

**Fall 2014 -- WWS 354 – Modern Genetics and Public Policy
Robertson 005**

Tuesday 1:30 p.m. – 4:20 p.m.

Professor Keith Wailoo, Townsend Martin Professor of History and Public Policy
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Preceptors:

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This course examines the impact of discoveries in modern genetics and advances in genetic technology on public policy.

The course is organized into three sections. First, we will examine broad scientific, social, political, and philosophical problems raised at the intersection of genetics and public policy, including the ways in which genetic knowledge shapes conceptions of the self and race; the relationship between the eugenics of the early 20th century and early 21st century genetics-informed policies; the question of who owns and controls one's genetic information; and the ways in which genetic disease plays out in different cultural settings. In the second section of the course, we examine specific genetic applications and practices: in the criminal justice system; commercial do-it-yourself genetic testing; insurance and employment policies; gene

therapy and the patenting of genes. Third, we turn our attention to the challenges that the relatively new branches of genetics, epigenetics and stem cell therapy, raises in health and public policy.

Each session will begin with a lecture, followed by a discussion-intensive seminar. Students are expected to have completed the required reading assignments in advance of the seminar, and come to class prepared to discuss the wide range of perspectives, agendas, and issues bearing on genetics and policy. Over the semester, we will be reading scientific studies, newspaper reports, policy documents, business reports, and scholarly analyses of the issue at hand. While this array may seem confusing at first, the diversity of sources forces students to analyze the perspectives, values, and social processes shaping how genetic information is debated, regulated, and managed in policy settings.

We will learn that turning genetic science into public policy is a messy process – influenced by the speed of new discoveries, and shaped by business and economic interests, social and religious values, political perspectives, and fears and hopes. We will also learn that “genetics” is not, indeed, one field but many – from classical Mendelian genetics to multi-factorial behavioral genetic, epigenetics and population genetics – each of which is generating issues that policy makers must address. The course aims to draw students into the detailed analysis of these genetics fields; the scientific products and social conflicts spawned by genetic sciences; the medical, health, legal and social implications of genetics today; and the cultural, philosophical, and regulatory challenges associated with this far-reaching yet contentious field.

Note: While there is no science prerequisite for the class, students must have a basic understanding of genetic principles.

Readings

Three books are required reading for the course, and are available at Labyrinth Bookstore:

- Keith Wailoo and Stephen Pemberton, *The Troubled Dream of Genetic Medicine: Ethnicity and Innovation in Cystic Fibrosis, Tay-Sachs, and Sickle Cell Disease* (Johns Hopkins, 2006)
- Keith Wailoo, Alondra Nelson, and Catherine Lee., eds., *Genetics and the Unsettled Past: The Collision of DNA, Race, and History* (Rutgers University Press, 2012)
- Ruha Benjamin, *People’s Science: Bodies and Rights on the Stem Cell Frontier* (Stanford University Press, 2013)

Note: For non-science majors who are enrolled in the course, we recommend: Charlotte K. Omoto and Paul F. Lurquin, *Genes and DNA: A Beginner's Guide to Genetics and Its Implications* (Columbia University, 2004) Copies can be purchased at Labyrinth.

The assigned and optional articles will be posted on Blackboard.

Reading Requirements. Students must have completed the required readings before each session. The optional readings are for those of you who wish to delve more deeply into the week's topic. Each student must also write a short **one-page response paper** to the assigned readings in advance of Tuesday's class. These weekly response papers should describe what the student sees as the most important issues, questions, and problems raised by the papers.

Leading the Class Discussion. Each student will take part in leading a class discussion. Students will work in groups of two or three – working with Professors Tilghman and Wailoo, and with the course preceptors. These discussion-leading assignments will be determined at our first meeting.

Discussion-leading and regular participation in weekly discussions will count towards 35% of the final grade.

Discussion Format. While there will be some variation from session to session, the format will be as follows:

- 1) Each session will begin with a 45-55 minute lecture by Professors Wailoo and Tilghman. The goal: to introduce the topic and to raise the broad questions and issues for discussion.
- 2) The rest of each session will focus on discussion, in which the students who have signed up for that session are expected to play a leading role. Occasionally, the class will break into two smaller groups for 45-55 minutes to facilitate this more detailed discussion.
- 3) The closing half hour of each class will focus on summary and conclusions from the readings, and discussion of issues requiring further analysis and investigation. The goal is not consensus, but deeper understanding of the science, the social and political debates, and the policy challenges surrounding each issue.
- 4) Each session will begin with a "question of the day." For session #1 that question might be, for example, "what are the crucial similarities and differences between the old eugenics and the new genetics?" At the end of each session, each student will have 5 minutes to write and hand in a response to the question.

Writing Requirements. In addition to the weekly one-page response papers, there are two writing requirements.

1. Midterm paper will count towards 25% of final grade. The first paper (due on Friday, October 24th, 5 p.m.) is a 5-7 page analysis of a case study in genetics and public policy chosen by the student. Ideally, this paper offers a more detailed, sustained, and original analysis of a topic on the syllabus or the readings, or another topic in genetics and public policy not covered by the syllabus. It may examine scientific questions, social problems, legal and economic concerns, medical issues, or regulatory challenges. The paper should not be narrowly confined to one single realm (that is, only science or only policy), but should examine issues cutting across both areas. Think of this first paper as a more extended and organized analysis than is possible in your one-page response papers.

2. The final paper will count towards 40% of final grade. The final paper (due January 15, 2015) should extend and deepen the analysis of the first paper, based on the feedback you have received. You may choose, however, to examine a new topic. The second paper will be a 15-18 page examination of the policy challenges in the case study you have chosen. The paper will devote significant attention to analyzing how the main actors in that controversy (physicians, scientists, consumers, genetic testing companies, politicians, regulators, policy, judges, or others) understand the issues, on how their interactions shape genetic policy, and on situating your views in relationship to the current scientific, social, or policy debate. Your paper should conclude with informed recommendations, assertions, or observations for the future of this issue.

Breakdown of All Grading

Oral Presentations, 35% of final grade. This includes discussion leading (roughly 15%), and sustained participation in weekly discussion (roughly 20%).

First Paper (25% of the final grade) – due October 24, 2014, 5 p.m.

Final Paper (40% of the final grade) – due January 15, 2015, 5 p.m.

Syllabus Outline

Part I

Session 1. Sept 16 – The Old Eugenics and the New Genetics: What are the Differences?

Session 2. Sept 23 – How Does Culture Shape Responses to Genetic Information?

Session 3. Sept 30 – Who Controls the Information in Your Genes? The Havasupai and DeCode Genetics Cases

Session 4. Oct 7 – How has Genetics Affected, and Been Affected By, Conceptions of Race?

Part II

Session 5. Oct 14 – Dangerous DNA: Collecting and Using Genes in Criminal Justice

Session 6. Oct 21 – Genetic Discrimination: What is it? Why Ban It?

**** First papers due: Friday, October 24th**

Fall Recess – Week of October 27

Session 7. Nov 4 – Who Owns Your Genes? Patenting, the Courts, and Myriad Genetics

Session 8. Nov 11 – Testing Yourself? The FDA, 23andMe, and Regulatory Challenges

Session 9. Nov 18 – Gene Therapy: New Genetics, Old Eugenics, or Both?

Part III

Session 10. Nov 25 – Science for Equality and Justice? The California Stem Cell Initiative

Session 11. Dec 2 – Epigenetics: The Policy Implications of an Emerging Field

Session 12. Dec 9 – Emerging Challenges in Genetics and Public Policy



"Here's my DNA sequence."

Session 1. September 16

The Old Eugenics and The New Genetics: What are the Differences?

Goals: Review syllabus and course requirements. Examine the history of the biological study of heredity focusing on the rediscovery of (and principles underlying) Mendelian inheritance. Examine the application and misapplication of those principles in eugenics-informed policies such as sterilization (deemed constitutional in the 1927 *Buck v. Bell* case, and dramatized in the 1937 film, *Tomorrow's Children*, to be shown in class). Analyze the relationship between eugenics and modern genetics. Discuss role of media, science, politics, and values in shaping genetics policy. Discuss relationship of public policy environment and issues in the era of eugenics and in the age of modern genetics.

Required Readings:

Eugenics then (1900-1940)

- Daniel Kevles, *In the Name of Eugenics: Genetics and the Uses of Human Heredity* (Daniel Kevles): 41-112 (Ch. 3, "Charles Davenport and the Worship of Great Concepts," Ch. 4., "The Gospel Becomes Popular," Ch. 5, "Deterioration and Deficiency," Ch. 6., "Measures of Regeneration," and Ch. 7, "Eugenic Enactments.")
- Maynard Olson, "Davenport's Dream," in Witkowski and Inglis, eds., *Davenport's Dream: 21st Century Reflections on Heredity and Eugenics* (Cold Spring Harbor, 2008)

Eugenics now

- "Virginia Governor Apologizes for Eugenics Laws," *USA Today*, 2002
- Kim Severson, "Payments for Victims of Eugenics are Shelved," *New York Times* (June 2012)

** *Tomorrow's Children* (1937, portions of film to be viewed in class)

Optional Readings and video:

- Philip Thompson, "Silent Protest: A Catholic Justice Dissents in *Buck v. Bell*," *Catholic Lawyer*, 2005
- Justice Holmes Majority Opinion in *Buck v. Bell*, 1927
http://www.law.cornell.edu/supct/html/historics/USSC_CR_0274_0200_ZO.html
- "Chosen Children: Issues in Reproductive Testing." *Genetics and Public Policy Center*
<http://www.dnapolicy.org/video/cc/webcast.htm?go=Launch+Video>

Session 2. September 23 – **How Does Culture Shape Responses to Genetic Information?**

Goals: Discuss the history of three classic autosomal recessive diseases (cystic fibrosis, Tay-Sachs, and sickle cell disease) as examples of how genetic disease policies evolve, and how debates about heredity and genetics are influenced by science, culture, values, business, and politics. Discuss stakeholders, stakes, risks, and benefits of new genetic technology. Discuss perspectives of government, legislators, businesses (from insurance companies to diagnostic testing companies to pharmaceutical firms), patients, citizens, scientists, physicians, and other stakeholders.

Required Reading:

Three Diseases in the Age of Genetic Innovation

- Wailoo and Pemberton, *The Troubled Dream of Genetic Medicine: Ethnicity and Innovation in Cystic Fibrosis, Tay-Sachs, and Sickle Cell Disease* (Johns Hopkins, 2006)

Optional Readings:

For Comparative Perspective: Recent Genetics/Disease/Race/Policy Controversies

- Amy Harmon, "Couples Culling Embryos to Halt Heritage of Cancer," NYT, (September 3, 2006)
- Amy Harmon, "Seeking Columbus's Origins, with a Swab," NYT (October 8, 2007)
- Amy Harmon, "Cancer Free at 33, but Weighing a Mastectomy," NYT (September 16, 2007)
- Amy Harmon, "Stalking Strangers' DNA to Fill in the Family Tree," NYT, (April 2, 2007)
- "'Angelina Jolie Effect' Sparks Surge in Genetic Testing," CBC News (October 17, 2013)

Session 3. September 30 –

Who Controls the Information in Your Genes? The Havasupai and DeCode Genetics Cases

Goals: Do the business of genetics and the practice of genetic research pose a threat to privacy, or do they open the door to better health and wellbeing? What controls, if any, should be placed on genetics research involving identifiable populations? In April 2010, Arizona State University agreed to pay \$700,000 to 41 members of the Havasupai Indian tribe to settle a decade-long legal battle over whether the university's genetics researchers had misused tribe members' blood samples by using them to study questions that had not been approved by the donors.. Discuss the case and its implications for genetic research, informed consent, and questions of identity, ownership, and genetic privacy. Examine these recent issues in light of the ideals, goals, and controversies that shadowed the Human Genome Diversity Project. Is the

U.S. unique in how it approaches genetics and public policy issues? How have other nations grappled with these policy questions?

Required Readings:

The Havasupai Case and Its Implications

- Amy Harmon, "DNA Gatherers Hit Snag: Tribes Don't Trust Them," NYT, (December 10, 2006); Amy Harmon, "Havasupai Case Highlights Risks in DNA Research," NYT (April 2010)
- Rex Dalton, "When Two Tribes Go To War," Nature (July 2004)
- Katherine Drabiak-Syed, "Lessons from the Havasupai Tribe v. Arizona State University Board of Regents: Recognizing Group, Cultural, and Dignitary Harms as Legitimate Risks Warranting Integration into Research Practice," Journal of Health and Biomedical Law (2010): 175-225.

DeCode Genetics (Iceland)

- David E. Winicoff, "Genome and Nation: Iceland's Health Sector Database and Its Legacy," innovations (Spring 2006)
- Michael Specter, "Decoding Iceland" (New Yorker, January 18, 1999): 40-51.
- "Iceland's Decode Signs Genetics Deal with Pfizer," Reuters (October 2011)
- Jocelyn Kaiser, "Agency Nixes deCODE's New Data-Mining Plan Science, 1388-9 (June 21, 2013)

Human Diversity Project

- Michael Dodson and Robert Williamson, "Indigenous Peoples and the Morality of the Human Genome Diversity Project," Journal of Medical Ethics 25 (1999): 204-208.

Optional Readings and video:

- Amy Harmon, "The DNA Age: Project Lets Anyone Take a Peek at the Experts' Genetic Secrets," *New York Times* (October 20, 2008); "Gene Map Becomes a Luxury Item," (March 4, 2008);
- Erika Check Hayden, "Informed Consent: A Broken Contract," Nature (June 2012)
- Helen Shen, "California Considers DNA Privacy Law," Nature (May 2012)
- Erika Check, "The Decode Database: Should a Private Company Market a Nation's Genetic Information?" Stanford Journal of International Relations (1999)

- **"DECODING ICELAND: THE DNA OF GREED"**
<http://vimeo.com/ondemand/decodingiceland>
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Session 4. October 7 –

How has Genetics Affected, and Been Affected by, Conceptions of Race?

Goals: What kinds of assertions about racial and ethnic differences can be supported by genetic evidence? How valid are such claims, and how should we differentiate among genetic claims relating to human characteristics as diverse as skin color, disease predilection, group psychology, ethnic customs practices, intelligence, or behavior? How has hereditary information been used and misused in the past? In what ways is modern genetics separate from, or connected to, the history of using and misusing genetics as a tool in race relations?

Required Readings:

Who Am I? Genes and Racial Identity

- Richard Cooper, "Race in Biological and Biomedical Research," Cold Spring Harbor Perspectives in Medicine (2013)
- Nicholas Wade, excerpts from *A Troublesome Inheritance: Genes, Race, and Human History* (Penguin, 2014). 6: "Societies and Institutions," 8: "Jewish Adaptations," 9: "The Rise of the West."
- H. Allen Orr, "Stretch Genes," [review of *A Troublesome Inheritance*], New York Review of Books, June 5, 2014.
- Allison Abbott and Nature Magazine, "Genome Test Slammed for Assessing 'Racial Purity'," Scientific American (June 12, 2012)

From Wailoo et.al., *Genetics and the Unsettled Past*

- Keith Wailoo, "Who Am I? Genes and the Problem of Historical Identity," chapter 1.
- Alondra Nelson, "Reconciliation Projects: From Kinship to Justice," chapter 2.
- Lundy Braun and Evelyn Hammonds, "The Dilemma of Classification: The Past in the Present," chapter 5.

Optional reading:

- Jenny Reardon and Kim Tallbear, "Your DNA is Our History: Genomics, Anthropology, and the Construction of Whiteness as Property," *Current Anthropology* (April 2012)
- Rajagopalan and Fujimura, "Making History via DNA, Making DNA from History," in *Genetics and the Unsettled Past*.
- Nina Kohli-Laven, "French Families, Paper Facts: Genetics, Nation, and Explanation," in *Genetics and the Unsettled Past*.
- Amy Hintenberger, "Categorization, Census and Multiculturalism: Molecular Politics and the Material of Nation," in *Genetics and the Unsettled Past*.
- Marianne Sommer, "It's Living History, Told by the Real Survivors of the Times': Anthropological Genetics in the Tradition of Biology as Applied History," in *Genetics and the Unsettled Past*.
- "Genetics Company Faces Inquiry After Certifying MP's Racial Purity," *New Scotsman* (June 28 2012)

Session 5. October 14 – **Dangerous DNA: Collecting and Using Genes in Criminal Justice**

Goals: What roles should genetics play in prosecution, exoneration, criminal investigation, and the pursuit of justice? Over the past 2-3 decades, DNA collection at crime scenes has become commonplace, as has the practice of maintaining DNA databases of convicted felons. DNA analysis has also become increasingly used to prove the innocence of prisoners. Why have these and other developments in DNA analysis in criminal justice – such as the XY link to criminal behavior – been controversial? Discuss the different attitudes toward collection of samples from arrestees and policemen (with the goal of better analysis of crime scene evidence when their DNA might be present), the XY controversy, and the relation of DNA analysis to social and racial profiling. Discuss also the Innocence Project, and the use of DNA to challenge prosecutors, and to favor those wrongfully convicted.

Required Readings:

Proving Guilt... and the Genetics of Innocence

- Margaret A. Berger, "The Impact of DNA Exonerations on the Criminal Justice System," *Journal of Medicine, Law, and Ethics* 34 (Summer 2006): 320-327
- Mark A. Rothstein and Meghan K. Talbott, "The Expanding Use of DNA in Law Enforcement: What Role for Privacy?" *Journal of Medicine, Law, and Ethics* 34 (Summer 2006): 153-164.
- Amy Harmon, "Defense Lawyers Fight DNA Samples Gained on Sly," *NYT*, (April 3, 2008)

- Mark A. Jobling and Peter Gill, "Encoded Evidence: DNA in Forensic Analysis," *Nature Reviews: Genetics* 5 (October 2004): 739-752
- Pamela Sankar, "Forensic DNA Phenotyping: Continuity and Change in the History of Race, Genetics, and Policing," in Keith Wailoo, Alondra Nelson, Catherine Lee, eds., *Genetics and the Unsettled Past: The Collision of Race, DNA, and History*

Court Rulings on Taking DNA Samples from Arrestees, 2013-2014

- Adam Liptak, "Justices Allow DNA Collection After an Arrest," *New York Times* (June 3, 2013)
- Richard Lempert, "Maryland v. King: An Unfortunate Supreme Court Decision on the Collection of DNA Samples," *Brookings* (June 6, 2013)
- Sarah Ferris, "Vermont Can No Longer Take DNA Samples from Suspected Criminals," *Washington Post* (July 14, 2014)

Optional readings:

- Greg Hampikian, et. al., "The Genetics of Innocence: Analysis of 194 U.S. DNA Exonerations," *Annual Rev. Genomics and Human Genetics* (2011)
- Jonathan Kahn, "Forensic DNA and the Inertial Power of Race in American Legal Practice," in Wailoo, *Genetics and the Unsettled Past*.
- Harold Edgar, "Impulsivity, Responsibility, and Criminal Law," chapter 8 in Parens, Chapman, and Press, *Wrestling with Behavioral Genetics*.
- Jay Aronson, selections from *Genetic Witness: Science, Law, and Controversy in the Making of DNA Profiling* (Rutgers, 2007) – excerpts
- "Police Making arrests 'Just to Get DNA samples'" *BBC* (November 2009): http://news.bbc.co.uk/2/hi/uk_news/8375567.stm

The XYY and Crime Controversy

- "Special Supplement: The XYY Controversy: Researching Violence and Genetics," *The Hastings Center Report* 10 (August 1980): 1-31
- Richard Fox, "The XYY Offender: A Modern Myth?" *Journal of Criminal Law, Criminology, and Police Science* 62 (March 1971): 59-73.
- Patricia Jacobs and Ernest Hook, "XYY Genotype," *Science* 189 (September 26, 1975): 1044-1045
- Garland Allen, "The Biological Basis of Crime: An Historical and Methodological Study," *Historical Studies in the Physical and Biological Sciences* 31 (2001): 183-222.

Session 6. October 21 – **Genetic Discrimination: What is it? Why Ban It?**

Goals: Scientists and society often seek to anticipate and prevent problems associated with new science. Today's session examines the Genetic Information Nondiscrimination Act (GINA), passed by U.S. Congress and signed into law by President Bush in 2008? Was this law driven by evidence of genetic discrimination or by other misuses of genetic information, or merely the fear of it? What values of rights, justice, and fairness shaped these developments and policies? Discuss the issues at stake in genetic nondiscrimination, and how those issues are understood in the context of insurance reform issues, civil rights concerns, questions of privacy, and scientific practice. What were the arguments for and against the GINA legislation, and what has been the legacy of GINA?

Required Readings:

- Henry Greely, "Banning Genetic Discrimination," *New England Journal of Medicine* 353 (September 1, 2005): 865-867.
- Jeffrey Morrow, "Insuring Fairness: The Popular Creation of Genetic Antidiscrimination," *Georgetown Law Journal* (2009)
- Amy Harmon "Insurance Fears Lead Many to Shun DNA Tests," February 24, 2008; "In DNA Era, New Worries about Prejudice," (November 11, 2007)
- "DNA and Insurance, Fate, and Risk – Room for Debate," *New York Times* (April 2014)
 - "Questions on Genetic Tests Remain; Some Rules Should be Clear," Francis Collins
 - "It's Yet to be Shown that Genetic Discrimination Exists," Bartha Maria Knoppers
 - "Guarantee Privacy to Ensure Proper Genetic Treatment," Jeremy Gruber
 - "Genetic Test Results are Not Always What they Seem," Joy Larsen Haidle
 - "Let Insurers Have Data and Trust to Get it Right," Shawn Hausman

Optional readings:

- Background and Details on Genetic Information NonDiscrimination Act (GINA, 2008) –from Human Genome project information website (gov)
http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml
- Eliot Marshal, "Whose Genome is it Anyway?" *Science* 273 (September 27, 1996): 1788-1789.
- Richard Spinello, "Property Rights in Genetic Information," *Ethics and Information Technology* (2004): 29-42
- Henry T. Greely, "The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks," *Annual Review of Genomics and Human Genetics* 343 (September 2007).

**** First papers due: Friday, October 24th – by 5 p.m.**

Fall Recess – Week of October 27

Session 7. November 4 – **Who Owns Your Genes? Patents, the Courts, and Myriad Genetics**

Goals: Discuss the case of Myriad Genetics, focusing on patenting genes, ownership, commerce, public policy, and the law in relation to genetic innovation. Shortly after the BRCA-1 gene was discovered and its link to breast cancer demonstrated, a new company (Myriad) established a gene patent claim. The question of gene patenting has been the focus of scientific, legal, and commercial controversy. Are opponents of Myriad's claim right to contend that a BRCA-1 patent sets a bad precedent and potentially harms, rather than improves, genetic testing and disease treatment? In 2012, the Appeals Courts and U.S. Supreme Court ruled on this issue, and additional judgments are expected in the coming months. Discuss the case and legal rulings. Broadening the viewpoint, discuss an earlier 2006 National Research Council report on the issue of patenting and genomics, and examine the underlying principles, values, scientific issues, and social interests.

Required Readings:

The Myriad Genetics Case and the BRCA-1 Patent

- Keselheim, Cook-Deegan, Winikoff and Mello. Gene Patenting – The Supreme Court Finally Speaks. *NEJM* 369:869-875 (2013)
- So and Joly, Commercial Opportunities and Ethical Pitfalls in Personalized Medicine: A myriad of Reasons to Revisit the Myriad Genetics Saga. *Curr. Pharmacogenomics and Personal. Med.* 11:98-109 (2013)
- E. Richard Gold and Julia Carbone, "Myriad Genetics: In the Eye of the Policy Storm," (September 2008)
- Ben McEniery, "Australia: Myriad Gene Patent Looks Good," *PatentlyO* (blog), September 7, 2014.

Balancing Intellectual Property Rights, Innovation, and Public Health

- Sally Smith Hughes, "Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980," *ISIS* 92 (September 2001): 541-575.

Optional readings:

- "Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing," Hearing before the Subcommittee on Courts, the Internet, and Intellectual Property of the Committee on the Judiciary, House of Representatives (October 30, 2007)
- Robert Cook Deegan and Christopher Heaney, "Patents in Genomics and Human Genetics," *Ann. Rev Genomics Human Genetics* 11 (September 22, 2010): 383-425.
- Natalie Angier, "Fierce Competition Marked Fervid Race for Cancer Gene," *New York Times* (September 1994)
- Heidi Ledford, "U.S. Supreme Court Opens Diagnostic Patents," *Nature* (March 2012)
- Andrew Pollack, "Despite Gene Patent Victory, Myriad Genetics Faces Challenges," *New York Times* (August 2011)
- Andrew Pollack, "Justices Send Back Gene Case," *New York Times* (March 2012)
- Michael Slezak, "Genes Still Patentable in Australia as Appeal Rejected," *New Scientist* (September 5, 2014)

Session 8. November 11 – Testing Yourself? The FDA, 23andMe, and Regulatory Challenges

Why are you allowed to send a saliva sample to 23andMe to learn about your ancestry and health possibilities, but not allowed to purchase Pathway Genomics do-it-yourself genetic testing kit at Walgreens? Why did the FDA approve at home HIV testing (OraQuick) in 2012 but refuse to approve Pathway Genomics' do-it-yourself kit?

Examine the recent legislative, judicial, and regulatory activity in genetics focused on responding to commercial innovations in gene testing and gene research. Examine how genetic science has become genetic business, and examine FDA's response to these developments and the policy controversies emerging at the intersection of science and business. Discuss FDA's evolving position on direct-to-consumer genetic testing by the company 23andMe. Discuss the Federal Trade Commission (FTC) 2006 consumer alert cautioning consumers to be skeptical about claims made by some DTC companies. Discuss of first paper assignment.

Required Readings:

The FDA, Genetic Testing, and 23andMe

- Rob Stein, "Company Plans to Sell Genetic Testing Kit at Drugstores," *Washington Post* (May 2010)

- *23andMe Statement to FDA Meeting (March 2011)*
- Anna Edney, "FDA Tells Google-Backed 23andMe to Halt DNA Test Service," Bloomberg News (November 25, 2013)
- Ezra Klein, "Should the FDA Stop you from Scaring Yourself with 23andMe's DNA Test?" Washington Post (December 6, 2013)
- Michael F. Murray, "Why We Should Care About What you Get for "Only \$99" from a Personal Genomic Service," Annals of Internal Medicine (February 2014): 507-8
- George Annas and Sherman Elias, "23andMe and the FDA," New England Journal of Medicine 370 (March 13, 2014): 985-988.
- Linnea M. Baudhuin, "The FDA and 23andMe: Violating the First Amendment or Protecting the Rights of Consumers?" Clinical Chemistry 60 (June 2014): 835-837.
- Robert D. Hof, "23andMe Tries to Woo the FDA," MIT Technology Review (July 21, 2014)

Perspectives on Commerce, Science, Consumerism, and the U.S.

- Stuart Hogarth, Gail Javitt, and David Melzer, "The Current Landscape for Direct-to-Consumer Genetic Testing: Legal, Ethical, and Policy Issues," Annual Reviews Genom. Human. Genetics 9 (2008): 161-182.
- Abram Gabriel, "A Biologist's Perspective on DNA and Race in the Genomics Era," chapter 4.

Optional Readings:

- FDA Letter to Pathway Genomics, May 2010
- Emily P. Walker, "FDA Panel Says Home Gene Tests Need Doctor Input," ABC News (March 2011)
- American Society for Human Genetics, 2007 ("ASHG Statement* on Direct-to-Consumer Genetic Testing in the United States")
- A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services (2010) – UK Publication of Human Genetics Commission
- "Direct-Access Genetic Testing: The View from Europe," Nature Reviews Genetics (September 2011)
- FDA Molecular and Clinical Genetics Panel (Executive Committee Report on Direct to Consumer (DTC) Genetic Tests that make medical claims), March 2011.
- <http://www.fdadblog.org/2011/03/fdas-shuren-accused-of-misleading.html>

FDABlog video and article commenting on the FDA, Congress, DTC Genetic Testing, and the difference between business, “snake oil,” science, and research. FDA's Shuren accused of misleading Congress about Google-backed 23andMe (March 8, 2011)

Session 9. November 18 – **Gene Therapy: New Genetics, Old Eugenics, or Both?**

Goals: The idea that genes could be drugs – i.e. used to treat disease - arose in the early 1980's, in the wake of the isolation of the first human genes. This class will consider two policy questions that gene therapy continues to pose. First should gene therapy be directed solely toward correcting genetic mutations that result in disease or should genetic enhancement of normal individuals be permitted? Is there a clear dividing line what would be considered the normal range and disease or disability that would help to distinguish between those two uses? Is this the new eugenics? Second should gene therapy be restricted to *somatic* treatments that affect the treated patient, but not the next generation – or – should *germline* gene therapy, in which the genetic change is transmitted to future generations, be permitted? The latter question has recently come to the fore with the possibility of mitochondrial replacement in oocytes with mutant mitochondria. The readings come from the popular press, scientific literature and the U.K. Human Fertilization & Embryo Authority.

Required readings:

- Kim Tingley, “The Brave New World of Three-Parent IVF. NYT Magazine June 27, 2014
- Third scientific review of the safety and efficacy of methods to avoid mitochondrial disease through assisted conception: 2014 update. U.K. Human Fertilization & Embryo Authority. June 2014
- Nuffield Council on Bioethics. [Novel techniques to prevent mitochondrial DNA disorders would be an ethical treatment option](http://nuffieldbioethics.org/news/novel-techniques-prevent-mitochondrial-dna-disorders-would-be-ethical-treatment-option) (<http://nuffieldbioethics.org/news/novel-techniques-prevent-mitochondrial-dna-disorders-would-be-ethical-treatment-option>)
- Human Genetic enhancement. The President’s Council on Bioethics. 2002. <https://bioethicsarchive.georgetown.edu/pcbe/background/humangenetic.html>
- Kathi Hanna. Genetic enhancement. <http://www.genome.gov/10004767>; Germ-line gene transfer. <http://www.genome.gov/10004764>

Optional readings:

- Robin McKie, "Families hope 'Frankenstein science' lobby will not stop gene cure for mitochondrial disease." *The Observer* February 15, 2014
 - Sabrina Tavernise. "F.D.A. Weighs Fertility Methods that Raises Ethical Questions" *NYT* February 26 2014
 - Kenneth Cornetta, Regulatory Issues in human gene therapy. *Blood Cells, Molecules and Diseases* **31**, 51-56 (2003)
 - Douglas C. Wallace. Mitochondrial Diseases in Man and Mouse. *Science* **283**, 1482-1488 (1999)
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Session 10. November 25 – Science for Equality and Justice? The California Stem Cell Initiative

Goals: In this session, we discuss the recent history of embryonic and adult stem cell therapy, the promise and peril of the scientific and commercial development, and regulatory concerns surrounding this research field. We will be joined by Princeton professor Ruha Benjamin to discuss her book, *People's Science*. The book takes the reader inside California's 2004 stem cell initiative, a state referenda on stem cell research that was passed at a time when the Bush administration looked askance at this line of research because of its implications for abortion. Our discussion with Professor Benjamin will examine the issues that drove the state to endorse stem cell research, how the initiative promised to affect health, and what the initiative reveals about the relationship between scientific innovation, social justice, and state and federal public policy.

Required Reading:

- Ruha Benjamin, *People's Science: Bodies and Rights on the Stem Cell Frontier* (Stanford University Press, 2013)

Optional readings:**Rick Perry, Texas, and State's Rights in Biomedical Regulation**

- Emily Ramshaw, "Perry's Adult Stem Cell Treatment was Doctor's First Attempt," *Texas Tribune* (August 4, 2011)
- "The Darker Side of Stem Cells," *Nature* (March 2012)
- Todd Ackerman, "FDA Report Faults Houston Stem-Cell Company," *Houston Chronicle* (June 2012)
- Minjae Park, "Texas Board Approves Rules of Use of Stem Cells," *NYT* (April 13, 2012)

Background on Stem Cell Research, Politics, and Policy

- Eugene Russo, "Follow the Money – The Politics of Embryonic Stem Cell Research," *PloS Biology* (July 2005)
- Shinya Yamanaka, "A Fresh Look at iPS Cells," *Cell* 137 (April 3, 2009): 13-17.

- George Q. Daley, "The Promise and Perils of Stem Cell Therapeutics," *Cell Stem Cell* 10 (June 14, 2012): 740-749.
- Johnson and Williams, "Stem Cell Research: Federal Research Funding and Oversight," Congressional Research Service Report (2007)
- "Stem Cell Policy in the Age of Obama: Texas, U.S. and U.K. Perspectives," Sept 2009 Conference Report (James A. Baker III Institute for Public Policy, Rice University)
- Joel W. Adelson and Joanna Weinberg, "The California Stem Cell Initiative: Persuasion, Politics, and Public Science," *American Journal of Public Health* 100 (March 2010): 446-451.

Genetics and America's Future

- Margaret Hamburg and Francis Collins, "The Path to Personalized Medicine," *New England Journal of Medicine* (July 2010)
- Amy Harmon, "Seeking Ancestry, and Privilege in DNA Ties Uncovered by Tests," *New York Times*, April 12, 2006.

Session 11. December 2 – Epigenetics: The Policy Implications of an Emerging Field

Goals: Is there more to inheritance than DNA alone, as the rapidly growing field of epigenetics suggests? How do mechanisms other than changes in DNA sequence (environmental toxins, consumer products, and other agents) produce heritable alterations in gene expression? What are the implications of this field for policy? Discuss what epigenetics theories could mean for ideas about personal responsibility, the management of disease susceptibility, health disparities, reproductive health policy, obesity, and a wide range of other policy domains.

Required Readings:

- Mark Rothstein and Gary Marchant, "The Ghost in Our Genes: Legal and Ethical Implications of Epigenetics," *Health Matrix* 19 (2009): 1-62
- "In the Womb's Shadow," Nicoletto and Rinaldi, *European Molecular Biology Organization (EMBO)*, 2011.
- Mihai D. Niculescu, MD, PhD "Epigenetic transgenerational inheritance: Should obesity- prevention policies be reconsidered?" *Synesis: Journal of Science, Technology, Ethics, and Policy* (2011)
- John A. McLachlan Commentary: Prenatal exposure to diethylstilbestrol (DES): a continuing story *Int. J. Epidemiology* 35, 868-70 (2006)

Optional readings:

- Randy Jirtle and Michael Skinner, “Environmental Epigenomics and Disease Susceptibility,” *Nature Reviews Genetics* (April 2007)
- Robert Feil and Mario Fraga, “Epigenetics and the Environment: Emerging Patterns and Implications,” *Nature Reviews Genetics* 13 (February 2012): 97-109.
- Kuzawa and Sweet, “Epigenetics and the Embodiment of Race: Developmental Origins of US Racial Disparities in Cardiovascular Health,” *American J. Human Biology* (2009)

Session 12. December 10 – **Emerging Challenges in Genetics and Public Policy**

Goals: Over the course of the semester, new findings on genetics will emerge stirring discussions about their policy implications. New legislation, regulations, or court decisions relating to genetics will be announced, new public policy discussions on the topics we have discussed (from criminal justice to privacy and FDA policy, and from patenting to gene therapy and epigenetics) will arise, and new research on genetics and public policy will appear. This final session will focus on analyzing a selection of these emerging issues at the intersection of genetics and public policy.

Reading and Discussion (to be selected from the following list):

- To be assigned the previous week.

Optional reading

- To be assigned the previous week.

Additional Resources

A Brief Primer on Genetic Testing, Francis S. Collins, M.D., Ph.D. (Then Director, National Human Genome Research Institute. January 24, 2003 to World Economic Forum)

<http://www.genome.gov/10506784>

Current state-by-state policies on DNA collection from convicted felons and DNA collection from arrestees. <http://www.propublica.org/article/where-states-stand-on-dna-collection-505>

Background Information: List of Federal Centers that Regulate Gene Therapy – from American Society for Gene and Cell Therapy website.

http://www.asgct.org/regulatory_issues/agencies.php

“Genome Statute and Legislative Database,” maintained by the National Human Genome Research Institute -- <http://www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm>

Bibliography

Alexandra Minna Stern, *Eugenic Nation*

Wendy Kline, *Building a Better Race: Gender, Sexuality, and Eugenics from the Turn of the Century to the Baby Boom*

Adbullah Kutlar, “Sickle Cell Disease: A multigenic perspective of a single gene disorder,” *Hematology* 2005: 92-99.

“One Step at a Time: Ethical Barriers... Home Genetic Testing,” *Legislation and Public Policy*, 2008

Sam Baker, “Burgess Hopes to Block FDA from Regulating Genetic Tests,” *The Hill* (November 2011)

Bloss, et. al., “Direct-to-consumer personalized genomic testing,” *Human Molecular Genetics* 20 (2011)

Mayo v. Prometheus Laboratories (U.S. Supreme Court Ruling, March 20, 2012)

“Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests,” Report of the Secretary’s [of Health and Human Services] Advisory Committee on Genetics, Health, and Society (April 2010)

Jennifer Reardon, *Race to the Finish*

Jonathan Kahn, *Race in a Bottle*

“*Regulatory Environment for Gene Transfer*,” Regulatory Brief from the Genetics and Public Policy Center