

# Strict Scrutiny and the FDA: A Model For Regulating Race Based Medicines or a Recipe for Disaster?



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7 April 2006

# Center for Genetics and Society



Mission statement: “working to encourage responsible uses and effective societal governance of the new human genetic and reproductive technologies”

- Pro-science and Pro-regulation
- Effective Policy Options

## CGS programs

- *Biotechnology Accountability*
- *Gender, Justice, and Human Genetics*

# Why we are here...



Emerging genetic and reproductive technologies have the potential to:

- Deepen social inequalities
- Lead to a future where social problems are viewed largely as genetic or biological issues
- Blur line between therapeutic and eugenic medical applications



# “Geneticizing” Social Problems





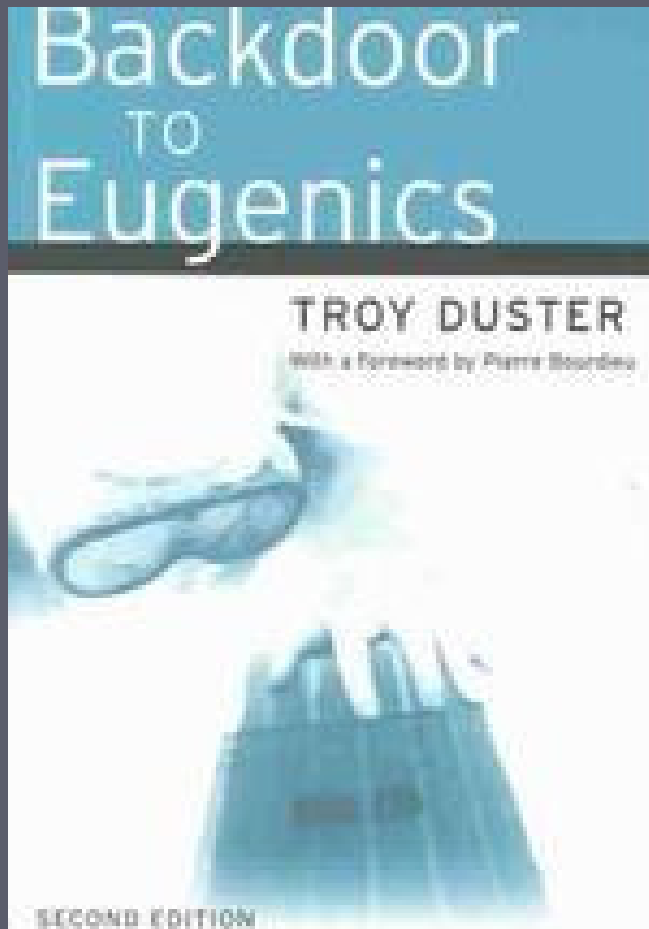
- Genetic explanations for phenomena previously understood as having a significant social or environmental component are on the rise.
- Crime
- Sexuality
- Intelligence
- Mental Illness
- Alcoholism
- Shyness
- Obesity

# Race and Biology

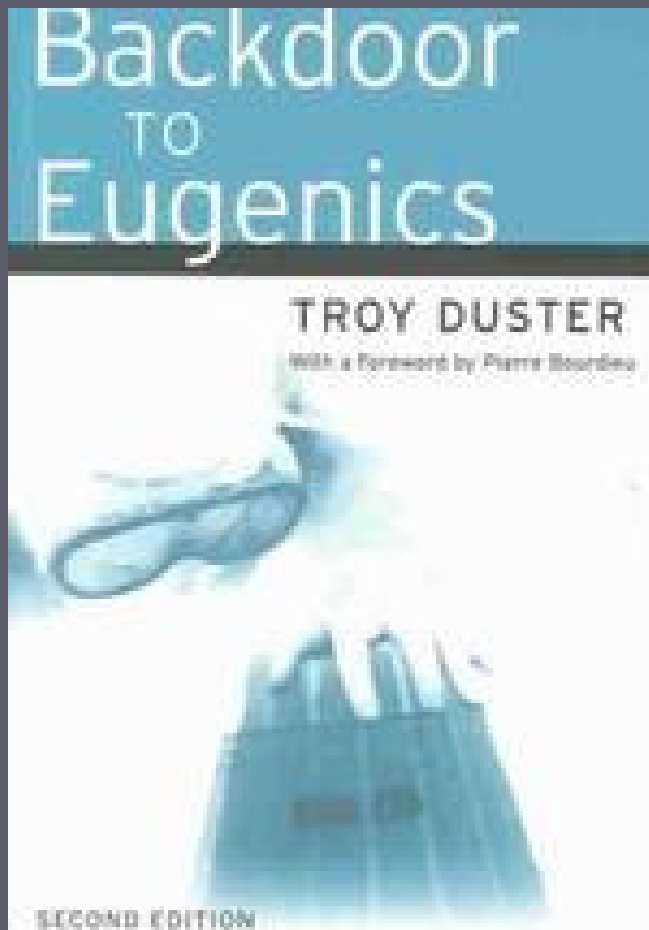


- Biological approaches to race lend themselves to a harmful form of reductionism
- A social constructionist approach to race challenges this
  - Asymmetrical outcomes are often produced by legal and social structures rather than by inherent biological differences.

# Backlash Against Social Constructionism



- “Those making claims about the genetic component of an array of behaviors and conditions come from a wide range of disciplines, tenuously united under a banner of an increased role for the explanatory power of genetics.”



- “How can the relative modesty, scientific tentativeness, even quietude of these laboratory geneticists on these subjects be explained, while researchers in these other traditions tend to be the most passionate advocates for the biological or genetic component?”



# Where Does BiDiI Come In?



# BiDil



- As the first drug to be:
  - (1) Patented as Race Specific
    - *A legal claim about race and biology*
  - (2) Approved by the Federal Gov't as Race Specific
    - *A claim by the State about race and biology*
  - (3) Marketed as Race Specific
    - *An economic claim about race and biology*
- BiDil represents a significant step in reinventing biological understandings of race.





- This isn't to say that race should never be a consideration in developing pharmaceuticals.
- Rather, it is to say that law, the State, and markets have a unique history with this “race as biology” narrative that has largely been harmful to Blacks.
- We need effective regulation to ensure that this history does not repeat itself.



*Image taken from Nitromed website*



# Strict Scrutiny as a Regulatory Model



# What is Strict Scrutiny?



- U.S. Constitution – 14<sup>th</sup> Amendment (1868)
  - No state shall “deny to any person within its jurisdiction the equal protection of the laws.”
  - Slaughterhouse Cases (1873): “The one pervading purpose . . . is the freedom of the slave race, the security and establishment of freedom, and the protection of [blacks] from the oppressions of those who had formerly exercised unlimited dominion over him.”
  - This focus has shifted over time.
- Strict scrutiny came about in the mid 1900s as a way for the court to determine when and under what circumstances the Government can use racial classifications.
  - Korematsu (1944): “All legal restrictions which curtail the civil rights of a single racial group are immediately suspect. . . . [C]ourts must subject them to the most rigid scrutiny.”

# Strict Scrutiny Today



- Grutter Court Reiterated Goals (2003)
  - Purpose of strict scrutiny is to “smoke out’ illegitimate uses of race by assuring that [government] is pursuing a goal important enough to warrant use of a highly suspect tool.” quoting *Richmond v. J.A. Croson* (1989).
- Two Prong Test
- Racial Classifications are Constitutional if:
  - (1) they are narrowly tailored, AND
  - (2) further a compelling state interest



# Strict Scrutiny Today



- This has been interpreted as:
  - (1) permitting benign or remedial classifications while invalidating those based on notions of racial inferiority
  - (2) permissible only if no race-neutral alternatives are available to achieve same goal
  - (3) should be framed as a temporary measure to promote racial equality



# Food and Drug Administration



- FDA is an administrative agency under the Dept. Health & Human Services
  - Created by statute
  - Accountable to Congress (quasi-independent)
  - Leaders appointed by President with Congressional approval
- Main power: Regulation
  - Safety and Efficacy
  - Food, Drugs, Medical Devices, Biologics, Animal Feed and Drugs, Cosmetics

# Public Interest



- FDA has a rigid understanding of protecting the public's interests
  - Example: Human Cloning
  - FDA has asserted regulatory jurisdiction
  - Ostensibly, if human cloning could be performed safely and effectively, the FDA could approve it.
  - “Safety and Efficacy” mandate does not address broader social and ethical concerns



# Strict Scrutiny and Congress: Closing the Gap



- Congress has at least two avenues through which it can enforce a “strict scrutiny” analysis of race-based medicines
  - (1) Basic regulatory authority over DHHS and FDA
  - (2) §5 of 14<sup>th</sup> Amendment gives Congress the power to enforce Equal Protection through appropriate legislation
- Thus, strict scrutiny in relation to Equal Protection need not be restricted to the courts.

# How Would It Fit Within Current Stages of Drug Development Review?



- Investigational New Drug Application
  - Company shows FDA preclinical testing results
- Clinical Trials
  - Phase 1: Healthy volunteers; emphasis on safety
  - Phase 2: Sick volunteers; emphasis on effectiveness
  - Phase 3: Different populations & dosages; focus on both safety and effectiveness
- New Drug Application
  - Formal request for FDA approval
  - FDA Review team of doctors, chemists, statisticians, microbiologists, pharmacologists, and others evaluate whether drug is safe and effective for proposed use
    - They Study both the clinical results and trial design/analysis

# FDA Advisory Committees



- Made up of outside experts who help the agency decide on drug applications.
  - Used when drug is the 1st in its class or for a given illness.
  - Findings are non-binding
  - FDA's Cardiovascular & Renal Drugs Advisory Committee unanimously approved BiDil; all but 2 approved race specific label
- AC to look at race and medicine beyond safety and efficacy?
  - Include social scientists, lawyers, historians, and community representatives of targeted population
  - Apply basic strict scrutiny principles: does the drug serve a compelling State and community interest? Is race being used in a narrowly tailored manner?
  - Findings should be more than non-binding

# Scrutinizing Strict Scrutiny



- Equal Protection and Strict Scrutiny have not always been applied in a manner that remedies past or ongoing injustices.
  - Example: Intent Doctrine
- “Strict in Theory, Fatal in Fact”
  - Gerald Gunther’s famous assessment; most laws using racial categories are struck down as impermissible
  - Strict Scrutiny’s legal fatalities are one thing, but we want to avoid this from translating into preventable human fatalities.

# Conclusion: The Case for Regulation



- Race-based medicines may offer new ways to treat illnesses that disproportionately affect minorities.
- But they also highlight important concerns over equality and the State's duty to protect historically vulnerable populations.
- These medicines raise several important questions
  - BiDil as an example:
    - Is the State only responsible for evaluating the safety and efficacy of medicines, using race as a proxy to target those who are suffering?
    - Or does the State have a broader responsibility to alleviate the underlying social, economic, and environmental conditions that produce Blacks' high rate of heart failure?