusion of racial and ethnic minorities as a specified population group. Congress believed that this was a "logical, and politically desirable, extension" of the mandate (S. Epstein 2004:188; see also NIH 2001: "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001," http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

objected to the intrusion of "affirmative action" or "quotas," into science (Satel 1995:76) and questioned the scientific validity of such measures. NIH agency and other federal health officials responded by implementing guidelines for the Inclusion Mandate that included a flexible interpretation of what inclusion truly meant. For example, researchers are required to conduct studies, which can assess gender- or minority-based differences due to a given intervention if previous research suggests such an outcome in Phase 3 clinical trials (studies designed to determine the efficacy of a given intervention), leaving aside the many smaller preliminary clinical trials studies. In addition, researchers must conduct their studies with sufficient representation of women and minority subjects to yield "valid analysis." This "valid analysis" has never been defined as analysis resulting from a study that *necessarily* generates statistically significant results. This means that clinical trials are not required to have a set number of women or minority test subjects in numbers sufficient to power a statistically significant finding. NIH's guidelines thus provided scientists with "work-arounds" and allowed them to "proceed with their scientific tasks" even though government health officials never resolved any underlying debates regarding scientific validity related to race- or sex-based research (S. Epstein 2007:111).

In 2001, the NIH issued its policy on the reporting of racial or ethnic data: It requires scientists it supports who are conducting clinical research to collect racial and ethnic data using the OMB Directive 15 categories for purposes of monitoring and enforcing its guidelines.[9] The 2001 guideline did not specify a reason for the new policy. It conformed to a report issued by the U.S. Department of Health and Human Services (HHS) in 1999, which recommended the use of OMB Directive 15 categories for data collection and reporting of HHS-funded statistics.[10] The report stressed the importance of improving the collection and use of racial and ethnic data across the department and of strategies related to the department's Initiative to Eliminate Racial and Ethnic Disparities in Health.

While the initial NIH efforts to require the inclusion of women and minorities stirred public debate (albeit mostly in favor of the mandate), the 2001 policy specifying racial and ethnic categories received seemingly no attention. No scientific organization, university, health advocacy group, or government officials appeared to have made any public or official announcements.[11] Though some

[9] See NIH 2001: "Policy on Reporting Race and Ethnicity Data: Subjects in Clinical Research," http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html.

[10] See HHS 1999: "Improving the Collection and Use of Racial and Ethnic Data in HHS," http://aspe.hhs.gov/datacncl/racerpt/index.htm.

[11] The NIH itself appears to have not requested public comments on the matter.

critics remain concerned that these NIH and other science regulatory policies help reify race, particularly as it relates to heredity, genetics, and disease (Stevens 2003), the earlier battle over the Inclusion Mandate had in some sense clarified the boundaries between science and government regulation. The NIH had assured scientists that their scientific methods and claims would not be undone by the new regulation. The debates over the use of race, which were stirred by the introduction of the Inclusion Mandate, helped articulate the point that scientists had the authority to determine their own work issues. Though they could not use cost as a reason for not including women and minorities as clinical subjects, regulations left the decision of what "valid analysis" meant and the specific matters over numbers to the scientists themselves. In contrast to what occurred with the drug industry and the FDA, as we show below, the NIH policies did not challenge the scientists' claims over their authority and legitimacy to the meaning of race or ethnicity in scientific research. Though NIH-regulated scientists may have had the symbolic and discursive power to resist, unlike businesses regulated by the EEOC or the FDA, they did not have the profit motive to do so. Instead, scientists did not raise objections to the legalization of the racial schema in their research, treating the reporting policy as simply the formalization of the new regime (S. Epstein 2007:111).

Regulating Race and Ethnicity at the FDA

While the story of policy changes at the NIH and FDA are certainly related (both were targeted by many of the same groups of activists and health advocacy organizations, for example), there is one critical difference between the two agencies that has fundamentally shaped the response to the FDA's efforts to introduce an official racial classificatory scheme. While the NIH guidelines govern actions of scientists who are funded by the NIH, FDA guidelines seek to regulate the actions of scientific investigations that are part of a *commercial* enterprise—the efforts to bring drugs to market upon approval from the FDA. Like businesses in 1965, the drug industry had similar profit motives for objecting to greater regulation. However, unlike them, the drug industry's scientists had the symbolic and discursive power of science to legitimately resist regulatory action.

As with the NIH, health advocacy activists targeted the FDA to draw attention to concerns about potential differences in drug safety and efficacy amongst population subgroups such as women (Baird 1999). The FDA issued several important guidelines to industry for new drug applications (NDAs) and investigational new drugs (INDs) beginning in the 1980s. In 1988, the agency

identified the importance of conducting subset analyses on data generated from clinical studies in support of NDAs. Specifically, it stated that race and ethnicity were important population subsets, which required separate analyses to assess product safety and efficacy.[12] In 1993, the FDA added teeth to this 1988 guideline by explaining that the FDA could use the refusal-to-file option, essentially rejecting an application for review of NDAs that did not conduct adequate analyses of population subsets if there was insufficient evaluation for safety and/or effectiveness of the intended population. Unlike the NIH, however, the FDA did not require inclusion of particular subjects.[13] When Congress ordered the agency to examine issues related to inclusion of women and racial and ethnic groups in clinical trials of new drugs as part of its FDA Modernization Act in 1997, the FDA established the Women and Minorities Working Group to review policies and to consider implementation of the new congressional directive. In 1998, the working group did not recommend an inclusion mandate and instead stated that the FDA would develop and implement procedures that would enhance data collection and analysis.

In 1998, the FDA issued the Demographic Rule, which requires sponsors of INDs to "tabulate" its participants in clinical trials by age group, gender, and race in their annual reports and sponsors of NDAs to present their data similarly.[14] In essence, these rules and guidelines did not ask drug developers to alter the science underlying their investigations. For example, the 1993 guidance and the 1998 Demographic Rule simply emphasized the importance of determining safety and efficacy. When the FDA issued its draft guidance on the collection of racial and ethnic data in clinical trials in 2003, it interjected what drug developers considered "nonscientific" instruments (OMB Directive 15 racial and ethnic categories) into scientific investigations. Thus, while the agency had previously requested race and ethnicity data on subjects in certain clinical trials, with this new guidance, it now formalized the categories to be used.

FDA's Guidance to Industry to Collect Racial and Ethnic Data

In January 2003, the FDA issued the "Draft Guidance for Industry on the Collection of Race and Ethnicity Data for Clinical Trials for FDA Regulated Products" (henceforth "Draft

[12] See FDA 1988: "Guideline for the Format and Content of the Clinical and Statistical Sections of New Drug Applications," http://www.fda.gov/cder/guidance/statnda.pdf.

[13] See FDA 1993: "Guideline for the Study and Evaluation of Gender Differences in Clinical Evaluation of Drugs," http://www.fda.gov/cder/guidance/old036fn.pdf.

[14] U.S. Department of Health and Human Services, Food and Drug Administration, "Investigational New Drug Applications and New Drug Applications, Final Rule," *Federal Register* 63, No. 8, February 11, 1998:6854–62. Unlike guidelines, FDA rules are binding.

Guidance").[15] The agency accepted public comments for 60 days following notice and issued a final guidance to industry in September 2005. The Draft Guidance asked sponsors of NDAs to "include in their applications analyses of effectiveness and safety data for important demographic subgroups, including racial subgroups" (*Federal Register* 68:4788–9). While this suggestion was a restatement of the Demographic Rule, the FDA went further than it previously had by stating that sponsors of NDAs should use the OMB Directive 15 categories for the collection of race and ethnicity data of human subjects in clinical trials.

In recommending the OMB categories, the agency noted the importance of facilitating comparisons of studies and data across the FDA and other federal agencies. Per OMB Directive 15, the guidance asked sponsors to ask clinical trial subjects to answer the two-part ethnicity ("Hispanic or Latino" and "Not Hispanic or Latino") and race questions. Even for studies conducted outside the United States, the FDA suggested that sponsors utilize the OMB categories with one minor change—the category "Black or African American" was changed to "Black, of African heritage." The FDA acknowledged that these American categories might not adequately describe racial and ethnic groups in foreign countries. Nevertheless, it requested sponsors to collect detailed information on race and ethnicity in a way that would "trace back to the recommended categories" (*Federal Register* 68:4788–9).

The FDA reiterated the point made by OMB—that the categories are not biological or genetic but rather sociopolitical. Nevertheless, it stressed the importance of consistency in data collection and subsequent analyses for doing *good science,* framing the issue as a matter of science in two ways. First, it explained that the use of standardized OMB categories for data collection would ensure comparability and consistency with other government-collected data, which would further scientific analysis. In particular, the guidance noted, "Differences in response to medical products have already been observed in racially and ethnically distinct subgroups of the U.S. population," which it cited to intrinsic factors such as genetics or extrinsic factors like "sociocultural issues" (*Federal Register* 68:4788). The guidance stated that consistent racial and ethnic data collection could potentially capture important findings of difference amongst OMB racial groups, thereby linking physiology to race (Kahn 2006:47). Second, the FDA argued that consistency in categories would provide more useful population subgroup analyses of potential differences in safety and efficacy. With regard to the former, it stated, "Collection of data using standard categories can enhance patient safety by helping FDA evaluate potential differences in

[15] See *Federal Register* 68, January 30, 2003:4788–9.

drug response among subpopulations . . . [which] may also facilitate analyses seeking to identify differences in response'' (*Federal Register* 68:4788). Thus, the FDA emphasized that a consistent and systematic racial classificatory system would further the agency's ability to do its regulatory work of ensuring safety and efficacy, the agency's central charge, by identifying scientific reasons for the introduction of the racial categories. However, it did not state that the categories themselves were based on any scientific claims. Despite its efforts to frame the guidance in terms of science, the FDA's call for the use of the OMB categories raised vociferous reaction. Unlike businesses or scientists who did not object to the introduction of racial and ethnic categories, the drug and biotechnology companies regulated by the FDA protested the agency's effort to formalize racial and ethnic racial categories in clinical trials.

Response to the FDA Guidance: Doing Scientific Boundary Work to Fend Off Legal Regulation

The FDA Draft Guidance stirred a strong response. Over the 60-day public comment period, the agency received 19 statements from individuals, medical and health organizations, political action groups, and pharmaceutical companies and representatives.[16] Their comments illustrate the uncertainty, conflict, and political contestations inherent in the debates over how race or ethnicity should be defined, measured, and evaluated (see Table 2).

The line of support or opposition could be drawn between non-industry and industry. The major medical associations, including the AMA and the National Medical Association, which represents black physicians, supported the guidance's call for the collection of racial and ethnic data. Political action and consumer advocacy groups such as the NAACP, the National Alliance for Hispanic Health, the National Center for Policy Research for Women and Families, and the National Women's Health Network

[16] Comments received (during the 60-day period) included the following: one submission from an individual physician; two from medical associations—the American Medical Association (AMA) and the National Medical Association; four from political action and consumer group organizations—the National Association for the Advancement of Colored People (NAACP), the National Alliance for Hispanic Health, the National Center for Policy Research for Women and Families, and the National Women's Health Network; two from government entities—the Tennessee Black Caucus of State Legislators and the NIH; three from biotech and pharmaceutical industry associations—the Biotechnology Industry Organization, DIA-Medical Writing SIAC Standards, and the Pharmaceutical Research and Manufacturers of America; and seven from biotech and pharmaceutical companies—Abbott Laboratories, AstraZeneca, Bristol-Myers Squibb, DNAPrint Genomics, Genaissance Pharmaceuticals, Merck, and Pharmacia. All public comments for Docket 02D-0018 can be searched and found at the FDA's Dockets Management Web site, available at http://www.fda.gov/ohrms/DOCKETS/.

Table 2. Public Comments Submitted to the FDA*

	Support or Oppose	Main reason(s) for decision
Medical Associations (3)	Support	1) Guidance addresses efforts to eliminate racial and ethnic health disparities 2) Guidance ensures consistency in health studies across agencies
Political Action and Consumer Group Organizations (5)	Support	1) Guidance addresses efforts to eliminate racial and ethnic health disparities 2) Demands FDA require inclusion in clinical research
Biotech and Pharmaceutical Industry Associations (3)	Oppose	1) OMB 15 categories are not scientific 2) Use of categories may generate false findings 3) Categories inappropriate outside U.S. 4) Guidance inconsistent with global drug development
Biotech and Pharmaceutical Companies (7)	Oppose	1) OMB 15 categories are not scientific 2) Use of categories may generate false findings 3) Categories inappropriate outside U.S. 4) Guidance inconsistent with global drug development

*19 comments were submitted during the 60-day public comments period. Not included in this table are submissions by a private individual and the NIH.

also favored the guidance. Concern over racial and ethnic health disparities in the United States motivated their support. They believed that the use of OMB Directive 15 categories would ensure consistency across studies, which would enable analyses of potential differences amongst racial and ethnic groups in the safety and efficacy of pharmaceutical products. They believed that this could be helpful in efforts to eliminate racial and ethnic health disparities. The only criticism was that the FDA did not go *far enough* by recommending the collection of racial and ethnic data. The NAACP and the National Center for Policy Research for Women and Families argued that the FDA should follow the NIH's lead and require inclusion of women and minorities in sponsors' studies. These groups did not caution against potential traps of biological essentialism of race or problems tied to the use of the OMB Directive 15 categories and the collection of racial and ethnic data in general. The overwhelming concern was in ensuring support for research and initiatives that could help address the issue of health disparities, in many ways, supporting the political and social goals of a civil rights framing of health.

Pharmaceutical and biotech companies and industry representative organizations' resistance to the legal regulations largely fit the pattern of scientific boundary work as they defended the autonomy of their science-for-profit. With both a profit motive and discursive power of scientific discourse, they unanimously spoke against the proposed guidance. They raised their objections, making four related points: (1) OMB Directive 15 categories were not scientific; (2)

use of the categories might generate false findings of difference (either falsely positive or negative); (3) categories were inappropriate for use outside the United States; and (4) the guidance was inconsistent with global drug development. In making these claims, the industry did crucial boundary work, employing discursive strategies to identify scientific integrity and legitimacy by challenging the "scientific merits" of the categories. Even when making the fourth point, which could be interpreted as a business argument about efficiency, companies couched their claim in terms of scientific reliability and consistency. Unlike businesses in 1965, the drug industry could cloak its profit motive under a guise of scientific claims.

Pharmaceutical and biotech companies and industry organizations restated what the OMB said all along—that there was no scientific basis for the OMB Directive 15 categories and rather that they were sociopolitical constructs. These groups did not object to the scientific claims about possible differences in drug metabolism that could affect safety or efficacy. However, they asserted their scientific methods and claims to discredit these categories. For example, Astra Zeneca argued, "The whole concept of 'race' has in later years been challenged based on a new understanding of the human genetic code, which indicates that the genetic differences between two person of the same race or ethnicity is [*sic*] just as great as between two persons of different race or ethnicity" (Letter, AstraZeneca, 27 March 2003, p. 1, http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/032803/80059cf3.pdf). It continued to say that these categories could not "address pharmacogenetic differences between race and ethnic groups" (Letter, Astra Zeneca, 27 March 2003, p. 1, http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/032803/80059cf3.pdf). The Biotechnology Industry Organization commented, "The concept of 'ethnicity' as a biological marker that would impact drug metabolism is not accepted scientifically" (Letter, Biotechnology Industry Organization, 28 March 2003, p. 4, http://www.fda.gov/ohrms/dockets/dailys/03/Apr03/040403/8005c374.pdf).

DNAPrint Genomics questioned whether the proposed racial and ethnic categories would "consistently confer the most accurate information about a subject's genetic or cultural heritage . . . particularly if reliance is made exclusively on self-reporting" (Letter, DNAPrint Genomics, 4 Feb. 2003, http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020603/8004e14c.html). Biological truth, the company claimed, cannot be ascertained from subjects themselves. Instead, some of the pharmaceutical companies stated that genetic testing may help get at true or real group categories and advocated genetic mapping to achieve "biogeographical ancestry" (DNAPrint Genomics, 4 Feb. 2003, http://www.fda.gov/ohrms/dockets/dailys/03/Feb03/020603/8004e14c.html). Companies such as DNAPrint Genomics had commercial projects, which claimed to do just this.

Genaissance Pharmaceuticals suggested that the FDA "stimulate the adoption of new genetic systems for ancestry determination rather than antiquated and potentially inaccurate racial denomination" (Letter, Genaissance Pharmaceuticals, 28 March 2003, p. 5, http://www.fda.gov/ohrms/dockets/dailys/03/Apr03/040103/8005b2de.pdf). Genaissance argued that the OMB categories were biologically false and hence scientifically untrue. For these companies with mechanisms for genetically determining one's "true race," a strong profit motive clearly underpinned much of their claims.

In addition to critiquing the categories themselves, Abbott Laboratories wondered if the two-part race and ethnicity questions could make the statistical subgroup analysis more difficult or even possibly meaningless. The company asked for "an alternate terminology and a more *objective* set of categories" (Letter, Abbott Laboratories, 26 March 2003, p. 2, http://www.fda.gov/OHRMS/DOCKETS/dailys/03/Mar03/032703/80059c93.pdf; emphasis added). These companies attacked the scientific integrity of the categories as well as the resultant analyses. Thus, they also claimed that without any credible scientific evidence to support the use of these categories, their use would generate false positive or negative findings of difference. These companies attacked the intrusion of political categories by using the logic and method of scientific investigation and thereby maintained the boundary between science and nonscience.

Pharmaceutical companies and industry organizations also questioned the applicability of the categories outside the United States and worried that conflicts would arise because these categories could be meaningless in a foreign setting. For example, Bristol-Myers Squibb asked what should be done with Australian Aborigines and complained that the categories were not "exhaustive" (Letter, Bristol-Myers Squibb, 24 March 2003, p. 2, http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/032603/02d-0018-c000006-01-vol1.pdf). The company could have questioned whether Australian Aborigines should be classified as "black," given their dark skin color. However, there is no genetic or geographic reason for linking them to, for example, African Americans. If the measurement of race were to get at some genetic "truth" about groups that would address differences in drug metabolism, for example, such characterizations would be nonsensical. That is, one could argue that subjects whose ancestry is rooted in western Africa are not very similar genetically to those who are aboriginal to Australia. On the other hand, if the race and ethnic measurements are to uncover some notions about social or political experiences that impact biological responses to certain drugs, perhaps Australian Aborigines are, in terms of social distance in a stratified society such as Australia's, similar to African Americans. However, the FDA did not specify whether a rationale based on a biological or sociopolitical conception of race under-

pinned its recommendation. By referring to race as both "intrinsic" (genetics) and "extrinsic" (sociocultural) factors that determine disease outcomes and response to drugs in the draft guidance, the FDA suggested that both constructions were significant (*Federal Register* 68:4788).

Drug companies and their industry association representatives argued that other conflicts could arise in using these categories outside the United States. Test subjects outside the United States would be unwilling, they claimed, to answer questions that many Americans might not find objectionable. A number of the pharmaceutical companies commented that in clinical studies conducted outside the United States, the Latino or Hispanic ethnicity question would render meaningless information from places such as Spain, where all subjects could be classified as Hispanic but whose cultural experiences and history may be more in alignment with France than with those of American Hispanics. Equally troubling as the Hispanic question was the lack of group specificity for the Asian category and uncertainty related to how multiracial subjects should be counted. In raising these concerns about how to identify and count Australian Aborigines, Spaniards, or Asians, these companies and organizations challenged the scientific integrity, applicability, and generalizability of the OMB categories. The lack of external validity violated a central tenet of the scientific method.

In addition, they also employed strategies to maintain legitimate boundaries over the work of drug development as a *business* enterprise by highlighting the guidance's inconsistencies with the science of global drug development. Merck reminded the FDA that there is an "extensive international component" to pharmaceutical development and that the use of the OMB categories was not "feasible when considered on a global basis for international clinical trials" (Letter, Merck, 26 March 2003, p. 2, http://www.fda.gov/ohrms/dockets/dailys/03/Mar03/032703/80059c8f.pdf). Their scientific research would be compromised. Furthermore, these companies argued that international drug development does not end with clinical trials conducted on international test subjects. Drug companies have a vested financial interest in marketing their new pharmaceutical products in a global market with customers in places like Japan and Europe. Thus, many of the companies and the industry organizations reminded the FDA that an international guideline on standardizing "ethnic factors" for foreign clinical trials already existed—the International Conference on Harmonization (ICH) Guideline Document E5 on "Ethnic Factors in the Acceptability of Foreign Clinical Data" (Kahn 2006).[17] They objected to

[17] International Conference on Harmonization, *Ethnic Factors in the Acceptability of Foreign Clinical Data,* 5 Feb. 1998, http://www.ich.org/LOB/media/MEDIA481.pdf.

the apparent contradictions between the FDA guidance and the industry-sponsored ICH guidance, which does not require the use of the OMB categories. As Weber would suggest, these businesses were concerned with the need for predictability.

These comments highlight the uncertainties and inconsistencies underlying industry and non-industry organizations' conceptualizations of race or ethnicity in the field of scientific regulation. Scientists do not agree that race is real. Nevertheless, given the long history of race and science, discursively, scientists may not move away from the categories completely. The development of the OMB categories and discourse surrounding the schema, which suggested a distinction between scientific and sociopolitical basis for the categories, provided an opening for these companies to challenge the imposition of the classification scheme even as it affirmed some biological or genetic "truth" to race. Furthermore, while the FDA's characterization of the need for guidance as a science issue drew science-based criticism from the companies, the lack of consensus amongst scientists regarding the meaning of race and rationale for its use in biomedical research perhaps enabled the FDA to sidestep the scientific criticism. Following the comments, the FDA made some changes in crafting its final guidance. Most significant, it stated that sponsors could omit the Hispanic or Latino ethnicity question from clinical trials conducted outside the United States although it continued to recommend the use of the Hispanic and Latino categories. It also amended the "Black" racial designation, removing the "of African heritage" phrase from the category.[18] Despite their resistance and efforts at boundary work, the companies were unable to stop the FDA's effort to formalize the way in which racial or ethnic data in clinical research are collected, and the final guidance was announced in September 2005.

Conclusion

A basic idea in Critical Race Theory is that law helps construct the meaning of race. This may occur in many ways and in many settings, including federal regulations governing organizations. We have sought to contribute to this body of scholarship through the use of sociological theories of institutions, culture, and science, paying attention to institutional dynamics and the regulation of business and science.

State regulation typically involves the crossing of institutional cultural boundaries. In doing so, regulations introduce political logics that institutional actors may perceive to be alien and

[18] See FDA 2005: "Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials," http://www.fda.gov/CbER/gdlns/racethclin.htm.

illegitimate. We have shown that for several decades, the American state created and institutionalized through regulations race categories that it derived through political means. The interests to be served in race categorizations created for civil rights purposes have been equality and justice.

We have also shown that these politically derived race categorizations faced almost no resistance when imposed on business despite their apparent conflicts with business logics of efficiency and profit. Although businesses in 1965 had profit motives to resist (such as avoiding paperwork, legal uncertainty, and hiring new staff in addition to keeping existing staff and tasks and maintaining discretion), they did not have a legitimate discursive framework to resist the regulatory introduction. Congruent with other studies of business responses to civil rights regulations, American businesses in 1965 complied quietly.

Science, however, presents a boundary that is more difficult to cross. As noted by Gieryn (1983, 1999) and Moore (1996), scientists are likely to police these boundaries and maintain them, fending off encroachments from nonscientific and (perhaps especially) overtly political interests. Although the NIH's Inclusion Mandate generated some objections from scientists, government officials were able to bring them on board by not challenging their scientific methods. By the time the NIH introduced its policy in 2001 on the reporting of race and ethnicity data in clinical research, scientists voiced no opposition to the introduction of an official racial classificatory scheme. Thus, despite NIH-supported scientists' ability to tap into a legitimate discursive framework for objecting to racial recordkeeping, they did not have strong motives to do so. When the FDA introduced its draft guidance in 2003 on the collection of racial and ethnic data in clinical trials, it had to contend with the institutional logics of both science and business. Unlike businesses, which did not protest racial categories for purposes of monitoring hiring practices, these science-for-profit companies regulated by the FDA objected. Like businesses in 1965, these companies had strong profit motives to object to increased regulation. However, unlike businesses, they also had scientific discourse with which to resist the guidance. Pharmaceutical and biotech companies sought to characterize the introduction of the racial and ethnic categories as illegitimate and junk science, however, with little success.

Our comparative analysis suggests that scientific logic, or more specifically scientific discourse, offers an opportunity to resist state measures to categorize and administer racial counting. This suggests that understanding resistance to regulation requires attention to both the interests of an organization (derived from its institutional logic) as well as the discourses that the institutional logic enables and legitimizes. Not just any institution will resist the

sacrifice of its autonomy and the imposition of new costs, and it will resist in ways that researchers may be able to predict.

However, pharmaceutical companies' ultimate failure to stop the FDA's guidance on race nevertheless suggests the limits of this discourse. What does this suggest for other business or scientific entities and different forms of regulation? Do all regulations of commercial uses of science result in similar levels of resistance and boundary work? Vogel (1996) and Kagan and Axelrad (2000) suggest it is the *style* of American regulation that engenders the most resistance. However, given that all regulations are politically derived, it is possible that the content of regulations, and specifically the extent to which they limit scientific autonomy, will lead to varying levels and kinds of boundary work. For example, environmental regulations may impact research and development in the energy or telecommunications industries. Do these regulations face scientific boundary work resistance similar to the race guidelines of the FDA—or is there something especially controversial about the race guidelines?

As we have shown, part of the ability of pharmaceutical and biotech companies to challenge the scientific validity of the racial and ethnic categories was rooted in the FDA's acknowledgment that these race categories were sociopolitical constructs, as the OMB previously had declared, and not based on scientific or anthropological claims, suggesting that there were indeed some true *scientific* constructs of race. This provided an opening for the regulated companies to argue that the classificatory scheme was antithetical to the scientific endeavors of the industry. The FDA-regulated companies' attack on the categories' scientific validity was also based on and enabled by a lack of consensus amongst scientists over the meaning and value of racial constructs in investigations of science and medicine. We know from the sociology of science (and even from reading journalistic accounts over the debates surrounding climate change) that science cannot provide some definitive "truth" beyond the reach of equivocation or political manipulation. This opens up the scientific discursive framework to use for resistance by any regulated entity tied to a scientific enterprise. Thus, we predict profit-seeking institutions that rely on scientific research to resist regulations that impose limitations on their autonomy to use science.

Despite the apparent availability of science discourse to scientific business enterprises, there does appear to be something unique about race guidelines in this post–civil rights, post-genomic era. The highly ordered and bureaucratic system for enforcing earlier civil rights regulations and gains of the minority rights revolution now extend beyond the early employment, voting, and education concerns. Activists, political leaders, and news media increasingly identify science and medicine as civil rights issues,

particularly as they relate to issues of racial and ethnic disparities in access to health care, research opportunities, and health outcomes. Thus, while regulated entities such as drug companies could use science to resist racial recordkeeping guidance, their failure to halt the intrusion of the official racial schema appears to be tied to the larger government and health and medical organizations' efforts to address racial and ethnic health disparities (Institute of Medicine 2003).

Furthermore, today there is reason to believe that folk-based and politically derived race categorizations can be the basis of industry development and market pursuit (Dávila 2001). Many businesses have brought race categories into everyday practices and human resources management, and they are now an institutionalized part of everyday activity (Kelly & Dobbin 2001). Even drug companies seek what they conceive as important shares of particular market niches, albeit under their own terms, by pursuing various "ethnic drugs" as evidenced by claims made in the introduction of BiDil for treating congestive heart failure amongst African Americans (Kahn 2004) and Iressa for battling lung cancer amongst patients of Asian descent (Duster 2007).

Does this suggest that the continued encroachment of racial recordkeeping may eventually present little to no challenge (including possibly cost) to regulated entities, including scientific enterprises? While drug companies' scientific critiques of the FDA guidance may have been more about their concerns over profit and less about scientific merit, there still remain significant political and scientific questions regarding the introduction of racial categorization in medical research and the drug industry. As the "official" racial classificatory scheme (as outlined in OMB Directive 15) supports, competes, or supplants existing notions of race and difference, scientists, social scientists, and government officials will have to examine how definitions and uses of race or ethnicity may impact the production of scientific knowledge, clinical practice, public health initiatives, and civil rights enforcement. In these classificatory schemes, some groups are identified and are included in the development of new drugs, public health programs, or civil rights policies. Others are not. Will who gets left out affect our understandings of health and difference, of inclusion and exclusion? How might, for example, a classificatory scheme that recognizes ethnic variation for racial groups such as Asians but not whites affect ideas about race (Bhopal & Donaldson 1998)? And will such definitions and categorizations address the social reality that racism and racial discrimination affect access to health care (Bach et al. 2004; A. Epstein et al. 2000; D. Williams 1997)?

These questions are particularly timely and urgent as government officials and activists continue to frame health as a civil right and participation in biomedical research as fundamental to not

only good science but also the democratic governance of scientific endeavors and society as a whole. We therefore expect more state efforts to bring civil rights interests, and thus race categories, into the fields of science and science-based industries. Given the politically contested nature of the categories and the construct of race itself, we also expect that such efforts will not resolve the debate over what race or ethnicity *really* mean or what their relevance is or should be in a post–civil rights, post-genomic era.

References

Adams, Christopher P., & Van V. Brantner (2006) "Estimating the Cost of New Drug Development: Is It Really $802 Million?," 25 *Health Affairs* 420–8.

Auerbach, Judith, & Anne Figert (1995) "Women's Health Research: Public Policy and Sociology," *Journal of Health and Social Behavior, Extra Issue (Forty Years of Medical Sociology)* 115–31.

Bach, Peter B., et al. (2004) "Primary Care Physicians Who Treat Blacks and Whites," 351 *The New England J. of Medicine* 575–84.

Baird, Karen L. (1999) "The New NIH and FDA Medical Research Policies: Targeting Gender, Promoting Justice," 24 *J. of Health Politics, Policy and Law* 531–65.

Bhopal, Raj, & Liam Donaldson (1998) "White, European, Western, Caucasian, or What? Inappropriate Labeling in Research on Race, Ethnicity, and Health," 88 *American J. of Public Health* 1303–12.

Blumrosen, Alfred W. (1971) *Black Employment and the Law*. New Brunswick, NJ: Rutgers Univ. Press.

Bonastia, Christopher (2006) "The Historical Trajectory of Civil Rights Enforcement in Health Care," 18 *The J. of Policy History* 362–86.

Bourdieu, Pierre (1991) "The Peculiar History of Scientific Reason," 6 *Sociological Forum* 3–26.

Bowker, Geoffrey C., & Susan Leigh Star (1999) *Sorting Things Out: Classification and Its Consequences*. Cambridge, MA: MIT Press.

Burchard, Eteban Gonzalez, et al. (2003) "The Importance of Race and Ethnic Background in Biomedical Research and Clinical Practice," 348 *The New England J. of Medicine* 1170–5.

Burstein, Paul (1985) *Discrimination, Jobs and Politics: The Struggle for Equal Employment Opportunity in the United States Since the New Deal*. Chicago: Univ. of Chicago Press.

Carpenter, Daniel P. (2001) *The Forging of Bureaucratic Autonomy: Reputations, Networks, and Policy Innovation in Executive Agencies, 1862–1928*. Princeton, NJ: Princeton Univ. Press.

Collins, Lee E. (2002) "Critical Race Theory: Themes, Perspective, and Directions," in J. L. Conyers, ed., *Black Cultures and Race Relations*. Chicago: Rowman and Littlefield.

Collins, Randall (1980) "Weber's Last Theory of Capitalism: A Systematization," 45 *American Sociological Rev.* 925–42.

Cooper, Richard S., et al. (2003) "Race and Genomics," 348 *The New England J. of Medicine* 1166–70.

Dávila, Arlene M. (2001) *Latinos, Inc.: The Marketing and Making of a People*. Berkeley: Univ. of California Press.

DiMasi, Joseph A., et al. (2003) "The Price of Innovation: New Estimates of Drug Development Costs," 22 *J. of Health Economics* 151–85.

Dobbin, Frank (2009) *Inventing Equal Opportunity*. Princeton, NJ: Princeton Univ. Press.

———, et al. (1993) "Equal Opportunity Law and the Construction of Internal Labor Markets," 99 *American J. of Sociology* 396–427.

Duster, Troy (2003) "Buried Alive: The Concept of Race in Science," in A. H. Goodman et al., eds., *Genetic Nature/Culture: Anthropology and Science beyond the Two-Culture Divide*. Berkeley: Univ. of California Press.

——— (2007) "Medicalisation of Race," 369 *The Lancet* 702–4.

Edelman, Lauren (1992) "Legal Ambiguity and Symbolic Structures: Organizational Mediation of Law," 97 *American J. of Sociology* 1531–76.

Edmonston, Barry, et al. (1996) *Spotlight on Heterogeneity: The Federal Standards for Racial and Ethnic Classification*. Washington, DC: National Academy Press.

Epstein, Arnold M., et al. (2000) "Racial Disparities in Access to Renal Transplantation: Clinically Appropriate or Due to Underuse or Overuse?," 343 *The New England J. of Medicine* 1537–45.

Epstein, Steve (2004) "Bodily Differences and Collective Identities: The Politics of Gender and Race in Biomedical Research in the United States," 10 *Body and Society* 183–203.

——— (2007) *Inclusion: The Politics of Difference in Medical Research*. Chicago: Univ. of Chicago Press.

Friedland, Roger, & Robert Alford (1991) "Bringing Society Back In: Symbols, Practices, and Institutional Contradictions," in W. Powell & P. DiMaggio, eds., *The New Institutionalism in Organizational Analysis*. Chicago: Univ. of Chicago Press.

Gamble, Barbara S. (1997) "Putting Civil Rights to a Popular Vote," 41 *American J. of Political Science* 245–69.

Gieryn, Thomas F. (1983) "Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists," 48 *American Sociological Rev.* 781–95.

——— (1999) *Cultural Boundaries of Science: Credibility on the Line*. Chicago: Univ. of Chicago Press.

Gould, Stephen Jay (1981) *The Mismeasure of Man*. New York: Norton.

Halfmann, Drew, et al. (2005) "The Biomedical Legacy in Minority Health Policy-Making, 1975–2002," 23 *Research in the Sociology of Health Care* 245–75.

Haney López, Ian (1996) *White By Law: The Legal Construction of Race*. New York: New York Univ. Press.

Hollinger, David A. (1995) *Postethnic America: Beyond Multiculturalism*. New York: Basic Books.

Institute of Medicine (2003) *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Washington, DC: National Academies Press.

Jorde, Lynn B., & Steven P. Wooding (2004) "Genetic Variation, Classification and 'Race,'" 36 *Nature Genetics* S28–33.

Kagan, Robert A. (2000) "How Much Do National Styles of Law Matter?," in R. A. Kagan & L. Axelrad, eds., *Regulatory Encounters: Multinational Corporations and American Adversarial Legalism*. Berkeley: Univ. of California Press.

Kagan, Robert A., & Lee Axelrad, eds. (2000) *Regulatory Encounters: Multinational Corporations and American Adversarial Legalism*. Berkeley: Univ. of California Press.

Kahn, Jonathan (2004) "How a Drug Becomes 'Ethnic': Law Commerce, and the Production of Racial Categories in Medicine," 4 *Yale J. of Health Policy, Law, and Ethics* 1–46.

——— (2006) "Harmonizing Race: Competing Regulatory Paradigms of Racial Categorization in International Drug Development," 5 *Santa Clara J. of International Law* 34–56.

Kelly, Robin, & Frank Dobbin (2001) "How Affirmative Action Became Diversity Management: Employer Response to Antidiscrimination Law, 1961–1996," in J. D. Skrentny, ed., *Color Lines: Immigration, Affirmative Action and Civil Rights Options for America*. Chicago: Univ. of Chicago Press.

Kempner, Joanna, et al. (2005) "Forbidden Knowledge," *Science* 854 (February).

Krieger, Nancy (1996) "Inequality, Diversity, and Health: Thoughts on 'Race/Ethnicity' and 'Gender,'" Commentary, 51 *J. of the American Women's Medical Association* 133.

Krieger, Nancy, & Elizabeth Fee (1994) "Social Class: The Missing Link in U.S. Health Data," 51 *International J. of Health Services* 133–4.

Lamont, Michéle, & Virag Molnár (2002) "The Study of Boundaries in the Social Sciences," 28 *Annual Rev. of Sociology* 167–95.

LaNoue, George R., & John C. Sullivan (1994) "Presumptions for Preferences: The Small Business Administration's Decisions on Groups Entitled to Affirmative Action," 6 *J. of Policy History* 439–67.

Lawson, Steven F., ed. (1984) *Civil Rights During the Johnson Administration, 1963–1969*. Frederick, MD: University Publications of America.

Lee, Catherine (2009) "'Race' and 'Ethnicity' in Biomedical Research: How Do Scientists Construct and Explain Difference in Health?," 68 *Social Science and Medicine* 1183–90.

Martin, Cathie Jo (1998) "Inviting Business to the Party: The Corporate Response to Social Policy," in M. Weir, ed., *Social Divide*. New York: Russell Sage Foundation Press and the Brookings Institution.

Minow, Martha (1990) *Making All the Difference: Inclusion, Exclusion, and American Law*. Ithaca, NY: Cornell Univ. Press.

Moore, Kelly (1996) "Organizing Integrity: American Science and the Creation of Public Interest Organizations, 1955–1975," 101 *American J. of Sociology* 1592–627.

Omi, Michael, & Howard Winant (1994) *Racial Formation in the United States: From the 1960s to the 1990s*, 2d ed. New York: Routledge and Kegan Paul.

President's Committee on Civil Rights (1947) *To Secure These Rights*. Washington, DC: Government Printing Office.

Ragin, Charles C. (1987) *The Comparative Method: Moving Beyond Qualitative and Quantitative Strategies*. Berkeley: Univ. of California Press.

Reardon, Jenny (2004) *Race to the Finish: Identity and Governance in an Age of Genomics*. Princeton, NJ: Princeton Univ. Press.

Risch, Neil, et al. (2002) "Categorization of Humans in Biomedical Research: Genes, Race and Disease," 3 *Genome Biology* 1–12.

Rosenberg, Noah A., et al. (2002) "Genetic Structure of Human Populations," *Science* 2381–5 (December).

Rotimi, Charles N. (2004) "Are Medical and Nonmedical Uses of Large-Scale Genomic Markers Conflating Genetics and 'Race?'," 36 *Nature Genetics* S43–7.

Satel, Sally (1995) "Can Science Survive Research by Quota?," *USA Today Magazine* 76 (September).

Schuman, Howard, et al. (1998) *Racial Attitudes in America: Trends and Interpretations, Revised Edition*. Cambridge, MA: Harvard Univ. Press.

Schwartz, Robert S. (2001) "Editorial: Racial Profiling in Medical Research," 344 *The New England J. of Medicine* 1392.

Shipman, Pat (1994) *The Evolution of Racism: Human Differences and the Use and Abuse of Science*. New York: Simon and Schuster.

Skrentny, John D. (1996) *The Ironies of Affirmative Action: Politics, Culture, and Justice in America*. Chicago: Univ. of Chicago Press.

——— (2001) "Republican Efforts to End Affirmative Action: Walking a Fine Line," in M. Landy et al., eds., *Seeking the Center: Politics and Policymaking at the New Century*. Washington, DC: Georgetown Univ. Press.

——— (2002) *The Minority Rights Revolution*. Cambridge, MA: Belknap Press of the Harvard Univ. Press.

——— (2008) "Are America's Civil Rights Laws Still Relevant?," 4 *Du Bois Rev.* 1–22.

Sohoni, Deenesh (2007) "Unstable Suitors: Anti-Miscegenation Laws, Naturalization Laws, and the Construction of Asian Identity," 41 *Law & Society Rev.* 587–618.

Stevens, Jacqueline (2003) "Racial Meanings and Scientific Methods: Changing Policies for NIH-Sponsored Publications Reporting Human Variation," 28 *J. of Health Politics, Policy, and Law* 1033–88.

Stigler, George (1971) "The Theory of Economic Regulation," 2 *Bell J. of Economic and Management Science* 2–21.

Sumner, William Graham [1906](1959) *Folkways; a Study of the Sociological Importance of Usages, Manners, Customs, Mores, and Morals*. New York: Dover Publications.

Timmermans, Stefan, & Marc Berg (2003) *The Gold Standard: The Challenge of Evidence-Based Medicine and Standardization in Health Care*. Philadelphia: Temple Univ. Press.

U.S. Congress (1994) "Review of Federal Measurements of Race and Ethnicity." Hearings Before the House of Representatives Subcommittee on Census, Statistics and Postal Personnel of the Committee on Post Office and Civil Service. Washington, DC: Government Printing Office.

U.S. Congress (1998) "Federal Measures of Race and Ethnicity and the Implications for the 2000 Census." Hearings Before the House of Representatives Subcommittee on Government Management, Information and Technology of the Committee on Government Reform and Oversight. Washington, DC: Government Printing Office.

Vogel, David (1996) *Kindred Strangers: The Uneasy Relationship Between Politics and Business in America*. Princeton, NJ: Princeton Univ. Press.

——— (2005) *The Market for Virtue: The Potential and Limits of Corporate Social Responsibility.* Washington, DC: Brookings Institution Press.

Williams, David R. (1997) "Race and Health: Basic Questions, Emerging Directions," 7 *Annals of Epidemiology* 322–33.

Williams, Kim M. (2006) *Mark One or More: Civil Rights in Multiracial America*. Ann Arbor: Univ. of Michigan Press.

Wilson, James Q. (1980) "The Politics of Regulation," in J. Q. Wilson, ed., *The Politics of Regulation*. New York: Basic Books.

Witzig, R. (1996) "The Medicalization of Race: Scientific Legitimization of a Flawed Social Construct," 125 *Annals of Internal Medicine* 675–9.

Statutes Cited

Civil Rights Act of 1964. Public Law 82-352 (78 Stat. 241). 42 U.S. Code Chapter 21.

Food and Drug Administration Modernization Act of 1997, Public Law 105–115 (S. 830), 105th Cong., November 21, 1997.

NIH Revitalization Act of 1993, PL 103-43, signed into law 10 June 1993.

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