January 29, 2022

New York University School of Law

Selected Topics in Health Law and Access to Medicines
Professors Rachel Sachs and Alison Bateman-House
Spring 2022
Monday & Wednesday (not every week), 4:20–6:20 PM, Vanderbilt Hall 208/ initially remote

SEMINAR DESCRIPTION

This course explores the legal and ethical frameworks within health law and policy that relate to access to investigational and prescription drugs. The course will focus on a number of foundational topics within health law, including the United States' fragmented structure of Medicare, Medicaid, and private insurance and how insurance relates to prescription drug affordability; the distribution of authority between legislators and regulators at the state and federal level as they make new law in this area; and how drug candidates are evaluated and, in the case of successful candidates, approved by federal regulators. The course will also apply these frameworks to a number of current issues in the area, including drug pricing reform, "Right to Try" legislation, the COVID-19 pandemic and its impact on drug and vaccine development, and the ongoing evolution of human subjects research regulation. Final grades will be based on a combination of class participation, a final research paper on a relevant topic of the student's choice, and the presentation of that paper.

READING ASSIGNMENTS

All readings for the course will be made available on the course website in Brightspace (either directly or linked). The readings for the weeks with the guest speakers will be made available at least one week before those class sessions.

Although we sometimes will only assign a specified range of pages from an article (these assignments are bolded), we include the full article in case you would like to read more of it. If there is no indication of specific pages assigned, the entire work is assigned. It will typically help to do the readings in the order in which they are listed.

WRITTEN WORK REQUIREMENT, CLASS PARTICIPATION, AND GRADES

The written work requirement for this course consists of a research paper due at the end of the semester, by May 12. This research paper must make and support an original argument involving health law and access to medicines. It must include research outside the bounds of our class. All students must select a topic and meet with Professors Sachs and/or Bateman-House to clear it by February 11th. Students who are using this class to satisfy the Option B writing requirement should complete a paper of at least 5,000 words, exclusive of footnotes, and students satisfying the Option A writing requirement should complete a paper of at least 10,000 words, exclusive of footnotes. Professors Sachs and Bateman-House will provide feedback on students' outlines and first drafts throughout the semester, though due dates for these may differ depending on which writing option is chosen. Students must present their work during the final week of class (on April 18th or April

20th). We encourage students to aim for publishable final products. Fifty percent of your semester grade will be based on the written paper, and fifteen percent on your presentation of the paper.

We expect students to attend every session, to have read and thought about the materials, and to be prepared to discuss them. If you cannot attend a session or will not be prepared for class, please let us know in advance by email. You will receive a grade of 0 for that session. At the end of the semester, we total participation for each student and drop the lowest session grade. Your class participation will account for thirty-five percent of your final grade.

OFFICE HOURS

Professor Sachs' office hours will be Mondays from 2-4 PM on Zoom (location linked on the front page of Brightspace). Having reviewed your class schedules with the registrar, that time works best for the largest number of students. If you cannot meet during her office hours, you may set up an appointment by emailing res9963@nyu.edu.

Professor Bateman-House's office hours will be by appointment. You may set up an appointment by emailing Alison.Bateman-House@nyulangone.org.

GETTING TO KNOW EACH OTHER

Before the first class, please fill out the Google Form information sheet available on the course website. Each of you has chosen this class for a reason, and each of you has something unique to contribute! The course will also go more smoothly if we have a sense of your level of familiarity with the concepts we'll be discussing and can prepare for it in advance.

ZOOM BEST PRACTICES AND GUIDELINES

We may hold class on Zoom sporadically, as either the university requires (for the first two classes of the semester) or as the pandemic may otherwise necessitate. If Professor Sachs, Professor Bateman-House, or one of our guest speakers must quarantine, we will convene synchronously on Zoom. If too many students must quarantine, we may move to a Zoom format as well. Due to the pandemic, we must be flexible as we work together to study the material. We know that we can have a thoughtful, fulfilling semester conducting class occasionally or even frequently online. We have taught seminars both online and in person and know the opportunities and the challenges that come with each environment.

When we are on Zoom, please keep your microphone muted unless you are speaking, as too many students with microphones on often creates harmful audio feedback and makes it difficult to hear the speaker. If you would like to ask a question or make a comment, please use the "raise hand" feature in Zoom.

We encourage you to turn on your video during class if you are comfortable doing so. Turning on your video helps build community in our class and encourages engagement. It also helps us as your professors. You do not need to explain why your video is off during a particular class, or during a particular portion of class, but please do let one or both of the professors know if you

are uncomfortable turning on your video at all. You should also feel free to use Zoom's "virtual background" feature, if you would like to avoid displaying your real-life setting.

In general, things will go well if you can treat Zoom as close to a classroom setting as possible. If you get up to go to the bathroom during class, do not take us with you. Please wear clothes. However, we also recognize that Zoom is very much not a traditional classroom setting. There will be times when a pet, child, partner, roommate, or other person becomes visible on your (or one of our) screens. This is fine, but please know that if a pet interrupts you during class, we may ask you to introduce them to us all.

Please respect the privacy of your fellow students. This means that you should not record classes using Zoom or any other software.

CLASS SCHEDULE NOTES

The work for this class will be front-loaded, with course meetings twice a week for the first three full weeks of the semester, and reducing the number of course meetings for the rest of the semester correspondingly. Students will present their papers to each other during the final full week of the course, during which the course will again meet twice. Please note that these dates may shift slightly due to guest speaker availability, COVID-19 restrictions, or other factors.

1. Meeting 1 – On Zoom (January 24th): Introduction – How do new drugs come to market, and how do patients access them?
    a. FOOD & DRUG ADMINISTRATION, CASE STUDY, DRUG APPROVAL: BRINGING A NEW DRUG TO THE MARKET **1–20** (2015).
    b. BROOKINGS CENTER FOR HEALTH POLICY, BREAKTHROUGH THERAPY DESIGNATION: EXPLORING THE QUALIFYING CRITERIA **1–4** (2015).
    c. Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307 (2018).
2. Meeting 2 – On Zoom (January 26th): Prescription Drug Pricing – Are prescription drug prices too high, and if so, what should we do about it?
    a. HENRY WAXMAN ET AL., GETTING TO THE ROOT OF HIGH PRESCRIPTION DRUG PRICES **1-33** (2017).
    b. Bruce Booth, *Innovators v. Exploiters: Drug Pricing and the Future of Pharma*, LIFESCIVC (Aug. 29, 2016), https://lifescivc.com/2016/08/innovators-vs-exploiters-drug-pricing-future-pharma/.
    c. Danny Hakim, *Humira's Best-Selling Drug Formula: Start at a High Price. Go Higher.*, N.Y. TIMES (Jan. 6, 2018), https://www.nytimes.com/2018/01/06/business/humira-drug-prices.html.
    d. Matthew Herper, *The Debate Over America's Drug-Pricing System Is Built on Myths. It's Time to Face Reality*, STAT NEWS (Dec. 23, 2019), https://www.statnews.com/2019/12/23/debate-over-us-drug-pricing-system-time-to-face-reality/.
    e. Juliette Cubanski et al., W*hat's the Latest on Medicare Drug Price Negotiations?*, KAISER FAMILY FOUNDATION (July 23, 2021), https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/.
3. Meeting 3 (January 31st): FDA Approval Standards – What should our standards of evidence be in enabling new drugs to come to market?

a. DANIEL CARPENTER, REPUTATION AND POWER, **Introduction** (2010).
b. Vahid Montazerhodjat & Andrew W. Lo, *Is the FDA Too Conservative or Too Aggressive? A Bayesian Decision Analysis of Clinical Trial Design*, NBER Working Paper No. 21499 (Aug. 2015).
c. Aaron S. Kesselheim & Jerry Avorn, *Approving a Problematic Muscular Dystrophy Drug: Implications for FDA Policy*, 316 JAMA 2357 (2016).
d. Rachel Sachs, *The FDA's Approval of Aduhelm: Potential Implications Across a Wide Range of Health Policy Issues and Stakeholders*, HEALTH AFFAIRS BLOG (June 10, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210609.921363/full/.

4. Meeting 4 (February 2nd): Reimbursement Requirements – What should be the relationship between drug approval and insurance coverage?
   a. Juliette Cubanski & Tricia Neuman, *FDA's Approval of Biogen's New Alzheimer's Drug Has Huge Cost Implications for Medicare and Beneficiaries*, KAISER FAMILY FOUNDATION (June 10, 2021), https://www.kff.org/medicare/issue-brief/fdas-approval-of-biogens-new-alzheimers-drug-has-huge-cost-implications-for-medicare-and-beneficiaries/.
   b. Rachel Dolan & Elizabeth Williams, *How Might the FDA's Approval of a New Alzheimer's Drug Impact Medicaid?*, KAISER FAMILY FOUNDATION (July 13, 2021), https://www.kff.org/medicaid/issue-brief/how-might-the-fdas-approval-of-a-new-alzheimers-drug-impact-medicaid/.
   c. Nat'l Ass'n of Medicaid Directors, *Letter to Administrator Chiquita Brooks-LaSure Regarding National Coverage Determination* (Aug. 11, 2021), https://medicaiddirectors.org/wp-content/uploads/2021/08/NAMD-Alzheimers-Medicare-NCD-comments.pdf.
   d. Centers for Medicare & Medicaid Services, *Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease – Proposed Decision Memo* **1, 28–38** (Jan. 11, 2022).
5. Meeting 5 (February 7th): Institutional Design – Who should be responsible for making these decisions?
   a. Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, **845-51, 867-75, 881-85** (2017).
   b. Carmel Shachar, *The Preemption Clause That Swallowed Health Care: How ERISA Litigation Threatens State Health Policy Efforts*, HEALTH AFFAIRS BLOG (Oct. 15, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201013.533063/full/.
   c. Jennifer S. Bard, *Legal and Ethical Analysis of Court-Ordered Ivermectin Treatment for COVID-19*, BILL OF HEALTH (Sept. 2, 2021), https://blog.petrieflom.law.harvard.edu/2021/09/02/court-ordered-ivermectin-covid/.
   d. Ellen Gabler, *States Say Some Doctors Stockpile Trial Coronavirus Drugs, for Themselves*, N.Y. TIMES (March 24, 2020), https://www.nytimes.com/2020/03/24/business/doctors-buying-coronavirus-drugs.html.
6. Meeting 6 (February 9th): Emergency Preparedness – How should these dynamics change in emergency situations, such as a pandemic?
   a. Bhaven N. Sampat & Kenneth C. Shadlen, *The COVID-19 Innovation System*, 40 HEALTH AFFAIRS 400 (2021).
   b. Nicholas Florko, *New Document Reveals Scope and Structure of Operation Warp Speed and Underscores Vast Military Involvement*, STAT NEWS (Sept. 28, 2020),

https://www.statnews.com/2020/09/28/operation-warp-speed-vast-military-involvement/.

c. Sharon LaFraniere et al., *Politics, Science, and the Remarkable Race for a Coronavirus Vaccine*, N.Y. TIMES (Nov. 21, 2020), https://www.nytimes.com/2020/11/21/us/politics/coronavirus-vaccine.html.

d. Nicholson Price et al., *Are COVID-19 Vaccine Advance Purchases a Form of Vaccine Nationalism, An Effective Spur to Innovation, or Something in Between?*, WRITTEN DESCRIPTION (Aug. 5, 2020), https://writtendescription.blogspot.com/2020/08/are-covid-19-vaccine-advance-purchases.html.

7. Meeting 7 (February 14th): Investigational Medical Products– Do/should we prioritize individual access or evidence generation for a population?
    a. Ed Silverman, *With Time Running Out, an ALS Patient Fights with Biogen over Expanded Access to its Drug*, STAT NEWS (Mar 25, 2021) https://www.statnews.com/pharmalot/2021/03/25/with-time-running-out-an-als-patient-fights-with-biogen-over-expanded-access-to-its-drug/.
    b. Michelle M. Mello & Troyen A. Brennan, *The Controversy Over High-Dose Chemotherapy With Autologous Bone Marrow Transplant For Breast Cancer*, 20 HEALTH AFFAIRS 101 (2001).
    c. Alex John London & Jonathan Kimmelman, *Against Pandemic Research Exceptionalism*, 368 SCIENCE 476 (2020).
8. Meeting 8 (February 28th): Guest speaker on the topic of ownership of human biological materials
9. Meeting 9 (March 7th): Human Subjects Research – How do our legal and ethical frameworks for governing human subjects research fail to answer important questions?
    a. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report* (Apr. 18, 1979), https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html.
    b. Nancy Kass et al., *The Research-Treatment Distinction: A Problematic Approach for Determining Which Activities Should Have Ethical Oversight*, 43 Supplement 1 HASTINGS CENTER REPORT S4 (2013).
    c. Anna Mastroianni et al., *Research with Pregnant Women: New Insights on Legal Decision-Making* 47 HASTINGS CENTER REPORT 38 (2017).
    d. Lainie Friedman Ross, *The Ethical Limits of Children's Participation in Clinical Research* 50 HASTINGS CENTER REPORT 12 (2020).
    e. Nir Eyal & Lisa Holtzman, *Symposium on Risks to Bystanders in Clinical Research: An Introduction* 34 BIOETHICS 879 (2020).
10. Meeting 10 (March 21st): Equity in Drug Development – Who is eligible to participate in clinical trials–and who isn't?
    a. US Food and Drug Administration, *Final Guidance for Industry, Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs* (Nov. 2020), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial.

   b. American Soc. Clinical Oncology, *News Release: ASCO and Friends of Cancer Research Recommend Expanding Patient Access to Cancer Clinical Trials by Further Broadening Eligibility Criteria* (Feb. 2021), https://www.asco.org/about-asco/press-center/news-releases/asco-and-friends-cancer-research-recommend-expanding-patient. Please visit the linked website for this reading.
   c. Kelly McBride Folkers et al., *Paying for Unapproved Medical Products* 11 Wake Forest Journal of Law and Policy **Part II: Clinical Trial 89-98** (Oct. 2020).

11. Meeting 11 (April 4th): Guest speaker on the topic of compulsory licensing of patents
12. Meeting 12 (April 18th): Student Presentations. Professors Sachs and Bateman-House will circulate a scheduling sign-up sheet during Week 10 of the semester.
13. Meeting 13 (April 20th): Student Presentations