

IGA-515 - BIOETHICS, LAW AND THE LIFE SCIENCES
SPRING 2012 (T-TH 10:10 – 11:30)
TAUBMAN 301

INSTRUCTOR

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COURSE OVERVIEW

Developments in biotechnology and the life sciences have called into question the adequacy of existing policy approaches and instruments for dealing with reproduction, privacy, informed consent, health care, and intellectual property. Rapid changes in science and technology appear to be reconstituting concepts of the self and its boundaries, kinship, ownership, and legal rights and obligations of people in relation to their governing institutions. Through reading primary materials and relevant secondary sources, this course seeks to identify and explore salient ethical, legal, and policy issues—and possible solutions—associated with these developments.

REQUIRED BOOKS (available at the Harvard Coop)

Lori B. Andrews, Maxwell J. Mehlman, Mark A. Rothstein, *Genetics: Ethics, Law and Policy* (St. Paul: West Group, 2002) [**abbreviated below as GELP**]

RECOMMENDED AND OPTIONAL BOOKS (on reserve and for optional purchase)

Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: Princeton University Press, 2005).
Sheila Jasanoff, ed., *Reframing Rights: Bioconstitutionalism in the Genetic Age* (Cambridge, MA: MIT Press, 2011).
Richard Lewontin, *It Ain't Necessarily So*, 2nd edition (New York: New York Review of Books, 2000).
Michael Sandel, *The Case against Perfection: Ethics in the Age of Genetic Engineering* (Cambridge, MA: Harvard University Press, 2009 [2007])
Lee Silver, *Remaking Eden* (New York: Perennial, 2007 [1997])

ON-LINE READINGS (linked to syllabus)

**** Books and materials not available on line are available at the KSG library on short-term reserve and can be purchased as course packets.**

ASSIGNMENTS AND WEIGHTING

50% - Two 8-10 page papers submitted during the term (equally weighted).
25% - Two class presentations with 2-3 page response papers and leading discussion.
25% - Weekly 1-page response papers on the readings and class participation.

(A single paper option will be available to students with special permission from the instructor. Weekly response papers will be guided by questions provided by the instructor.)

PLEASE FAMILIARIZE YOURSELF WITH THE ACADEMIC INTEGRITY POLICY

COURSE SYLLABUS

0. OVERVIEW

0. January 24 Overview of Course

GELP, "Scientific Overview," 16-43.

I. FOUNDATIONS

1. January 26: Promises

B. J. Strasser, "Who Cares About the Double Helix," *Nature* 422: 803-804 (24 April 2003).

L. Silver, *Remaking Eden*, Ch. 1, "What is Life?" 17-26.

F. S. Collins, et al., "A vision for the future of genomics research," *Nature* 422:835 – 847. (24 April 2003) <http://www.nature.com/nature/journal/v422/n6934/pdf/nature01626.pdf>

H. Varmus, et al., "Grand Challenges in Global Health," *Science* 302:398-9 (2003).

<http://www.sciencemag.org/content/302/5644/398.full>

E. Kac, "Natural History of the Enigma," <http://www.ekac.org/nat.hist.enig.html> (browse).

J. Craig Venter on Synthetic Biology at NASA Ames, January 12, 2011, http://www.youtube.com/watch?v=KTzG_HIUu9c (55 minutes; skim).

2. January 31: Limits?

L. Silver, *Remaking Eden*, Prologue, 1-13.

F. Fukuyama, *Our Posthuman Future*, Ch. 5, "Genetic Engineering," 72-83.

G. Annas, "Mapping the Human Genome and the Meaning of Monster Mythology," *Emory Law Journal* 39(3) (1990), 629-664,

<http://heinonline.org/HOL/LandingPage?collection=journals&handle=hein.journals/emlj39&div=31&id=&page=> [available via Hollis]

R. Kwok, "Five Hard Truths for Synthetic Biology," *Nature*, January 20, 2010,

<http://www.nature.com/news/2010/100120/full/463288a.html>

W. Broad, "Science and Censorship: A Duel Lasting Centuries," *New York Times*, December 26, 2011,

<http://www.nytimes.com/2011/12/27/science/science-and-censorship-a-duel-lasting-centuries.html?ref=williamjbroad>

Optional

P. Rabinow, "Getting to Know You," *Nature Biotechnology* 20:545-546 (June 2002).

3. February 2: Biopower and Bioconstitutionalism

M. Foucault, *The History of Sexuality*, Vol. 1 (New York: Vintage, 1990 [1976]), ("Biopower"), 135-145.

P. Rabinow, "Artificiality and Enlightenment: From Sociobiology to Biosociality," in Jonathan Crary, ed., *Zone 6: Incorporations* (Cambridge, Mass.: MIT, 1992), 234-252.

N. Rose, *The Politics of Life Itself* (Princeton: Princeton University Press, 2007), Ch. 5, "Biological Citizens," 130-154.

S. Jasanoff, "Introduction: Rewriting Life, Reframing Rights," in Jasanoff, ed., *Reframing Rights*, 1-9.

D. Grady, "A Lasting Gift to Medicine That Wasn't Really a Gift," *New York Times*, February 1, 2010,

<http://www.nytimes.com/2010/02/02/health/02seco.html>

A. Harmon, "Indian Tribe Wins Fight to Limit Research of Its DNA," *New York Times*, April 21, 2010,

<http://www.nytimes.com/2010/04/22/us/22dna.html?scp=2&sq=arizona%20state%20havasupai&st=ce>

4. February 7: Institutional Bioethics

GELP, 83-84.

P. Singer, "Moral Experts," *Writings on an Ethical Life* (New York: Harper Collins, 2000), 3-6.

E. W. Clayton, "Ethical, Legal, and Social Implications of Genomic Medicine," *New England Journal of Medicine* 349:562-9 (2003), <http://content.nejm.org/cgi/reprint/349/6/562.pdf>.

J. Evans, "Between Technocracy and Democratic Legitimation: A Proposed Compromise Position for Common Morality Public Bioethics," *Journal of Medicine and Philosophy* 31(3): 213-234 (2006).

President's Commission for the Study of Bioethical Issues, *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*, Executive Summary, 1-18, available at <http://bioethics.gov/cms/synthetic-biology-report>

II. CONSTITUTING THE GENETIC HUMAN

5. **February 9: Eugenics**

GELP, "Eugenics", 40-84, esp. *Buck v. Bell*, *Skinner v. Oklahoma*.

Look at image archive on the American Eugenics Movement, posted by the Cold Spring Harbor Laboratory, available at <http://www.eugenicsarchive.org/eugenics/>

A. Wellerstein, "States of Eugenics: Institutions and Practices of Compulsory Sterilization in California," in Jasanoff, ed., *Reframing Rights*, 29-58.

6. **February 14: Ontological Politics**

GELP, 872-876.

A. Lakoff, *Pharmaceutical Reason: Knowledge and Value in Global Psychiatry* (Cambridge: Cambridge University Press, 2005), Ch. 6, "The Segmented Phenotype," 160-177.

S. Jasanoff, "In the Democracies of DNA: Ontological Uncertainty and Political Order in Three States," *New Genetics and Society* 24(2):139-155 (2005).

A. Berenson, "Drug Approved. Is Disease Real?" *New York Times*, January 14, 2008,

<http://www.nytimes.com/2008/01/14/health/14pain.html?em&ex=1200718800&en=7a8c3b486fb1f949&ei=5087%0A>

7. **February 16: Genetics and the Family: Assisted Reproduction**

GELP 586-588, 627-636, *Buzanca*

C. Thompson, *Making Parents: The Ontological Choreography of Reproductive Technologies* (Cambridge, MA: MIT Press, 2005), Ch. 4, "Is Man to Father as Woman Is to Mother?" 117-143.

S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: Princeton University Press, 2005), Ch. 6, "Natural Mothers and Other Kinds," 146-170.

J. Mroz, "One Sperm Donor, 150 Offspring," *New York Times*, September 5, 2011,

<http://www.nytimes.com/2011/09/06/health/06donor.html?scp=1&sq=sperm%20donor&st=cse>

8. **February 21: Genetic Enhancement: Clones and Designer Babies**

L. Silver, *Remaking Eden*, Ch. 18, "The Designer Child," 266-280.

A. Buchanan et al., *From Chance to Choice: Genetics and Justice* (Cambridge: Cambridge University Press, 2000), Ch. 5, "Why Not the Best?," 156-203.

M.J. Sandel, "The Case against Perfection," *Atlantic*, April 2004: 51-62,

<http://www.theatlantic.com/doc/200404/sandel>

9. **February 23: Genes and Sexuality**

I. Hacking, Ch. 5, "Kind-making: The Case of Child Abuse," in *The Social Construction of What?* (Cambridge, MA: Harvard University Press, 1999), 125-162.

Bowers v. Hardwick (U.S. 1986), [edited version],

<http://caselaw.lp.findlaw.com/scripts/getcase.pl?court=US&vol=478&invol=186>

Lawrence v. Texas (U.S. 2002), <http://www.law.cornell.edu/supct/html/02-102.ZS.html>

10. **February 28: Genes and Behavior**

GELP, 713-734 (esp. cases), 752-756 (Genetic Exceptionalism)

R. Lewontin, Ch. 2, "All in the Genes?" in *Biology as Ideology: The Doctrine of DNA* (New York: Perennial, 1991), 17-38.

G.E. Allen, "Modern Biological Determinism: The Violence Initiative," in M. Fortun and E. Mendelsohn, eds., *The Practices of Human Genetics* (Dordrecht: Kluwer, 1999), 1-23.

N. Wade, "Genes Play Major Role in Primate Social Behavior, Study Finds," *New York Times*, December 19, 2011, <http://www.nytimes.com/2011/12/20/science/genes-play-major-role-in-primate-social-behavior-study-finds.html?scp=1&sq=genes%20behavior&st=cse>

S. Jasanoff, "DNA's Identity Crisis," in D. Lazer, ed., *DNA and the Criminal Justice System* (Cambridge: MIT Press, 2004), 337-355.

11. **March 1: Genes and Human Diversity**

HapMap Project Web Sites:

International HapMap Homepage, <http://www.hapmap.org/>

- NIH HapMap page, <http://www.genome.gov/page.cfm?pageID=10001688>
- J. Couzin, "New mapping project splits community," *Science* 296:1391-1392 (2002), available at http://biosci.usc.edu/courses/2002-fall/documents/bisc403-nordborg_HapMap.pdf
- A. Stockdale and S. F. Terry, "Advocacy Groups and the New Genetics," Ch. 4, in J. S. Alper, et al, *The Double-Edged Helix: Social Implications of Genetics in A Diverse Society* (Baltimore: Johns Hopkins University Press, 2002), 80-101.
- J.E. Reardon, "The Human Genome Diversity Project: A Case Study in Co-Production," *Social Studies of Science* 31:357-388 (2001).

III. RIGHTS AND INTRUSIONS

12. March 6: Rights to Life: Abortion, Embryos, Stem Cells

GELP 161-182.

S. Jasanoff, "Making the Facts of Life," in Jasanoff, ed., *Reframing Rights*, 59-83.

Roe v. Wade, <http://www.foxnews.com/projects/pdf/roevwade.pdf>

Planned Parenthood v. Casey,

<http://www.law.cornell.edu/supct/html/91-744.ZO.html>

Quintavalle v. Human Fertilisation and Embryology Authority [2002] EWCA Civ 667 (UK),

www.hfea.gov.uk/docs/ELC_CA_Judgement_June04.pdf

13. March 8: Testing, Screening, Stigmatizing

GELP 371-374 (newborn screening), 412-426 (predictive testing and counseling), 749-752 (medical privacy), 783-788 (insurance), 849-863 (employment).

D. Beeson, T. Duster, "African-American Perspectives on Genetic Testing," Ch. 7, in J. S. Alper, et al, *The Double-Edged Helix: Social Implications of Genetics in A Diverse Society* (Baltimore: Johns Hopkins University Press, 2002), 151-174.

J. Couzin, "The Twists and Turns in BRCA's Path," *Science*, 302:591-93 (24 October 2003).

S. Parthasarathy, "Regulating Risk: Defining Genetic Privacy in the US and Britain," *Science, Technology, and Human Values* 9(3):332-352 (2004).

[Spring Break: March 13 and 15]

14. March 20: Our Genes, Our Selves?

GELP 267-293, esp. *Moore v. Regents of the University of California*.

J. Boyle, Ch. 9, "Spleens," in *Shamans, Software and Spleens* (Cambridge, MA: Harvard University Press, 1996).

H. Landecker, "Between Beneficence and Chattel: The Human Biological in Law and Science," *Science in Context* 12:203-225 (1999).

R. Skloot, "Taking the Least of You," *New York Times Magazine*, April 16, 2006,

<http://www.nytimes.com/2006/04/16/magazine/16tissue.html>

M. Crichton, "Bodysnatchers 2006," *Wall Street Journal*, December 2006,

<http://www.michaelcrichton.net/essay-wsj-bodysnatchers.html>

D. Caruso, "Someone (Other Than You) May Own Your Genes," *New York Times*, January 28, 2007,

http://www.nytimes.com/2007/01/28/business/yourmoney/28reframe.html?_r=1&scp=1&sq=hilgartner&oref=slogin

15. March 22: Genetic Surveillance and Criminal Law

GELP, 662-712.

Browse The Innocence Project website, <http://www.innocenceproject.org/>.

B. Steinhardt, "Privacy and Forensic DNA Data Banks," in Lazer, ed., *DNA and the Criminal Justice System*, 173-196.

S. Jasanoff, "Just Evidence: The Limits of Science in the Legal Process," *Journal of Law, Medicine & Ethics* 34(2):328-341(2006).

J. D. Aronson, "Certainty vs. Finality: Constitutional Rights to Postconviction DNA Testing," in Jasanoff, ed., *Reframing Rights*, 125-146.

Optional: *District Attorney v. Osborne*, -- US -- (2009) [available as pdf].

**** [1st paper due in class: 8-10 pages] ****

IV. MONEY, MARKETS, PROPERTY

16. March 27: Visions of Progress

S. Jasanoff, *Designs on Nature*, Ch. 9, "The New Social Contract," 225-246.

V. Rabeharisoa and M. Callon, "The involvement of patients in research activities supported by the French Muscular Dystrophy Association," in S. Jasanoff, ed., *States of Knowledge: The Co-Production of Science and Social Order* (London: Routledge, 2004), 234-253.

HFEA Policy Statement on Eggs for Research, February 2007, <http://www.hfea.gov.uk/471.html>

National Bioethics Advisory Commission, Ethical and Policy Issues in Research Involving Human Participants, Appendix C, 151-16 <http://bioethics.georgetown.edu/nbac/human/overvoll.pdf>

17. March 29: Science and (Private) Money

GELP 233-236, 263-269.

E. Press and J. Washburn, "The Kept University," *Atlantic Monthly* (March 2000):39-54,

S. Krinsky, "Conflict of Interest Policies in Science and Medical Journals: Editorial Practices and Author Disclosures" (with L.S. Rothenberg). *Science and Engineering Ethics* 7 (April 2001): 205-218, available at <http://www.tufts.edu/~skrimsky/PDF/conflict.PDF>

W. Lepkowski, "Biotech's OK Corral," *Science and Policy Perspectives* 13 (9 July 2002), <http://www.cspo.org/ourlibrary/documents/060902.html>

J. Couzin-Frankel, "Penn Institute Sues Prominent Researcher Over Discoveries, Seeking \$1 Billion," *Science*, December 29, 2011, <http://news.sciencemag.org/scienceinsider/2011/12/penn-institute-sues-prominent.html>

R. Pear, "U.S. to Force Drug Firms to Report Money Paid to Doctors," *New York Times*, January 16, 2012, http://www.nytimes.com/2012/01/17/health/policy/us-to-tell-drug-makers-to-disclose-payments-to-doctors.html?_r=1&hp

18. April 3: Patenting Life

GELP 202-233, esp. *Diamond v. Chakrabarty*, *Amgen v. Chugai*, *Madey v. Duke University*

S. Jasanoff, *Designs on Nature*, Ch. 8, "Making Something of Life," 203-224.

President and Fellows of Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45, available at <http://reports.fja.gc.ca/eng/2000/2000fc27094.html>

M. Crichton, "This Essay Breaks the Law," *New York Times*, March 19, 2006,

<http://www.michaelcrichton.net/essay-nytimes-thisessaybreaksthelaw.html>

Association for Molecular Pathology et al. v. USPTO and Myriad Genetics, USCA Federal Circuit, July 29, 2011.

ACLU, Petition for Writ of Certiorari, *Association for Molecular Pathology et al. v. USPTO and Myriad Genetics*, December 7, 2011.

19. April 5: Intellectual Property and Technology Transfer

P. Rabinow, *Making PCR: A Story of Biotechnology* (Chicago: University of Chicago Press, 1996), 19-45.

A. Rai, R. Eisenberg, "Bayh-Dole Reform and the Progress of Biomedicine," *Law and Contemporary Problems* 66 (2003):289-314,

<http://www.law.duke.edu/journals/lcp/downloads/LCP66DWinterSpring2003P289.pdf>

J. Kaiser, "Court Decides Tissue Samples Belong to University, Not Patients," *Science* 312(5772):346 (April 21, 2006), <http://www.sciencemag.org/cgi/content/full/312/5772/346>; see Court Order at

<http://www.whoownsyourbody.org/catalona.html>

Washington University v. Catalona, 490 F. 3d 667 (8 Cir. 2007),

http://scholar.google.com/scholar_case?case=7283524957057325487&hl=en&as_sdt=2&as_vis=1&oi=scholar

20. April 10: Biobanks: Uses and Abuses

GELP, 706-712, *Mayfield*.

H. Rose, *The commodification of bioinformation: the Icelandic Health Sector Database*. London: Wellcome Trust (2001), available at

http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/WT_D003281.pdf

J. Kaiser, "Population Databases Boom, From Iceland to the US," *Science* 298 (2002):1158-61, available at

http://www.genomics.ee/files/artiklid/science_08_11_02.pdf

- Harvard Law Review, "Comparative Law – Genetic Privacy – Icelandic Supreme Court Holds That Inclusion of an Individual's Genetic Information in a National Database Infringes on the Privacy Interests of his Child – *Guðmundsdóttir v. Iceland*, No. 151/2003 (Nov. 27, 2003) (Ice.), <http://www.jstor.org.ezp-prod1.hul.harvard.edu/stable/pdfplus/4093398.pdf?acceptTC=true>
- D. Winickoff, R. Winickoff, "The Charitable Trust Model for Genomic Biobanks," *New England Journal of Medicine* 349 (18 Sept. 2003):1180-4, available at <http://content.nejm.org/cgi/reprint/349/12/1180.pdf>
- K. Saha and J.B. Hurlbut, "Research ethics: Treat donors as partners in biobank research," *Nature*, October 20, 2011, <http://www.nature.com/nature/journal/v478/n7369/full/478312a.html>

V. BIOTECH AND GLOBAL GOVERNANCE

21. April 12: Agricultural Biotechnology: Northern Controversies

- J. Lassen, et al., "Testing times – the reception of Roundup Ready Soya in Europe," Ch. 10 in M.W. Bauer and G. Gaskell, eds., *Biotechnology: The Making of a Global Controversy* (Cambridge: Cambridge University Press, 2002), 279-312.
- S. Jasanoff, *Designs on Nature*, Ch. 4, "Unsettled Settlements," 94-118
- R. Doubleday and B. Wynne, "Despotism and Democracy in the United Kingdom: Experiments in Reframing Citizenship," in Jasanoff, ed., *Reframing Rights*, 239-261.
- Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, available at <http://scc.lexum.org/en/2004/2004scc34/2004scc34.html>

22. April 17: Biotechnology and The Politics of Development

- S. Jasanoff, "Biotechnology and Empire: The Global Power of Seeds and Science," *Osiris* 21(1):273-292 (2006).
- D.L. Kleinman, *Science and Technology in Society* (Malden: Blackwell, 2005), Ch. 2, "Ceding Debate: Biotechnology and Agriculture," 15-33.
- R. Paarlberg, *Starved for Science: How Biotechnology Is Being Kept out of Africa* (Cambridge, MA: Harvard University Press, 2008), Conclusion, "An Imperialism of Rich Tastes," 179-196.
- I. Scoones and D. Glover, "Africa's Biotechnology Battle," *Nature* 460 (2009):797-798.

24. April 19: Pharmaceuticals and Global Governance

- Commission on Intellectual Property Rights (UK), *Integrating Intellectual Property Rights and Development Policy* (September 2002), http://www.iprcommission.org/graphic/documents/final_report.htm; see Ch. 6, "Patent Reform," 111-136; Ch. 8, "International Architecture," 155-170.
- Patently Ambitious: The Global Ambitions of India's Biggest Drug Firms*, *The Economist* (6 September 2003):56.
- A. Gentleman, "Setback for Novartis in India over Drug Patent," *New York Times*, August 7, 2007, <http://www.nytimes.com/2007/08/07/business/worldbusiness/07drug.html?scp=2&sq=glivec+patent>
- K. Sunder Rajan, "Two Tales of Genomics: Capital, Epistemology, and Global Constitutions of the Biomedical Subject," in Jasanoff, ed., *Reframing Rights*, 193-216.

25. April 24: Genomic Populations: Difference and Control

- J. Reardon, "Human Population Genomics and the Dilemma of Difference," in Jasanoff, ed. *Reframing Rights*, 217-238.
- Indigenous Peoples Council on Biocolonialism, *Indigenous Research Protection Act*, at <http://www.ipcb.org/publications/policy/files/irpa.html>
- J. Pomfret and D. Nelson, "In Rural China, a Genetic Mother Lode," *Washington Post*, December 20, 2000, A01, <http://www.washingtonpost.com/wp-dyn/content/article/2008/10/01/AR2008100101158.html>
- Universal Declaration on the Human Genome and Human Rights, 1997, http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html
- Council of Europe, Protection of the human genome, Recommendation 1512 (2001)[1], <http://assembly.coe.int/Documents/AdoptedText/ta01/EREC1512.htm>