

DRUG LAW AND POLICY
Fall 2019

Final Paper Assignment

Rationale

This assignment is designed to:

- (1) Provide an opportunity for you to become expert in a drug law and policy issue of special interest and/or relevance to you;
- (2) Simulate the kind of a legal research, policy analysis, and writing assignment that you may encounter in the workplace, and
- (3) Add to the work product “portfolio” that you can draw on in pursuing employment, fellowship, writing competitions, or other opportunities.

Paper Framework Options

Envision your dream job after law school and tailor the paper to the kind of assignment you may be given as part of that job. Given the possible range of approaches, there are several possible options for framing the paper. Below is an illustrative list of options:

- A. Expanded Legal Memo (Industry): you are a junior associate at a law firm. The overseeing partner asks you to write a memo detailing the state of current law and regulations on a specific legal question for a pharmaceutical industry client. (e.g. Provide an overview of the statutory and regulatory environment for outsourcing our API and excipient production to China).
- B. Policy Memo (Government): you are working as a junior attorney in the legal department of a government agency on a city, state, or federal level. The agency is asked by the legislature to generate a policy memo to help shape policymaking or regulatory decisionmaking. The head of the department looks to you to draft this document. (e.g. How can the FDA increase oversight over compounding pharmacies? Or what possible legal avenues does the City of Baltimore have for creating a drug tolerance zones and what are the key issues concerning federal and state law?)
- C. Policy Assessment: you are a policy researcher with the RAND Corporation, which receives a grant to assess the impact of a certain policy change and issue recommendations on how the policy can be improved. For instance: Did the passage of California’s Proposition 47 in 2014 produce a positive effect on health and safety in the state? What reforms may be needed to amend the law to make it better tailored to accomplish its aims?
- D. Advocacy Report: you are working at an advocacy organization that has a mandate to promote a certain cause. The organization issues periodic reports to assess the current developments in the area of its work and uses this information to advocate for certain changes, including legal reforms on the

international level and various levels of national government, industry, and other actors.

You can choose from within the above frameworks or formulate a different approach, but it is recommended that you identify an existing model (i.e. find a specific document to serve as a model) for such a framework before proceeding.

Process and Parameters

1. Brainstorm a drug law or policy topic of special interest or significance and spend 45-60 minutes doing preliminary research using news, scientific, legal, or other sources to narrow down your focus to a specific issue. Please focus attention to topics related to the FDA and addressed (directly or indirectly) in the syllabus.
2. Identify at least one key informant who is an expert on the issue of your choice.
3. Discuss the topic with the instructor, classmates, and key informants.
4. Submit a proposal containing: a. an overview paragraph stating the topic and its significance, b. key questions, c. proposed outline and d. preliminary sources and key informant(s) (**due before class on Monday, September 16, 2019**).
5. Based on instructor feedback, conduct additional research of legal and scientific literature to educate yourself about the issue of your choice and conduct interview(s) with key informant(s).
6. Prepare a slide-assisted presentation, summarizing your topic, relevance, main findings, and sources. Our last class session on **Wednesday, November 6, 2019** will be dedicated to student presentations.
7. Write 18-20 page paper, final draft **due before 3PM on Friday, November 15, 2019**, including some version of components (actual components/length may vary depending on your choice of framework):
 - a. *Executive Summary* (500 words max), including a section containing bullet points with key recommendations/findings
 - b. *Introduction/Background*: (5-6 pages): articulate a problem statement, evidence that the problem is timely and significant, and the objectives of your paper (e.g. what is the gap in knowledge or analysis that you are aiming to address).
 - c. *Analysis*: (6-9 pages): analyze the legal, regulatory, and policy dimensions of the issue, with special focus on its causes. How is the law being used to address the issue? Is it working? What are the limitations of the current approaches? How may this approach fare in the context of anticipated changes in the foreseeable future?
 - d. *Recommendations/Next Steps*: (3-5 pages): How may the problem be improved or resolved using legal, regulatory, and policy tools? What action is required? Who should undertake it? How will these changes affect the stakeholders? What evidence is there that it will work? What are the strategies for avoiding the pitfalls of the past?

- e. *Conclusion*: (1 page) Provide a short synthesis of the paper.
- f. *Tables and Figures* (1-2 recommended, with attribution)
- g. *Sources Cited* (not counted towards the page length guidelines)

Presentation Format

The presentation will be in the “flash talk” format, lasting 8-10 minutes followed by a brief Q&A and should be delivered with the aid of slides (estimate 1 minute per slide). Use images and figures to illustrate your points. The principal parts of the presentation should generally reflect the structure of the paper, including a listing of the key references.

Paper Format

- Title
- 6,500 words minimum (not including citations)
- Double-spaced
- 12-point font (Times New Roman or Cambria)
- Bluebook style
- Page numbers in footer

<u>Final Project Weight (as part of total)</u>	<u>65%</u>
Final Project Topic Statement/Proposal	5%
Final Project Presentation	15%
Final Project Paper	45%

Writing Requirement

Those planning to use the paper to satisfy the upper-level writing requirement must state so in their proposals.

Wikipedia (Extra Credit)

Students wishing to receive extra credit (up to 7%) are asked to review and edit at least one Wikipedia entry pertinent to their research topic. Existing entry text should be submitted pasted into a MS Word document with changes highlighted using the “Track Changes” function.