

PUBPOL 495: Health and Environmental Policy through the Lens of Biotechnology
Tuesdays and Thursdays, 10-11:30AM, Winter 2015
1220 Weill Hall; 4 credit course

Instructor:

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Office Hours: Tuesdays, 8-10am or by appointment

Born in the 1970s, the field of biotechnology has begun to revolutionize our daily lives in fundamental ways. As it has promised benefits for health, food, the environment, and society, however, it has also raised difficult challenges for policymakers across the world. Should those with genetic conditions be covered under the Americans with Disabilities Act? Should governments consider the ecological implications of genetic engineering, and if so, how? To what extent should members of the World Trade Organization be allowed to develop their own approaches to regulating biotechnology? How might genetics research reshape policies based on racial categorization? In this course, we will explore the policy challenges raised by new genetic and bio- technologies, examine how they are being resolved, and assess alternative approaches. We will also investigate how politics and policy related to biotechnology are shaping food, health, and environmental policymaking more generally.

Students will learn the following:

- Major issues of controversy in genetics and biotechnology across the world;
- Major stakeholders in the politics of genetics and biotechnology across the world;
- Laws and regulatory frameworks that have been developed to deal with the new science and technology;
- How to engage in ongoing debates over biotechnology, both in the US and elsewhere;
- Mechanisms for public participation in science and technology that have been devised to deal with these issues;
- To present their ideas and arguments persuasively in writing and through oral presentations.

Do not be concerned that we are covering topics that are somewhat technical in nature. To the extent that you need to know the underlying science, I will help you learn it!

Course Work:

<i>Participation</i>	<i>10%</i>
<i>Reading Responses</i>	<i>10%</i>
 <i>Deliberative Policy Forum Project:</i>	
<i>Topic choice</i>	<i>N/A</i>
<i>Issues Assessment Memo</i>	<i>10%</i>
<i>Policy Options Memo</i>	<i>10%</i>
<i>Policy Forum Choice, Justification, Design</i>	<i>15%</i>
<i>Preparatory Materials</i>	<i>10%</i>
<i>Forum</i>	<i>15%</i>
<i>Forum Critique and Analysis</i>	<i>5%</i>
<i>Final Assessment</i>	<i>15%</i>

Assignment Descriptions:

Regular class *participation*—*i.e.*, doing the readings and being ready to talk about them. In order to do this properly, you will need to read actively in advance of class (writing down any questions or reflections you may have) and come prepared to talk about them. To facilitate active reading, I suggest that you take notes as you read before each day's class. As you do each reading, underline or highlight passages that you think are important or interesting. Once you've finished the reading, spend a few moments writing down answers to the following questions: 1) What was the article/chapter about? 2) What was the main argument? Were there any secondary arguments? 3) Was the argument compelling? Not compelling? Why or why not? 4) Were there any tidbits that you thought were particularly interesting or provocative, which you'd like to discuss more in class? 5) Did the reading raise any additional questions for you? What were they? 6) How does that reading connect to other readings for the day? How about previous readings you've done for the class?

Your participation grade will be based on a number of factors, including: evidence of preparation for and intellectual engagement in class discussions and activities, quality and regularity of contributions to class discussion, participation in small groups, and evidence of attentive listening to peers. See below for attendance policies. **Both attendance and participation are mandatory and will be important parts of your final grade.**

Please also keep in mind that we will be discussing very controversial and difficult topics, in which there will be (hopefully!) multiple points of view. Be respectful and empathetic towards one another. This includes careful listening, and also asking questions (respectfully) of one another when you don't understand something.

- 1) **Reading Responses**—Occasionally, I will ask you to begin class by spending 10 minutes writing a response to or reflection on the reading, guided by a question that I provide. In these questions I may ask you to summarize an argument made in the day's reading, reflect on the connections between the readings (or between that day's readings and those you've done for a previous day), or to outline your response/reflection on the particular argument made in the day's readings. Or, I might draw from the questions I've listed in the "active reading" section above, designed to facilitate your active reading. These responses are designed to help you analyze the readings assigned for the class, and to develop critical thinking skills related to policy analysis. They will be considered and graded according to their engagement with concepts and cases discussed in the reading.
- 2) **Deliberative Policy Forum Project:** The main project for the term is the development, execution, and evaluation of a "deliberative policy forum" on a controversial policy area related to genetics and biotechnology. Policymakers and scholars have begun to turn to these "deliberative" approaches in order to tackle policy problems that require both evidence and values. They are considered more useful than surveys or polls in gauging public opinion (and recommendations) because they allow the public to deliberate on a particular issue over a period of time, with the help of facilitators, preparatory documents, and occasionally outside experts. They are also considered better than traditional expert-driven approaches because they are more democratically representative, and because they bring values and evidence together for decisionmaking.

- a) **Topic choice (Group Assignment):** For this term project, you will be split into 4 groups of 5-6 students based on your policy interests. Each group will decide on a central policy question of interest (with some help from me) that seems particularly good for this type of deliberative policy forum. The policy question should focus on a current controversy, anywhere in the world.
- b) **Controversy Assessment Memo (Individual Assignment):** Your first major assignment in the course is to write a “backgrounder” memo (addressed to the relevant policymaker) assessing the controversy. All of the backgrounders should start with a short, non-technical, overview of the scientific or technological dimensions of the controversy. You should explain this area of science and technology in simple terms (as if you were explaining it to a 6th grader.) This part of the memo should be no more than 250 words.

The rest of your backgrounders will differ. Half of the members of each group will identify all of the issues of controversy. What are the issues of controversy? What are the different values at stake? Who will be affected by this policy? The other half of the group members will identify the relevant experts and stakeholders (political interests) who have been involved in the controversy. What are their positions? What is their interest/expertise? What kind of involvement have they had? This part of the memo should be no more than 400 words.

In order to do all of these analyses, you will have to use ideas from (and cite) the relevant scholarly literatures. Citing journalistic and web sources will not be sufficient.

- c) **Policy Options Memo (Individual Assignment):** This memo, also a backgrounder written to the relevant policymaker, should describe and evaluate the various policy options that have been suggested by scholars (or used in other policy contexts) to address your policy question. You must identify 2-4 options, and for each, evaluate its benefits, drawbacks, and appropriateness for the context you are focused on (including who and what stands to win and lose most with each one). You should provide your own recommendation on which option is best. This memo should not exceed 750 words. In order to conduct this analysis, you will draw from both academic, news, and policy sources. Again, citing journalistic and web sources will not be sufficient.
- d) **Policy Forum Choice, Justification, Design (Group Assignment):** This is a persuasive memo, addressed to the same decisionmaker. In this memo, you will advocate for the use of a deliberative policy forum to address the ongoing policy controversy. You will also propose a particular design for this forum (be as detailed as possible, using insights from both our class and your outside research), and also justify both the use of a deliberative forum and the specific type of forum you have chosen. This memo should be no longer than 1250 words.

Finally, as an appendix (not to be included in the word count) this memo will outline the written materials you will need to prepare for the forum, provide an agenda for the forum itself, and identify any outside speakers (or others) that you plan to invite to participate in the forum itself.

- e) **Preparatory Materials (Group Assignment):** All of the groups will need to prepare documents for use at the forum (including documents for your classmates to read in advance of the forum

itself). These are likely to be drawn heavily from the Controversy Assessment and Policy Options Memos, but will likely be polished and rewritten depending on my comments and also the design/schedule of your Deliberative Policy Forum. After you turn them in, I will give you another round of comments so that you can polish them in advance of the Forum itself. You should focus on creating the appropriate documents, don't just write down a lot of information!

- f) Forum (Group Assignment):** You will conduct your Forum during one class period at the end of the semester. As stated above, your group will have the freedom to design it as you see fit, so long as it achieves the basic objectives of a deliberative policy forum (we'll discuss these in more detail throughout the term). Your fellow students will be the main participants, but you can shape it (including assigning them identities, or bringing in outside participants or speakers) as you see fit.
- g) Forum Critique and Analysis (Individual Assignment):** Every student who is not part of that day's Forum must provide an anonymous critique about what worked, what didn't work, and how you might improve the process to better achieve the goals of policymakers and the public. I will provide you with a template for these critiques. The Forum Critique is due the class period after the forum that you are analyzing.
- h) Final Assessment (Individual Assignment):** This final memo should be addressed to the same relevant policymaker, and is designed to be a summary and evaluation of the Forum process. After briefly summarizing the basic idea and design of the Forum, it should address the following questions:
- What were the conclusions of the Forum? (what did the participants conclude regarding the policy controversy?)
 - In what ways was the Forum successful or unsuccessful? Did it achieve the objectives of a deliberative policy forum? (Use your peer critiques to help you with this evaluation.)
 - If you were to use a Forum to influence policymaking in this controversial area, what would you change? What might you expand? What would you leave the same?
 - Might this deliberative approach be useful in other areas of policy? Which ones, and why? Where might it not be so useful, and why?

Course policies:

CTools: All of the readings used in the course are posted on CTools.

Attendance: Attendance is mandatory. I may grant you an excused absence for illness or religious observance, but it *must* be cleared with me *prior to class*. I will not grant excused absences after you've already missed class. Do not arrive late to class; it is disrespectful to me and to your peers. Your final grade will be adversely affected if you are regularly late.

Citing Sources: For *all* written work, I expect proper sourcing and citation. To maintain consistency, you should all use the style used by the US Government. The government's Style Guide is available online here: <http://www.gpo.gov/fdsys/pkg/GPO-STYLEMANUAL-2008/pdf/GPO-STYLEMANUAL-2008.pdf>

Also, when citing a source over the course of multiple sentences, cite after the first sentence. In addition, *do not use Wikipedia as a direct source*. It is anonymously produced, with un-vetted contributors from all over the world, so the information you

find there should *never* be automatically trusted as legitimate. That said, I understand that **Wikipedia** can be extremely useful to introduce you to a particular topic. My suggestion is that you use it to learn the basics about a particular subject, and then follow the links provided there (or the insights you gain) to find a more credible source.

Plagiarism: Plagiarism will be harshly penalized. For more information on what constitutes sourcing, see UM's plagiarism handout: <http://www.lib.umich.edu/handouts/plagiar.pdf>.

Laptops: Laptops, tablets, and smartphones are not permitted in the classroom (if you have one with you, keep it in your bag). There may be occasions when you will need to bring your laptop or tablet for work in class; I will let you know about this in advance.

Syllabus: While the syllabus is fairly stable (especially for the first few weeks), I reserve the right to make slight changes to it. I do not expect, however, the themes, assignments, or even the readings to change significantly. If I do make even a slight alteration, I will tell you at least a week in advance.

Class and Reading Schedule

January 8th: Genetics and Biotechnology Policy: Introduction

January 13th: The American Legacy of Eugenics

Belle Boggs (2013). "For the Public Good".

January 15th: The Modern History of Genetic Testing

Diane Paul (2000). "A double-edged sword." *Nature*. Vol. 405, p. 515.

Diane Paul and Jeffrey P. Brosco (2013). *The PKU Paradox: A Short History of a Genetic Disease*. Baltimore, MD: Johns Hopkins University Press. Chapter 9.

Mairi Levitt and Elisa Pieri (2009). "'It could just be an additional test couldn't it?' Genetic testing for susceptibility to aggression and violence." *New Genetics and Society*. 28(2): 189-200.

January 20th: Biotechnology and Regulatory Challenges

Sheila Jasanoff (2003). "Technologies of Humility: Citizen Participation in Governing Science." *Minerva*. 41: 223-244.

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

Stephanie Solomon and Julia Abelson (2012). "Why and When Should We Use Public Deliberation?" *Hastings Center Report*. 42(2): 17-20.

January 22nd: The Dilemmas of Susceptibility Testing (the Breast Cancer case)

Karina L. Brierley et al (2010). "Errors in Delivery of Cancer Genetics Services: Implications for Practice." *Connecticut Medicine*. 74(7): 413-423.

Shobita Parthasarathy (2007). *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care*. Chapter 4.

Angelina Jolie (2013). "My Medical Choice." *The New York Times*. May 14.

Gayle Sulik (2013). "Angelina Jolie and the One Percent." *Scientific American*. May 20.

January 26th, noon: Topic Choice due!

January 27th: The Brave New World of Genetic Testing

Leslie G. Biesecker et al. (2012). "Next Generation Sequencing in the Clinic: Are We Ready?" *Nature Reviews Genetics*. 13: 818-824.

Deborah A. Bolnick et al. (2007). "The Science and Business of Genetic Ancestry Testing." *Science*. 318: 399-400.

Shobita Parthasarathy (2014). "Producing the Consumer of Genetic Testing: The Double-Edged Sword of Empowerment." In *Routledge Handbook of Science, Technology, and Society*. Edited by Kelly Moore and Daniel Kleinman. New York: Routledge.

Kyle T. Edwards and Caroline J. Huang (2014). "Bridging the Consumer-Medical Divide: How to Regulate Direct-to-Consumer Genetic Testing." *Hastings Center Reports*. 44(3): 17-19.

January 29th: New Possibilities for Regulating Genetic Testing

Secretary's Advisory Committee on Genetics, Health, and Society (2008). *US System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services*. Washington, DC: GPO. Front Matter (especially list of committee members).

Secretary's Advisory Committee on Genetics, Health, and Society (2008). *US System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of Health and Human Services*. Washington, DC: GPO. Chapter 2.

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.

February 3rd: Governing Prenatal Testing and Newborn Screening

Christopher H. Wade, Beth A. Tarini, and Benjamin S. Wilfond (2013). "Growing Up in the Genomic Era: Implications of Whole-Genome Sequencing for Children, Families, and Pediatric Practice." *Annual Reviews of Genomics and Human Genetics*. 14: 535-555.

Beth Daley and New England Center for Investigative Reporting (2014). "Oversold and Misunderstood." <http://features.necir.org/prenatal-testing>

February 5th: Introducing Public Deliberation as a Policy Tool

Steven Epstein (1995). "The Construction of Law Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials." *Science, Technology, and Human Values*. 20.4: 408-437.

Paola Mosconi, Carlo Castellani, Walter Villani, and Roberto Satolli (2014). "Cystic Fibrosis: to screen or not to screen?" *Health Expectations*. 1-12.

February 9th, noon: Controversy Assessment due! (to be shared within the groups)

February 10th: Biobanks, Bioethics, and Citizen Deliberation

David Winickoff and Richard Winickoff (2003). "The Charitable Trust as a Model for Genomic Biobanks." *New England Journal of Medicine*. 1180-1184.

Kieran C. O'Doherty, Alice K. Hawkins, and Michael M. Burgess (2012). "Involving citizens in the ethics of biobank research: Informing institutional policy through structured public deliberation." *Social Science & Medicine*. 75: 1604-1611.

Amy A. Lemke, Colin Halverson, and Lainie Friedman Ross (2012). “Biobank Participation and Returning Research Results: Perspectives from a Deliberative Engagement in South Side Chicago.” *American Journal of Medical Genetics: Part A*. 1029-1037.

February 12th: Race as a Genetic Category

Keith Wailoo, Alondra Nelson, and Catherine Lee, editors (2012). *Genetics and the Unsettled Past: The Collision of DNA, Race, and History*. New Brunswick, NJ: Rutgers University Press. Chapter 4.

Linda M. Hunt and Mary S. Megyesi (2008). “The Ambiguous Meanings of the Racial/Ethnic Categories Routinely Used in Human Genetics Research.” *Social Science and Medicine*. 66(2): 349-361.

(2009) “Race and Genetics.” *GeneWatch*. July/August. p. 4-11.

February 17th: Race and Research Policy Today

Darcell P. Scharff et al. (2010). “More than Tuskegee: Understanding mistrust about research participation.” *Journal for the Health Care for the Poor and Underserved*. 21(3): 879-897.

Sara Georing et al. (2008). “Transforming Genetic Research Practices with Marginalized Communities: A Case for Responsive Justice.” *The Hastings Center Report*. 38(2): 43-53.

Rose Eveleth (2015). “Genetic Testing and Tribal Identity.” *The Atlantic*. January 26.

February 19th: Race and Genetic Medicine

Jonathan Kahn (2013). “How a Drug Becomes ‘Ethnic’: Law, Commerce, and the Production of Racial Categories in Medicine.” *Yale Journal of Health Policy, Law, and Ethics*. 4.1: 1-47.

Keith Wailoo, Alondra Nelson, and Catherine Lee, editors (2012). *Genetics and the Unsettled Past: The Collision of DNA, Race, and History*. New Brunswick, NJ: Rutgers University Press. Chapter 10.

February 20th, noon: Policy Options Memos due!

February 24th: Meet in your groups to discuss Policy Forum! I will be available for consultation.

February 26th: Race, Big Genetic Data, and Criminal Justice Policy

Sheldon Krimsky and Tania Simoncelli (2010). *Genetic Justice: DNA Databanks, Criminal Investigations, and Civil Liberties*. New York: Columbia University Press. Excerpt from Chapter 1 and Chapter 15.

Richard Tutton, Christine Hauskeller, and Steve Sturdy (2014). “Suspect Technologies: Forensic Testing of Asylum Seekers at the UK Border.” *Ethnic and Racial Studies*. 37.5: 738-752.

SPRING BREAK!

March 10th: Patenting Biotechnology in the United States

Diamond v. Chakrabarty decision.

Tania Simoncelli and Sandra S. Park (2015). “Making the Case Against Gene Patents. *Perspectives on Science*. 23.1: 106-145.

Sandra S. Park (2014). “Gene Patents and the Public Interest: Litigating *Association for Molecular Pathology v. Myriad Genetics* and Lessons Moving Forward.” *North Carolina Journal of Law and Technology*. 15.4: pp. 12-18.

March 11th, noon: Policy Forum Choice, Justification, and Design due! (Group Assignment)

March 12th: Patenting Biotechnology in Europe and Beyond

- Stephanie T. Rosenberg (2014). “Asserting the Primary of Health over Patent Rights: A Comparative study of the Processes that Led the Use of Compulsory Licensing in Thailand and Brazil.” *Developing World Bioethics*. 14.2: 83-91.
- E. Richard Gold and Alain Gallochat (2001). “The European Biotech Directive: Past as Prologue.” *European Law Journal*. 7.3: 331-366.

GROUP MEETINGS (with me) between March 12th and March 19th.

March 17th: Patenting Seeds?

- Aoki, Keith (2008). *Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property*. Durham, NC: Carolina Academic Press. Selected chapters.
- Center for Food Safety (2005). “Monsanto vs. US Farmers.” Overview.

March 19th: New Models of Intellectual Property

- Kiernan A. Murphy (2009). “The Precautionary Principle in Patent Law: A View from Canada.” *Journal of World Intellectual Property*. 12(6): 649-689.
- Arti Rai and James Boyle (2007). “Synthetic Biology: Caught between Property Rights, the Public Domain, and the Commons.” *PLOS Biology*. 5.3: 389-393.
- Swathi Padmanabhan et al. (2010). “Intellectual property, technology transfer, and manufacture of low-cost HPV vaccines in India,” *Nature Biotechnology*. 28.7: 671-678.

March 20th, noon: Preparatory Materials due! (Group Assignment)

March 24th: Regulating GMOs in the United States and Europe

- Nina V. Federoff (2011). “Burdensome and unnecessary regulation.” *GM Crops*. 2.2: 87-88.
- Sheila Jasanoff (2000). “Commentary: Between risk and precaution—reassessing the future of GM crops.” *Journal of Risk Research*. 3.
- Dorothy Du (2012). “Rethinking Risks: Should Socioeconomic and Ethical Considerations Be Incorporated into the Regulation of Genetically Modified Crops?” *Harvard Journal of Law and Technology*. 26(1): 375-401.

March 26th: Regulating GMOs in the Developing World

- Nina V. Federoff and Drew L. Kershen (2014). “Agricultural Biotechnology—An Opportunity to Feed a World of Ten Billion.” *Penn State Law Review*. 118.4: 859-875.
- Miguel A. Altieri and Peter Rosset (1999). “Ten Reasons Why Biotechnology Will Not Ensure Food Security, Protect the Environment, and Reduce Poverty in the Developing World.” *AgBioForum*. 2(3&4): 155-162.
- Julia Freeman (2012). “How do ‘imagined farmers’ negotiate actual risks? Biosafety tradeoffs in Bt cotton production in Andhra Pradesh, India.” *Journal of Political Ecology*.

March 30th, noon: Revised Preparatory Materials due! (Group Assignment)

March 31st: Regulating GMOs: Emerging Issues

Uli Beisel and Christophe Boëte (2015). “The Flying Public Health Tool: Genetically Modified Mosquitoes and Malaria Control.” *Science as Culture*. 22(1): 38-60.

(2015). “Can Genetically Modified Mosquitos Eliminate Dengue Fever?” *The New York Times*. February 23.

Lizette Alvarez (2015). “A Mosquito Solution (More Mosquitos) Raises Heat in Florida Keys” *The New York Times*. February 19.

April 2nd: Deliberative Policy Forum 1—Ethics of Vaccine/Drug Trials in Public Health Emergencies

April 7th: Deliberative Policy Forum 2—E-Cigarette Regulation in the United States (*critiques for 4/2 forum due by classtime!*)

April 9th: Deliberative Policy Forum 3—Compulsory Licensing Policy in the United States (*critiques for 4/7 forum due by classtime!*)

April 14th: Deliberative Policy Forum 4—Labeling GMOs in Michigan (*critiques for 4/9 forum due by classtime!*)

April 16th: NO CLASS! (*critiques for 4/14 forum due by 10:10am!*)

April 21st: Discussion and wrap-up

Selected pages from “GM Nation: Findings from the Public Debate”

April 29th, noon: FINAL ASSESSMENTS DUE!!!