DRUG LAW AND POLICY
Fall 2019

Public Comment Brief

Rationale

This assignment is designed as an experiential, skill-building exercise in drug law research and policy advocacy. It is also an applied orientation for the FDA's rulemaking and public notice-and-comment framework as it exists under the Administrative Procedure Act (APA) (5 U.S.C. Chapter 5). This mechanism is utilized by an entire range of interest groups, including industry lobbyists, patients' groups, public health advocacy organizations, and interested individuals. More information FDA's notice-and-comment mechanism is accessible here.

Process and Parameters

1. Review the docket announcement and related materials for the Proposed Rule, "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements." (Docket No. FDA-2019-N-3065-0001).
2. Consult relevant legal, regulatory, and public health material to educate yourself about the context and implications for the proposed action.
3. Write a 5-6 page public comment brief, following the below framework:
    a. *Executive Summary* (250 words max, not counted toward page max): stating your position on the issues presented in the docket notice, major supporting arguments and evidence, and recommendations.
    b. *Background*: (1-2 pages) Brief overview of the evolution and current state of the process.
    c. *Analysis*: (1-2 pages) Your position and its rationale, including which stakeholders' interests you are seeking to protect and how.
    d. *Actions Recommended*: (1-2 pages) state the recommended course of action and what action steps would be needed to accomplish it.
    e. *Tables and Figures* (optional, with attribution)
    f. *Endnotes/Sources Cited* (not counted towards page limit)

Format

- 5-6 pages (not including executive summary and endnotes)
- Double-spaced, 1-inch margins
- 12-point font (Times New Roman or Cambria)
- Endnote references (citation format of your choice, as long as it's consistent)
- Page numbers

Evaluation

The assignment is worth 20% of your final grade, and will be evaluated based on the following criteria:

1. Clear and cogent positions and arguments
2. Grammar and style
3. Adherence to format guidelines

4. Credible and well-cited sources
5. Timely submission

After one round of edits, you will upload your public comment to the Federal Register here: https://www.regulations.gov/document?D=FDA-2019-N-3065-0001.

A statement that the document was prepared for a law school class will be added to the final comment prior to submission.