FROM DISPARITY TO DIFFERENCE: HOW RACE-SPECIFIC MEDICINES MAY UNDERMINE POLICIES TO ADDRESS INEQUALITIES IN HEALTH CARE.

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On June 23, 2005, the U.S. Food and Drug Administration ("FDA") formally approved the heart failure drug BiDil to treat heart failure in "self-identified black patients."[1] The drug itself is not actually new; it is merely a combination of two generic drugs that have been used to treat heart failure for over a decade. BiDil's newness derives primarily from its public presentation as the world's first "ethnic" drug.

BiDil made its first public appearance as a race-specific drug on March 8, 2001, when NitroMed, a biotech firm based in Massachusetts, issued a press release triumphantly announcing the receipt of a letter from the FDA "describing the regulatory status and ultimate approvability of BiDil," pending the successful completion of a confirmatory trial of the drug in African Americans with heart failure.[2] The trial, known as A-HeFT, the African American Heart Failure Trial, enrolled only "self identified [African Americans]" and dramatically came to an early conclusion last July due to strong indications of BiDil's efficacy in treating heart failure.[3] The results of the trial were published in the November 2004 issue of the *New England Journal of Medicine*.[4] The following February, the FDA agreed to review NitroMed's amended new drug application for BiDil.

This analysis begins with a consideration of A-HeFT results and then moves on to elaborate upon some of the broader implications of BiDil in the context of genomic medicine and the politics of heath care. It briefly relates the story of how law and commerce played a central role in the emergence of BiDil as an "ethnic" drug. Then it explores the "strategic reification" of race as genetic in the context of BiDil and connects the drug to larger issues concerning genetics and the politics of difference in health care and perhaps beyond. In particular, the Article explores three areas in this process of reification:

1) the statistical manipulation of racial difference in drug development;

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[1] Food and Drug Admin., *FDA Approves BiDil Heart Failure Drug for Black Patients*, FDA NEWS, June 23, 2005, http://www.fda.gov/bbs/topics/NEWS/2005/NEW 01190.html.
[2] Press Release, NitroMed, NitroMed Receives FDA Letter on BiDil® NDA, a Treatment for Heart Failure in Black Patients (Mar. 8, 2001), http://www.nitromed.com/prress/03-08-01.html [hereinafter *NitroMed Press Release*].
[3] *See* Joseph A. Franciosa et al., *African-American Heart Failure Trial (A-HeFT): Rationale, Design, and Methodology*, 8 J. CARDIAC FAILURE 128, 129 (2002); A. Taylor et al., *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure*, 351 NEW ENGL. J. MED 2049, 2050 (2004).
[4] *See* Taylor et al., *supra* note 3.

2) the conflation of racial difference with genetics; and

3) the relationship between genetic explanations of difference, market ideologies, and backlash against state action to redress racial injustice.

I. A-HEFT[5]

First to A-HeFT: The good news is that clinical findings indicate that BiDil appears to be effective in treating heart failure.[6] A-HeFT took about 1,000 subjects who were already on an array of treatments for heart failure and divided them two groups — one received BiDil on top of the existing therapies, the other, a placebo.[7] The trial, however, was conducted only in African American patients[8], and the results, therefore, give the impression that BiDil works only in African Americans. This is not the case. The trial investigators themselves concede that BiDil will work in people regardless of race.[9] Without a comparison population, the investigators cannot even claim that the drug works differently in African Americans. The only responsible scientific claim that can be made on the basis of these trials is that BiDil works in some people who have heart failure, period.

By seeking approval of BiDil as a drug solely to treat African Americans, NitroMed, the corporate sponsor of the trials and owner of the rights to BiDil, has opened up a Pandora's box of racial politics without fully appreciating the implications of what it is doing.

First, at a minimum, race-specific labeling will make it more likely that non-African Americans who would benefit from the drug will not have access to the drug or even know of its availability. Health care providers simply may not think of prescribing the drug to non-African Americans and insurance carriers may not cover such "off-label" use.

Second, given that the BiDil researchers admit that their drug will work in non-African Americans,[10] the most plausible reason for conducting a race-specific clinical trial is that NitroMed holds the rights to a race-specific patent[11] that will give them control over profits from BiDil until

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[5] This section is drawn from Jonathan Kahn, Perspective, *Ethnic Drugs*, 35 HASTINGS CENTER REP., (2005) (back cover).

[6] *See* Taylor, *supra* note 3, at 2049-2057.

[7] *See id.*; Franciosa, *supra* note 3, at 129.

[8] *See* Franciosa, *supra* note 3, at 129.

[9] For example, Jay Cohn, the original holder of both of BiDil's patents has stated that he himself prescribes the generic combination to white patients who do not respond well to other drugs and concluded, "I actually think everybody should be using it." *See* Denise Gellene, *Heart Pill Intended Only for Blacks Sparks Debate*, L.A. TIMES, June 16, 2005, *available at* http://www.latimes.com/business/ la-fi-bidil16jun16,1,5518742.story?coll=la-headlines-business (last visited June 16, 2005).

[10] *Id.*

[11] U.S. Patent No. 6,465,463 (issued Oct. 15, 2002). A modern patent is a "government issued grant which confers upon the patent owner the *right to exclude* others from 'making, using, offering for sale, or selling the invention throughout the invention throughout the United States or importing the invention into the United States' for a period of 20 years ending from the filing date of the application." CHISUM, D. ET AL., PRINCIPLES OF PATENT LAW 2 (2d ed. 2001) (citing 35 U.S.C. § 154 (1994)). This authority derives from the United States Constitution, Article I, section 8, which states: "The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to

2020 if it is approved by the FDA. Of course, this hardly constitutes a sound scientific basis for designing a clinical trial. But it is a good economic one. An older patent, which does not refer to race, expires in 2007.[12] Thus, if NitroMed had gotten the drug approved for treatment regardless of race, it would have had only a year or two of patent protection. If the drug is to be approved for race-specific use, NitroMed would presumably count on off-label prescription use by non-African Americans to boost the market for BiDil. Morever, if a follow-up study demonstrated efficacy regardless of race, NitroMed would get a "three-year market exclusivity" license from the FDA to retain effective control over the market for a "new indication." [13]

Third, marketing a race-specific drug can lead to a misallocation of health care resources. This is not to advocate "color blind" medicine; to the contrary, there are very real health disparities in the United States that can be correlated with race. A disproportionate number of African Americans suffer from a number of diseases, including hypertension and diabetes.[14] Like heart failure, these are complex conditions caused by an array of environmental, social, economic, and genetic factors. Central among these factors is the fact that African Americans experience discrimination, both in society at large and in the health care system specifically. The question, once you identify these disparities in health outcomes, is how to address the underlying causes. Of course any situation can have multiple causes, both social and genetic. But health disparities are not caused by an absence of "black" drugs. As studies by the Institute of Medicine among others make clear, they are caused by social discrimination and economic inequality.[15] The problem with marketing race-specific drugs is that it becomes easier to ignore the social realities and focus on the hard science.

Finally, the FDA approval of BiDil specifically for the use by African Americans, has given the federal government's stamp of approval to use race as, in effect, a genetic category. But race does not necessarily predetermine genetic characteristics, as even the BiDil researchers admit, and once we sanction such talk, it is a short step to talking about certain races as inferior or superior to others. Given our nation's troubled history of racial oppression, race is not something that should be taken lightly.

Stunningly, in July 2004, a *New York Daily News* columnist reported that Dr. Clyde Yancy, one of the primary A-HeFT researchers, stated, "Tuskegee is almost irrelevant now, especially with more blacks and others sensitive to ethical issues and having a voice in 'investigative medicine.'"[16]

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authors and inventors the exclusive rights to their respective writings and discoveries." U.S. CONST. art. I, § 8.

[12] U.S. Pat. No. 4,868,179 (issued Sept. 19, 1989).

[13] For a brief discussion of race and "market exclusivity" for drugs, see A. Berdon, *Exclusivity Requests Based On Race, Age On The Horizon*, 19 GENERIC LINE No. 24, Dec. 20, 2002.

[14] *See* INST. OF MED., UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE (2002).

[15] *See id*.

[16] Shipp E.R., *Commentary: When Meds Target Blacks*, N.Y. DAILY NEWS, July 24, 2004, *available at* http://www.nydailynews.com/news/ideas_opinions/story/215390p-185450c.html (last visited on Feb. 1, 2005). In the Tuskegee Syphillis Study, conducted under the auspices of the U.S. Public Health Service

This casual dismissal of one of the most infamous examples of racist exploitation of African Americans by the United States health care establishment was framed by the assertion that in the context of BiDil, "health benefits . . . outweigh racial politics."[17] Dr. Yancy seems to be implying that a mere awareness of Tuskegee is enough to transcend its legacy. Memory, here, paradoxically leads to oblivion. He also posits a false dichotomy between health and politics — as if the mere fact that BiDil shows efficacy were enough to trump any concerns about how, whether, or why it is being framed as a race-specific drug.

Since NitroMed's initial announcement in 2001 and the subsequent completion of the A-HeFT trial, BiDil has emerged as a central player in ongoing debates over whether and how to use race or ethnicity as categories in biomedical research. It has also played a significant role at the forefront of broader political and legal discussions of the legitimacy of identifying and acting upon perceived biological or genetic differences among the races. This is hardly surprising, given NitroMed's own emphasis on "ethnic differences in the underlying pathophysiology of heart failure."[18] More surprising, however, is the lack of attention paid to how BiDil came to be an "ethnic" drug.

A. BiDil's Origins[19]

How did we get to this point? If we go back to BiDil's origins, we find that BiDil did not begin as an ethnic drug. Rather, it became ethnic over time and through a complex array of legal, commercial, and medical circumstances that transformed the drug's identity.

Over the past twenty years, a revolution has occurred in heart failure treatment with the development of a wide array of pharmaceutical interventions to improve both the longevity and quality of life of people suffering from heart failure. One of the earliest breakthroughs came in the 1980s with the first Vasodilator Heart Failure Trial ("V-HeFT I") which lasted from 1980 to 1985. V-HeFT I was led by Dr. Jay Cohn of the University of Minnesota and involved cardiologists from around the country working together with the United States Veterans Administration. The trials found that patients receiving a combination of two vasodilators, called hydralazine and isosorbide dinitrate ("H/I"), seemed to have a lower

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from the 1930s to the 1970s, black men with syphilis were allowed to go untreated for years, even decades after effective treatments were discovered in the 1940s in order to provide researchers with information on the progression of the disease. *See, e.g.*, J.W. Leavitt& R. Numbers, Sickness and Health in America 331-346 (1985) (citing A.M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*). In 1997 President Clinton offered a formal apology for the U.S. government's conduct in this affair. *See* William J. Clinton, President of the United States of America, Remarks in Apology for Study Done in Tuskegee (May 16, 1997), *available at* http://www.cmh.pitt.edu/presremarks.html (last visited Dec. 17, 2003).

[17] *See* Shipp, *supra* note 16.

[18] NitroMed Press Release, *supra* note 3.

[19] For an extended discussion of this story, see Jonathan Kahn, *How a Drug Becomes "Ethnic": Law, Commerce, and the Production of Racial Categories in Medicine*, 4 Yale J. Health Pol'y. L. & Ethics 1 (2004).

rate of mortality. These two generic drugs later combined would become "BiDil."[20]

The V-HeFT I trial was soon followed by V-HeFT II, which lasted from 1986 to 1989. This trial compared the efficacy of the H/I combination against the drug, enalapril, an angiotestin-converter enzyme ("ACE") inhibitor, and concluded that there was an even more pronounced beneficial effect on mortality in the enalapril group, establishing ACE inhibitors as a front line therapy for heart failure.[21] The V-HeFT investigators did not build the trials around race or ethnicity. They enrolled both black and white patients and in the published reports of the trials' successes, they did not break down the data by race. Rather, they presented H/I (the BiDil drugs) as generally efficacious in the population at large, without regard to race.[22]

B. THE LEGAL CONSTRUCTION OF BIDIL

The role of law as a player in the emergence of BiDil as an ethnic drug began most recently in 1980, around the same time as the initiation of V-HeFT I. That year, President Carter signed two pieces of legislation that would come to translate the relationship between industry and academic researchers into law.[23] The first, the Stevenson-Wydler Technology Transfer Act,[24] encouraged government laboratories, universities, big industries, and small businesses to interact and cooperate with one another. The second, the Bayh-Dole Patent and Trademark Laws Amendment,[25] allowed institutions conducting research with federal funds, such as universities, to retain the intellectual property rights to their discoveries. It was in this context that V-HeFT's research findings, produced in cooperation with the United States Veterans Administration, could be commercialized through patent and trademark law. Thus, the lead cardiologists in the V-Heft trials, Drs. Jay Cohn and Peter Carson, were later able to obtain intellectual

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[20] *See* Kahn, *supra* note 19, at 11-16.

[21] *See* Jay N. Cohn et al., *A Comparison of Enalapril with Hydralazine-Isosorbide Dinitrate in the Treatment of Chronic Congestive Heart Failure*, 325 NEW ENG. J. MED. 303 (1991).

[22] The reports were numerous, bearing on a variety of characteristics measured in the trials. As far as I could tell, none of them broke the data out by race until a study published in 1999. Peter Carson et al., *Racial Differences in Response to Therapy for Heart Failure: Analysis of the Vasodilator-Heart Failure Trials*, 5 J. OF CARDIAC FAILURE 178 (1999).

[23] *See, e.g.*, Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.KENT L. REV. 15 (1999). Krimsky notes,

> The new federal initiatives on technology transfer and academic-industry-government collaborations were responsible for a marked rise in university patents. In 1980, American university patents represented one percent of all U.S. origin patents. By 1990, the figure rose to 2.4%. Within that decade, the number of applications for patents on NIH-sponsored inventions increased by nearly 300%.

Id. at 22.

[24] *See* 15 U.S.C. § 3701 (1994). In particular, the Act encourages the transfer of technology developed in federal laboratories to the private sector for further development through Cooperative Research and Development Agreements ("CRADA"). In some instances, this involves the transfer of legal rights, such as the assignment of patent title to a contractor or the licensing of a government-owned patent to a private firm. In other cases, the transfer endeavor involves the informal movement of information, knowledge, or skills through person-to-person interaction.

[25] *See* 35 U.S.C. §§ 200-212 (1994).

property rights in BiDil-related patents and thereupon entered into deals with the likes of NitroMed to commercialize the discoveries made through the V-HeFT trials.

The first intervention of patent law in the development of BiDil, however, was negative and restrictive, rather than productive. Following the successful completion of V-HeFT II in 1989, the next logical step would have been to conduct a trial that explored the combined effects of ACE inhibitors and H/I. Dr. Cohn himself pushed for such a trial and openly bemoaned the lack of corporate support that would enable him and other cardiologists to go forward.[26] The key reason for such corporate resistance, as Cohn later noted, was that hydralazine and isosorbide dinitrate were both generic drugs and in the absence of intellectual property rights to the therapeutic compound, corporate support for further tests involving the BiDil drugs were not be forthcoming.[27] Thus, even years before BiDil was ever taken before the FDA for approval as a new drug, the lack of relevant intellectual property value seemed likely to condemn hydralazine and isosorbide dinitrate to obscurity as treatments for heart failure.

Cohn revived the prospects of BiDil by obtaining a patent in 1989, on a "method of reducing mortality associated with congestive heart failure using hydralazine and isosorbide dinitrate,"[28] and then by developing BiDil as a new drug as a combination of H/I in single dose form. BiDil was a breakthrough of convenience — it made heart failure medication easier to use and to dispense — but it was not itself a new therapy. Again, at this point it was still a drug for everyone, regardless of race. It was not until Medco, a North Carolina biotech firm who first acquired the rights to BiDil in the early 1990s, started investing resources in conducting bioequivalence tests and developed marketing strategies, did BiDil begin the process of submitting its New Drug Application ("NDA") to the FDA in 1996.

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[26] *See* Jay N. Cohn, *Lessons from V-HeFT: Questions for V-HeFT II and the Future Therapy of Heart Failure*, 16 HERZ 267, 270 (1991).

[27] Reviewing the course of the V-HeFT trials, Cohn notes,

> The natural evolution of V-HeFT would have mandated that the vasodilator regimen [to be combined with enalapril in V-HeFT III] would be the combination of the hydralazine and isosorbide dinitrate, which has been so effective in V-HeFT I and V-HeFT II. Unfortunately, the need for financial support has made it necessary that the vasodilator be an agent with potential commercial interest. Thus, a calcium antagonist has been substituted in V-HeFT III for the hydralazine nitrate combination, and it will be felodipine — a calcium antagonist with considerable vasoselectivity.

Jay N. Cohn, *Introduction*, *87-6 Circulation, Supplement VI*, VI-1, VI-2--VI-3 (1993). *See also* Jay N. Cohn, *Invited Editorial: Treatment of Infarct Related Heart Failure: Vasodilators Other Than ACE Inhibitors*, 8 CARDIOVASCULAR DRUGS & THERAPY 119, 120 (1994) ("One of the problems with advocating non-ACE vasodilators in treatment of the post-infarct period relates to the inadequacy of the database on these drugs. Since hydralazine and isosorbide dinitrate are generic agents, there has been no effort on the part of a pharmaceutical company to mount large-scale trials or to develop an NDA for drug approval. In contrast, the ACE inhibitors have been heavily marketed and their use for infarct related heart failure appears to be growing rapidly.").

[28] U.S. Pat. No. 4,868,179 (issued Sept. 19, 1989), *available at* http://www.uspto.gov (last visited Aug. 12, 2002).

There was a measure of convenience to BiDil, but that alone was not sufficient to drive its development nor, as it turned out, to obtain FDA approval. One consultant to the FDA panel that ultimately rejected the BiDil NDA in 1997 noted that the two generic component drugs of BiDil are there for anyone to use for heart failure.[29] The FDA's denial of the BiDil NDA would not change that. Rather, he observed, "the practical impact of the FDA not approving this combination today is that there won't be an economic incentive for the sponsor to get out and provide educational material for a lot of doctors to know how to use the drugs best."[30]

The truly "convenient" breakthrough for BiDil, therefore, was not simply the combination of two generic drugs into one: it was the development of new intellectual property rights whose value was contingent upon FDA approval of the new drug. With a patentable therapy in hand, drug companies would have an incentive to educate physicians and market the new drug; thus, changing the behavior of both doctors and patients. Patent law (and to a lesser extent trademark law, which allowed for added brand name value in the marking of BiDil) provided a critical impetus toward the creation of BiDil. In contrast to the classic justification for patents as incentives to develop new products, intellectual property rights in BiDil's case provided an incentive for developing a new marketing strategy based on an existing therapy. Moreover, the fact that the two drugs comprising BiDil were already available as generics also indicates how patent law may distort a market, potentially obscuring less expensive generic alternatives that have the same therapeutic value.

The FDA ultimately rejected BiDil's first NDA because it found the retrospective analysis of data from the V-Heft trial insufficient to meet the regulatory criteria of statistical significance. It is important to note that the FDA advisory committee reviewing the drug did not think that BiDil did not work. To the contrary, many of the doctors on the panel were generally convinced of its clinical efficacy. They turned down the application because the V-HeFT trials were not designed as a new drug trial and as a result, the data produced could not meet the regulatory criteria of statistical significance required for new drug approval.[31]

Following the FDA rejection in 1997, the value of BiDil's intellectual property rights plummeted along with Medco's stock.[32]The rights reverted to Cohn and Medco exited the story of BiDil's development. It was at this point, that Cohn, together with Carson and others, went back to the V-HeFT data and categorized the results by race. In 1999, Carson, the lead author on the first article discussing this re-analysis, argued for a race-based differential response to H/I treatment based on this retrospective analysis of

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[29] Ctr. for Drug Evaluation and Research, Food and Drug Admin., *Cardiovascular and Renal Drugs Advisory Committee, 80th Meeting,* Feb. 27, 1997, at 210, *available at* http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3264t1.pdf (last visited Aug. 5, 2002).
[30] *Id.*
[31] *See* Kahn, *supra* note 5, at 14-15.
[32] *See Medco drug hits FDA wall*, TRIANGLE BUS. J., Feb. 27. 1997, *available at* http://www.bizjournals.com/triangle/stories/1997/02/24/daily12.html (last visited Nov 23, 2005).

the V-HeFT data, in particular, the nearly 15 year-old data from the V-HeFT I trials.[33]

The intervention of the federal regulatory system to deny the NDA marks the turning point on BiDil's journey toward becoming an ethnic drug. The regulatory action taken by the Advisory Committee provoked BiDil researchers to reconceptualize their drug along racial lines in order to get a "second bite" at FDA approval. After the publication of Carson's article, the value of BilDil's intellectual property rights rebounded not because of any changes to the underlying molecular structure or biological effects of BiDil as a drug, but due to the reanalysis of old V-HeFT data along racial lines.

NitroMed acquired the intellectual property rights to BiDil in September 1999[34] — the same month Carson published his paper on purported racial differences in response to the drug during the 1980 trials. In the hands of its new corporate handlers, together with their public relations consultants, BiDil was reborn as an ethnic drug. Hearkening back to the comment by the FDA panel consultant, the subsequent spate of publicity attending the inauguration of A-HeFT marked how the renewed value of BiDil's patent provided an incentive for NitroMed to educate doctors and the public about the nature and value of this "new" drug for African Americans.

In the next logical extension of patent rights in the process of creating an ethnic drug, Cohn and Carson jointly filed for a new BiDil-related patent on September 8, 2000. With the title *Methods of Treating and Preventing Congestive Heart Failure with Hydralazine Compounds and Isosorbide Dinitrate or Isosorbide Mononitrate*, the patent appears to be much the same as Cohn's original 1989 patent.[35] Upon closer inspection, however, the abstract to the patent specifies that the "present invention provides methods for treating and preventing mortality associated with heart failure in an *African American* patient."[36]

The issuance of the new patent is commercially important because the original patent is set to expire in 2007. The new race-based patent will not expire until 2020, extending NitroMed's monopoly market control over the use of the drug for thirteen years. Significantly, (and rather astonishingly) in issuing the second patent, the Patent Trademark Organization ("PTO") found that Cohn's first method-of-use patent for BiDil did not constitute "prior art" with respect to the new patent application. Rather, it found the application's race-specific method of treatment to be a "non-obvious" extension of the earlier concept and hence patentable.[37] In this chapter of

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[33] *See* Carson, *supra* note 19, at 178-87.
[34] *See* Press Release, NitroMed, NitroMed Acquires BiDil New Drug Application for Treatment of Congestive Heart Failure (Sept. 10, 1999), http://www.nitromed.com/newsindex.html (last visited Dec. 7, 2003).
[35] *See* U.S. Patent No. 6,465,463 (filed Sep. 8 2000) (issued October 15, 2002), *available at* http://www.uspto.gov (last visited Nov. 11, 2002).
[36] *Id.* (emphasis added).
[37] *See* NitroMed, Inc., SEC Securities Act Filing (Form S-1/A), at 12 (Oct. 2, 2003).

BiDil's development, *patent law did not spur the invention of a new drug, but rather, prompted the reinvention of an existing therapy and labeled it to be ethnic.*

With the issuance of the patent on October 15, 2002, race entered the world of patent law in a new and explicit way. The scope of patent protection is typically referred to in terms of "metes and bounds."[38] The allusion to physical property is quite deliberate. Cohn's and Carson's new patent racializes the "metes and bounds" of their intellectual property claims. Scholars, such as Cheryl Harris[39] and Richard Thomson Ford,[40] have noted that American law has a long tradition of characterizing property and physical spaces in racial terms — often to devastating effects. Whether in the most egregious and obvious form of race-based slavery or in subtler identifications of neighborhoods or even race-identifiable names,[41] which make it more difficult to obtain mortgages or jobs, the nature and value of property has long been profoundly influenced by and through its association with race.

Previous associations of race and property have generally involved a devaluing of property associated with racial minorities. Certain more recent legal classifications of race, as in affirmative action, have the potential to offer challenges to exclusionary conceptions of racialized property rights.[42] The racialization of BiDil's patent appears to be more in line with such assertedly "benign" uses of racial categories and has actually added value to the drug, resulting in a readiness of such groups as the Association of Black Cardiologists and the Congressional Black Caucus to support A-HeFT.[43] In this regard, BiDil gains cultural capital by being characterized as a means to redress an important health disparity in a historically underserved population.

But there is something very different about race-specific drugs, which distinguishes them from other well-intentioned attempts to use racial categories to overcome past social, political and economic injustices: they legitimize the use of race as a genetic category. With the emergence of critical race theory among an array of progressive scholars over the past two decades, there has been a growing awareness of the legitimacy and power of "race conscious" approaches to identifying, analyzing and addressing racial inequality in American society.[44] As the Civil Rights

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[38] A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention. Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607 (1950).

[39] *See* Cheryl I. Harris, *Whiteness as Property*, 106 HARV. L. REV. 1707 (1993).

[40] *See* Richard T. Ford, *The Boundaries of Race: Political Geography in Legal Analysis,* 107 HARV. L. REV. 184 (1994).

[41] *See, e.g.*, Alan B. Kruger, *Sticks and Stones Can Break Bones, but the Wrong Name Can Make a Job Hard to Find*, N.Y. TIMES, Dec. 12, 2002, at C2.

[42] *See, e.g.*, Harris, *supra* note 34, at 1768-91.

[43] *See* NitroMed, The A-Heft Coalition, *available at* http://www.nitromed.com/BiDil.asp (last visited Mar. 25, 2005).

[44] *See* Gary Peller, *Race Consciousness*, 1990 DUKE L. J. 758, 758-834. Critical race theory is a large and diverse area of scholarship. For several useful anthologies, see also K. Anthony Appiah & Amy Gutmann, *Color Conscious* (1996) and Kimberle Crenshaw et al., *Critical Race Theory* (1995).

Movement emerged in the aftermath of World War II, it focused first on breaking down the legal regime of apartheid institutionalized in the pervasive Jim Crow laws that segregated all aspects of life in the American South.[45] From *Brown v. Board of Education* in 1954 to the Civil Rights Act of 1964 and the Voting Rights Act of 1965, great strides were made to break down formal legal barriers to civic and political participation.[46] After the mid-1960s, the movement for civil rights began to broaden its focus to include issues of economic rights. Thus, for example, in 1967, Martin Luther King, Jr. began working with others to plan a Poor People's Campaign and March on Washington to highlight issues of economic justice.[47]

Thus, the major civil rights struggles of the past several decades have focused around issues of desegregation, affirmative action and discrimination in such areas as housing, public accommodations, and employment.[48] To identify and address discrimination in these areas, it is necessary to collect and categorize data by race. Indeed, the current racial and ethnic categories used in the United States Census emerged largely in response to needs and pressures created by the Civil Rights Movement and the legislation emerging from it.[49] Thus, to track violations of voting rights or employment discrimination claims, it is essential to aggregate data by race. While highly problematic for an array of social and political reasons,[50] the use of racial and ethnic categories in such contexts does not directly implicate them as biological or genetic constructs.

Over the past two decades, however, the movement for civil rights has continued, for very good reasons, to broaden its focus to encompass a much more explicit concern for health rights. From the creation of the Office of Minority Health in 1985[51] to the Minority Health and Health Disparities Research and Education Act of 2000[52] and the proposed Closing the Health Care Gap Act of 2004,[53] major federal initiatives have been undertaken to identify and address racial disparities in health care.

As the above discussed initiatives and related plans engage social, economic, and political influences on disparate health *outcomes*, they implicate racial and ethnic categories to be social, economic and political

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[45] *See, e.g.*, ROBERT WEISBROT, FREEDOM BOUND: A HISTORY OF AMERICA'S CIVIL RIGHTS MOVEMENT (1991).
[46] *See, e.g.*, J. HARVIE WILKINSON, FROM BROWN TO BAKKE: THE SUPREME COURT AND SCHOOL INTEGRATION: 1954 – 1978 (Oxford University Press 1979).
[47] *See, e.g.*, STEPHEN B. OATES, LET THE TRUMPET SOUND: THE LIFE OF MARTIN LUTHER KING, JR. 448-481 (Harper Perennial 1994).
[48] *See* Weisbrot, *supra* note 40.
[49] *See* MELISSA NOBLES, SHADES OF CITIZENSHIP: RACE AND THE CENSUS IN MODERN POLITICS 14-22 (Stanford University Press 2000).
[50] *See id.*; Michael Omni, *Racial Identity and the State: Dilemmas of Classification*, LAW AND INEQUALITY, Winter 1997, at 7.
[51] *See* United States Office of Minority Health, About OMH (2005), http://www.omhrc.gov/OMH/sidebar/aboutOMH.htm. (last visited Mar. 25, 2005).
[47] Minority Health and Health Disparities Research and Education Act of 2000, 42 U.S.C. § 202 (2000).
[53] *See* OFFICE OF LEGISLATIVE POLICY AND ANALYSIS, CLOSING THE HEALTH CARE GAP ACT (2004), http://olpa.od.nih.gov/legislation/108/pendinglegislation/clhealthgap.asp (last visited Mar. 25, 2005).

constructs.[54] Such concerns mark a natural progression of civil rights activism from political and economic rights into the realm of health. However, when racial and ethnic categories are used to guide initiatives to uncover the underlying *causes* of disease, the implication arises that these categories serve as biological and/or genetic concepts. To the extent that otherwise well-intentioned attempts to redress health disparities implicitly or explicitly invoke race as a genetic concept, these attempts also run the risk of fueling what anthropologist Alan Goodman has characterized as a "comeback" in "racialized notions of biology."[55] This marks a fundamental difference between civil rights activism in the arena of health as opposed to political or economic rights.

Prominent among such otherwise well-intentioned federal mandates are the National Institutes of Health ("NIH") Revitalization Act of 1993[56] and the Food and Drug Administration Modernization Act of 1997.[57] The former directs the NIH to develop guidelines for women and minorities in NIH-sponsored clinical research,[58] and the latter directs the FDA to examine issues related to the inclusion of racial and ethnic groups in clinical trials of new drugs.[59] Pursuant to these mandates, the NIH and FDA have issued detailed guidelines mandating certain procedures and practices concerning the inclusion of ethnic and racial minorities in clinical trials.[60] While clinical trials and drug development may sometimes look at an array of factors, including social and economic variables, they also frequently look *only* at biomedical variables. This is especially true of drug development, which necessarily focuses primarily on establishing the biological safety and efficacy of chemical compounds to gain FDA approval.[61] When a drug's efficacy or safety is correlated to racial or ethnic categories, it opens the door to reifying those categories as genetic.

This, of course brings us back to BiDil. The role of the federal legal and regulatory system in producing BiDil as an ethnic drug is especially important because it lends the imprimatur of the state to the use of race as a biological category. Between the FDA's letter commenting on the ultimate approvability of BiDil as a race-specific drug[62] and the PTO's recent

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[54] *See, e.g.*, INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTHCARE (2003).
[55] Alan H. Goodman, *Why Genes Don't Count (for Racial Differences in Health)*, 90 AM. J. PUB. HEALTH 1699-1702 (2000).
[56] National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 201 (1993).
[57] Food and Drug Modernization Act of 1997, Pub.L. No. 105-115, 111 Stat. 2296.
[58] *See* National Institutes of Health Revitalization Act of 1993, 42 U.S.C. § 201 (1993).
[59] *See* Food and Drug Modernization Act of 1997, Pub.L. No. 105-115, 111 Stat. 2296.
[60] *See* UNITED STATES NATIONAL INSTITUTES OF HEALTH, NIH GUIDELINES ON THE INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN CLINICAL RESEARCH (2000), http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm (last visited February 9, 2006); UNITED STATES FOOD AND DRUG ADMINISTRATION, Guidance for Industry: Collection of Race and Ethnicity Data in Clinical Trials (2005), *available at* http://www.fda.gov/cder/guidance/5656fnl.htm (last visited Nov. 1, 2005).
[61] *See, e.g.*, Michelle Meadows, Food and Drug Admin., The FDA's Drug Approval Process: Ensuring Drugs are Safe and Effective (2002), *available at* http://www.fda.gov/fdac/features/2002/402_drug.html (last visited Mar. 25, 2005).
[62] *See* NitroMed, *NitroMed Receives FDA Letter on BiDil® NDA, a Treatment for Heart Failure in Black Patients* (Mar. 8, 2001), http://www.nitromed.com/newsindex.html (last visited Dec. 7, 2003).

issuance of the patent for using H/I in African American patients,[63] powerful federal agencies have legitimized the use of race as a marker for biological difference. To the extent that institutions of the state, such at the PTO or the FDA, come to mark certain biological conditions as "racial," race may become a surrogate not only for medical research, but also for a wide array of legally sanctioned discrimination.

II. POST-A-HEFT DEVELOPMENTS

Bearing this story in mind, we now turn to developments that have transpired since the A-HeFT trials were concluded in July 2004. In particular, we will explore the strategic reification of race in three related contexts: (1) identify the past and current manipulations of statistical data to make it appear as if the race-specific character of BiDil's development was driven more by medicine than by commerce; (2) consider how the appearance of difference created by such manipulations becomes conflated with genetics; and (3) broaden the analysis to examine how particular themes in debates about race and drug development connect to strategies that use genetics to recharacterize race-specific health disparities caused by structural inequality or discrimination as mere differences rooted in genetics and personal choice. The resulting focus on "difference" prioritizes market mechanisms over state intervention to redress persistent problems of social and economic inequality.

A. STATISTICAL MANIPULATION

From its outset, the development of BiDil has been strategically framed by misleading and sometimes entirely incorrect statistics. The spate of media reports following NitroMed's initial announcement of the race-specific A-HeFT trials in early 2001 almost uniformly repeated NitroMed's own assertion that African-Americans died from heart failure at a rate twice that of white Americans. Proponents of BiDil used the statistical disparity to buttress claims that heart failure was somehow a "different disease"[64] in African Americans that needed to be addressed at the genetic level.

This statistic, however is wrong — egregiously wrong.[65] Through a curious series of events, involving mis-citations to a decade-old study and the too-ready acceptance of assertions of racial difference, the 2:1 mortality statistic was taken up widely throughout the media (via NitroMed's press releases) and professional journals. Of particular significance and influence was a 1999 article in the *New England Journal of Medicine* which asserted that "the population-based mortality rate from congestive heart failure is 1.8 times as high in black men as for white men and 2.4 times as high for

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[63] U.S. Patent No. 6,465,463 (issued Oct. 15, 2002).
[64] Clyde W. Yancy, *The Role of Race in Heart Failure Therapy*, CURRENT CARDIOLOGY REPORTS, May 2002, at 218.
[65] *See* Jonathan Kahn, *Getting the Numbers Right: Statistical Mischief and Racial Profiling in Heart Failure Research*, 46 PERSPECTIVES IN BIOLOGY AND MEDICINE 473 (2003).

black women as white women."[66] These figures, it turns out, were derived from a 1987 editorial by Richard Gillum of the National Center for Health Statistics.[67] Gillum's article used these figures, but with an important qualification: he specified explicitly that they applied only to "persons aged 35 to 74 years."[68] Leaving out this age-specific qualification is a major problem on its own, but Gillum also noted in the same editorial that the ratio of black to white mortality in persons over age 75 approached 1, i.e. 1:1. Moreover, this data was based on information from 1981.[69] For current information that includes overall mortality from all age ranges, a simple visit to the Centers for Disease Control's statistical information website, http:// wonder.cdc.gov, reveals the actual black to white ratio of individuals suffering from congestive heart failure to be approximately 1:08 to 1.[70]

The article on these statistical missteps was published in late 2003. By mid-2004, it appeared that NitroMed and the doctors around A-HeFT changed their rhetoric by asserting that African Americans had a "higher rate" of mortality than the "corresponding" white population.[71] It appears that the article might have had some effect. The drive to perceive racial difference in the context of biology, however, is relentless. No matter how many times you strike it down, it keeps coming back to life. This is doubly true when dealing with statistics, as Mark Twain is reputed to have said, "Facts are stubborn things, but statistics are more pliable."

So it was on January 11, 2005, that NitroMed, in a press release announcing that BiDil had been named to the American Heart Associations annual "Top Ten Advances List," asserted that "African Americans between the ages of 45 and 64 are 2.5 times more likely to die from heart failure than Caucasians in the same age range."[72] NitroMed then repeated this statistic in a February press release announcing the FDA's acceptance of its Abbreviated New Drug Application ("ANDA").[73] Unlike the previous 2 to 1 statistic, this new statistic is technically accurate. NitroMed fails to mention, however, that only about 6% of overall mortality from heart failure occurs in the 45-64 age range.[74] About 93% of mortality occurs after age 65, and in that group there is almost no difference in age-adjusted

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[66] Daniel L. Dries et al., *Racial Differences in the Outcome of Left Ventricular Dysfunction*, NEW ENGL. J. MED. 340, 609-616 (1999).
[67] *See* Richard F. Gillum, *Heart Failure in the United States, 1970-1985*, 113 AM. HEART J. 1043 (1987).
[68] *Id.*
[69] *See id.* at 1043-45.
[70] *See* Kahn, *supra* note 58, at 474.
[71] *See, e.g.*, Press Release, NitroMed (July 19, 2004), http://www.nitromed.com/07_19_04a.asp. (last visited Mar. 21, 2005).
[72] NitroMed, *BiDil® Named to American Heart Association's 2004 'Top 10 Advances'*, Jan. 11, 2005, *available at* http://www.mi3.com/pressreleases/2005.01.11.NitroMed.pdf.
[73] NitroMed, *FDA Accepts NitroMed's New Drug Application Resubmission for BiDil; Submission Granted a June 23, 2005 PDUFA Date*, Feb. 3, 2005, *available at* http://investors.nitromed.com/phoenix.zhtml?c=130535&p=irol-newsArticle&ID=670434&highlight= (last visited February 9, 2006).
[74] To obtain this information, I visited the CDC's Wonder website. The percentages are derived from queries for information concerning compressed mortality by race, age adjusted for ages 45 to 64 and ages 65 and above. *See* CDC Wonder, *available at* http://wonder.cdc.gov (last visited Jan. 11, 2005).

mortality rates between blacks and whites.[75] Indeed, the crude death rate for blacks is actually lower than that for whites.[76]

Then, as if to add insult to injury, on March 22, 2005, Current Communications Company, with a grant from NitroMed, launched a new website, http://www.aheft.org.[77] Presenting an array of information about the A-HeFT trials and supported by an advisory board of the major cardiologists behind BiDil, including Jay Cohn and A-HeFT principal investigator, Ann Taylor, the site confidently asserts that "mortality rates were 1.8 times higher for African American men than for white men and 2.4 times higher for African American women than for white women."[78] They support this assertion with a reference to the 1999 *New England Journal of Medicine* article, and while providing the caveat that "not all observations have demonstrated a mortality risk due to race," the article makes no reference to the dated and age specific nature of the original Gillum data.[79]

Why this investment in creating a major racial difference where none exists? One can only ask: if you have a medical interest in the underlying etiology of a disease do you look at a subgroup where 6% of mortality occurs or at one in which 93% of mortality occurs? If, however, you have a commercial interest in convincing the FDA and capital markets that there is a legitimate basis for approving a race-specific drug, then showing a huge difference becomes central to marketing your product, but, of course, you do not mention that your subgroup represents only 6% of the overall mortality rate.

In the emerging field of pharmacogenomics, where drug companies are hoping to tailor therapies ever more closely to the genetic profile of individuals or groups of consumers, identifying racial or ethnic correlations with disease is becoming big business. One announcement for a 2005 industry conference on "Multicultural Pharmaceutical Market Development and Outreach" stated:

> The unprecedented growth in ethnic populations across various regions in the United States opens doors to a wide array of new market opportunities for healthcare and pharmaceutical companies. Untapped consumers for both new and proven therapeutics sold as prescription or over-the-counter products represent a total population of almost 80 million whose combined purchasing power by 2009 is estimated $2.5 trillion.
>
> With the onslaught of generics, pricing battles and DTC competition, reaching out effectively to America's emerging majority is a clear road to

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[75] *Id.*
[76] In the over 65 age group, the crude death rate for blacks is 142.9 per 100,000; for whites it is 153.3 per 100,000. *Id.*
[77] *See* Current Communications Company, *New Web Site Explains Significance of the First Major Clinical Trial to Test Effectiveness of Heart Failure Medication in African Americans*, *available at* http://biz.yahoo.com/prnews/050322/phtu027_3.html (last visited Mar. 22, 2005).
[78] AHeFT.org, *Implications of A-HeFT for Patient Care*, http://www.aheft.org/implications.asp (last visited Mar. 22, 2005).
[79] *Id.*

> brand building and market growth for U.S. pharmaceutical and healthcare companies.[80]

The drive to develop race-specific therapies is not subtle, and NitroMed's A-HeFT model of race-specific trials is also on its way to becoming a new market paradigm. Thus, Waine Kong, the CEO of the Association of Black Cardiologists, which co-sponsored A-HeFT, was one of four featured "thought leaders" who gave a keynote address on BiDil to this same Multicultural Pharmaceutical Marketing conference.[81] The sponsoring web site urges attendees to "find out how NitroMed partnered with the Black Cardiologists Association [sic] to conduct this study [A-HeFT] and understand the opportunities and implications for drug manufacturers, disease management, clinical trials and health care companies."[82] Similarly, NitroMed's Chief Medical Officer, Manuel Worcel, was a featured speaker at the 2005 Bio-IT World Conference and Expo in Boston, where he gave a presentation on A-HeFT as part of the section on "Advances in Genomic Medicine."[83] Additionally, a recent report on "Cardiovascular Marketing: Budgets, Staffing and Strategy," from Cutting Edge Information, which bills itself as "The World's Largest Market Research Resource," features BiDil as a teaser to sell the report which retails for $5,995.[84] As one senior analyst at Cutting Edge put it: "If trials prove successful, and drug responses prove different based on ethnicity, drug companies will certainly have new avenues for the discovery, development, and marketing of medications."[85]

In webcast presentations to the 23rd Annual JP Morgan Healthcare Conference[86] and the UBS Global Life Sciences Conference,[87] NitroMed CEO Michael Loberg discussed the company's marketing strategy for BiDil. As part of the roll out for BiDil, the company hired 195 sales representatives through Publicis exclusively to sell NitroMed products. NitroMed has been using this sales force to uniquely focus on those doctors who are providing cardiovascular and metabolic care to African Americans and it is especially interested in "specializing in the African American cardiovascular marketplace."[88] In the context of pharmacogenomic marketing, it is important to consider that when a drug such as BiDil gets

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[80] Strategic Research Institute, *6th Annual Multicultural Pharmaceutical Market Development and Outreach Conference*, *available at* http://www.srinstitute.com/CustomerFiles/upload/brochure/CM453_brochure.pdf (last visited Mar. 30, 2005).
[81] A copy of this address is on file with the author.
[82] *Id.*
[83] *See* Kevin Davies, *Coming Attractions*, *available at* http://www.bio-itworld.com/archive/030805/firstbase.html (last visited Mar. 28, 2005).
[84] *Cardiovascular Marketing: Budgets, Staffing and Strategy*, *available at* http://www.researchandmarkets.com/reportinfo.asp?report_id=53547&t=o&cat_id=16 (last visited Feb. 15, 2005).
[85] *Clinical Trials Target Specific Ethnic Groups, available at* http://www.biobn.com/index.cfm?Page=viewnews&NewsID=0002150187 (last visited Feb. 23, 2005).
[86] *See* Michael Loberg, NitroMed Webcast Presentation at 23rd Annual JP Morgan Healthcare conference, Jan. 11, 2005, http://www.mapdigital.com/jpmorgan/healthcare05/ondemand.html#n.
[87] *See* Michael Loberg, NitroMed Webcast Presentation at UBS Global Life Sciences Conference, Sept. 26, 2005, http://event.streamx.us/event/default.asp?event=ubs20050926.
[88] Loberg, *supra* note 74.

produced, researchers understand that it works at the molecular level, affecting, for example, levels of nitric oxide in the blood. AHeFT has a webpage on "A-HeFT and Genomic Medicine," which notes that the A-HeFT researchers "theorize that race may serve as a marker for multifactorial variations in endothelial dysfunction" that affect nitric oxide levels, and "[f]inding effective medical therapy for the subset of heart failure patients with these genetic differences may be a step toward personalized therapy based on pharmacogenomics."[89]

Even if there is a distinctive genetic component to BiDil's efficacy (which has *not* been established), NitroMed could not effectively market BiDil to the biological group of individuals who have a particular genetic polymorphism that may lead to lower levels of nitric oxide. Rather, NitroMed has hired Vigilante, a subsidiary of Publicis, to help market BiDil to African Americans. NitroMed's Vice President of Marketing, B.J. Jones, described Vigilante as "a leader in the field of advertising and marketing to the African American, minority, and urban communities."[90] The firm also handled the publicity for the give-away of a fleet of Pontiac automobiles to audience members on the *Oprah Winfrey Show*.[91]

Targeting a racial audience becomes necessary for BiDil developers because drug developers simply do not have the resources or technology to scan every individual's genetic profile. Instead one must market the product to a particular social group that is hypothesized to have a higher prevalence of a relevant genetic variation. It is far easier to target African Americans than to identify a market of particular individuals who happen to respond well to BiDil because of their genetic makeup regardless of race. NitroMed has used the Carson article to support its claims that they have identified a racial difference in response to BiDil to create a market based on a social group. Medical researchers may say they are using race as a surrogate to get at biology in drug development, but corporations are using biology as a surrogate to get at race in drug marketing.

In this context, commercial imperatives can drive drug companies to seek out and emphasize racial difference such that it becomes conflated with genetic difference. Thus, for example, in 2003, we witnessed the spectacle of VaxGen's attempt, on the heels of its failed trials, to prove the efficacy of an AIDS vaccine when it tried to revive its commercial prospects by claiming that a retrospective analysis of the results seemed to indicate a beneficial impact on African Americans.[92] In February 2003, VaxGen announced the results of the first-ever successful trial of an AIDS vaccine.[93] The overall findings were that the vaccine failed to protect

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[89] AHeFT.org, *A-HeFT and Genomic Medicine*, www.aheft.org/genomic.asp (last visited Mar. 22, 2005).
[90] Tamara E. Holmes, *Vigilante Awarded BiDil Ad Campaign*, Dec. 27, 2004, http://www.blackenterprise.com/ExclusivesEKOpen.asp?id=981 (last visited Jan. 26, 2005).
[91] *See id.*
[92] *See* Andrew Pollack & Lawrence K. Altman, *Large Trial Finds AIDS Vaccine Fails to Stop Infection,* N.Y. TIMES, Feb. 24, 2003, *available at* www.nytimes.com/2003/02/24/scinece/24VACC.html (last visited Feb. 25, 2003).
[93] *See id.*; Jon Cohen, *VaxGen's Sketchy Statistics*, SCI. NOW, Feb. 27, 2003. *available at* http://sciencenow.sciencemag.org/cgi/content/full/2003/227/1 (last visited Mar. 17, 2003).

against infection with the virus that causes the disease. The VaxGen researchers claimed to be surprised by the findings, but they were also undeterred. Like the BiDil researchers before them, they decided, *post hoc,* to break the results out by race and claimed that a retrospective analysis of the data revealed "significant efficacy in 66.8% of Blacks, Asians, and people of mixed race, and 78.3% in Blacks alone."[94] One headline for a Gannett News wire service story obligingly accepted VaxGen's spin on the results when it reported: "AIDS Vaccine Protects Asians, Blacks" with the sub-headline, "AIDSVAX seems ineffective in Whites and Hispanics. Results may be good news for HIV-plagued Africa."[95] VaxGen's race-based claims, however, were quickly shot down by the medical and scientific communities as being a deeply flawed, even tortured reading of the data,[96] but not before VaxGen's stock value momentarily rallied — giving rise to current class action law suits for stock manipulation.[97] As one HIV specialist at Emory University School of Medicine put it, "It was a desperate act by a company that was trying to save a failed product. . . . If they really cared about racial and ethnic differences, they would have structured a very different trial."[98] Nonetheless, in January 2004, a VaxGen spokeswoman said the company would have liked to do a trial focused on an African-American study population to settle the question, but the company did not have the funding.[99] This is the BiDil model at work.

More recently, on the same day last November that A-HeFT Principal Investigator, Anne Taylor, announced their successful results at the Annual Convention of the American Heart Association, Dr. Keith Ferdinand, a cardiologist and co-investigator on A-HeFT, announced separate positive results for a different race-specific trial—ARIES: African American Rosuvastatin Investigation of Efficacy and Safety.[100] From all indications, Dr. Ferdinand is a committed and principled cardiologist working hard to address the legitimate health needs of a woefully underserved population in New Orleans. But it is important to put this trial in context. The trade name for Rosuvastatin is CRESTOR.[101] It is a cholesterol-lowering statin marketed by AstraZeneca, which also sponsored the ARIES trial. CRESTOR was approved by the FDA in 2003 amid some controversy

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[94] Cohen, *supra* note 81.

[95] *AIDS Vaccine Protects Asians, Blacks*, GANNETT NEWS SERV., Feb. 24, 2003, http://www.tucsoncitizen.com/national/2_24_03aids.html (last visited Mar. 6, 2003).

[96] *See, e.g., id.;* Jon Cohen, *AIDS Vaccine Trial Produces Disappointment and Confusion*, 299 SCI. 1290-91 (2003); Andrew Pollack, *AIDS Vaccine Numbers Off, Statistician Says: Effectiveness for Minorities may be Overstated*, S.F. CHRON., Feb. 27, 2003, at A4.

[97] *See* Stanford Law School, *Vaxgen, Inc.*, Securites Class Action Clearinghouse http://securities.stanford.edu/1027/VXGN03-01/ (last visited Mar. 25, 2005). *See also, e.g.*, *Johnson & Perkinson Announces Class Action Lawsuit Against VaxGen, Inc.*, BUS. WIRE, Mar. 24, 2003.

[98] Victoria Stagg Elliott, *Color-blind? The Value of Racial Data in Medical Research*, AMEDNEWS.COM, Jan. 5, 2004, http://www.ama-assn.org/amednews/2004/01/05/hlsa0105.html (quoting Mark Feinberg, M.D., Ph.D., Professor of Medicine and HIV Specialist at Emory University School of Medicine).

[99] *See id.*

[100] *See* AstraZeneca, *AstraZeneca Presents New Data for CRESTOR(R) in African-American Patients with High Cholesterol at American Heart Association Annual Meeting*, Nov. 9, 2005, http://sev.prnewswire.com/health-care-hospitals/20041110/NYTU07009112004-1.html.

[101] *See* http://www.crestor.com/.

concerning its safety.[102] In March 2004, Dr. Sidney Wolf, the Director of Public Citizen's Health Research Group, petitioned the FDA to withdraw CRESTOR from the market for safety reasons.[103] His petition noted that two major U.S. insurance companies had refused to cover reimbursement for the drug.[104] In November 2004, FDA whistle-blower David Graham also cited CRESTOR as one of the drugs the FDA should remove from the market.[105] In December 2004, the FDA actually issued a warning letter to AstraZeneca concerning its misleading advertisement, asserting that the FDA had concluded that "the [safety] concerns [about Crestor] that have been raised have no medical or scientific basis."[106] In short, Crestor's safety is of central concern to AstraZeneca's marketing strategy for the drug. It is therefore important to note that in an AstraZeneca press release presenting the ARIES data, Dr. Ferdinand emphasized that the trial showed both the safety and efficacy of Crestor.[107] Later, Dr. Ferdinand reiterated that the ARIES trial should "add to physicians' comfort level [since] it's an additional study to show that Crestor is more effective and safe."[108]

One need not question Dr. Ferdinand's sincerity to consider that AstraZeneca has a powerful incentive to produce findings of Crestor's safety, and one way to do that is through race-specific subgroup trials. Beyond ARIES, AstraZeneca is also sponsoring two other race and ethnic-specific Crestor trials: the IRIS trial (Investigation of Rosuvastatin In South-Asian Subjects) and the STARSHIP trial (Study Assessing RosuvaStatin in the Hispanic Population).[109]

B. BEYOND BIDIL: 29 DRUGS

The dynamic relation between markets and statistical manipulation has recently moved beyond BiDil to support larger claims about the legitimacy of developing race-specific drugs. In November2004, in a special supplement on race and genetics, *Nature Genetics* published an article by Sarah Tate and David Goldstein titled, "Will Tomorrow's Medicines Work for Everyone?"[110] Among other things, the article identified that "twenty-nine medicines (or combinations of medicines) have been claimed, in peer-reviewed scientific or medical journals, to have differences in either safety

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[102] *See, e.g.,* Petition from Sidney M. Wolfe, M.D., Director, Public Citizen Health Research Group, to Mark B. McClellan, M.D., Ph.D., Commissioner, Food and Drug Administration, to Remove the Cholesterol-lowering Drug Rosuvastatin (CRESTOR) from the Market (Mar. 4, 2004), *available at* www.citizen.org/publications/print_release.cfm?ID=7305.
[103] *Id.*
[104] *Id.*
[105] *See* Todd Zwillich, *Scientist: FDA Incapable of Protecting Safety*, WEBMD, Nov. 18, 2004, http://my.webmd.com/content/article/97/104115.htm.
[106] Letter from Christine Hemler Smith, Pharm.D., Consumer Promotion Analyst & Regulatory Review Officer, Division of Drug Marketing, Advertising, and Communication, U.S. Department of Health & Human Services to Mark R. Szewczak, Ph.D., Director, Promotional Regulatory Affairs, AstraZeneca LP, Dec. 21, 2004, http://www.fda.gov/cder/warn/2004/12779.pdf.
[107] *See* Press Release, AstraZeneca, *supra* note 88.
[108] Amanda Gardner, *Gender, Ethnic Gaps Found in Health Care*, MEDICINENET.COM, Nov. 10, 2004, www.medicinenet.com/script/main/art.asp?articlekey=40477&pf=3.
[109] *See* Press Release, AstraZeneca, *supra* note 88.
[110] *See* Sarah K. Tate & David B. Goldstein, *Will Tomorrow's Medicines Work for Everyone?*, 36 NATURE GENETICS S34 (Nov. 2004).

or, more commonly, efficacy among racial or ethnic groups."[111] This number was immediately taken up throughout the media and certain professional contexts as providing "further" evidence of supposedly "real" biological differences among races. Moreover, reports of these striking results were almost invariably paired with a discussion of the near contemporaneous formal announcement of the A-HeFT results for BiDil. For example, after discussing BiDil, an article in the *Seattle Times* referred to "a report in the journal *Nature Genetics* last month [that] listed 29 drugs that are *known* to have different efficacies in the two races."[112] Similarly, a *Times* (London) article asserted that "only last week, Nature Genetics revealed research from University College London *showing* that 29 medicines have safety or efficacy profiles that vary between ethnic or racial groups."[113] Also, a *New York Times* editorial titled, "Toward the First Racial Medicine," began with a discussion of BiDil and went on to note that "[b]y one count, some 29 medicines show evidence of being safer or more effective in one racial group or another, suggesting that more targeted medicines may be coming."[114] Linking BiDil to the "29 medicines" is of course not accidental.[115] They are paired to give the impression that there is some "real" difference underlying racial response to these drugs.

One small problem with these stories are that they totally misrepresent the findings and assertions of the Tate and Goldstein piece. Remember first that Tate and Goldstein asserted that these twenty-nine medicines have only been "claimed" to have racial differences in safety or efficacy. They go on in the next sentence to assert, "[b]ut these claims are universally controversial, and there is *no consensus* on how important race or ethnicity is in determining drug response."[116] If one took the trouble to actually read their analysis of the claims, one would see that of the twenty-nine medicines, "Tate and Goldstein considered only four to provide evidence of a genetic caus[ation]"[117] being related to the differential drug response, and only an additional nine to provide evidence that "the association has a reasonable underlying physiological basis."[118] For the remaining sixteen medicines, Tate and Goldstein found either no demonstration of a physiological basis to any observed difference, nor any possible false positive claims**[119].** Moreover, of the thirteen medicines with some supporting evidence of racial difference, three were ACE inhibitors—whose claims of racial difference have been thoroughly contested in professional literature—and one of these drugs was BiDil.[120] All of the thirteen drugs dealt with hypertension, and the International Society on

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[111] *Id.* at S34.
[112] Thomas H. Maugh II, *New Drug for Heart Endorsed for Blacks*, SEATTLE TIMES, Nov. 9, 2004, at A1 (emphasis added).
[113] Anjana Ahuja, *We can Treat Your Heart Disease…If You're Black*, TIMES (London), Oct. 29, 2004, at 4 (emphasis added).
[114] Editorial, *Toward the First Racial Medicine*, N.Y. TIMES, Nov. 13, 2004, at A14.
[115] *See* Tate & Goldstein, *supra* note 95.
[116] *Id.* at S34.
[117] Jonathan Kahn, *Misreading Race and Genomics after BiDil*, 37 NATURE GENETICS 655, 655 (2005).
[118] Tate & Goldstein, *supra* note 95, at S37.
[119] *Id.* at S34.
[120] *See id.* at S34.

Hypertension in Blacks has issued guidelines arguing against race-specific treatment of hypertension on the grounds that any asserted population-based difference in response was not substantial enough to warrant denying effective therapy to the many Blacks who would respond well to these drugs.[121]

One might dismiss the distortion of the Tate and Goldstein article as sloppy journalism. But the use, or rather misuse, of the "29 medicines" statistic has been embraced in expert and often more conservative circles. I refer, here, specifically to John Entine and Sally Satel, both fellows at the American Enterprise Institute. Both have gained a good deal of notoriety for their popular works of race and genetics: Entine, for his book, *Taboo: Why Black Athletes Dominate Sports and Why We are Afraid to Talk About It*,[122] and Satel for, among other writings, a prominent *New York Times Magazine* article titled "I Am a Racially Profiling Doctor."[123] Entine framed a recent AEI symposium on BiDil by noting that, "[o]nly last month, the *prestigious* journal Nature Genetics reported that at least 29 medicines have so far been identified that are either safer or more effective in certain *populations because of genetic* differences between those population groups."[124] Satel echoed Entine's move in a more qualified manner later in the AEI symposium when she asserted, "Generally, when we're talking about BiDil and things like that, its skin color as a marker for genetic heritage."[125] Then, a month later she repeated Entine's claim about the "29 medicines" and genetics almost word for word in an article for the conservative Manhattan Institute titled, "Race and Medicine Can Mix without Prejudice: How the Story of BiDil Illuminates the Future of Medicine."[126] Not only do Entine and Satel elide any reference to Tate and Goldstein's qualifying analysis, they also extend the purported connection between race and drug response into the realm of genetics. BiDil provides the starting point for this move toward identifying race with genetic difference — a difference that the A-HeFT investigators themselves do NOT make.

Here then is another critical moment of reification. By connecting BiDil to the manipulated "29 medicines" statistic, Satel and Entine cast BiDil as the poster drug for the future of addressing racial difference in medicine — much as the corporate analysts cast it as the new paradigm for multicultural pharmaceutical marketing. Entine and Satel's message is that race and genetics correlate closely enough to provide a basis not only for

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[121] *See* Jeremy Moore, *Hypertension Treatment Among Blacks: Should it be Different?*, TODAY IN CARDIOLOGY, Oct. 2003, http://www.todayincardiology.com/200310/treatment.asp?old=never.
[122] *See* JON ENTINE, TABOO: WHY BLACK ATHLETES DOMINATE SPORTS AND WHY WE ARE AFRAID TO TALK ABOUT IT (2000).
[123] *See* Sally Satel, *I Am a Racially Profiling Doctor*, N.Y. TIMES, May 5, 2002 §6 (Magazine), at 56.
[124] Jon Entine, Welcome and Opening Presentation at the American Enterprise Institute for Public Policy Research Conference: Race, Medicine, and Public Policy (Nov. 12, 2004), www.aei.org/include/event_print.asp?eventID=937 (emphases added).
[125] Sally Satel, Presenter at the American Enterprise Institute for Public Policy Research Conference: Race, Medicine and Public Policy (Nov. 12, 2004), www.aei.org/include/event_print.asp?eventID=937.
[126] *See* Sally Satel, *Race and Medicine Can Mix without Prejudice: How the Story of BiDil Illuminates the Future of Medicine*, MED. PROGRESS TODAY, Dec. 10, 2004, http://www.medicalprogresstoday.com/spotlight/spotlight_indarchive.php?id=449.

general medical practice, but also for addressing specific health disparities (remember these discussions are also indirectly being framed by using the misleading 2.5 times heart failure mortality statistic). The related message is that the correlation also provides the basis for market driven pharmaceutical development to produce new drugs, such as BiDil, to address these differences.

C. FROM DISPARITY TO DIFFERENCE

This is where reification in the context of medical practice intersects with broader strategies regarding commerce and the politics of difference. At work here is an appropriation of race as reified in the BiDil story to serve larger political agendas aimed at transmuting health disparities rooted in social and economic inequality into mere health "differences" rooted in biology and genetics. Attempts to address social "disparity" generally implicate the power of the state or other non-market institutions to intervene consciously both in the allocation of resources and the sanctioning of racist practices. In contrast, attempts to address genetic "difference" may be located at the molecular level and targeted by pharmaceuticals developed and dispensed through the purportedly impersonal forces of the market.

Implicit in the logic of conservatives such as Satel and Entine, who use BiDil to characterize disparate health outcomes in terms of genetics, is an argument that issues currently characterized as health disparities should be privatized. This argument goes far when explaining why free market conservative organizations such as the American Enterprise Institute and the Manhattan Institute have taken such an interest in BiDil and the Tate and Goldstein article.

This observation was driven home by the recent publication of two articles by Satel and Richard Epstein, a law and economics professor at the University of Chicago, in a special issue of *Perspectives in Biology and Medicine*. Both pieces attack the Institute of Medicine's ("IOM's") 2002 Report, "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care" ("IOM Report"),[127] which chronicled an array of health disparities and connected them directly to social and economic issues of equity, access, and racism. Epstein posits that "the leap from disparity to discrimination is not, on balance, established,"[128] thereby rendering disparity to be the functional equivalent of mere difference. In addition, Satel and her co-author, Jonathan Klick, complain that the IOM Report was "too quick to diagnose bias," and they object that "many medical schools, health philanthropies, policymakers, and politicians are proceeding as if 'bias' were an established fact. In other words, they consider part of the

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[127] *See* UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE (Inst. of Med. of the Nat'l Acads. ed., 2003).

[128] Richard A. Epstein, *Disparities and Discrimination in Health Care Coverage: A Critique of the Institute of Medicine Study*, 48 PERSS. IN BIOL. & MED, S26, S29 (2005).

solution to the disparity problem to be located in the arena of race politics."[129] As an alternative, Satel and Klick argue that:

> understanding health disparities as an economic problem tied to issues of access to quality care and health literacy, rather than as a civil rights problem borne of overt or unconscious bias on the part of physicians, is a more efficient and rational way to address the problem of differential health outcomes.[130]

In contrasting "race politics" with economics, Satel prioritizes private action operating in the market over affirmative institutional action as the preferred mechanism of response to inequality.

In their articles, Satel and Epstein provide a discussion to revive a previous and far more egregious attempt by former Department of Health & Human Services ("DHHS") Secretary, Tommy Thompson, to transmute the IOM's focus on disparity into difference. In December 2003, the DHHS issued a report on health disparities, supposedly based on the IOM Report. The DHHS report, however, dismissed the "implication" that racial differences in care "result in adverse health outcomes."[131] It turns out that top officials told DHHS researchers to drop their initial conclusion that racial disparities are "pervasive in our health care system," and to delete or recharacterize findings of "disparity" as mere evidence of health care "differences."[132] For example, an earlier version of the report mentioned the term "disparity" thirty times in the "key findings" section, while the final report mentioned it only twice and left the term undefined.[133] DHHS officials accompanied this push to use the term "difference" to emphasize "the importance of . . . personal responsibility" for health outcomes.[134] Ultimately, Tommy Thompson backtracked when word of the report's manipulation was leaked by concerned DHHS staff. Nonetheless, Satel and Epstein effectively continue where Thompson stopped — emphasizing personal choice and market forces, rather than racism or inequality, as the basis of health "differences" among races.

Support for BiDil and the repudiation of the IOM Report are related. Together they constitute a strategic move to locate the responsibility for individual health disparities through biology or "personal choice," rather than society. The implicit goals are to undermine calls for further state action to address the underlying racism that leads to disparities, and also to privatize the move to address health disparities by leaving it to market forces, exemplified by the drug development model of BiDil and the "29 medicines." In the world of law, this is a way of saying that disparate impact is not due to discrimination, but due to "natural" forces, meaning

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[129] Sally Satel & Jonathan Klick, *The Institute of Medicine Report: Too Quick to Diagnose Bias*, 48 PERSS. IN BIOL. & MED. S15, S22 (2005).
[130] *Id.* at S23.
[131] Maxwell Gregg Bloche, *Health Care Disparities–Science, Politics, and Race*, 350 NEW ENG. J. MED. 1568, 1568 (2004).
[132] *Id.*
[133] *See* Shankar Vedantam, *Racial Disparities Played Down*, WASH. POST, Jan. 14, 2004, at A17.
[134] Bloche, *supra* note 115, at 1568.

that it is nobody's "fault" and therefore, requires no conscious effort to redress.

The strategy of reifying race to turn inequality into mere difference, and consequently privileging market over institutional intervention, has echoes beyond the realm of health disparities. Two recent examples are particularly suggestive of how this reasoning has reached broader debates in an array of social policy initiatives including: (1) the current debate over Social Security reform, and (2) Harvard President Lawrence Summers's comments in February 2005 at a meeting of the National Bureau of Economic Research concerning women in engineering and science.

First, Social Security: in October 2004, in the Oklahoma race for the U.S. Senate, conservative Republican candidate, Tom Coburn (a doctor), criticized the existing Social Security system to be unfair to black males because they were statistically more likely to die before they could collect Social Security. "What kind of plan is that," Coburn asked, "that we are going to take from those who have a *genetic predisposition* of less life expectancy, that we are going to steal from those and give it to somebody else?"[135] It should also be noted that Coburn has called for the death penalty for doctors performing abortion so he may not represent mainstream thinking.[136] However, he is now a member of the U.S. Senate and he is in step with the Bush administration regarding Social Security reform.

In January, the Bush administration tied the President's call to privatize part of Social Security to Coburn's same argument that Black males "have had a shorter life span than other sectors of America."[137] Here, the Bush administration appropriated a purportedly biological difference to serve the cause of transferring state responsibility for Social Security to the market. This loose connection of race and genetics is being used instrumentally, not only to reify race in a manner that might encourage new forms of racism, but also to undergird attempts to privatize parts of Social Security. Commenting on the Bush administration's statements, an editorial in the *Minneapolis Star Tribune* noted that the idea of a biological difference resulting in a shorter lifespan actually had its origin several years earlier in a study conducted by the conservative Heritage Foundation.[138] In a post-genomic world, however, that old critique is being given a new genetic context by the likes of Senator Coburn.

Liberal economist and *New York Times* columnist Paul Krugman was also critical of Bush's appeal to Black Americans to sell his Social Security plan.[139] In a column on bankruptcy reform several weeks later, Krugman

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[135] Reuters, *Oklahoma Black Leaders Upset Over Candidate Remark*, POL. NEWS, Oct. 29, 2004, http://www.political-news.org/breaking/15/oklahoma-black-leaders-upset-over-candidate-remark.html.
[136] *See id.*
[137] Elizabeth Bumiller, *President Discusses Issues with Black Leaders*, N.Y. TIMES, Jan. 26, 2005, at A13.
[138] *See* Editorial, *Social Security: Blacks Get More, Not Less from It*, MINNEAPOLIS STAR TRIB., Jan. 17, 2005, at 12A.
[139] *See* Paul Krugman, Editorial, *Little Black Lies*, N.Y. TIMES, Jan. 28, 2005, at A23.

introduced the concept of "risk privatization," characterizing it as "a steady erosion of the protection the government provides against personal misfortune, even as ordinary families face ever-growing economic insecurity."[140] This concept of risk privatization, developed by Yale political scientist Jacob Hacker, also applies to social security reform and to attempts to reconfigure health disparities as mere differences. Hacker himself charts a "wave of retrenchment" against welfare state risk management polices dating back to 1994 — with opponents of Clinton's abortive health care reform initiative being one of the first examples of a "counter-mobilization among affected interests and political conservatives, who denied that government should step in to deal with the increasing hardships caused by skyrocketing costs and dwindling protections."[141] Hacker goes on to identify several other key areas of state intervention where a similar dynamic of retrenchment is at work, including health insurance and retirement security.[142] Connecting Social Security benefits to Black life expectancy adds a new twist to the dynamic identified by Krugman and Hacker. It adds greater force to attempts to privatize the risks of retirement by enlisting the authority of biology and genetics.

The second example leads us to Harvard President Lawrence Summers's remarks on women in science and engineering on January 14, 2005, at a conference on "Diversifying the Science and Engineering Workforce," hosted by the National Bureau of Economic Research in Cambridge, Massachusetts. In considering possible explanations for why women are disproportionately under-represented in the fields of science and engineering at elite academic institutions, Summers presented three explanatory hypotheses:

> The first is what I call the high-powered job hypothesis. The second is what I would call different availability of aptitude at the high end, and the third is what I would call different socialization and patterns of discrimination in a search. And in my own view, their importance probably ranks in exactly the order that I just described.[143]

As he goes on to explain these hypotheses, it becomes clear that he sees three forces at work: individual choice operating in the market, genetics, and, only lastly, discrimination. Note that Summers not only lists these hypotheses, but he also ranks them. As an economist, he sees rational choice operating in the market as the prime force creating the under-representation, and hence, the appropriate locus for addressing or justifying such under-representation.

Referring to the work of economist Gary Becker, Summers later asserts:

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[140] Paul Krugman, Editorial, *The Debt-Peonage Society*, N.Y. TIMES, Mar. 8, 2005, at A23.
[141] Jacob Hacker, *Privatizing Risk Without Privatizing the Welfare State: The Hidden Politics of Social Policy Retrenchment in the United States*, 98 AM. POL. SCI. REV. 243, 245 (2004).
[142] *See id.* at 252-56.
[143] Lawrence H. Summers, Remarks at NBER Conference on Diversifying the Science & Engineering Workforce (Jan. 14, 2005), www.president.harvard.edu/speeches/2005/nber.html.

> If it was really the case that everybody was discriminating, there would be very substantial opportunities for a limited number of people who were not prepared to discriminate to assemble remarkable departments of high quality people at relatively limited cost simply by the act of their not discriminating, because of what it would mean for the pool that was available.[144]

Summers sees "relatively little evidence" of institutions taking advantage of such potential market imbalances and therefore concludes that the disparity can be explained primarily by the personal preferences or "tastes" of individual women who have chosen not to make the trade-offs demanded by a "high powered job," or genetics.

In contrast to his inability to find evidence of discrimination against women in academia, Summers readily embraces highly controversial and contested propositions of behavioral genetics to assert that "there is relatively clear evidence" of "systemic differences in variability [i.e. genetic variability] in different populations" that relate to such characteristics as "propensity for criminality, overall IQ, mathematical ability, [and] scientific ability."[145] The geneticization of difference, here gender difference, again combines with market ideology to transmute unjust disparity into mere difference, thereby rendering it undeserving of deliberate intervention. Summers's approach, of course, echoes both Tommy Thompson's emphasis on "personal responsibility" over systemic discrimination for disparate health outcomes, and BiDil proponents' championing of market mechanisms of drug development to address purportedly genetic racial differences in heart failure.

III. CONCLUSION

The story of BiDil clearly raises concerns over the dangers of reifying race in a manner that could lead to new forms of discrimination. BiDil, however, is part of a much larger dynamic of reification in which the purported "reality of race" as genetic is used to obscure the social reality of "racism." This dynamic ranges from the appropriation and distortion of the report on the "29 medicines" to attacks on the IOM Report and has political analogues in the realms of Social Security reform and employment discrimination. To the extent that this dynamic succeeds in reductively reconfiguring health and other types of disparity in terms of genetic difference, it casts personal responsibility on the market as the appropriate arena for addressing differential outcomes while also undermining the rationale for deliberate state or institutional interventions to address discrimination.

For all the legitimate concerns that the genomics revolution might lead to new forms of discrimination, we must also be alert to the potential appropriation of genetics to obscure or justify existing inequalities.

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[144] *Id.*
[145] *Id.*