

Topics in Politics: Health Politics

Pol Sci 399

Syllabus

G. Darl Lewis

December 3, 2019

Course Overview

In recent decades, health care spending in the United States has ballooned and is now approaching 20 percent of the country's GDP compared to only five percent as recently as the 1960s. Along with this growth in spending, there has been an equally large and salient expansion of the political economy of public health. In this course, we will explore many different debates and their role in public health, beginning with an overview of the structure and origins of the current U.S. health care system. This will lead into a discussion of many special topics that contribute to health care costs and preferences in the United States, including insurance, labor, pharmaceuticals, pollution, genetics, and medical technology. Within each of these topics, we will focus on how ethical, legal, and practical concerns influence the choices made by relevant stakeholders and the resulting effects on policy. We will also consider how and why these decisions often differ from those made by other countries.

The course will be broadly divided into three sections. In the first two weeks, we will jump back from today's headlines to explore the origins of health policy in the United States and, to a lesser extent, the rest of the world. This whirlwind tour will provide an outline of the status of healthcare prior to the arrival of the administrative state and modern medicine, including germ theory. In the second section, occupying most of the remaining time before Spring Break, we will focus on the current state of affairs, with a particular emphasis on the United States. We will focus on both the tools used to analyze health policy and on the state of policy itself in the lead-up to our final section. After Spring Break, we will turn to the future, exploring the frontiers of health policy, especially as it relates to new developments in our understanding of genetics and bioengineering. We will spend this time learning about the major problems facing policy-makers today while simultaneously searching for solutions to these problems.

Instructors

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Lectures: TR 11:30 AM – 1:00 PM, Seigle 301

Website: Canvas

Materials and Prerequisites

There is no prerequisite for the class; however students must have a basic understanding of genetic principles and biology generally. We will also build on this understanding throughout the course through a variety of reading which can be found online either through the course website or elsewhere. We will also use material from the following books:

Howard Markel, *Quarantine!: East European Jewish Immigrants and the New York City Epidemics of 1892* (Johns Hopkins, 1999)

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)

If you feel you would benefit from a review of basic genetics or biology more generally, the following texts may also prove useful:

Charlotte K. Omoto and Paul F. Lurquin, *Genes and DNA: A Beginner's Guide to Genetics and Its Implications* (Columbia University, 2004)

Alberts, et al, *Molecular Biology of the Cell* (Garland Science; 6th edition, 2014)

Of course, there are plenty of other resources available for general reference; do not feel bound by these books in particular. While we will be discussing the science of genetics and health, the focus here lies on the public policy implications and so a general understanding should be sufficient.

All remaining readings will be posted on the course website. These readings are also listed below, and in most cases are available elsewhere online. Note, however, that this list may and likely will change over the course of the semester. The politics of health and healthcare are rapidly evolving and as such, there is new material being generated on a daily basis. Indeed, I encourage you to be on the lookout for news that may be relevant to this class and to bring it to my attention if you do come across such material.

Assignments and Grading

While there will be some variation from session to session, the basic course format will be as follows:

- Each Tuesday session will consist of a lecture and discussion to introduce the week's topic and to raise the broad questions and issues for discussion.
- The Thursday session will focus on discussion of the week's topic among the class. This section should provide students with an opportunity to clarify difficult topics and develop a more in-depth understanding of any points of interest. The first half-hour of this session will be led by myself followed by student presentations (see below). Thursday's readings will typically be lighter than those for Tuesday lectures.

Students must complete the required readings prior to each class in order to fully participate in the day's discussion. The optional readings are for those of you who wish to delve more deeply into the week's topic.

Written Requirements

- *Weekly Response Papers:* Each student must write a short 1-2 page response to the week's assigned readings to be turned in by 9:00 AM every Tuesday. These weekly response papers should describe what the student sees as the most important issues, questions, and problems raised by the readings. While it is perfectly acceptable to address any of the week's readings, it is perfectly acceptable if the initial submissions only address Tuesday's readings. After class on Thursday, students will edit their papers (while tracking changes) based on the discussion, and resubmit it by Friday at 5:00 PM. Please take sympathy on your graders and try to keep these responses under two pages before incorporating track changes.
- *Panel Arguments:* By 5:00 PM on the day before your panel, you should submit a short summary of your main points for the panel. This summary need only be ~ 1 page and may be in bullet point format if you so choose. Note, however, that you do not need to fully stick to these points during the presentation.
- *Midterm Stakeholder Paper:* The first paper (due at 5:00 PM on March 7) is a 5-7 page analysis of a case study in health politics chosen by the student. Ideally, this paper offers a detailed, sustained, and original analysis of a topic on the syllabus or the readings, although it is also acceptable for a student to choose another topic related to health politics not covered by the syllabus. It may examine scientific questions, social problems, legal and economic concerns, medical issues, or regulatory challenges while identifying the key stakeholders involved (physicians, scientists, consumers, genetic testing companies, politicians, regulators, policy, judges, etc.) and positioning them within the policy debate. The paper should not be narrowly confined to one single realm (eg. only science or only policy), but should address both the technical problem and the relevant policies.
- *Final White Paper:* The final paper (due at 5:00 PM on April 29) should extend and deepen the analysis of the first paper based on the feedback you have received. You may choose,

however, to write on a new topic in consultation with the instructor. This paper will be a 15-18 page white paper 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 understand the issues, on how their interactions shape health 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.

Panel Discussions

Each student, as part of a group, will take part in leading a panel discussion regarding a policy proposal of their choice relevant to their week's readings. Within each group, students should take on the role of a major stakeholder in the week's policy discussion and be prepared to defend and argue for their stakeholder. While the presenters will take the lead in this discussion, students should expect full engagement from the class as well.

Sign up for a panel here: <https://goo.gl/forms/TyRPgsmIY6WPdsob2>

Grading Breakdown

- Weekly papers (15%)
- Panel Discussion (20%)
- Midterm Stakeholder Paper (15%)
- Final Paper (40%)
- Participation in weekly discussion (10%)

Late Policy

As a general rule, I do not accept late work. If you request an extension for a compelling reason, you must obtain approval in writing (email is fine) prior to the deadline. Without prior approval, a doctor's or dean's note is required.

Schedule

1. **Week of January 13: *The Old and the New***

- (a) *Introduction and Overview:* What are the problems of health politics and why are they important? We will spend the first lecture outlining the questions we will be asking throughout the semester and laying out a road map to try to answer them. We will also go over the syllabus and expectations for the class. We will then jump into an exploration of the evolution of genetics in relation to health politics throughout the 20th Century and use this as the starting point for our subsequent analysis of health policy in the United States, with a special emphasis on the persistence of debates over

time and the relationship of the historical to the contemporary. Are today's debates really new?

No response paper this week.

Be sure to sign up for a presentation slot by midnight on Tuesday!

Required Readings:

- Syllabus
- Meagan Flynn, "The Father of DNA says he still believes in a link between race, intelligence. His lab just stripped him of his titles," *Washington Post* January 14, 2019.
- Daniel Kevles, *In the Name of Eugenics: Genetics and the Uses of Human Heredity*, pp. 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 *Davenport's Dream: 21st Century Reflections on Heredity and Eugenics*, Witkowski and Inglis, eds., (Cold Spring Harbor, 2008)
- *Regulating Eugenics* Harvard Law Review, (2008), pp. 1578-1599

Optional Readings:

- Philip Thompson, "Silent Protest: A Catholic Justice Dissents in *Buck v. Bell*," *Catholic Lawyer*, 2005
 - Justice Holmes Majority Opinion in *Buck v. Bell*, 1927
 - Kim Severson "Payments for Victims of Eugenics are Shelved" *New York Times* June 20, 2012
 - "Virginia governor apologizes for eugenics laws" *USA Today* May 2, 2002
 - "Chosen Children: Issues in Reproductive Testing." Genetics and Public Policy Center
- (b) *Due to a prior commitment, there will be no class on Thursday, January 17.* In lieu of lecture, please watch the short movie, *Tomorrow's Children*

Required Viewing:

- Tomorrow's Children:
<https://www.youtube.com/watch?v=0EVdAOKjR-s>

2. **Week of January 20: Quarantine!**

- (a) *Health Politics and Germ Theory:* This week we will focus on early government efforts to improve public health. We will give special attention to the use of quarantines and early uses of inoculation as means of preventing the spread of disease. We will also discuss the rise of germ theory as an alternative to the predominant miasma theory of earlier centuries.

Required Readings:

- Howard Markel, “The Concept of a Quarantine” and “The Microbe as a Social Leveller” in *Quarantine!: East European Jewish Immigrants and the New York City Epidemics of 1892* (Johns Hopkins, 1999)
- John Blake, “The Origins of Public Health in the United States,” *Am. J. of Pub. Health.* (Nov, 1948) p. 1539.
- Joshua Lederberg, “Infectious History,” *Science* 288:5464 (2000) pp. 287
- Joel Grover and Amy Corral, “Typhus Epidemic Worsens in Los Angeles,” *NBC Los Angeles* (2019).

Optional Readings:

- George Rosen, “The Fate of the Concept of Medical Police 1780-1890,” *Centaurus* 50 (2008) pp. 46-62.
 - Patrick Carroll, “Medical Police and the History of Public Health,” *Medical History*, 46 (2002) pp. 461.
 - Robin Weiss and Jose Esparza, “The Prevention and Eradication of Smallpox: A Commentary on Sloane (1755) ‘An Account of Innoculation,’” *Philos. Trans. R. Soc. Lond. B. Biol. Sci.* 370 (2015) pp. 1666.
 - Marianna Karamanou, et al. “From Miasmas to Germs: A Historical Approach to Theories of Infectious Disease Transmission,” *Le Infezioni in Medicina* 1 (2012) pp. 52.
- (b) *The New York Experience:* We will explore a case study in New York’s response to typhus and cholera epidemics during the late 19th Century. We will focus on both the role of newly dominant germ theory, as well as socioeconomic factors on the decisions promulgated by New York officials and, eventually Congress.

Required Readings:

- Howard Markel, *Quarantine!: East European Jewish Immigrants and the New York City Epidemics of 1892* (Johns Hopkins, 1999)

3. **Week of January 27: Taking the Temperature**

- (a) *Measuring Health:* Given it’s importance in determining public policy, what is the proper way to measure health? Should we focus on individuals or society as a whole? What factors are relevant when we talk about health? This week we will examine different measures of individual and public health with an eye to interpreting policy in the modern era as well as reassessing earlier policy.

Required Readings:

- Daniel Kahneman and Angus Deaton, “High Income Improves Evaluation of Life but Not Emotional Well-Being,” *PNAS*, 107:38 (2010) pp. 16489.
- Paul Dolan and Matthew White, “How can Measures of Subjective Well-Being be Used to Inform Public Policy?” *Perspectives in Psy. Sci.* 2:1 (2007) pp. 71.
- David Cutler, Angus Deaton, and Adriana Lleras-Muney, “The Determinants of Mortality,” *JEP*, 20:3 (2006) pp. 97.
- Robert Blendon and John Benson, “Americans’ Views on Health Policy: A Fifty-Year Historical Perspective,” *Health Affairs* (2001)

Optional Readings:

- Marc Fleurbaey, “Beyond GDP: The Quest for a Measure of Social Welfare,” *JEL* 47:4 (2009) pp. 1029. (Sections 6-8)
- Daniel Sacks, Betsy Stevenson, and Justin Wolfers, “Subjective Well-Being, Income, Economic Development, and Growth,” *NBER Working Paper 16411* (2010).
- Gary Becker, Thomas Philipson, and Ricardo Soares, “The Quantity and Quality of Life and the Evolution of World Inequality,” *AER* 95:1 (2005) pp. 277.
- Samuel Preston, “American Longevity: Past, Present, and Future,” *Working Paper* (1996)

(b) *Responding to Data:* Our measurements of health are only as useful as their applications. In the second half of the week, we will consider how information on public health is transmitted into the political system, both through direct and indirect means.

Required Readings:

- Angus Deaton, “Global Patterns of Income and Health: Facts, Interpretations, and Policies,” *WIDER Annual Lecture* (2007).
- *RWJF Culture of Health Community Portrait: Louisville, Kentucky* June 2018.
- *RWJF Culture of Health Community Portrait: San Juan County, New Mexico* June 2018.

4. **Week of February 3: Sticker Shock**

(a) *The Costs of Health:* Why is healthcare so costly? This week we will look at what drives the cost of healthcare and what makes the United States unique in this regard. We will also ask the question, “How much is too much?” Is there a limit to what we should be spending on healthcare? How does technology affect our willingness to pay?

Required Readings:

- Sean Keehan, et al. “National Health Expenditure Projections, 2016-25: Price Increases, Aging Push Sector to 20 Percent of Economy,” *Health Affairs* 36:3 (2017) pp. 1.
- Mike Chernow, “Interpreting New Data on Health Care Spending Growth,” *Health Affairs Blog* (2015).
- G. Anderson, “It’s the Prices Stupid: Why the United States is So Different from Other Countries,” *Health Affairs* (2003)
- Amitabh Chandra and Douglas Staiger, “Productivity Spillovers in Health Care: Evidence from the Treatment of Heart Attacks,” *JPE* (2007) pp. 103.

Optional Readings:

- Douglas Almond et al, “Estimating Marginal Returns to Medical Care: Evidence from At-Risk Newborns,” *QJE* 125:2 (2010) pp. 591.
- Martin Gaynor and Robert Town, “Competition in Healthcare Markets,” *NBER Working Paper 17208* (2011).
- Daron Acemoglu and Simon Johnson, “Disease and Development: The Effects of Life Expectancy on Economic Growth,” *JPE* 115:6 (2007) pp. 925.

- Mark Duggan and Fiona Scott-Morton, “The Impact of Medicare Part D on Pharmaceutical Prices and Utilization,” *AER* (2010) pp. 590.
 - CBO, “An Update to the Budget and Economic Outlook: 2017 to 2027,” (2017).
- (b) *Miracle Drugs*: On of the fastest-growing costs in healthcare is that of prescription drugs. Is Big Pharma taking advantage of people in distress, or are they providing a valuable service? Why do Americans pay more than other countries for the same drugs? These questions will take our focus during the second half of the week.

Required Readings:

- Thomas Stossel, “Prescription Drug Pricing: Scam or Scapegoat?” *AEI* (2016).
- JA Greene and WV Padula, “Targeting Unconscionable Prescription-Drug Prices—Maryland’s Anti-Price-Gouging Law,” *NEJM* 377 (2017) pp. 101.
- Alfred Engelberg, “How Government Policy Promotes High Drug Prices,” *Health Affairs Blog* (2015).
- Dana Goldman and Darius Lakdawalla. “The Global Burden of Medical Innovation,” Brookings (2018).

5. **Week of February 10: *Sharing the Risk***

- (a) *The Preexisting Condition*: What is the role of insurance in the healthcare marketplace? This week’s focus will be on the evolution of insurance in the United States (and to a lesser extent, the rest of the world) over the course of the 20th Century and into the 21st. What is the purpose of insurance? Who is responsible for what? And what about elective procedures?

Required Readings:

- Liran Eivav and Amy Finkelstein, “Selection in Insurance Markets: Theory and Empirics in Pictures,” *JEP* 25:1 (2011) pp. 115.
- Leemore Dafny, “Are Health Insurance Markets Competitive?” *AER* 100:4 (2010) pp. 1399.
- David Blumenthal et al, “Medicare at 50—Origins and Evolution,” *NEJM* (2015).
- M. Sparer, “Medicaid at 50: Remarkable Growth Fueled by Unexpected Politics,” *Health Affairs* 34:7 (2015) pp. 1084.
- David Blumenthal et al, “Employer-Sponsored Health Insurance in the United States—Origins and Implications,” *NEMJ* 355:1 (2006) pp. 82.

Optional Readings:

- Kenneth Arrow, “Uncertainty and the Welfare Economics of Medical Care,” *AER* 53:5 (1963) pp. 941.
- Katherine Ho, “Insurer-Provider Networks in the Medical Care Market,” *AER* 99:1 (2009) pp. 393.
- Willard Manning, et al, “Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment,” *AER* 77:3 (1987) pp. 251.
- J. Gruber and K. Simon, “Crowd-Out 10 Years Later: Have Recent Public Insurance Expansions Crowded Out Private Health Insurance?” *J. Health Econ.* 27:2 (2008) pp. 201.

- (b) *Repeal and Replace:* We examine the passage of the Affordable Care Act and subsequent responses during the second half of the week. This legislation oversaw the most significant changes to US healthcare policy in fifty years and brought with it both strong support and widespread opposition. Will the legislation survive the resulting fallout?

Required Readings:

- Kaiser Family Foundation, “Summary of the Affordable Care Act,” (2013)
- Robert Blendon and John Benson, “Public Opinion about the Future of the Affordable Care Act,” *New England J. of Pub. Med.* 377:9 (2017)
- K. Baicker, “Coordination versus Competition in Health Care Reform,” *NEJM* (2013).
- C. Koller, “United’s Withdrawal from Exchanges—Much Ado about the Wrong Things?” *NEJM* (2016).
- Texas, et al. v. United States, et al., 4:18-cv-00167-O (Syllabus is sufficient)
- Charles Blahous, “The Costs of a Single-Payer Healthcare System,” Mercatus Working Paper (2018).

Optional Readings:

- Matthew Fielder, et al, “Moving in the Wrong Direction—Health Care under the AHCA
- Barack Obama, “ United States Health Care Reform: Progress to Date and Next Steps,” *JAMA* 316:5 (2016) pp. 525.
- S. Butler, “The Future of the Affordable Care Act: Reassessment and Revision,” *JAMA* 316:5 (2016) pp. 495.
- Paige Cunningham, “The Health 202: Here’s What Ex-HHS Secretary Donna Shalala Wants to do in Congress,” *Washington Post* (2019).

6. **Week of February 17: Health Ed**

- (a) *Determinants of Health:* During this week we will examine the different non-biological determinants of health, ranging from socioeconomic status to education to pollution. We will examine how these factors influence health directly and through the behaviors they induce, and then we will consider how differences arising from these factors might be addressed.

Required Readings:

- D. Cutler, A Lleras-Muney, and T. Vogl, “Socioeconomic Status and Health: Dimensions and Mechanisms,” *Oxford Handbook of Health Economics* (2011).
- C. Ruhm, “Good Times Make You Sick,” *J. Health Economics* 22:4 (2003) pp. 637.
- S.Dorn, M McGreath, and J. Holohan, “What is the Result of States Not Expanding Medicaid?” *Urban Institute* (2014).
- Dana Goldman and James Smith, “ Can Patient Self-Management Explain the SES Health Gradient?” *PNAS* 99:16 (2002).

- B. Mazumder, “Does Education Improve Health? A Reexamination of the Evidence from Compulsory Schooling Laws,” *Fed. Res. Bank. of Chi. Econ. Per.* Q2 (2016).
- Steven Johnson, “Poor Communities Wait Longer for Ambulances, Causing Health Disparities,” *Modern Healthcare* (Nov. 30, 2018).
- Patrice Harris, “Unlocking the Potential of Digital Health Care,” *AMA* (Dec. 12, 2018).

Optional Readings:

- C. Ruhm, “Are Recessions Good for your Health?” *QJE* 115:2 (2000) pp. 617.
 - Gary Becker and Kevin Murphy, “A Theory of Rational Addiction,” *JPE* (1988).
 - D. Goldman and J. Smith, “Socioeconomic Differences in the Adoption of New Medical Technologies,” *AER Papers and Proc.* 95:2 (2005) pp. 234.
 - Joel Shannon, “Doctor Delivers End-of-Life News Via ‘robot,’ leaving family frustrated,” *USA Today* (2019).
- (b) *Health as a Determinant:* In Part II, we will explore the feedback loops that are generated by health effects as a result of socioeconomic circumstances and related factors. Is it possible to escape the cycle of bad health outcomes?

Required Readings:

- A. Goodman, R. Joyce, and J. Smith, “The Long Shadow cast by Childhood Physical and Mental Problems on Adult Life,” *PNAS* (2011).
- A. Aron-Dine, L. Einav, and A. Finkelstein, “The RAND Health Insurance Experiment, Three Decades Later,” *NBER Working Paper 18642* (2012).

Optional Readings:

- Heather Royer, “Separated at Girth: US Twin Estimates of the Effects of Birth Weight,” *Am. Ec. J.: App. Ec.* 1:1 (2009) pp. 49.
- James Smith, “The Impact of Childhood Health on Adult Labor Market Outcomes,” *Rev. Ec. & Stat.* 91:3 (2009) pp. 478.

7. **Week of February 24: The Culture Factor**

- (a) *Follow the Leader:* Building on last week’s discussion, we consider how culture impacts public health behavior and participation with an eye to developing policies that work for everybody. Are there any one-size-fits-all approaches to healthcare, or is it necessary to tailor everything to the targeted group. How should we address health concerns that are unique to culturally-isolated or distinct groups, and how can we ensure that these groups are engaged themselves?

Required Reading:

- Wailoo and Pemberton, *The Troubled Dream of Genetic Medicine: Ethnicity and Innovation in Cystic Fibrosis, Tay-Sachs, and Sickle Cell Disease* (Johns Hopkins, 2006). (Introduction and Conclusion)
- A. Dukelow, “Hirono Introduces Legislation to Address Health Disparities,” *Maui Now* (Dec. 3, 2018)

- Amy Harmon, “Couples Culling Embryos to Halt Heritage of Cancer,” NYT, (September 3, 2006)
- “‘Angelina Jolie Effect’ Sparks Surge in Genetic Testing,” CBC News (October 17, 2013)

Optional Readings:

- Amy Harmon, “Cancer Free at 33, but Weighing a Mastectomy,” NYT (September 16, 2007)
- (b) *Addressing Diversity:* In the second part of the week, we focus on three case studies, specifically those efforts at addressing Tay-Sachs, Sickle Cell disease, and Cystic Fibrosis. What made these efforts successful, or what made them fail. We explore these questions with an eye to up-and-coming treatments that are appearing as our knowledge of genetics and gene therapy grow in ways that make such targeted efforts even more salient.

Required Reading:

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

8. **Week of March 3: *Bump the App!***

- (a) *Privacy and Control:* In the era of genetic testing, who controls your genetic information, and what are the bounds on its use. As genetic testing becomes more and more widespread, a wealth of information on individuals is being made available to those individuals themselves, as well as researchers. How is this information being used, and what are the appropriate boundaries on its use? We will also consider what happens when the state or insurers and corporations get a hold of this information.

Required Reading:

- Michael Specter, “Decoding Iceland” (New Yorker, January 18, 1999): 40- 51.
- David E. Winicoff, “Genome and Nation: Iceland’s Health Sector Database and Its Legacy,” *innovations* (Spring 2006)
- Jocelyn Kaiser, “Agency Nixes deCODE’s New Data-Mining Plan” *Science*, 1388-9 (June 21, 2013)
- *Genome Study Predicts DNA of the Whole of Iceland* (2015)
- Kirk Johnson “By Accident, Utah is Proving an Ideal Genetic Laboratory” *NY-Times* (July 2004)
- *Book of Mormon and DNA Studies*
- “Kissing Cousins? Icelandic App Warns if Your Date is a Relative,” *Associated Press*, April 18, 2013.

Optional Readings:

- Helen Shen, “California Considers DNA Privacy Law,” *Nature* (May 2012)
- “DECODING ICELAND: THE DNA OF GREED”

- Reuter’s October 2011; “Iceland’s Decode Signs genetics deal with Pfizer”.
 - Mike Fortun, *Promising Genomics: Iceland and deCODE in a World of Speculation* (California, 2008)
- (b) *What Can Go Wrong?:* In Thursday’s discussion, we turn to what can happen when privacy is breached, focusing on the special case of the Havasupai Tribe in Arizona. What are the boundaries of using genetic information? Who gets to determine those boundaries?

Required Reading:

- Rex Dalton, “When Two Tribes Go To War,” *Nature* (July 2004)
- Amy Harmon, “Where’d you go with my DNA?” *NYT* (April 2010)
- 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.

Be sure to turn in you midterm paper before 5:00PM, March 7!

9. **Week of March 17: *Frankenfish!***

- (a) *GMOs and Big Agro:* This week we turn away from medicine briefly to focus on food. We explore the development of GMO crops and their explosive use worldwide, as well as the resulting legislative responses. We will look at both the benefits and costs of GMOs, and we will consider the role of these products in the future of the American and wrld diet. We will take a particularly comparative approach this week as we examine the differing responses of Europe and the United States.

Required Reading:

- Brad Plumer, “ The Controversial GMO Labeling Bill That Just Passed Congress, Explained,” *Vox* (July 14, 2016)
- Jef Akst “Designer Livestock”, *The Scientist* June 1, 2014
- Jennifer Ackerman “Food: How Altered?” *National Geographic Magazine* May 2002
- “Should Companies be required to label genetically modified food?” *Wall Street Journal* July 12, 2015
- G.M.O. Labeling Bill Gains House Approval. *New York Times*, July 14, 2016
- Genetically engineered salmon approved for consumption. *New York Times* November 19 2015.
- Adrienne LaFrance. Genetically modified Mosquitoes: What Could Possibly Go wrong? *The Atlantic* April 26, 2016
- Greg Allen. Florida Keys approves trial of genetically modified mosquitoes to fight Zika. *NPR* November 20, 2016
- Kate Kelland, “Scientists Make Gene-Edited Chickens in Bid to Halt Next Pandemic,” *Science News* (2019).

- Veronica Stracqualursi, “FDA Allows Genetically Engineered ‘Frankenfish’ Salmon to be Imported to US,” CNN (2019).

Optional Readings:

- Robert Paarlberg “Reinvigorating genetically modified crops” *Issues in Science and Technology*
- David Freedman “The Truth about Genetically Modified Food” *Scientific American* August 20, 2013
- Thomas Bernauer “Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology” Princeton University Press
- Diahanna Lynch. *The Regulation of GMOs in Europe and the United States.* Council on Foreign Relations. April 2001.
- Timothy Searchinger, et al, “Assessing the Efficiency of Changes in Land Use for Mitigating Climate Change,” *Nature* 564 (2018) pp. 249.

- (b) *Taking Sides:* Thursday will be devoted to a discussion of the different reactions of the United States and Europe to GMOs, as well as the resulting fallout on the international market. Which side is right? What are the costs of being wrong?

Required Reading:

- Chelsea Gohd, “A Review of 6,000 Studies Over Two Decades Delivers its Verdict on GMO Corn,” *Futurism* (2019).
- Steven Salzgberg. “EU Court Tries, but Fails, to Clarify Rules on GMOs and CRISPR,” *Forbes* (July 30, 2018).
- Ewan Callaway, “EU Law Deals Blow to CRISPR Crops,” *Nature* 560 (August 2018) pp. 16.
- Nyasha Mudukuti “We May Starve, but at Least We’ll be GMO-Free”, *Wall Street Journal* March 10, 2016
- Jessica Lau. *Same science, Different Policies: Regulating Genetically Modified Goods in the U.S. and Europe.*
- Philip Fernbach, et al. “Extreme Opponents of Genetically Modified Foods Know the Least but Think They Know the Most,” *Nature Human Behavior* (2019).
- Alison Van Eenennaam, “Gene-Edited Food Regulations: Whether It’s a Plant or Animal Shouldn’t Matter, but it Does Now,” *The Conversation* (2019).

Optional Readings:

- Narayanan Narayanan, et al. “Biofortification of Field-Grown Cassava by Engineering Expression of an Iron Transporter and Ferritin,” *Nature Biotechnology* (2019) pp 144-151.

10. **Week of March 24: A Myriad of Problems?**

- (a) *Patenting Genes for Food and Profit:* Who owns your genes? Can your genetic material be patented? This week we will address these questions with an exploration of gene patenting policies. We will focus in particular on the high-profile Myriad and Monsanto cases that brought the question to the forefront of intellectual property law, and we will

explore the ways in which policies must be sensitive to both the rights of the public and the economic realities of medical research and engineering.

Required Reading:

- 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)
- Andrew Pollack Myriad Genetics Ending Patent Dispute on Breast Cancer Risk Testing. *NY Times* (Jan. 27 2015)
- Amy Corderoy. Landmark High Court ruling on BRCA1 gene patent as pensioner wins legal case. *The Sydney Morning Herald* (October 7, 2015)
- *Bowman v. Monsanto Co. et al.* U.S. Supreme Court Decision (2013) (Syllabus)
- Adam Liptak. Supreme Court Supports Monsanto in Seed-Replication Case *NY Times* (May 13, 2013)

Optional Readings:

- E. Richard Gold and Julia Carbone, “Myriad Genetics: In the Eye of the Policy Storm,” (September 2008)
 - 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.
 - “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.
 - Heidi Ledford, “U.S. Supreme Court Upends 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)
 - *D’Arcy v. Myraid Genetics, Inc.* [2015] HCA 35. 7 October 2015, S28/2015.
- (b) *Sticking It to the Little Man:* In the second half of the week, we focus on the efforts of Monsanto to enforce its patents against farmers, including through the use of strict monitoring and burdensome licensing requirements. Is Monsanto being overzealous, or are they just defending their property? Are there ways to mitigate the problems that are arising under the current enforcement regime?

Required Reading:

- Erika Check Hayden. Myriad Genetics embroiled in breast-cancer data fight - again. *Nature* May 20, 2016
- Joseph Stiglitz. How Intellectual Property reinforces Inequality. *NY Times* (July 14 2013)
- Donald Bartlett and James B. Steele. Monsanto's Harvest of Fear *Vanity Fair* (May 2008)
- Tamar Haspel. Unearthed: Are patents the Problem? *Washington Post* September 29, 2014.
- Sophia Chen. Generic GMOs aren't going to Bring down Monsanto's Empire. *Wired*. August 5, 2015

11. **Week of March 31: Pop Genetics**

(a) *The FDA and 23andMe*: This week we look at knowledge and privacy in the age of at-home testing. Touching on discussion from earlier weeks, What are the implications of widely-available home testing kits. Do these tools make self-care easier or do they have the potential to induce excessive consumption of healthcare, especially preventative care?

Required Reading:

- Charles Seife, "23andMe Is Terrifying, but Not for the Reasons the FDA Thinks," *Scientific American* (November 27, 2013).
- Alberto Gutierrez. Warning Letter to 23andMe; November 22, 2013
- George Annas and Sherman Elias, "23andMe and the FDA," *New England Journal of Medicine* 370 (March 13, 2014): 985-988.
- Robert Hof. In Big shift FDA plans to let 23andMe market genetic tests to consumers. *Forbes* Feb. 19, 2015
- "Anne Wojcicki: FDA Shutdown was 'a transformative moment,'" *CNN Money* (February 25, 2016)
- Stephanie M. Lee, "23andme Has Abandoned the Genetic Testing Tech its Competition is Banking on," *Buzzfeed News* (October 26, 2016)
- Stephanie M. Lee, "23andme is Mining Your DNA for the Next Big Drug," *Buzzfeed News* (September 12, 2017)
- Margaret Curnutte, "Regulatory Controls for Direct-to-Consumer Genetic Tests: A Case Study of How the FDA Exercises Authority," *New Genetics and Society* 36 (2017): 209-226
- Stuart Hogarth and Paula Saukko, "A Market in the Making: The Past, Present, and Future of Direct-to-Consumer Genomics," *New Genetics and Society* 36 (2017): 197-208.

Optional Readings:

- Ezra Klein. Should the FDA stop you from scaring yourself with 23andMe's DNA test? *Washington Post* December 6, 2013
- Emily Walker, FDA Panel says home gene tests need doctor input. *ABC News* March 12, 2011

- American Society for Human Genetics, 2007 (“ASHG Statement* on Direct-to-Consumer Genetic Testing in the United States”)
 - 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
 - Stuart Hogarth, Gail Javitt and David Melzer. The Current Landscape for Direct-to-consumer testing: legal, ethical and policy issues. *Ann. Rev. Genomics Hum., Genet.* 9, 161-182 (2008)
 - FDA Molecular and Clinical Genetics Panel (Executive Committee Report on Direct to Consumer (DTC) Genetic Tests that make medical claims), March 2011.
 - Amy Harmon Taking a peek at the Experts’ genetic secrets. *New York Times* October 19,2008
 - Madelaine Ball et al. Harvard Personal Genome Project: Lessons from participatory public research. *Genome Medicine* 6, 10 (2014)
 - Sara Reardon, Giant study poses DNA sharing dilemma. *Nature* (September 1 2015)
 - Background and Details on Genetic Information Non-Discrimination Act (GINA, 2008) from Human Genome project information website
 - 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).
- (b) *For My Eyes Only*: How should at-home tests be regulated? Can they be made to be compulsory? How is the resulting data stored? We will explore the threats to privacy and discrimination that are arising with the increase in home testing, including the role of the state in obtaining individual information from third parties.

Required Reading:

- 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)
- Timothy Caulfield and Amy McGuire. Direct-to-Consumer Genetic Testing: Perceptions, Problems and Policy Responses. *Ann. Rev. Med.*63,23-33 (2012)
- Michael Balsamo, “A look at DNA Testing that ID’d a Suspected Serial Killer,” *Washington Post* (April 27, 2018).

12. **Week of April 7: Epigenetics**

- (a) *Genes Beyond Genetics*: Lying at the forefront of medicine, epigenetics is concerned with the effect of environment on genetic expression. How does our environment affect our genes, and with them our long-term health. Can long-term health disparities be

addressed by short-term environmental improvements, or are these effects built in to longer-term consequences?

Required Readings:

- Carl Zimmer, “Can a Parent’s Life Experience Change the Genes a Child Inherits?” *The Atlantic* (June 21, 2018).
- Kevin Laland, “Beyond Epigenetics,” *Science* 360:6396 (2018) pp. 1408.
- Denny Vagero, et al, “Paternal Grandfather’s Access to Food Predicts All-Cause and Cancer Mortality in Grandsons,” *Nature Communications* 9:5124(2018)
- Nicoletto and Rinaldi, “In the Womb’s Shadow,” *EMBO* (2011).
- John McLachlan, “Commentary: Prenatal Exposure to Diethylstilbestrol (DES): A Continuing Story,” *Int. J. Epidemiology* 35 (2006) pp. 868.
- Anne Ferguson-Smith and Mary-Elizabeth Patti, “You Are What Your Dad Ate,” *Cell Metabolism* 13 (2011) pp. 115.

Optional Readings:

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

- (b) *Regulating Tomorrow*: What is the appropriate policy response to new discoveries in epigenetics? How should regulators respond to the possibility that their policies will potentially have impacts that last for generations, especially when the effects of those policies may be irreversible?

Required Readings:

- Mark Rothstein and Gary Merchant, “The Ghost in Our Genes: Legal and Ethical Implications of Epigenetics,” *Health Matrix* 19 (2009) pp. 1.
- Sarah Richardson, “Comment: Don’t Blame the Mothers,” *Nature* 512 (2014) pp. 131.
- Mihai Niculescu, “Epigenetic Transgenerational Inheritance: Should Obesity Prevention Policies be Reconsidered?” *Synesis* (2011) pp. G:18.

13. **Week of April 14: *New Genetics or Old Eugenics?***

- (a) *Gene Therapy and Ghosts of the Past*: How does modern gene therapy relate to the eugenic movement of the last century? Is it something new, or just the same old idea in a new wrapper? This week, we come full circle and address this question with an examination of new medical procedures and the ethical challenges that arise with them.

Required Reading:

- Denise Grady. FDA Approves First Gene-altering Leukemia Treatment, costing \$475,000. *New York Times* August 30, 2017.

- Kim Tingley, “The Brave New World of Three-Parent IVF.” NYT Magazine June 27, 2014
- MPs vote in favour of three-person embryo law. The Guardian Feb. 3, 2015
- Anne Clairborne, Rebecca English and Jeffrey Kahn, Eds. Mitochondrial Replacement Techniques: Ethical, Social and Policy Considerations. National Academies Press (2016) pg. 1-15.
- Eric Lander. Brave New Genome. New England Journal of Medicine July 2, 2015.
- Sara Reardon. Gene-editing wave hits clinic. Nature 527, 146-147 (2015).
- Chapter 2, Oversight of Human Genome Editing and Overarching Principles for Governance. Human Genome Editing: Science, Ethics and Governance. National Research Council 2017
- Chapter 6, Enhancement. Human Genome Editing: Science, Ethics and Governance. National Research Council 2017

Optional Readings:

- Jennifer Doudna and Emmanuelle Charpentier. The New Frontier of genome engineering with CRISPR-Cas9. Science 346, 1077 (2014).
- 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
- Matthew Cobb. The New York Review of Books. July 13, 2017.
- Douglas C. Wallace. Mitochondrial Diseases in Man and Mouse. Science 283, 1482-1488 (1999)
- Michael Specter. The Gene Hackers. The New Yorker, November 16, 2015.
- 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
- “Three-Parent DNA Treatment for Rare Defect Raises Debate,” PBS Newshour discussion (February 3, 2016).
- David B.T. Cox, Randall J. Platt and Feng Zhang. Therapeutic genome editing: prospects and challenges. Nature Medicine 21, 121-131 (2015).
- Steve Olson, International Summit on Human Gene Editing: A Global Discussion. National Academies Press (December 2015)

(b) *Designer Babies:* To close out the week, we will discuss the groundbreaking work of Dr. He Jiankui, who claims to have engineered the first genetically-modified babies using CRISPR. What are the ethical considerations that arise in this scenario? How should the world react? This is a rapidly-developing story, and will likely see several updates through the semester that we will wish to look at.

Required Reading:

- Gerry Shih and Carolyn Johnson, “Chinese Genomics Scientist Defends His Gene-Editing Research in First Public Appearance,” *Washington Post* (November 28, 2018).

- Jennifer Willows, “WHO to Discuss Genome Editing While Dr. He Jiankui is Missing,” *BioNews* (December 10, 2018).
- Edward Lanphier et al. Don’t edit the human germ line. *Nature* 519, 410 (2015).
- Cary Funk, Brian Kennedy, and Elizabeth Sciupac, “U.S. Public Wary of Biomedical Technologies to ‘Enhance’ Human Abilities,” Pew Research Center (July 26, 2016)

Optional Readings:

- Dennis Normite, “Scientist Behind CRISPR Twins Sharply Criticized in Government Probe, Loses Job.” AAAS (2019).
- Linqi Zhang, et al, “Open Letter from Chinese HIV Professionals on Human Genome Editing,” *The Lancet* (Nov. 30, 2018).
- Rob Stein, “Chinese Scientist Says He’s First to Create Genetically Modified Babies using CRISPR,” *NPR* (November 26, 2018).

14. **Week of April 21: *Ethics on the Frontier***

- (a) *Regulating Advances in Healthcare:* In our final week, we will take a last look at the state of healthcare in the United States and the world so that we may ask ourselves, “Where do we go from here?” We will make our final considerations of the path that we believe policy should take from here, and ask ourselves whether it is moving in the right direction. We may not reach a consensus, but we will place our cards on the table. Is there an ace in the hole?

Required Reading:

- Alexander Capron, “Remembering Asilomar? Reexamining Science’s Ethical and Social Responsibility,” *Perspectives in Biology and Medicine* 44 (Spring 2001): 162-169
- Paul Berg. Asilomar 1975: DNA modification secured. *Nature* 455, 290-291 (2008).
- Scientific and Medical Aspects of Human Reproductive Cloning. National Academies Press. Executive Summary (pg. 1-18)
- Andreas von Bubnoff. The 1918 flu virus is resurrected. *Nature* 437, 794-795 (2005).
- Ed Yong. Mutant-flu paper published. *Nature* 485, 13-14 (2012).
- Amy Patterson et al. A Framework for Decisions about Research with HPAI H5N1 Viruses. *Science* 339, 1036-1037 (2013)
- Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values. National Academies Press (2016). Summary
- Kelly Servick. Scientists reveal proposal to build human genome from scratch. *Science* Jun 2, 2016.
- George Church. Encourage the innovators. *Nature* 528, 87 (2015).
- Chapter 7. Public Engagement. *Human Genome Editing: Science, Ethics and Governance*. National Research Council 2017

Optional Readings:

- Kevin M. Esvelt et al. Concerning RNA-Guided gene drives for the alteration of wild populations. eLife DOI:10.7554/eLife.03401 (2016).
- Peiyuan Qiu, et al. “BMAL1 Knockout Macaque Monkeys Display Reduced Sleep and Psychiatric Disorders,” Neuroscience (2019).
- “First Paralyzed Human Treated with Stem Cells has Now Regained his Upper Body Movement,” Higher Perspective (2019).

(b) Summary Discussion

Be sure to turn in your final paper by 5:00PM, April 29!