

PUBPOL 759: GENETICS AND BIOTECHNOLOGY POLICY

**Tuesdays and Thursdays, 10-11:30AM, Winter 2006
2232 School of Education Building; 3 credit course**

Instructor:

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In one of the hottest areas of scientific and technological development today, genetics and biotechnology are raising a variety of difficult and controversial policy questions. Should the Americans with Disabilities Act be extended to include individuals with genetic conditions? Do the President and Congress have the power to decide whether or not stem cell research, an area of investigation that angers those who believe that life begins at conception, should be conducted? Should genes and stem cells be treated like any other type of intellectual property under the law? Do the World Trade Organization and other international governing bodies need to change their trade policies to accommodate the environmental, economic, health, and social concerns of countries with regard to genetically modified organisms? Who should make decisions about how this new science and technology should be built? How should these decisions be made? Not only do laws and regulatory frameworks need to be devised to promote this area of innovation and regulate the technologies that are developed, but the new powers that this science and technology allow—to peer into human genomes and predict future disease and behavior and manipulate the genomes of humans, plants, and animals, among others things—will require action from policymakers far beyond those who monitor the activities of the laboratory and the clinic.

In this course, we will explore how genetics and biotechnology are raising new political and policy challenges as they challenge our understandings of our bodies, our health, our pasts and futures, and even our social and political orders, discuss the laws and regulatory frameworks that have already been developed to deal with this new area of research and technology, and learn analytic tools that will help us assess and regulate new research and innovation. It aims to accomplish the following things:

- Introduce the major issues of controversy in genetics and biotechnology;
- Introduce the major stakeholders in the politics of genetics and biotechnology;
- Explore and assess the laws and regulatory frameworks that have been developed to deal with the new science and technology;
- Investigate the mechanisms for public participation in science and technology that have been devised to deal with these issues; and
- Provide tools to assess new developments and articulate policy positions to influence directions of research and innovation.

This course is designed for graduate students from public policy, public health, and the social, biological, and physical sciences. Topics include: politics, religion, and stem cell research; international development and genetically modified organisms; the politics of race and pharmacogenetics; implications for medical and health policy; the history of biotechnology policy; the ownership of genes and stem cells; public hype and excitement over the new science and technology; discrimination in insurance and employment; the creation of national DNA databanks; and genetics and biotechnology policy in comparative and international perspective. Students will be asked to

prepare short policy memos, actively participate in classroom discussions and debates, and prepare a term paper on a topic of their choice.

Course Requirements

1. Regular class attendance, participation, and preparation—*i.e.*, doing the readings and being ready to talk about them. Because this is a discussion-intensive course, students are expected to keep up with weekly readings and come to class each week prepared with questions and topics for discussion. **Both attendance and participation are mandatory and will be important parts of your final grade.** If I find that students are not attending *and* participating, I will ask you to prepare summaries of the readings or presentations for the class. You should also make an effort to pay attention to current news in genetics and biotechnology. In order to do this, you can read popular journals such as Scientific American (www.scientificamerican.com). Check out The New York Times (<http://www.nytimes.com>) Science Times section, which runs every Tuesday. (20%)
2. Two short policy memos on topics to be assigned. The second will be part of a policy exercise which I will discuss in further detail as the semester progresses. (30%)
3. One term paper (approx. 15-20 pp.) on the topic of your choice, analyzing a particular issue in genetics and biotechnology. A proposal of the paper will be due early in the semester, with the paper due the end of the course. (45%)
4. A proposal for your term paper (approx. 1 page) describing the subject you have chosen and how you plan to analyze it (including the kind of research you plan to do to support your analysis). (5%)

Course Readings:

Please do all the required readings before you come to class. There is a lot of reading, but the rest of the course workload isn't heavy, so the readings should be manageable. Class discussions won't work if you don't read. I have also spent considerable time ensuring that the readings are both informative and interesting, so hopefully you won't mind the work! The readings include books and articles as well as primary documents from participants in the politics of genetics and biotechnology.

Books:

Troy Duster (2003). *Backdoor to Eugenics*. New York: Routledge.

Susan Wright (1994). *Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982*. Chicago, IL: University of Chicago Press, 1994.

David Magnus, Arthur L. Caplan, Glenn McGee (2002). *Who Owns Life?* New York: Prometheus Books.

Bill Lambrecht (2001). *Dinner at the New Gene Café: How Genetic Engineering is Changing What We Eat, How We Live, and the Global Politics of Food*. New York: Thomas Dunne Books.

National Research Council (2004). *Biotechnology Research in an Age of Terrorism: Confronting the 'Fual' Use Dilemma*. Washington, DC: National Academy Press.

CTools:

A number of articles (the majority that will be used in the course) are available for download via CTools.

Course Reader:

A course reader is also available for purchase that includes book chapters that we will be reading in the course.

All of the course readings will be available on reserve at Foster Library (in Lorch Hall).

January 10th: Genetics and Biotechnology: Introduction to the Science and Politics

No reading required.

January 12th: The Rise of Genetics and Biotechnology: Genetic Hope and Hype

WATCH *GATTACA*.

Nelkin, Dorothy and Susan Lindee (2004). *The DNA Mystique*. Ch. 8 (course reader)

Condit, Celeste (2004). "What is 'public opinion' about genetics?" *Nature Reviews Genetics*. 2: 811-815. (CTools)

Duster, Troy. *Backdoor to Eugenics*. Ch. 6. (text)

Kirby, D.A. (2000) "The New Eugenics in Cinema: Genetic Determinism and Gene Therapy in *GATTACA*," *Science Fiction Studies*, 27(2): 193-215. (CTools)

January 17th: Our Eugenic Past and Our Genetic Future

Paul, Diane. *Controlling Human Heredity*, Ch. 1. (course reader)

Court Opinion: *Buck v. Bell* (1927). (course reader)

Duster, Troy. *Backdoor to Eugenics*. Chs. 1 and 2. (text)

January 19th: The Rise of Genetics and Biotechnology: The Promise of Economic Growth

Wright, Susan (1994). *Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982*. Chicago, IL: University of Chicago Press. Skim Chapter 1 and read Chapter 2. (text)

Magnus, David, Arthur L. Caplan, Glenn McGee (2002). *Who Owns Life?* New York: Prometheus Books. Chapter 9. (text)

January 24th: Keep the public out of science: The recombinant DNA controversy

Wright, Susan (1994). *Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982*. Chicago, IL: University of Chicago Press. Ch. 3 (text)

Dickson, David (1993). *The New Politics of Science*. Chicago, IL: University of Chicago Press. Chs. 5, 7. (course reader)

January 26th: Genetic Testing: Divining Our Futures—Risk, Disease, and Identity

Duster, Troy. *Backdoor to Eugenics*. Chs. 3 and 4. (text)

Lock, Margaret (1998). "Breast Cancer: Reading the Omens." *Anthropology Today*. 14.4:7-16. (CTools)

Lerner, Barron (1999). "Great expectations: historical perspectives on genetic breast cancer testing." *American Journal of Public Health*. 89.6: 938-944. (CTools)

Shakespeare, Tom (2003). "Disability, Human Rights, and Contemporary Genetics." *Encyclopedia of the Human Genome*. 1-3. (CTools)

January 31st: Genetic Testing: Discrimination in Insurance and Employment on the Basis of Genetic Information

Billings, Paul R. (2005). "Genetic nondiscrimination." *Nature Genetics*. 37.6: 559-560. (CTools)

Miller, PS. "Is there a pink slip in my gene? Genetic discrimination in the workplace." *Journal of Health Care Law and Policy*. 3(2): 225-65. (CTools)

Jeffords, James M. and Tom Daschle (2001). "Political Issues in the Genome Era." *Science*. 291.5507: 1249-1251. (CTools)

* Hall, Mark A. and Stephen S. Rich (2000). "Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination." *American Journal of Human Genetics*. 66: 293-307. (CTools)

February 2nd: Genetic Testing: How Should We Regulate New Technologies?

Guston, David H. and Daniel Sarewitz. (2002). "Real-time technology assessment." *Technology in Society*. 24: 93-109. (CTools)

Holtzman, Neil and D. Shapiro. "Genetics Testing and Public Policy." *British Medical Journal*. Vol. 316: 852-6. (CTools)

Holtzman, Neil A. (1999). "Promoting Safe and Effective Genetic Tests in the United States: Work of the Task Force on Genetic Testing." *Clinical Chemistry*. 45.5: 732-738. (CTools)

Parthasarathy, Shobita (2005). "Architectures of Genetic Medicine: Comparing the Development of Genetic Testing for Breast Cancer in the USA and UK." *Social Studies of Science*. (CTools)

February 7th: Navigating the Stem Cell Debate: Destabilizing the Beginning of Life

Holm, Soren. (2002), "Going to the Roots of the Stem Cell Controversy." *Bioethics*, Vol. 16, pp. 493-507. (CTools)

Gottweis, Herbert (2002). "Stem Cell Policies in the US and in Germany: Between Bioethics and Regulation." *Policy Studies Journal*. 30(4): 444-69. (CTools)

Lopez, Kathryn Jean (2001). "The Truth About Stem Cells." *National Review Online*. February 26, 2001. (CTools)

Doerflinger, Richard M. (1999). "The Ethics of Funding Embryonic Stem Cell Research: A Catholic Viewpoint." *Kennedy Institute of Ethics Journal*. 9.2: 137-150. (CTools)

McGee, Glenn and Arthur Caplan (1999). "The Ethics and Politics of Small Sacrifices in Stem Cell Research." *Kennedy Institute of Ethics Journal*. 9.2: 151-158. (CTools)

Vogel, Gretchen (2001). "Bush Squeezes Between the Lines on Stem Cells." *Science*. 293: 1242-5. (CTools)

Holden, Constance (2001). "HHS Inks Cell Deal; NAS Calls for More Lines." *Science*. 293(5537): 1966-1967. (CTools)

Holden, Constance (2001). "NIH's List of 64 Leaves Questions." *Science*. 293: 1567. (CTools)

Michael J. Fox Foundation (2001). "Bush Unveils Tentative Policy on Embryonic Stem Cell Research." Policy Statement. August 9, 2001. (CTools)

February 9th: Navigating the Stem Cell Debate: Understanding the Political Debate and the Role of Bioethics Committees

* Kelly, Susan E. (2003). "Public Bioethics and Publics: Consensus, Boundaries, and Participation in Biomedical Science Policy." *Science, Technology, and Human Values*. 28.3: 339-364. (CTools)

Charo, R.A. (2004). "Passing on the Right: Conservative Bioethics is Closer Than It Appears." *Journal of Law, Medicine, and Ethics*. 32.2: 307-320. (CTools)

President's Council on Bioethics (2004). *Monitoring Stem Cell Research*. Washington, DC: GPO. Selections. (CTools)

National Bioethics Advisory Commission (1999). *Ethical Issues in Human Stem Cell Research*. Washington, DC: GPO. Executive Summary. (CTools)

February 14th: Navigating the Stem Cell Debate: Science by State Initiative

Sarewitz, Daniel. (2004). "Stepping Out of Line in Stem Cell Research; Proposition 71 would cut the link between science and democracy." *Los Angeles Times*, p. B11. (CTools)

Holden, Constance. (2005) "U.S. States Offer Asia Stiff Competition." *Science*. 307:662-663. (CTools)

Holden, Constance (2004) "California's Proposition 71 launches stem cell gold rush" *Science*. 306: 1111. (CTools)

Perry, Daniel (2000) "Patients' Voices: The Powerful sound in the Stem Cell Debate." *Science*. 287: 1423. (CTools)

Knight, Jonathan (2004) "Critics slate ethical leeway in California stem-cell proposal." *Nature*. 431: 232. (CTools)

Aldhous, Peter (2005) "After the gold rush." *Nature*. 434: 694-696. (CTools)

*Articles from *The Michigan Daily* and the *University Record*. (course reader)

February 16th: Navigating the Stem Cell Debate: Shaping the Directions of Science

Kolata, Gina (2005). "Embryonic Cells, No Embryo Needed: Hunting for Ways Out of an Impasse." The New York Times. October 11, 2005. (CTools)

Fukuyama, Francis (2002). "How to Regulate Science." *The Public Interest*. 146: 3-22. (CTools)

Vogel, Gretchen (2005). "Deriving 'Controversy-Free' ES Cells is Controversial." *Science*. 310: 416-7. (CTools)

Guston, David (2004). "Forget Politicizing Science, Let's Democratize Science!" *Issues in Science and Technology*. pp. 25-28. (CTools)

February 21st: Patenting genes and biotechnology: Can Life Be Owned?

Court Opinion: *Diamond v. Chakrabarty* (1980) (course reader)

Court Opinion: *Moore v. Regents of CA* (1990) (course reader)

Magnus, David, Arthur L. Caplan, Glenn McGee. *Who Owns Life?* New York: Prometheus Books, 2002. Chapters 1, 2, 6. (text)

February 23rd: Patenting genes and biotechnology: Is it stifling innovation?

POLICY MEMO DUE

Magnus, David, Arthur L. Caplan, Glenn McGee (2002). *Who Owns Life?* New York: Prometheus Books. Chapter 12. (text)

Bobrow, Martin and Sandy Thomas (2001). "Patents in a Genetic Age." *Nature*. 409: 763-764. (CTools)

Thomas, Sandy et al. (2002). "Shares in the human genome—the future of patenting DNA." *Nature Biotechnology*. 20: 1185-1188. (CTools)

Rai, Arti K. (2005). "Open and Collaborative Research: A New Model for Biomedicine." In Hahn, Robert, Eds. *Intellectual Property Rights in Frontier Industries: Software and Biotech*. AEI-Brookings Press (CTools).

March 7th: Advocacy Groups Shaping Genetics Research

Merz, Jon (2002). "Discoveries: are there limits on what may be patented?" in *Who Owns Life?* David Magnus, Arthur Caplan, and Glenn McGee, eds. Amherst, NY: Prometheus Press. Chapter 5. (text)

Marshall, Eliot (2004). "Patient Advocate Named Co-Inventor On Patent for the PXE Disease Gene." *Science*. 305: 1226. (CTools)

Hall, Carl T. (2005). "The \$3 Billion Bet." *San Francisco Chronicle*. April 11, 2005. (CTools)

Rabeharisoa, Vololona and Michel Callon (2002). "The involvement of patients' associations in research." *International Social Science Journal*. 54.171: 57-63. (CTools)

March 9th: Biobanks and Genetic Databases: Who Should Consent to Genetic Research?

- Santos, Ricardo Ventura (2002). "Indigenous Peoples, Postcolonial Contexts and Genomic Research in the Late 20th Century: A View from Amazonia (1960-2000)." *Critique of Anthropology*. 22: 81-104. (CTools)
- Dodson, M. and R. Williamson (1999). "Indigenous peoples and the morality of the Human Genome Diversity Project." *Journal of Medical Ethics* 25(2): 204-208. (CTools)
- The International HapMap Consortium (2004). "Integrating ethics and science in the International HapMap Project." *Nature Reviews Genetics*. 5: 467-475. (CTools)
- Resnick, DB (1999). "The Human Genome Diversity Project: Ethical Problems and Solutions." *Politics and the Life Sciences*. 18(1): 15-23. (CTools)

March 14th: Biobanks and Genetic Databases: Privacy and Civil Liberties

PAPER PROPOSAL DUE

- *Shelton v. Ann Arbor Police Department (1995). Vol. 95—1994 NZ (Mich. Cir. Ct. Washtenaw County.) (course reader)
- *Leonard, J. (2001). "Using DNA to trawl for killers." *Los Angeles Times*. (CTools)
- Kaye, D. (2000). "Bioethics, Bench, and Bar; Selected arguments in Landry v. Attorney General." *Jurimetrics*. 40: 193-219. (CTools)
- Willing, R. (2003). "LA case triggers battle over DNA." *USA Today*. (CTools)
- *Brown, J. (2001). "Oklahoma police begin unusual DNA dragnet, privacy concerns raised." *Kansas City Star*. (CTools)
- Cho, Mildred K. and Pamela Sankar (2004). "Forensic genetics and ethical, legal and social implications beyond the clinic." *Nature Genetics*. 36(11): S8-S12. (CTools)
- Simoncelli, Tania (2005). Background and Analysis of the "DNA Fingerprint Act of 2005." (CTools)
- Simoncelli, Tania (2004). "Retreating Justice." *GeneWatch*. 17.2: 3-6. (CTools)
- Bieber, Frederick R., Charles H. Brenner, David Lazer, "Finding Criminals Through DNA of Their Relatives." *Science*. 312 (2 June 2006): 1315.

March 16th: Biobanks and Genetic Databases: How to Ensure Good Science

- Sigurdsson, Skúli. "Yin-Yang Genetics, or the HSD deCODE Controversy." *New Genetics and Society*. 20.2 (2001): 103-117. (CTools)
- * Winickoff, David (2001). "Biosamples, Genomics, and Human Rights: Context and Content of Iceland's Biobanks." *Act, 4 Journal of Biolaw and Business* 2:11-17. (CTools)
- Winickoff, David and R. Winickoff (2003). The Charitable Trust as a Model for Genomic Biobanks, 349 *New England Journal of Medicine* 12: 1180-1184 (18 September). (CTools)
- Gertz, Renate (2004). "An analysis of the Icelandic Supreme Court judgement on the Health Sector Database Act." *SCRIPT-ed*. 1.2: 1-17. (CTools)

March 21st: Personalized medicine: The Promise and Pitfalls

- Nuffield Council on Bioethics (2003). *Pharmacogenetics: Ethical Issues*. Report. (CTools)
- Berenson, Alex. "Blockbuster Drugs are So Last Century." *The New York Times*. July 3, 2005. (CTools)

March 23rd: Personalized medicine: Implications for our Understandings of Race

- Kahn, Jonathan (2004). "How a Drug Becomes 'Ethnic': Law, Commerce, and the Production of Racial Categories in Medicine." *Yale Journal of Health Policy and Ethics*. Vol. 4. (CTools)

- Duster, Troy (2005). "Policy forum: Race and reification in science." *Science*. 307: 1050-1051. (CTools)
- Saul, Stephanie (2005). "FDA Approves a Heart Drug for African-Americans." *The New York Times*. June 24, 2005. (CTools)
- Wade, Nicholas (2005). "Genetic Find Stirs Debate on Race-Based Medicine." *The New York Times*. November 11, 2005. (CTools)
- Dreifus, Claudia. "A Sociologist Confronts 'the messy stuff.'" *The New York Times*, October 18, 2005. (CTools)

March 28th: Pre-implantation genetic diagnosis: A Backdoor to Eugenics?

POLICY EXERCISE; MEMO DUE

- King, D.S.. (1999) "Preimplantation Genetic Diagnosis and the 'new' eugenics." *Journal of Medical Ethics*. 25: 176-182. (CTools)
- Robertson, J.A. (2003). "Extending preimplantation genetic diagnosis: medical and non-medical uses." *Journal of Medical Ethics*. 29: 2123-216. (CTools)
- Dahl, Edgar (2003). "Ethical issues in new uses of preimplantation genetic diagnosis." *Human Reproduction*. 18.7: 1368-1369. (CTools)
- de Wert, Guido (2005). "Preimplantation genetic diagnosis: the ethics of intermediate cases." *Human Radiation*. 20.12: 3261-3266. (CTools)

March 30th: Genetically Modified Organisms: Safety and Politics in the US

- Lambrecht, Bill (2001). *Dinner at the New Gene Café: How Genetic Engineering is Changing What We Eat, How We Live, and the Global Politics of Food*. New York: Thomas Dunne Books. Parts One and Two. (text)

April 4th: Genetically Modified Organisms: Safety and Politics in Europe

- Lambrecht, Bill (2001). *Dinner at the New Gene Café: How Genetic Engineering is Changing What We Eat, How We Live, and the Global Politics of Food*. New York: Thomas Dunne Books. Part Three except chapters 17 and 18. (text)
- Gaskell, George, et al. (1999). "Worlds Apart? The Reception of Genetically Modified foods in Europe and the US." *Science*. 285: 384-7. (CTools)
- Jasanoff, Sheila. "Commentary: Between risk and precaution—reassessing the future of GM crops." *Journal of Risk Research*. 3(3): 277-282. (CTools)

April 6th: Genetically Modified Organisms in the developing world

- Lambrecht, Bill (2001). *Dinner at the New Gene Café: How Genetic Engineering is Changing What We Eat, How We Live, and the Global Politics of Food*. New York: Thomas Dunne Books. Chapters 17 and 18. (text)
- Shiva, Vandana (2000). *Stolen Harvest: The Hijacking of the Global Food Supply*. New York: South End Press. selections. (course reader)
- *BIO background papers. (course reader)

April 11th: Genetically Modified Organisms: Negotiating International Trade

- Lambrecht, Bill (2001). *Dinner at the New Gene Café: How Genetic Engineering is Changing What We Eat, How We Live, and the Global Politics of Food*. New York: Thomas Dunne Books. Part Four. (text)

- Winickoff, David, S. Jasanoff, L. Busch, R. Grove-White, B. Wynne (2005). "Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law," *Yale Journal of International Law* (forthcoming, Winter 2005). (CTools)
- Gupta, Aarti (2000). "Creating a global biosafety regime." *International Journal of Biotechnology*. 2.1/2/3: 205-229. (CTools)
- De Greef, Willy (2004). "The Cartagena Protocol and the future of agbiotech." *Nature Biotechnology*. 22(7): 811-2. (CTools)

April 13th: Genetically Modified Organisms: Using Citizen's Juries and Stakeholder Dialogues

- Matz, David and Michele Ferenz (2004). "Consensus-Building Process in Society and Genetically Modified Organisms: The Concept and Practice of Multistakeholder Processes." *European Review of Agriculture Economics*. 37-70. (CTools)
- Institute of Development Studies (2003). *Public Participation and the Cartagena Protocol on Biosafety*. (CTools)

April 18th: Biosecurity

- National Research Council (2004). *Biotechnology Research in an Age of Terrorism: Confronting the 'Fuel' Use Dilemma*. Washington, DC: National Academy Press. selections. (text)