

**LAWM 5300-301-24A – Health Law and Policy**  
**University of Pennsylvania Carey School of Law**

**Tuesdays, 5:30-8:00pm**  
**January 16 – April 23, 2024**

<b>Instructor:</b>	<a href="#">Holly Fernandez Lynch, JD, MBE</a> Assistant Professor of Medical Ethics, Perelman School of Medicine Assistant Professor of Law, Carey Law School (secondary) University of Pennsylvania
<b>Office Hours:</b>	By appointment (typically open the 60-90 minutes before class)
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### Overview

Health Law and Policy is a survey course intended to introduce non-lawyers to a selection of foundational legal issues arising in the U.S. health care system. It is taught as a seminar, meaning it will rely on a combination of lectures and discussion. Grading is based on written assignments and Canvas discussion posts.

The course addresses how statutes, regulations, case law, and other policy levers – across local, state, and federal levels – shape health and health care and influence various stakeholders, including patients, clinicians, payers, institutions, and others. Across topics, we will take a multidisciplinary approach to consider not only what the law is, but also what it should be, relying on insights from bioethics, public health, economics, and other fields. We will also consider the role of health law as a structural determinant of health, both contributing to structural racism and serving as a potential lever to redress its consequences.

Specific course topics include health insurance and reform; regulating the medical profession and clinical relationship; mental health and disability law; legal governance of reproduction and death; public health law; biopharmaceutical pricing and regulation; and human subjects research oversight, among others. Because this is an introductory course, it aims for breadth over depth; even in breadth, however, it is not intended to be comprehensive. More advanced legal issues related to insurance, health care fraud, antitrust, medical malpractice, and intellectual property should be pursued in specialized courses.

### Learning Objectives

- Understand the role of and relationships between various sources of U.S. health law and policy, including legislatures, agencies, courts, and other institutions, at the federal, state, and local level
- Identify and explain key legal issues and trends arising in the U.S. health care system
- Critically analyze and contribute to public debate relevant to selected legal issues arising in the U.S. health care system
- Recognize instances in which health law entrenches inequities and identify potential solutions

## Course Snapshot

<b>Session:</b>	<b>Topic:</b>
Session 1 January 16, 2024	Course Overview Introduction to the US Legal System Introduction to Health Law and Policy
Session 2 January 23, 2024	Health Law and Anti-Racism
Session 3 January 30, 2024	Health Care Spending and Insurance <i>Guest Lecturer: <a href="#">Emily Largent</a></i> The Affordable Care Act and Health Reform <i>Guest Lecturer: <a href="#">Allison Hoffman</a> (via Zoom)</i>
Session 4 February 6, 2024	The Treatment Relationship The Law of Conscience in Medicine
Session 5 February 13, 2024	Informed Consent Confidentiality and Privacy
<b>Assignment: 2/20/24</b>	<b>Complete brief response prompt in preparation for Session 7</b>
Session 6 February 20, 2024	Regulating the Medical Profession Medical Error and Malpractice
<b>Assignment: 2/23/24</b>	<b>Op Ed #1 *or* Term Paper Topic Selection Due</b>
<b>Session 7: VIA ZOOM (no in person meeting)</b> February 27, 2024	Mental Health Law <i>Guest Lecturer: <a href="#">Dom Sisti</a></i> Disability Law <i>Guest Lecturer: <a href="#">Jasmine Harris</a></i>
<i>Spring Break March 5, 2024</i>	<i>No class</i>
Session 8 March 12, 2024	Organ Procurement and Allocation
Session 9 March 19, 2024	End of Life Issues
Session 10 March 26, 2024	Regulation of Research with Human Participants
<b>Assignment: 3/29/24</b>	<b>Op Ed #2 *or* Term Paper Outline Due</b>
<b>Session 11: VIA ZOOM (no in person meeting)</b> April 2, 2024	Reproductive Justice and Abortion <i>Guest Lecturer: <a href="#">Aziza Ahmed</a></i>
Session 12 April 9, 2024	Public Health Law I: Public Health Law Foundations Noncommunicable Disease Prevention
<b>Session 13: VIA ZOOM (no in person meeting)</b> April 16, 2024	Public Health Law II: Communicable Disease Prevention and Response COVID-19 and the Future of Public Health Law <i>Guest Lecturer: <a href="#">Ross Silverman</a></i>
Session 14 April 23, 2024	Pharmaceutical Regulation and Pricing
<b>Assignment: 4/26/24</b>	<b>Op Ed #3 *or* Term Paper Due</b>

## Course Requirements and Grading

Regular attendance and high-quality class participation are expected, both to facilitate understanding of the course material and promote student-to-student learning.

Your grade is based on analytical writing assignments (75%) and response posts on Canvas (25%). Exceptional class participation can provide a grading boost in close cases at the end of the semester.

### Analytical writing – 75%

You may choose from the following assignment options. I am unable to review drafts in advance of submission. However, you may make an appointment to discuss topics or grading feedback on prior submissions, as needed.

#### Option 1. Three Op-Eds

This option requires three short writing assignments in the form of op-ed style essays applying material learned in class to current issues and events. These should be written for an educated lay audience (e.g., readership of the New York Times or Wall Street Journal). Op-eds demand both precision and persuasion; they are not reports or summaries, but rather short *arguments*. They are a helpful way to hone your ideas and may result in publishable work. Here are a few published examples from prior students:

- <https://bioethicstoday.org/blog/its-never-too-early-to-look-death-in-the-eye/>
- <https://bioethicstoday.org/blog/coercive-sterilization-isnt-a-matter-of-the-past/>
- <https://bioethicstoday.org/blog/does-our-organ-transplant-system-exploit-undocumented-immigrants/>

Each op-ed should be 900-1200 words. Do not go over word count. Rather than traditional citations, use in-text hyperlinks (as in a real op-ed).

If you choose this option, make sure to read several op-eds, e.g., from [STAT's First Opinion](#), to get a sense of the style. Please also watch this video lecture for additional guidance: <https://upenn.box.com/s/ja8wo6x5aj54f57dxrmct7bmqs9aq27>.

You may also find these resources helpful:

- [https://journals.lww.com/academicmedicine/Fulltext/9900/Writing\\_an\\_Op\\_Ed\\_for\\_a\\_Lay\\_Audience\\_How\\_to.306.aspx](https://journals.lww.com/academicmedicine/Fulltext/9900/Writing_an_Op_Ed_for_a_Lay_Audience_How_to.306.aspx)
- <https://twitter.com/thekibosch/status/1635736976405004290?s=43&t=kRDOo1WcdAFI9mnky8r9LQ>

Due dates:

**Op-Ed 1 (25%): Due by 11:59pm ET on Friday, February 23, 2024**

Select a topic related to course sessions 1-6

**Op-Ed 2 (25%): Due by 11:59pm ET on Friday, March 29, 2024**

Select a topic related to course sessions 1-10

**Op-Ed 3 (25%): Due by 11:59pm ET on Friday, April 26, 2024**

Select a topic related to course sessions 1-14

Op-eds will be graded using the following rubric:

Clearly stated thesis	5 points
Demonstrated importance of topic, adequate background	5 points
Well-reasoned argument using principles and themes from class	5 points
Fair and well-reasoned responses to objections	5 points
Appropriate support/references	5 points
	Total: 25 points

## Option 2. Term Paper

This option requires a single term paper on any topic covered in the course. The paper should take a position and defend it; it should not be a mere summary of a topic. Term papers should be no more than 3,000 words, plus references. (NB: If following a somewhat different format/length would allow this paper to fulfill a writing requirement for another program, we can discuss appropriate adjustments.)

As you consider this option and your topic, note that the American Society for Law, Medicine, and Ethics runs an annual graduate student writing competition in Health Law and Anti-Racism. I will share this year's call when it is posted, but here is the 2023 announcement: <https://aslme.org/wp-content/uploads/2023/01/ASLME-3rd-Annual-Anti-Racism-Writing-Competition-Call-2023.pdf> (I am a judge for this competition and recuse myself from reviewing my own students' entries.)

### **Topic Selection: Due by 11:59pm ET on Friday, February 23, 2024**

Submit a tentative paper title and 1-2 paragraph description of your selected topic and position.

### **Outline: Due by 11:59pm ET on Friday, March 29, 2024**

Submit a detailed outline of the paper with preliminary references.

### **Final Paper: Due by 11:59pm ET on Friday, April 26, 2024**

Submit the complete, fully referenced paper.

Term papers will be graded using the following rubric:

Clearly stated thesis	15 points
Demonstrated importance of topic, adequate background	15 points
Well-reasoned argument using principles and themes from class	15 points
Fair and well-reasoned responses to objections	15 points
Appropriate support/references	15 points
	Total: 75 points

## Group Work

It is permitted – and in fact, I encourage you – to work in groups of 2-3 on the written assignments for this course. Ideal partnerships will combine different areas of student expertise and backgrounds. If you choose the op-ed option, you may write some op-eds in a group and some individually, whatever you

prefer (i.e., you don't have to take the same approach each time and you could choose to work with a different group for each submission). For group submissions, you must include a brief description of each author's contribution. All members of the group will receive the same grade.

### Response posts – 25%

Students are expected to critically engage with course materials, identify themes and inconsistencies, and contribute meaningful perspective from their own experience and current events, both in class (to the extent time permits) and through response posts.

**Beginning with Session 2 and in advance of at least 5 course sessions (by 9am ET on the day of class), students should post one paragraph (5-7 sentences) to Canvas responding to the readings for that week.** Response paragraphs can take many forms. For example, you might draw connections between the various readings, highlight a fact or argument that surprised you, point to a gap in the literature, link the readings to your personal/professional experiences or to current events, or pose a question raised for you by the readings. Please avoid simply summarizing the materials.

Responses will not be graded individually and I will not respond to them online (although you are welcome to respond to each other). Instead, I will use these posts to guide in-class content. To receive full credit, you will need to post responses for 5 different class sessions. There is no "extra credit" for posting more often, although you are certainly welcome to do so.

NB: There is an activity in Session 7 that requires a response on Canvas. This does not count as one of the five required discussion posts.

### Expectations and Accommodations

If you need to miss class, please do your best to email me in advance. No explanation or excuse is needed. If you need to miss class more than twice, let's discuss how to make sure you're able to still achieve the learning objectives.

If you need an extension, please request it before the due date, if possible.

I know that life doesn't stop just because you're a student. You may face personal, professional, or other demands that make it difficult for you to complete course requirements. My goal is to support you as both a learner and a whole person. If you need help or accommodation of any kind, please let me know and we will work out a reasonable solution.

### Office Hours

I would love to meet with you in person or virtually to discuss the course, current events, career goals, graduate school, etc. I don't maintain regular office hours, but I will happily schedule meetings at a mutually convenient time. It usually works well to try to meet in the hour before class and I will try to keep that time open. Because I have young children, I'm usually not able to stay after class.

### Academic Integrity

You may use AI programs, e.g., ChatGPT, to help generate ideas and brainstorm for your assignments. However, you should note that the material generated by these programs is often inaccurate, incomplete, or otherwise problematic. Beware that use may also stifle your own independent thinking and creativity.

You may not submit any work generated by an AI program as your own. If you include material generated by an AI program, it should be cited like any other reference material (with due consideration for the quality of the reference, which may be poor).

Any plagiarism or other form of cheating will be dealt with severely under relevant Penn policies: <https://catalog.upenn.edu/pennbook/code-of-academic-integrity/>

### Readings and Assignments

All information for this course, including readings, can be found on Canvas, which you can access with a PennKey and password. Note that although PDFs have been provided, they are often from websites and may not be formatted correctly. You may find it easier to go directly to the provided URLs.

Please try to read all required readings before class. Optional readings are completely up to you and may be helpful for your op-eds and to inform class discussion; I will not assume that anyone has read the optional material.

I recognize that the reading load is somewhat heavy. **If you are strapped for time, I have designated the most important materials for each session with an asterisk.**

NOTE: I may need to adjust readings throughout the semester in response to current events. Please check the syllabus and Canvas frequently. I will notify you when changes are made.

### How to read for this course:

Although it may seem like a lot, the materials I have selected reflect only a narrow sample of those available on any given topic. They are intended to provide an overview of important concepts and arguments, as well as an introduction to key issues.

Try not be overwhelmed by the number of documents provided. There is no exam and I will not call on students with the expectation that you will remember specific details of each reading. You should do more than skim (unless skimming is specified) but you can focus on main ideas and the gestalt of each piece. Imagine trying to summarize each piece in a few sentences or main points.

When reading, ask yourself the following questions:

1. What legal principles and concepts are relevant to this piece?
2. Why is it included in the syllabus?
3. How does it relate to other readings this week?
4. How does it relate to other issues covered in this course?
5. As relevant: Do I agree or disagree with the arguments presented?
6. What questions or points would I like to discuss with the class?

Session 1: January 16, 2024

## Introduction to the US Legal System

### Introduction to Health Law and Policy

#### Objectives:

- Develop a basic understanding of the US legal system and sources of law
- Describe the foundations of health law and policy in the US
- Begin to identify the goals of various stakeholders within the healthcare system

#### Readings:

1. \*Gostin LO. The Formulation of Health Policy by the Three Branches of Government, in IOM Committee on the Social and Ethical Impacts of Developments in Biomedicine, Society's Choices: Social and Ethical Decision Making in Biomedicine. 1995. <https://www.ncbi.nlm.nih.gov/books/NBK231979/>
2. \*Fuse Brown EC, Kesselheim AS. The History of Health Law in the United States. N Engl J Med 2022; 387:289-292. <https://www.nejm.org/doi/full/10.1056/NEJMp2207360>
3. Health Policy: Resources for Congressional Staff, <https://www.everycrsreport.com/reports/R43889.html>. *SKIM only the following:*
  - The Federal Government's Role in Health Policy, [https://www.everycrsreport.com/reports/R43889.html#\\_Toc9004346](https://www.everycrsreport.com/reports/R43889.html#_Toc9004346)
  - Federal Agencies, [https://www.everycrsreport.com/reports/R43889.html#\\_Toc9004348](https://www.everycrsreport.com/reports/R43889.html#_Toc9004348)
4. \*Auerbach JN, Sharfstein JM. The Supreme Court's New Direction and the Public's Health. JAMA Health Forum. 2022;3(7):e222978. <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2794725>
5. Mello MM, Parmet WE. US Public Health Law — Foundations and Emerging Shifts. N Engl J Med 2022; 386:805-808. <https://www.nejm.org/doi/full/10.1056/NEJMp2200794>
6. Gostin LO, Hodge JG, Levin DE. Legal Interventions to Address US Reductions in Life Expectancy. JAMA. 2020;324(11): 1037-38. <https://jamanetwork.com/journals/jama/fullarticle/2769931>

#### Optional:

- Farnsworth EA. An Introduction to the Legal System of the United States. 4<sup>th</sup> ed. 2010.
  - Judicial System (pp. 43-46), Case Law (pp. 53-55, 58-65)
  - Legislative System (pp. 69-76)
  - Private Law: contracts, torts (pp. 133-142)
  - Public Law: constitutional and administrative (pp. 163-173)
- Kerr OS. How to Read a Legal Opinion. The Green Bag. 2007;11:51-63. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1160925](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1160925)

## Session 2: January 23, 2024

### Health Law and Anti-Racism

#### Objectives:

- Recognize law as a structural determinant of health
- Identify law and policy tools to improve healthy equity

#### Readings:

1. \*Jones CP. Levels of Racism: A Theoretic Framework and a Gardener's Tale. *American Journal of Public Health*. 2000;90(8):1212–1215. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446334/>
2. Rebouche R, Burris S. The Social Determinants of Health, in *The Oxford Handbook of U.S. Health Law*, 2016. *Skip ACA section, read conclusion.*
3. \*Paul-Emile K. Race and Health Law, in *The Oxford Handbook of Race and Law in the United States*, 2022. <https://doi.org/10.1093/oxfordhb/9780190947385.013.15>
4. Allsbrook JF, Keith K. ACA Section 1557 as a Tool for Anti-Racist Health Care. *Health Affairs Forefront*. Dec. 8, 2021. <https://www.healthaffairs.org/doi/10.1377/forefront.20211207.962085/>
5. Largent EA. Public Health, Racism, and the Lasting Impact of Hospital Segregation. *Public Health Reports*. 2018;133(6):715-720. <https://journals.sagepub.com/doi/full/10.1177/0033354918795891>
6. \*Jost TS. Considering Race and Ethnicity in Covid Risk Assessments — Legal Concerns and Possible Solutions. *N Engl J Med*. 2022; 387:481-483. <https://www.nejm.org/doi/full/10.1056/NEJMp2206524>
7. Mensah MO, Sommers SR, Sommers BD. Worse Access, Quality, and Leadership—Redressing the Affirmative Action Ruling's Litany of Harms. *JAMA Health Forum*. 2023;4(10):e234099. <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2810590>

#### Strongly Recommended:

- Gamble VN. Under the Shadow of Tuskegee: African Americans and Health Care. *American Journal of Public Health*. 1997;87:1773-78. <https://ajph.aphapublications.org/doi/10.2105/AJPH.87.11.1773>

#### Optional:

- Crear-Perry J et al. Social and Structural Determinants of Health Inequities in Maternal Health. *Journal of Women's Health*. 2021;30(2):230-235. <https://www.liebertpub.com/doi/full/10.1089/jwh.2020.8882>
- Lai KKR, Medina J. An American Puzzle: Fitting Race in a Box [US Census categories]. *NY Times*. October 16, 2023. <https://www.nytimes.com/interactive/2023/10/16/us/census-race-ethnicity.html>
- Kenen J, Bachlor E. Racist Doctors and Organ Thieves: Why So Many Black People Distrust the Health Care System. *Politico Magazine*. December 18, 2022. <https://www.politico.com/news/magazine/2022/12/18/black-mistrust-healthcare-00060324>



Session 3: January 30, 2024

## Health Care Spending and Insurance

Guest Lecturer: [Emily Largent](#)

## The Affordable Care Act and Health Reform

Guest Lecturer: [Allison Hoffman](#) (via Zoom)

### Objectives:

- Understand the drivers of health care spending and cost
- Explain and critique how US healthcare is currently financed – and how we got here
- Describe key features of the Affordable Care Act, gaps, major legal challenges, and current status

### Readings:

1. Ruger JP, Ruger TW, Annas GJ. The Elusive Right to Health Care Under US Law. *NEJM*. 2015;372(26):2558-2563. <https://www.nejm.org/doi/full/10.1056/NEJMhle1412262>
2. Interlandi J. Why doesn't the United States have universal health care? The answer has everything to do with race. *NY Times*. August 14, 2019. <https://www.nytimes.com/interactive/2019/08/14/magazine/universal-health-care-racism.html>
3. \*Corlette S, Monahan CH. U.S. Health Insurance Coverage and Financing. *New Eng J Med*. 2022;387(25):2297-2300. <https://www.nejm.org/doi/full/10.1056/NEJMp2206049>
4. CMS. Brief Summaries of Medicare and Medicaid. Nov. 1, 2023. *Read pp. 8-13, briefly skim the section on beneficiary payment liabilities (pp. 17-19), read pp. 25-35.* <https://www.cms.gov/files/document/brief-summaries-medicare-medicaid-november-1-2023.pdf>
5. \*Gluck AR, Regan M, Turret E. The Affordable Care Act's Litigation Decade. *Georgetown L J*. 2020;108:1471-34. *Read only the Introduction and sections I and II, don't worry about the footnotes.* [https://www.law.georgetown.edu/georgetown-law-journal/wp-content/uploads/sites/26/2020/06/Gluck-Reagan-Turret\\_The-Affordable-Care-Act%E2%80%99s-Litigation-Decade.pdf](https://www.law.georgetown.edu/georgetown-law-journal/wp-content/uploads/sites/26/2020/06/Gluck-Reagan-Turret_The-Affordable-Care-Act%E2%80%99s-Litigation-Decade.pdf)
6. Buchmueller TC, Levy HG. The ACA's Impact on Racial and Ethnic Disparities in Health Insurance Coverage and Access to Care. *Health Affairs*. 2020;39(3):395-402. *Focus on the results and discussion sections.* <https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01394>

### Optional:

- American Academy of Actuaries. Risk Pooling: How Health Insurance in the Individual Market Works. 2017. <https://www.actuary.org/content/risk-pooling-how-health-insurance-individual-market-works-0>
- Scott D. Why the US is the only country that ties your health insurance to your job. *Vox*. October 16, 2023. <https://www.vox.com/23890764/healthcare-insurance-marketplace-open-enrollment-employer-sponsored-united-blue-cross-shield-aetna>
- Owen D. A Freelancer's Forty-Three Years in the American Health Care System. *New Yorker*. March 26, 2022. <https://www.newyorker.com/culture/personal-history/a-freelancers-forty-three-years-in-the-american-health-care-system>

- Hoffman AK. What Health Reform Reveals About Health Law, in The Oxford Handbook of U.S. Health Law. 2016. <https://www.oxfordhandbooks.com/view/10.1093/oxfordhb/9780199366521.001.0001/oxfordhb-9780199366521-e-3>
- Oberlander J. Long Time Coming: Why Health Reform Finally Passed. Health Affairs. 2010;29(6):1112-1116. <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2010.0447>
- Institute of Medicine. Summary. In Essential Health Benefits: Balancing Coverage and Cost. 2012. <https://www.nap.edu/read/13234/chapter/3>

Session 4: February 6, 2024

## The Treatment Relationship

### The Law of Conscience in Medicine

#### Objectives:

- Describe how the treatment relationship is created and terminated
- Explain the evolution of the common law duty to treat and limits on emergency care
- Explain and critique the law's approach to discrimination and conflicts of conscience in clinical practice

#### Readings:

1. \*Derse AR. The Physician-Patient Relationship. NEJM. 2022;387(8):669-672. <https://www.nejm.org/doi/full/10.1056/NEJMp2201630>
2. \*Rosenbaum S, Frankford DM. LAW AND THE AMERICAN HEALTH CARE SYSTEM (2<sup>nd</sup> Ed.), pp. 17-20 (stop after Note 1); 21-25 (read Ricks v. Budge only); 26-31 (read Campbell v. Mincey). *Read the cases carefully to understand the plaintiff's theory of the case, defendant's counterarguments, and the court's reasoning.*
3. Hyman D, Studdert D. Emergency Medical Treatment and Active Labor Act: What Every Physician Should Know About the Federal Antidumping Law. Chest. 2015;147(6):1691-1696. <https://pubmed.ncbi.nlm.nih.gov/26033130/>
4. Paul-Emile K. US Law and Discrimination in Health Care. NEJM. 2023;388(21):1921-1924. <https://www.nejm.org/doi/full/10.1056/NEJMp2202164>
5. \*Sepper E. Conscientious Refusals of Care, in the Oxford Handbook of US Health Law (I. Glenn Cohen, Allison K. Hoffman, & William M. Sage, eds.) (2017). *Skip Section IV.*
6. Lynch HF, Stahl RY. Protecting Conscientious Providers of Health Care. NY TIMES, Jan. 26, 2018. <https://www.nytimes.com/2018/01/26/opinion/protecting-conscientious-providers-of-health-care.html>

#### Optional:

- Bloche MG. The Supreme Court and the Purposes of Medicine. NEJM. 2006; 354:993-995. <https://www.nejm.org/doi/full/10.1056/NEJMp068019>
- Sawicki N. Protections from Civil Liability in State Abortion Conscience Laws. JAMA. 2019;322(19):1918-1919, <https://jamanetwork.com/journals/jama/fullarticle/2755604>

Session 5: February 13, 2024

## Informed Consent Confidentiality and Privacy

### Objectives:

- Learn how to read a judicial opinion (while examining the legal history of informed consent)
- Identify and critique legal standards for informed consent to clinical care
- Describe the parameters and evaluate the limits of clinical confidentiality obligations
- Explain key health privacy protections and gaps

### Readings:

1. Berg JW, Appelbaum PS, Lidz CW, Parker LS. The Legal Requirements for Disclosure and Consent: History and Current Status, in INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE (2d ed.), pp. 41-74. *Focus on pp. 53-70.*
2. \*Rosenbaum R, Frankford DM. LAW AND THE AMERICAN HEALTH CARE SYSTEM (2<sup>nd</sup> Ed.), pp. 730-739 (*Canterbury v. Spence*).
3. \**Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334 (Cal. 1976).  
<https://law.justia.com/cases/california/supreme-court/3d/17/425.html> *Read up to section 3 on p. 12, pick up again on p. 17 for the conclusion and the additional judge's opinions till the end of p. 26. (Footnotes are often important in legal cases, but you can skip them here.)*
4. \*Hoffman S. Privacy and Security – Protecting Patients' Health Information. NEJM. 2022;387(21):1913-1916. <https://www.nejm.org/doi/pdf/10.1056/NEJMp2201676>
5. Price WN, Kaminski ME, Minssen T, Spector-Bagdady K. Shadow health records meet new data privacy laws. Science. 2019;363(6426):448-450.  
<https://www.science.org/doi/epdf/10.1126/science.aav5133>
6. Michelson KN, Adams JG, Faber JMM. Navigating Clinical and Business Ethics While Sharing Patient Data. JAMA. 2022;327(11):1025–1026. <https://jamanetwork.com/journals/jama/fullarticle/2789636>

### Optional:

- Faden RR, Beauchamp TL (with King NMP). A History and Theory of Informed Consent (1986), pp. 116-150. *Review for more on the historical trajectory of informed consent.*
- Rothstein MA. Tarasoff Duties after Newtown. J. L. Med. & Ethics. 2014;42(1):104-109.  
<https://journals.sagepub.com/doi/abs/10.1111/jlme.12123>
- Kipnis K. In Defense of Absolute Confidentiality. AMA Journal of Ethics. 2003;5(10).  
<https://journalofethics.ama-assn.org/article/defense-absolute-confidentiality/2003-10>
- HHS, Your Rights Under HIPAA, <https://www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html>

Session 6: February 20, 2024

**Regulating the Medical Profession  
Medical Error and Malpractice**

**\*Make sure to complete the brief response needed for Session 7 and submit by February 20.**

**Objectives:**

- Describe and critique the basic legal approach to regulating the practice of medicine
- Identify the causes and frequency of errors in health care
- Describe the goals of medical malpractice liability and assess reform options

**Readings:**

1. \*Roy CG. Patient Safety Functions of State Medical Boards in the United States. *Yale Journal of Biology and Medicine*. 2021;94(1):165-173.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7995940/>
2. Cortez N. The Law of Licensure and Quality Regulation. *NEJM*. 2022;387:1053-1056.  
<https://www.nejm.org/doi/full/10.1056/NEJMp2201802>
3. Baker RB, Washington HA, Olakanmi O, et al. African American Physicians and Organized Medicine, 1846-1968: Origins of a Racial Divide. *JAMA*. 2008;300(3):306–313.  
<https://jamanetwork.com/journals/jama/article-abstract/182255>
4. Avi-Yonah S. Medicine without doctors? State laws are changing who treats patients. *Washington Post*. August 20, 2023. <https://www.washingtonpost.com/health/2023/08/20/nurse-doctor-scope-medical-titles/>
5. Institute of Medicine. *To Err Is Human: Building a Safer Health System*. 1999. *SKIM Executive Summary only*. <https://www.ncbi.nlm.nih.gov/books/NBK225179/>
6. \*Hyman DA, Silver C. Medical Malpractice Litigation, in *Oxford Research Encyclopedia: Economics and Finance*. 2019. <https://doi.org/10.1093/acrefore/9780190625979.013.365>
7. Studdert DM, Hall MA. Medical Malpractice Law – Doctrines and Dynamics. *NEJM*. 2022;387: 1533-1537. <https://www.nejm.org/doi/full/10.1056/NEJMp2201675>
8. Mello MM, Frakes MD, Blumenkranz E, Studdert DM. Malpractice Liability and Health Care Quality: A Review. *JAMA*. 2020;323(4):352–366. *Read full abstract and discussion section only*.  
<https://jamanetwork.com/journals/jama/article-abstract/2759478>

**Optional:**

- Federation of State Medical Boards, *An Introduction to Medical Regulation*,  
<https://www.fsmb.org/siteassets/education/pdf/best-module-text-intro-to-medical-regulation.pdf>
- Pennsylvania Medical Practice Act, *skim to get a sense of coverage*  
<https://www.legis.state.pa.us/cfdocs/Legis/LI/uconsCheck.cfm?txtType=PDF&yr=1985&sessInd=0&smthLwInd=0&act=0112>

- American Association of Medical Colleges. 20 Years of Patient Safety. 2019.  
<https://www.aamc.org/news-insights/20-years-patient-safety>
- Doroshow J, Widman A. The Racial Implications of Tort Reform. Washington University Journal of Law and Policy. 2007;25:161-187.  
[https://openscholarship.wustl.edu/law\\_journal\\_law\\_policy/vol25/iss1/9/](https://openscholarship.wustl.edu/law_journal_law_policy/vol25/iss1/9/)
- Kachalia A et al. Effects of A Communication-And-Resolution Program on Hospitals' Malpractice Claims and Costs. Health Affairs. 2018;37(11):1836-1844.  
<https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.0720>

Session 7: February 27, 2024 (via ZOOM)

## Mental Health Law

Guest Lecturer: [Dom Sisti](#)

## Disability Law

Guest Lecturer: [Jasmine Harris](#)

### Objectives:

- Explain and critique legal responses to and safeguards for individuals with mental illness
- Describe key models of disability
- Outline core aspects of the law's response to disability and relevant gaps/shortcoming

**Brief Response:** *Our guest lecturer, Professor Harris, asks the following: "To prepare for our discussion on disability and conservatorship, consider a major decision you've all had to make – the decision of where to attend college. How did you make this decision? What steps did you take? What information did you want to gather and how did you go about getting that information? Did you speak to anyone about the decision you had to make? Who? How did you decide what information you needed and who could help you? Please respond to these questions in no more than 1-2 paragraphs."*

### Readings:

1. \*SAMHSA. Civil Commitment and the Mental Health Care Continuum: Historical Trends and Principles for Law and Practice. 2019. *Read pp. 1-13 and Table 2 only.* <https://www.samhsa.gov/sites/default/files/civil-commitment-continuum-of-care.pdf>
2. Newman A, Fitzsimmons EG. New York City to Involuntarily Remove Mentally Ill People From Streets. NY Times. November 29, 2022. <https://www.nytimes.com/2022/11/29/nyregion/nyc-mentally-ill-involuntary-custody.html>
3. Rafla-Yuan E, Chhabra DK, Mensah MO. Decoupling Crisis Response from Policing — A Step Toward Equitable Psychiatric Emergency Services. NEJM. 2021; 384:1769-1773. <https://www.nejm.org/doi/full/10.1056/NEJMms2035710>
4. \*Pelka F. What Have We Done: An Oral History of the Disability Rights Movement. 2012. *Read pp. 1-19.*
5. Dvorak P. Why a man with intellectual disabilities has fewer rights than a convicted felon. Washington Post. September 21, 2015. [https://www.washingtonpost.com/local/why-a-man-with-intellectual-disabilities-has-fewer-rights-than-a-convicted-felon/2015/09/21/2281f5c0-605e-11e5-b38e-06883aacba64\\_story.html](https://www.washingtonpost.com/local/why-a-man-with-intellectual-disabilities-has-fewer-rights-than-a-convicted-felon/2015/09/21/2281f5c0-605e-11e5-b38e-06883aacba64_story.html)
6. *In re: Dameris L.* 956 N.Y.S.2d 848 (N.Y. Surr. Ct. 2012). <https://casetext.com/case/in-re-guardianship-of-dameris-l>

### Optional:

- Farrow R, Tolentino J. Britney Spears's Conservatorship Nightmare. The New Yorker. July 3, 2021. <https://www.newyorker.com/news/american-chronicles/britney-spears-conservatorship-nightmare>

- Wortzel H. The Right to Refuse Treatment. *Psychiatric Times*. 2006;23(14).  
<https://www.psychiatrytimes.com/view/right-refuse-treatment>
- Francis L, Silvers A, Stein M. Disability and Health Law. In *The Oxford Handbook of U.S. Health Law* (L. Glenn Cohen, Allison K. Hoffman, & William M. Sage, eds.) (2017).



## Organ Procurement and Allocation

### Objectives

- Describe the legal elements of the current organ transplant system, from procurement to allocation
- Evaluate challenges raised by and alternatives to current legal definitions of death
- Assess the strengths and weaknesses of the dead donor rule
- Identify and critique legal strategies for addressing the organ shortage and mitigating the potential for discriminatory organ allocation

### Readings:

1. Model legislation: Revised Uniform Anatomical Gift Act (UAGA), 2006. *Read only the prefatory note, pp. 1-9 (background/summary)*
2. National Organ Transplant Act (NOTA). Public Law 98-507, 1984. *Read only Title II, Sec. 371, Sec. 372, Sec. 373; Title III, Sec. 301*
3. Model legislation: Uniform Determination of Death Act (UDDA), 2008.
4. \*Truog R, Magnus D. The Unsuccessful Effort to Revise the Uniform Determination of Death Act. JAMA, online first. December 7, 2023. <https://jamanetwork.com/journals/jama/fullarticle/2812876>
5. Truog R, Miller F, Halpern S. The Dead-Donor Rule and the Future of Organ Donation. 2013. NEJM;369:1287-1289. <https://www.nejm.org/doi/full/10.1056/NEJMp1307220>
6. Bernat JL. Life or Death for the Dead-Donor Rule. NEJM. 2013;369:1289-1291. <https://www.nejm.org/doi/full/10.1056/NEJMp1308078>
7. \*NY Times, Room for Debate: How Much for a Kidney? 2014, <https://www.nytimes.com/roomfordebate/2014/08/21/how-much-for-a-kidney>
8. Persad G, Wertheimer A, Emanuel E. Principles for Allocation of Scarce Medical Interventions. Lancet. 2009;373(9661):423-431. [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(09\)60137-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)60137-9/fulltext) *Review Table 1 only*
9. \*National Research Council 2022. Realizing the Promise of Equity in the Organ Transplantation System. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>. *Read Summary (pp. 1-17), then SKIM Ch 1 excerpts (pp. 19-23), Ch 2 excerpts (pp. 35-40), Ch 4 excerpts (pp. 88-97) and focus on the tables/figures*

### Optional:

- Organ Donation and Transplantation Legislation History, <https://www.organdonor.gov/about-us/legislation-policy/history>
- Sadler BL, Sadler AM. Organ Transplantation and the Uniform Anatomical Gift Act: A Fifty-Year Perspective. Hastings Center Report. 2018;48(2):14-18. <https://www.jstor.org/stable/26628089>

- American Journal of Bioethics, Volume 23, Issue 2 (2023): several recent articles on the dead donor rule, <https://www.tandfonline-com/toc/uajb20/23/2>
- UNOS, Talking About Transplantation: What Every Patient Needs to Know (2021), <https://unos.org/wp-content/uploads/Brochure-113-What-every-patient-needs-to-know.pdf>
- UNOS, How We Match Organs, <https://unos.org/transplant/how-we-match-organs/>
- National Council on Disability. Organ Transplant Discrimination Against People with Disabilities. 2019. [https://ncd.gov/sites/default/files/NCD\\_Organ\\_Transplant\\_508.pdf](https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf)

## End of Life Issues

### Objectives:

- Assess landmark cases in right to die jurisprudence
- Identify and critique legal mechanisms to express treatment preferences in the event of incapacity
- Explain legal developments regarding medical aid-in-dying (MAID)
- Describe controversies regarding medical futility

### Readings:

1. \*Furrow BR et. al. Health Law: Cases, Materials and Problems (7th ed.), pp. 1538-1549 (*Cruzan*).
2. American Bar Association, Living Wills, Health Care Proxies, & Advance Health Care Directives (2017). [http://www.americanbar.org/groups/real\\_property\\_trust\\_estate/resources/estate\\_planning/living\\_wills\\_health\\_care\\_proxies\\_advance\\_health\\_care\\_directives.html](http://www.americanbar.org/groups/real_property_trust_estate/resources/estate_planning/living_wills_health_care_proxies_advance_health_care_directives.html)
3. \*Aviv R. What Does It Mean to Die? The New Yorker. February 5, 2018. *Skim*. <https://www.newyorker.com/magazine/2018/02/05/what-does-it-mean-to-die>
4. Goodwin M. Revisiting Death: Implicit Bias and the Case of Jahi McMath. Hastings Center Report. 2018;48(Supp 4):S77-S80. *Only the sections titled "The Politics of Health Care" and "Implicit Bias and Medicine: A System Problem."* <https://onlinelibrary.wiley.com/doi/10.1002/hast.963>
5. \*Furrow BR et. al. Health Law: Cases, Materials and Problems (7th ed.), 1688-1704. (*Glucksberg*).
6. Pope TM. Medical Aid in Dying: When Legal Safeguards Become Burdensome Obstacles. ASCO Post. December 25, 2017. <https://www.ascopost.com/issues/december-25-2017/medical-aid-in-dying-when-legal-safeguards-become-burdensome-obstacles/>
7. Laws T. How Race Matters in the Physician-Assisted Suicide Debate. Religion & Politics. September 3, 2019. <https://religionandpolitics.org/2019/09/03/how-race-matters-in-the-physician-assisted-suicide-debate/>

### Recommended:

- Dresser R. Autonomy and Its Limits in End-of-Life Law. In The Oxford Handbook Of U.S. Health Law (2017). <https://www.oxfordhandbooks.com/view/10.1093/oxfordhb/9780199366521.001.0001/oxfordhb-9780199366521-e-19>
- Dworkin R, Nagel T, Nozick R, et al. Assisted Suicide: The Philosophers' Brief. NY Review of Books. March 27, 1997. <https://www.nybooks.com/articles/1997/03/27/assisted-suicide-the-philosophers-brief/>

### Optional:

- Rachels J. Active and Passive Euthanasia. NEJM. 1975;292:78-80. <https://pubmed.ncbi.nlm.nih.gov/1109443/>
- Huang IA, Neuhaus JM, Chiong W. Racial and Ethnic Differences in Advance Directive Possession: Role of Demographic Factors, Religious Affiliation, and Personal Health Values in a National Survey

of Older Adults. *J Palliat Med.* 2016; 19(2): 149–156.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4753625/>

- Pope T. Texas Advance Directives Act: Nearly a Model Dispute Resolution Mechanism for Intractable Medical Futility Conflicts. *QUT Law Review.* 2016;16(1):22-53.  
[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2699959](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2699959)
- Death with Dignity, FAQs. 2021. <https://deathwithdignity.org/learn/faqs/>
- Oregon Death with Dignity Act: 2022 Data Summary.  
<https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/DEATHWITHDIGNITYACT/Documents/year25.pdf>
- Isai V. Death by doctor may soon be available for the mentally ill in Canada. *NY Times.* December 28, 2023. <https://www.nytimes.com/2023/12/27/world/canada/medical-assisted-death-mental-illness.html>

## Regulation of Research with Human Participants

### Objectives:

- Describe the history of human research abuses and evolving human subjects protections
- Explain current federal requirements for human subjects research and important gaps
- Consider challenges around diverse inclusion in research and legal responses

### Readings:

1. Shuster E. Fifty Years Later: The Significance of the Nuremberg Code. *NEJM*. 1997;337:1436-1440. <https://www.nejm.org/doi/full/10.1056/nejm199711133372006>
2. \*Brandt AM. Racism and Research: The Case of the Tuskegee Syphilis Study. *Hastings Center Report*. 1978;8(6):21-29. <https://pubmed.ncbi.nlm.nih.gov/721302/>
3. \*National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. The Belmont Report (1978). <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>
4. \*The Common Rule – 45 CFR Part 46. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>. *Skim whole regulation, but focus on 46.102: definitions of human subject and research; 46.104: general sense of research exemptions; 46.111: criteria for IRB approval; 46.116: informed consent*
5. National Academy of Medicine. Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. 2022. <https://www.ncbi.nlm.nih.gov/books/NBK584396/> *Read Summary.*
6. Mello MM, Wolf LE. The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples. <https://www.nejm.edu/doi/full/10.1056/NEJMp1005203>
7. Coy P. The Unsettled Debate at the Heart of the Henrietta Lacks Case. *NY Times*. August 4, 2023. <https://www.nytimes.com/2023/08/04/opinion/henrietta-lacks-cells-property.html>

### Optional:

- Bierer BE, Barnes M, Lynch HF. Revised Common Rule Shapes Protections for Research Participants. *Health Affairs*. 2017;36(5):784-788. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0307>
- Roberts DE. Legal Constraints on Use of Race in Biomedical Research. *JLME*. 2006;34(3):526-534. <https://journals.sagepub.com/doi/abs/10.1111/j.1748-720X.2006.00066.x>
- Spector-Bagdady K. Governing secondary research use of health data and specimens: The inequitable distribution of regulatory burden between federally funded and industry research. *Journal of Law and the Biosciences*. 2021;8(1): Isab008. <https://academic.oup.com/jlb/article/8/1/Isab008/6278990>

## Session 11: April 2, 2024 (Zoom)

### Reproductive Justice and Abortion

Guest Lecturer: [Aziza Ahmed](#)

#### Objectives:

- Describe the trajectory of foundational legal cases on abortion
- Evaluate modern approaches to regulating abortion and their legal status
- Identify core principles of reproductive justice

#### Readings:

1. \*Congressional Research Service. Abortion: Judicial History and Legislative Response. February 25, 2022. *Stop on p. 17* <https://fas.org/sgp/crs/misc/RL33467.pdf>
2. \**Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022). *Read case syllabus.* <https://supreme.justia.com/cases/federal/us/597/19-1392/#tab-opinion-4600823>
3. Cohen IG, Murray M, Gostin LO. The End of Roe v Wade and New Legal Frontiers on the Constitutional Right to Abortion. *JAMA*. 2022;328(4):325-326. <https://jamanetwork.com/journals/jama/fullarticle/2794257>
4. \*Kozhimannil KB, Hassan A, Hardeman RR. Abortion Access as a Racial Justice Issue. *NEJM*. 2022;387(17):1537-1539. <https://www.nejm.org/doi/full/10.1056/NEJMp2209737>
5. Donley G. What Happened to Kate Cox Is Tragic, and Completely Expected. *NY Times*. December 17, 2023. <https://www.nytimes.com/2023/12/17/opinion/kate-cox-abortion-texas-exceptions.html>
6. Gluck A. The Mifepristone Case and the Legitimacy of the FDA. *JAMA*. 2023;329(24):2121-2122. <https://jamanetwork.com/journals/jama/fullarticle/2805777>
7. Ross LR. Understanding Reproductive Justice: Transforming the Pro-Choice Movement. *Off Our Backs*. 2006;36(4):14-19. [https://www.law.berkeley.edu/php-programs/centers/crrj/zotero/loadfile.php?entity\\_key=6NK5BUG9](https://www.law.berkeley.edu/php-programs/centers/crrj/zotero/loadfile.php?entity_key=6NK5BUG9)

#### Recommended:

- The Wide Reach of Dobbs: Impacts Beyond Abortion. (Penn Law Panel), <https://www.youtube.com/watch?v=0DL05vzh1uo>
- Guttmacher Institute. State Bans on Abortion Throughout Pregnancy. (See website for most up-to-date information). <https://www.guttmacher.org/state-policy/explore/state-policies-later-abortions>

#### Optional:

- Congressional Research Service. Congressional Authority to Regulate Abortion. July 8, 2022. <https://crsreports.congress.gov/product/pdf/LSB/LSB10787>
- Congressional Research Service. State Laws Restricting or Prohibiting Abortion. March 23, 2023. <https://crsreports.congress.gov/product/pdf/LSB/LSB10779>
- Kaiser Family Foundation. Abortion in the United States. <https://www.kff.org/womens-health-policy/press-release/abortion-in-the-united-states/>

Session 12: April 9, 2024

**Public Health Law I:**

**Public Health Law Foundations**

**Noncommunicable Disease Prevention**

**Objectives:**

- Describe key models of public health law intervention
- Identify and critique public health law tools to address noncommunicable diseases
- Describe legal challenges to public health law authority

**Readings:**

1. \*Gostin LO, Hougenobler D, Roberts AE. American Public Health Law. In *The Oxford Handbook of U.S. Health Law* (I. Glenn Cohen, Allison K. Hoffman, & William M. Sage, eds.) (2017). *Only section I (Exploration) and II.c.vi (Barriers)*.
2. [Refresh from Session 1] \*Mello MM, Parmet WE. U.S. Public Health Law — Foundations and Emerging Shifts. *N Engl J Med* 2022; 386:805-808.  
<https://www.nejm.org/doi/full/10.1056/NEJMp2200794>
3. [Refresh from Session 1] Gostin LO, Hodge JG, Levin DE. Legal Interventions to Address US Reductions in Life Expectancy. *JAMA*. 2020;324(11):1037-1038.  
<https://jamanetwork.com/journals/jama/fullarticle/10.1001/jama.2020.7715>
4. \*Kappagoda M, Wiley L, Pearson A. Public Health: Noncommunicable Disease Prevention. In *The Oxford Handbook of U.S. Health Law*.
5. Wailoo K. The FDA's Proposed Ban on Menthol Cigarettes. *NEJM*. 2019;380(11):995-997.  
<https://www.nejm.org/doi/pdf/10.1056/NEJMp1900204>
6. The Network for Public Health Law, Learning from the Flint Water Crisis: Protecting the Public's Health During a Financial Emergency. January 2018. *Executive Summary only*.  
<https://www.networkforphl.org/resources/learning-from-the-flint-water-crisis-protecting-the-publics-health-during-a-financial-emergency/>
7. Webster DW, Gostin GO. The Supreme Court Expands Second Amendment Rights as the Nation Experiences Historic Levels of Firearms Violence. *JAMA*. 2022;328(12):1187-1188.  
<https://jamanetwork.com/journals/jama/fullarticle/2796684>
8. Mendez DD et al. Racism as Public Health Crisis: Assessment and Review of Municipal Declarations and Resolutions Across the United States. *Frontiers in Public Health*. 2021;9:1-11. *Focus on tables*.  
<https://www.frontiersin.org/articles/10.3389/fpubh.2021.686807/full>

**Optional:**

- Public Health Law Center. The Tobacco Industry & the Black Community: The Targeting of African Americans. June 2021.  
<https://www.publichealthlawcenter.org/sites/default/files/resources/Tobacco-Industry-Targeting.pdf>

- Jacobson PD et al. The Role of the Legal System in the Flint Water Crisis. *Milbank Quarterly*. 2020;98(2):554-580. <https://onlinelibrary.wiley.com/doi/epdf/10.1111/1468-0009.12457>
- Paine L et al. Declaring Racism a Public Health Crisis in the United States: Cure, Poison, or Both? *Frontiers in Public Health*. 2021;9:1-17. <https://www.frontiersin.org/articles/10.3389/fpubh.2021.676784/full>



Session 12: April 16, 2024 (Zoom)

**Public Health Law II:**

**Communicable Disease Prevention and Response**

**COVID-19 and the Future of Public Health Law**

**Guest Lecturer:** [Ross Silverman](#)

**Objectives**

- Describe foundational legal responses to public health emergencies at the state and federal level
- Explain how these foundations have been tested and changed by the COVID-19 pandemic

**Readings**

1. \*Lazzarinni Z. Communicable Disease Law and Emerging Issues. In *The Oxford Handbook of U.S. Health Law* (I. Glenn Cohen, Allison K. Hoffman, & William M. Sage, eds.) (2017). *Sections I-IV*.
2. Hodge J. Public Health Emergency Legal and Ethical Preparedness. In *The Oxford Handbook of U.S. Health Law* (I. Glenn Cohen, Allison K. Hoffman, & William M. Sage, eds.) (2017). *Sections I-III*.
3. Gostin LO, Wiley LF. Governmental Public Health Powers During the COVID-19 Pandemic: Stay-at-home Orders, Business Closures, and Travel Restrictions. *JAMA*. 2020;323(21):2137-2138.  
<https://jamanetwork.com/journals/jama/fullarticle/2764283>
4. *Jacobson v. Massachusetts*. *PUBLIC HEALTH LAW AND ETHICS: A READER* (2010), pp. 140-148.
5. Gostin LO, Reiss D, Mello MM. Vaccination Mandates – An Old Public Health Tool Faces New Challenges. *JAMA*. 2023;330(7):589-90.  
<https://jamanetwork.com/journals/jama/fullarticle/2807811>
6. Schmidt H, Gostin LO, Williams MA. Is It Lawful and Ethical to Prioritize Racial Minorities for COVID-19 Vaccines? *JAMA*. 2020;324:20;2023-2024.  
<https://jamanetwork.com/journals/jama/fullarticle/2771874>
7. \*Yearby R, Mohapatra S. Law, Structural Racism, and the COVID-19 Pandemic. *JLB*. 2020;7(1):Isaa036. *Skip footnotes* <https://academic.oup.com/jlb/article/7/1/Isaa036/5849058>
8. \*Parmet WE, Khalik F. Judicial Review of Public Health Powers Since the Start of the COVID-19 Pandemic: Trends and Implications. *Am J Public Health*. 2023;113(3):280–287.  
<https://ajph.aphapublications.org/doi/full/10.2105/AJPH.2022.307181>

**Optional**

- Friedersdorf C. The Danger of Treating Everything as an Emergency. *The Atlantic*. 2021.  
<https://www.theatlantic.com/ideas/archive/2021/09/perils-public-health-emergencies/620104/>
- Baker M, Ivory D. Why Public Health Faces a Crisis Across the U.S. *NY Times*. October 18, 2021.  
<https://www.nytimes.com/2021/10/18/us/coronavirus-public-health.html>

Session 14: April 23, 2024

## Pharmaceutical Regulation and Pricing

### Objectives:

- Articulate the justifications for FDA's regulatory authority and describe the agency's approach to overseeing drug products
- Catalog FDA's expedited pathways, including their benefits and drawbacks
- Describe the causes of high drug prices and evaluate legal reform options

### Readings:

1. \*Grossman L. Drugs, Biologics, and Devices: FDA Regulation, Intellectual Property, and Medical Products in the American Healthcare System. In *The Oxford Handbook of U.S. Health Law* (I. Glenn Cohen, Allison K. Hoffman, & William M. Sage, eds.). *Read Section I, II.a, IV.*
2. Kapczynski A. Dangerous Times: The FDA's Role in Information Production, Past and Future. *Minn. L. Rev.* 2018;102:2357-2382. *Stop at p. 2374, skip footnotes.*  
<https://scholarship.law.umn.edu/mlr/130/>
3. Liu S, Kesselheim A. Experiences With and Challenges Afforded by Expedited Regulatory Pathways. *Clinical Pharmacology and Therapeutics.* 2019;105(4):795-797.  
<https://pubmed.ncbi.nlm.nih.gov/30883712/>
4. Lynch HF, Robertson C. Challenges in Confirming Drug Effectiveness After Early Approval. *Science.* 2021;374(6572):1205-1207. <https://www.science.org/doi/10.1126/science.abk3495>
5. \*Kesselheim A, Avorn J, Sarpatwari A. The high cost of prescription drugs in the United States: Origins and prospects for reform. *JAMA.* 2016;316(8):858-871.  
<https://jamanetwork.com/journals/jama/fullarticle/2545691>
6. \*Congressional Research Service. Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects. December 8, 2023.  
<https://crsreports.congress.gov/product/pdf/R/R47872>
7. Horrow C, Kesselheim A. Confronting High Costs and Clinical Uncertainty: Innovative Payment Models For Gene Therapies. *Health Affairs.* 2023;42(11):1532-1540.  
<https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00527>

### Recommended:

- Lewis-Kraus G. When Dying Patients Want Unproven Drugs. *The New Yorker.* June 19, 2023.  
<https://www.newyorker.com/magazine/2023/06/26/relyvrio-als-fda-approval>

### Optional:

- U.S. Food and Drug Administration. Development and Approval Process – Drugs. 2022.  
<https://www.fda.gov/drugs/development-approval-process-drugs>
- U.S. Food and Drug Administration. FDA Drug Approval Process Infographic. 2016.  
<https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fda-drug-approval-process-infographic-horizontal>

- FDA Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics. 2014. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics>
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