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

| Instructor: | Holly Fernandez Lynch, JD, MBE  
Assistant Professor of Medical Ethics, Perelman School of Medicine  
Assistant Professor of Law, Carey Law School (secondary)  
University of Pennsylvania |
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Blockley Hall, Room 1426 |

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

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

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/2ja8wo6x5aj54f57dxrmct7bmqs9aq27.

You may also find these resources helpful:
- https://twitter.com/thekibosch/status/1635736976405004290?s=43&t=kRDOo1WcdAFl9mnky8r9LQ

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:

<table>
<thead>
<tr>
<th>Clearly stated thesis</th>
<th>5 points</th>
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<tbody>
<tr>
<td>Demonstrated importance of topic, adequate background</td>
<td>5 points</td>
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<tr>
<td>Well-reasoned argument using principles and themes from class</td>
<td>5 points</td>
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<tr>
<td>Fair and well-reasoned responses to objections</td>
<td>5 points</td>
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<tr>
<td>Appropriate support/references</td>
<td>5 points</td>
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<td><strong>Total:</strong></td>
<td><strong>25 points</strong></td>
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**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](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:

<table>
<thead>
<tr>
<th>Clearly stated thesis</th>
<th>15 points</th>
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<tbody>
<tr>
<td>Demonstrated importance of topic, adequate background</td>
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<tr>
<td>Appropriate support/references</td>
<td>15 points</td>
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<tr>
<td><strong>Total:</strong></td>
<td><strong>75 points</strong></td>
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**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:


3. Health Policy: Resources for Congressional Staff, https://www.everycrsreport.com/reports/R43889.html. SKIM only the following:


Optional:
• Farnsworth EA. An Introduction to the Legal System of the United States. 4th ed. 2010.
  o Judicial System (pp. 43-46), Case Law (pp. 53-55, 58-65)
  o Legislative System (pp. 69-76)
  o Private Law: contracts, torts (pp. 133-142)
  o Public Law: constitutional and administrative (pp. 163-173)
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:

Strongly Recommended:

Optional:
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:


Optional:

• 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]

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:

2. *Rosenbaum S, Frankford DM. LAW AND THE AMERICAN HEALTH CARE SYSTEM (2nd 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.


Optional:
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:


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](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.)


Optional:
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:


Optional:
- Pennsylvania Medical Practice Act, skim to get a sense of coverage https://www.legis.state.pa.us/cfdocs/Legis/StatuteCheck.cfm?txtType=PDF&yr=1985&sessInd=0&smthLwInd=0&act=0112
• American Association of Medical Colleges. 20 Years of Patient Safety. 2019.  

  https://openscholarship.wustl.edu/law_journal_law_policy/vol25/iss1/9/

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.*


Optional:

  https://www.psychiatrictimes.com/view/right-refuse-treatment
Session 8: March 12, 2024
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
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:
• UNOS, How We Match Organs, https://unos.org/transplant/how-we-match-organs/
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:

Recommended:

Optional:
• 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
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4753625/


• Oregon Death with Dignity Act: 2022 Data Summary.  

• Isai V. Death by doctor may soon be available for the mentally ill in Canada. NY Times. December 28, 2023.  
Session 10: March 26, 2024

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:


Optional:
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:


Recommended:
- The Wide Reach of Dobbs: Impacts Beyond Abortion. (Penn Law Panel), https://www.youtube.com/watch?v=0DL05vHz1uo

Optional:
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:


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


Optional:

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


Optional
Session 1: 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:


Recommended:

Optional:
• 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

  https://www.nap.edu/download/24946

• Wouters OJ, et al. Association of Research and Development Investments With Treatment Costs 
  for New Drugs Approved From 2009 to 2018. JAMA Network Open. 2022;5(9):e2218623. 
  https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796669

• Patients for Affordable Drugs Now. High Prescription Drug Prices Perpetuate Systemic Racism. We 