Intro. to the Regulation of Healthcare Technology and Pharmaceutical Products Syllabus

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Office hours: Mondays from 6-8pm EST; https://ufl.zoom.us/j/9926094743

COURSE DESCRIPTION:

This course provides a comprehensive introduction to the U.S. regulatory framework governing healthcare technologies and pharmaceutical products, focusing on the Food and Drug Administration (FDA). Students will explore statutory foundations, administrative procedures, jurisdictional definitions, enforcement strategies, and regulatory pathways for foods, drugs, devices, biologics, cosmetics, tobacco, and emerging technologies. Emphasis is placed on legal interpretation, policy analysis, and application of regulatory standards in modern healthcare markets. This class includes at least 25 hours (1,500 minutes) of instruction directly supervised by the instructor through recorded lectures, optional live sessions, office hours, and personalized feedback. It also requires students to engage in at least 60 hours (3,600 minutes) of out-of-class work, including reading assignments, research, written submissions, and discussion activities.

COURSE OBJECTIVES AND LEARNING OUTCOME:

Upon successful completion of this course, students will be able to:

- Explain the FDA's origins, mission, structure, and statutory authority.
- Analyze administrative law principles governing FDA rulemaking, adjudication, and guidance.
- Distinguish key statutory definitions such as "drug," "device," "biological product," "cosmetic," and "tobacco product."
- Evaluate enforcement tools, including inspections, injunctions, recalls, civil money penalties, and criminal liability.
- Describe regulatory pathways for human drugs, generics, OTC drugs, medical devices, and emerging digital health technologies.
- Examine the complexities of regulating biologics, vaccines, regenerative medicine, and blood products.
- Assess the legal requirements for food labeling, safety, identity, sanitation, and additives.
- Analyze the regulation of cosmetics, tobacco, and carcinogenic substances.
- Interpret key cases and apply FDA regulatory frameworks to real-world scenarios.

REQUIRED AND RECOMMENDED TEXTBOOKS:

REQUIRED: Hutt, P. B., Merrill, R. A., & Grossman, L. B. (2022). Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law (5th ed.). Foundation Press.

WEEKLY COURSE SCHEDULE OF TOPICS AND ASSIGNMENTS, INCLUDING A LIST OF IMPORTANT DEADLINES:

WEEK 1 – January 20-25, 2026 – FDA History, Context, and Mission

Assignment

Discussion Postings: Introduce yourself to the class and Discussion Reflection: How and what has shaped the FDA's modern enforcement philosophy?

Office Hours: Wednesday, January 21, 2026, 5-7pm EST

Optional Live Class Via Zoom: Wednesday, January 21, 2026, at 7pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 1: History and Context (pages 1-36)
    - Global precedents in food and drug control
    - Development of FDA as an institution
    - Evolution of American food and drug legislation
    - Mission, structure, organization, interagency relationships
    - Regulatory landscape and industry-agency dynamics

WEEK 2 – January 26-February 1, 2026 - Administrative Law & FDA Procedures Part I: Rulemaking & Guidance

Assignment

Discussion Posting: Evaluate the role of guidance in FDA policymaking

Office Hours: Monday, January 26, 2026, 6-8pm EST

Optional Live Class Via Zoom: Wednesday, January 28, 2026, at 7pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 2: Administrative Law and Procedure at FDA (§§A–C, E pages 37–78, 93-118)

- Administrative Procedure Act
- Notice-and-comment rulemaking
- Guidance documents and policy statements
- Public information and FOIA

WEEK 3 – February 2–8, 2026 - Administrative Law & FDA Procedures Part II: Advisory Committees & Judicial Review

Assignment

Discussion Posting: When courts overrule FDA decisions—how far should judicial power extend?

Office Hours: Monday, February 2, 2026, 6-8pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 2: Administrative Law and Procedure at FDA (§§D & F pages 78–93, 118-137)
    - Judicial review of FDA actions
    - Advisory committee structures and influence
    - Scientific evidence and administrative decision-making

WEEK 4 – February 9-15, 2026 – Determining FDA Jurisdiction: Key Definitions

Assignment

No Discussion Posting

Office Hours: Monday, February 9, 2026, 6-8pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 3: FDA Jurisdiction: A Matter of Definitions (§§A-H pages 139–220)
    - Definitions of food, drug, device
    - Food-drug and cosmetic-drug spectra
    - Health claims and dietary supplements
    - Human biological products (intro)

WEEK 5 – February 16–22, 2026 – Labeling, Advertising & Speech Regulation; Enforcement & Compliance Authority

Assignment

Create a first draft of a labeling-compliance checklist for a hypothetical drug/device. (50 Points)

Instructions: Labeling is one of the most important regulatory responsibilities under the Federal Food, Drug, and Cosmetic Act (FDCA). FDA-approved labeling shapes risk communication, intended use, safety information, clinical decision-making, and enforcement actions. This assignment allows you to apply course concepts by creating a draft labeling-compliance checklist for either a hypothetical drug **or** hypothetical medical device**.**

This exercise will help you understand how FDA regulates labeling, what information must be included, and how manufacturers ensure compliance before a product is marketed.

Assignment Instructions

1. Choose a hypothetical product.

Select ONE:

- A prescription drug
- An over-the-counter (OTC) drug
- A Class II or Class III medical device
- A digital health device/software-as-a-medical-device (SaMD)

Give your hypothetical product a name, intended use, and brief description.

2. Review applicable FDA requirements.

Use your textbook and course materials to identify the labeling requirements that apply to your selected product type. These may include:

- 21 CFR Part 201 (drug labeling)
- 21 CFR Part 801 (device labeling)
- 21 CFR 809 (IVDs, if applicable)
- FDA Guidance Documents
- Required statements, warnings, directions, contraindications, etc.

3. Create a compliance checklist.

Your checklist should identify all FDA-required labeling elements relevant to your product. These may include (examples):

For Drugs

- Proprietary and established names
- Dosage form/route of administration
- Active and inactive ingredients
- Indications and usage
- Contraindications

- Warnings and precautions
- Adverse reactions
- Drug interactions
- Dosage and administration
- Storage and handling
- NDC number
- Required boxed warnings (if applicable)

For Medical Devices

- Intended use and indications
- Directions for use
- Contraindications
- Warnings
- Precautions
- Device description
- Sterility/expiration information
- Unique Device Identifier (UDI)
- Manufacturer/importer details
- Required instructional materials

Your checklist should include checkboxes or bullet points that a manufacturer could actually use during internal review.

4. Format and submit. Your submission should be:

- 1–2 pages
- Organized as a checklist (tables, checkboxes, or bullet list acceptable)
- Professional and clear
- Labeled with your product name and category (drug/device/SaMD)

Office Hours: Monday, February 16, 2026, 6-8pm EST

Optional Live Class Via Zoom: Wednesday, February 18, 2026, at 7pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 3: FDA Jurisdiction: A Matter of Definitions (§J pages 225–234)
    - "Label," "labeling," and "advertising" distinctions
    - First Amendment considerations
    - Promotion vs. scientific exchange
    - Off-label communication frameworks
- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 4: Enforcement and the Geographic Range of FDA Power (§§A-C pages 235–272)
    - Enforcement jurisdiction

WEEK 6 – February 23-March 1, 2026 – Enforcement & Compliance Authority Continued; Human Drugs I: New Drug Approval Pathways

Assignment

Create a FINAL draft of a labeling-compliance checklist for a hypothetical drug/device. (150 Points)

Instructions: Labeling is one of the most important regulatory responsibilities under the Federal Food, Drug, and Cosmetic Act (FDCA). FDA-approved labeling shapes risk communication, intended use, safety information, clinical decision-making, and enforcement actions. This assignment allows you to apply course concepts by creating a draft labeling-compliance checklist for either a hypothetical drug **or** hypothetical medical device**.**

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- 21 CFR Part 801 (device labeling)
- 21 CFR 809 (IVDs, if applicable)
- FDA Guidance Documents
- Required statements, warnings, directions, contraindications, etc.

3. Create a compliance checklist.

Your checklist should identify all FDA-required labeling elements relevant to your product. These may include (examples):

For Drugs

- Proprietary and established names

- Dosage form/route of administration
- Active and inactive ingredients
- Indications and usage
- Contraindications
- Warnings and precautions
- Adverse reactions
- Drug interactions
- Dosage and administration
- Storage and handling
- NDC number
- Required boxed warnings (if applicable)

For Medical Devices

- Intended use and indications
- Directions for use
- Contraindications
- Warnings
- Precautions
- Device description
- Sterility/expiration information
- Unique Device Identifier (UDI)
- Manufacturer/importer details
- Required instructional materials

Your checklist should include checkboxes or bullet points that a manufacturer could actually use during internal review.

4. Format and submit. Your submission should be:

- 1–2 pages
- Organized as a checklist (tables, checkboxes, or bullet list acceptable)
- Professional and clear
- Labeled with your product name and category (drug/device/SaMD)

Office Hours: Monday, February 23, 2026, 6-8pm EST

Optional Live Class Via Zoom: Wednesday, February 25, 2026, at 7pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 4: Enforcement and the Geographic Range of FDA Power (§§D-F pages 272–325)
    - Enforcement jurisdiction
    - Factory inspections
    - Seizures, injunctions, civil money penalties

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 6: Human Drugs (§§A-B pages 831–863)
    - Historical development of drug regulation
    - What constitutes a "new drug"
    - Drug development phases

WEEK 7 – March 2-8, 2026 – Human Drugs II: New Drug Approval Pathways

Assignment

Discussion Posting - What was the most surprising information this week? Why?

Office Hours: Monday, March 2, 2026, 6-8pm EST

Optional Live Class Via Zoom: Wednesday, March 4, 2026, at 7pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 6: Human Drugs (§C pages 863-964)
    - Drug development phases

WEEK 8 – March 9-15, 2026 - Human Drugs III: New Drug Approval Pathways

Assignment

Discussion Posting - Most Interesting Topic and Why?

Office Hours: Monday, March 9, 2026, 6-8pm EST

Optional Live Class Via Zoom: Wednesday, March 11, 2026, at 7pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 6: Human Drugs (§D pages 964-1039)
    - Drug development phases
    - INDs, NDAs, accelerated approval

MARCH 16-22, 2026: SPRING BREAK

WEEK 9 – March 23-29, 2026 - Human Drugs IV: New Drug Approval Pathways

Assignment

No Discussion Posting

Office Hours: Monday, March 23, 2026, 6-8pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 6: Human Drugs (§§E-G pages 1039-1140)
    - Drug distribution and labeling
    - Drug development phases

WEEK 10 – March 30-April 5, 2026 - Human Drugs V: New Drug Approval Pathways; Over the Counter (OTC)

Assignment

Flowchart: NDA approval process (200 points)

Create a flowchart representing the entire NDA pathway. Your flowchart should include all major steps, in proper sequential order. You may use:

- Flowchart boxes
- Arrows
- Decision diamonds
- Color coding
- Swim lanes (optional)

You may create your flowchart in Word, PowerPoint, Google Drawings, Lucidchart, Canva, Visio, or any other diagramming tool. Submit as PDF, image, or PowerPoint file.

No minimum page length is required—flowcharts vary based on design.

Office Hours: Monday, March 30, 2026, 6-8pm EST

Optional Live Class Via Zoom: Wednesday, April 1, 2026, at 7pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 6: Human Drugs (§§H-I pages 1141-1252)
    - Communication
    - OTC Drugs

WEEK 11 – April 6-12, 2026 - Prescription, Generic & Post-Market Duties

Assignment

Draft policy memo on balancing innovation and generic competition (200 points)

Write a concise policy memo (1–2 pages). Your memo should follow a professional policy-making format and be addressed to:

To: U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP)
From: [Your Name], Policy Analyst
Subject: Strategies for Balancing Innovation and Generic Competition in the U.S. Drug Market

(You may format headings according to your preferred memo style.)

Choose a specific issue or angle to focus on. You only need to focus on **one major issue** to keep the memo concise and persuasive.

Formatting Requirements:

- 1–2 pages, single-spaced (typical policy memo format)
- Clear section headings (Background, Analysis, Recommendation, etc.)
- Professional tone suitable for policy work
- APA citations (in-text or as footnotes)
- At least 3 scholarly, legal, or governmental sources

Your memo must include the following sections:

A. Background (2–3 paragraphs). Explain:

- The issue you are addressing
- Why it matters to Congress
- How current law or FDA policies influence the issue
- The key tension between innovation and access

B. Analysis (3–4 paragraphs). Provide a balanced assessment of:

- How current regulatory structures incentivize innovation
- How barriers or delays affect generics/biosimilars
- Relevant case law or FDA decisions (optional but encouraged)
- Public health, economic, and ethical implications

Demonstrate understanding of actual regulatory mechanisms, not general statements.

C. Policy Recommendation (2–3 paragraphs). Make a clear argument for how Senate Committee should act.

Your proposal may include:

- Statutory reforms
- FDA policy changes
- Exclusivity adjustments

- Enhanced competition safeguards
- Increased transparency
- Targeted enforcement enhancements

This is the persuasive portion of your memo—your recommendations must be supported by evidence, logically argued, and practical.

D. Consideration of Counterarguments (1–2 paragraphs). Examples could include:
- Potential concerns from innovators
- Industry pushback
- Effects on patient access or safety

Then explain why your recommendation remains preferable.

Office Hours: Monday, April 6, 2026, 6-8pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 6: Human Drugs (§§J-L pages 1253-1373)
    - Prescription vs OTC status
    - Labeling for physicians and patients
    - Post-approval surveillance
    - OTC monographs
    - Generic drugs & therapeutic equivalence
    - Innovation, access, and state tort law interactions

WEEK 12 – April 13-19, 2026 - Medical Devices & Digital Health

Assignment

No Discussion Posting

Office Hours: Monday, April 13, 2026, 6-8pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 9: Medical Devices (§§A-F pages 1587-1676)
    - Device Amendments of 1976
    - Classification (Class I, II, III)
    - 510(k), De Novo, PMA pathways
    - Digital health technologies & software as a medical device

WEEK 13 – April 20-26, 2026 – Medical Devices & Digital Health Continued

Assignment

Final Persuasive Paper Due (300 points)

You will self-select a contemporary issue related to the regulation of healthcare technology, pharmaceutical products, or FDA authority and prepare a persuasive paper of 6–10 pages. This is a policy-oriented argument essay, and your task is to take a clear position on a current regulatory debate and convince Congress that your viewpoint should guide future federal legislation or FDA reforms.

Your goal is to use regulatory reasoning, statutory analysis, scientific considerations, and policy arguments to persuade federal lawmakers that your position is the correct one for protecting public health, promoting innovation, and strengthening the nation's regulatory infrastructure.

In persuasive writing, the author takes a position for or against a regulatory or legal proposal and uses logic, evidence, and authoritative sources to convince the audience. In this course, that means drawing on:

- FDA statutory authority under the FDCA
- Drug, device, biologic, or digital health regulatory pathways
- Case law and enforcement doctrines
- Risk-benefit frameworks
- Public health and safety considerations
- Innovation, access, and equity concerns

You must argue your position using sound reasoning**,** solid evidence, and expert support**,** demonstrating your command of FDA law and policy.

<u>How to Plan Your Paper</u>

1. Choose your position. Select a regulatory issue and choose one clear side. Examples:

- Should the 510(k) pathway be reformed or replaced?
- Should the FDA allow broader off-label communication by manufacturers?
- Should Congress expand FDA authority over lab-developed tests, dietary supplements, or cosmetic ingredients?
- Should accelerated approval be limited, expanded, or abolished?
- Should digital health algorithms and AI tools be regulated as medical devices?

Identify the solution or policy recommendation you are proposing.

2. Analyze your audience. Your audience is **Congress**—lawmakers who:

- Often lack scientific and technical expertise
- Are influenced by political, economic, and public-health pressures
- Must balance innovation with patient safety

Decide whether Congress is likely supportive, neutral, or skeptical of your position.

3. Research your topic thoroughly. A persuasive policy paper must provide specific, credible, and convincing evidence, such as:

- FDA guidance, rules, and statutory language
- Federal case law
- Enforcement actions and advisory committee discussions
- Peer-reviewed studies
- Government reports (GAO, OIG, NAS, etc.)
- Academic commentary

4. Structure your essay logically. Plan the order of your arguments and evidence. Address:

- The problem
- The existing legal/regulatory framework
- Your proposed solution
- Evidence supporting your proposal
- Anticipated objections and counterarguments

Office Hours: Monday, April 20, 2026, 6-8pm EST

Reading

- Textbook (*Introduction to the Regulation of Healthcare Technology & Pharmaceutical Products: Food and Drug Law - 5th Edition*) Chapter 9: Medical Devices (§§G-J pages 1676-1761)
    - Digital health technologies & software as a medical device
    - Radiation control
    - Preemption of state law

ADDITIONAL ASSIGNMENT INFORMATION:

- **5 Weekly Discussion Posts**

There is no length requirement for the discussion post; however, they need to be substantial enough to fully address the topic you are reviewing. Students should read all the other responses from their peers. As an online course, this is how we can collaborate and learn from each other.

You are required to post at least an initial discussion post in response to the question posed and a response to another student's post by Sunday (11:55pm).

Discussion- 20 Points Each Week

- **First Draft Labeling-Compliance Checklist**

Due Date: February 22, 2026

Create a first draft of a labeling-compliance checklist for a hypothetical drug/device.

Instructions: Labeling is one of the most important regulatory responsibilities under the Federal Food, Drug, and Cosmetic Act (FDCA). FDA-approved labeling shapes risk communication, intended use, safety information, clinical decision-making, and enforcement actions. This assignment allows you to apply course concepts by creating a draft labeling-compliance checklist for either a hypothetical drug **or** hypothetical medical device**.**

This exercise will help you understand how FDA regulates labeling, what information must be included, and how manufacturers ensure compliance before a product is marketed.

Assignment Instructions

1. Choose a hypothetical product.

Select ONE:

- A prescription drug
- An over-the-counter (OTC) drug
- A Class II or Class III medical device
- A digital health device/software-as-a-medical-device (SaMD)

Give your hypothetical product a name, intended use, and brief description.

2. Review applicable FDA requirements.

Use your textbook and course materials to identify the labeling requirements that apply to your selected product type. These may include:

- 21 CFR Part 201 (drug labeling)
- 21 CFR Part 801 (device labeling)
- 21 CFR 809 (IVDs, if applicable)
- FDA Guidance Documents
- Required statements, warnings, directions, contraindications, etc.

3. Create a compliance checklist.

Your checklist should identify all FDA-required labeling elements relevant to your product. These may include (examples):

For Drugs

- Proprietary and established names
- Dosage form/route of administration
- Active and inactive ingredients
- Indications and usage
- Contraindications
- Warnings and precautions
- Adverse reactions

- Drug interactions
- Dosage and administration
- Storage and handling
- NDC number
- Required boxed warnings (if applicable)

For Medical Devices

- Intended use and indications
- Directions for use
- Contraindications
- Warnings
- Precautions
- Device description
- Sterility/expiration information
- Unique Device Identifier (UDI)
- Manufacturer/importer details
- Required instructional materials

Your checklist should include checkboxes or bullet points that a manufacturer could actually use during internal review.

4. Format and submit. Your submission should be:

- 1–2 pages
- Organized as a checklist (tables, checkboxes, or bullet list acceptable)
- Professional and clear
- Labeled with your product name and category (drug/device/SaMD)

First Draft: 50 points

- **Final Draft Labeling-Compliance Checklist**

Due Date: March 1, 2026

Create a FINAL draft of a labeling-compliance checklist for a hypothetical drug/device.

Instructions: Labeling is one of the most important regulatory responsibilities under the Federal Food, Drug, and Cosmetic Act (FDCA). FDA-approved labeling shapes risk communication, intended use, safety information, clinical decision-making, and enforcement actions. This assignment allows you to apply course concepts by creating a draft labeling-compliance checklist for either a hypothetical drug **or** hypothetical medical device**.**

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- Manufacturer/importer details
- Required instructional materials

Your checklist should include checkboxes or bullet points that a manufacturer could actually use during internal review.

4. Format and submit. Your submission should be:

- 1–2 pages
- Organized as a checklist (tables, checkboxes, or bullet list acceptable)
- Professional and clear
- Labeled with your product name and category (drug/device/SaMD)

Final Draft: 150 points

- ❖ **Flowchart: NDA Approval Process**

Due Date: April 5, 2026

Create a flowchart representing the entire NDA pathway. Your flowchart should include all major steps, in proper sequential order. You may use:

- Flowchart boxes
- Arrows
- Decision diamonds
- Color coding
- Swim lanes (optional)

You may create your flowchart in Word, PowerPoint, Google Drawings, Lucidchart, Canva, Visio, or any other diagramming tool. Submit as PDF, image, or PowerPoint file.

No minimum page length is required—flowcharts vary based on design.

Flowchart: 200 points

- ❖ **Policy Memo**

Due Date: April 12, 2026

Draft policy memo on balancing innovation and generic competition (200 points)

Write a concise policy memo (1–2 pages). Your memo should follow a professional policy-making format and be addressed to:

To: U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP)
From: [Your Name], Policy Analyst
Subject: Strategies for Balancing Innovation and Generic Competition in the U.S. Drug Market

(You may format headings according to your preferred memo style.)

Choose a specific issue or angle to focus on. You only need to focus on **one major issue** to keep the memo concise and persuasive.

Formatting Requirements:

- 1–2 pages, single-spaced (typical policy memo format)
- Clear section headings (Background, Analysis, Recommendation, etc.)
- Professional tone suitable for policy work
- APA citations (in-text or as footnotes)
- At least 3 scholarly, legal, or governmental sources

Your memo must include the following sections:

A. Background (2–3 paragraphs). Explain:

- The issue you are addressing
- Why it matters to Congress
- How current law or FDA policies influence the issue
- The key tension between innovation and access

B. Analysis (3–4 paragraphs). Provide a balanced assessment of:

- How current regulatory structures incentivize innovation
- How barriers or delays affect generics/biosimilars
- Relevant case law or FDA decisions (optional but encouraged)
- Public health, economic, and ethical implications

Demonstrate understanding of actual regulatory mechanisms, not general statements.

C. Policy Recommendation (2–3 paragraphs). Make a clear argument for how Senate Committee should act.

Your proposal may include:

- Statutory reforms
- FDA policy changes
- Exclusivity adjustments
- Enhanced competition safeguards
- Increased transparency
- Targeted enforcement enhancements

This is the persuasive portion of your memo—your recommendations must be supported by evidence, logically argued, and practical.

D. Consideration of Counterarguments (1–2 paragraphs). Examples could include:

- Potential concerns from innovators
- Industry pushback
- Effects on patient access or safety

Then explain why your recommendation remains preferable.

Policy Memo: 200 points

- **Final Persuasive Paper**

Due Date: April 26, 2026

You will self-select a contemporary issue related to the regulation of healthcare technology, pharmaceutical products, or FDA authority and prepare a persuasive paper of 6–10 pages. This is a policy-oriented argument essay, and your task is to take a clear position on a current regulatory debate and convince Congress that your viewpoint should guide future federal legislation or FDA reforms.

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- Should accelerated approval be limited, expanded, or abolished?
- Should digital health algorithms and AI tools be regulated as medical devices?

Identify the solution or policy recommendation you are proposing.

2. Analyze your audience. Your audience is **Congress**—lawmakers who:

- Often lack scientific and technical expertise
- Are influenced by political, economic, and public-health pressures
- Must balance innovation with patient safety

Decide whether Congress is likely supportive, neutral, or skeptical of your position.

3. Research your topic thoroughly. A persuasive policy paper must provide specific, credible, and convincing evidence, such as:

- FDA guidance, rules, and statutory language
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- Academic commentary

4. Structure your essay logically. Plan the order of your arguments and evidence. Address:

- The problem
- The existing legal/regulatory framework
- Your proposed solution
- Evidence supporting your proposal
- Anticipated objections and counterarguments

Final Paper: 300 points

CLASS DEMEANOR EXPECTATIONS:

As a graduate-level course, students are expected to engage in a manner that reflects professionalism, respect, and academic integrity. The following expectations apply to all online interactions, including discussion boards, virtual meetings, and email correspondence:

1. Respectful Communication
    - Treat peers, instructors, and guest speakers with courtesy and respect, even during disagreements.
    - Avoid offensive, discriminatory, or inflammatory language.
    - Listen actively and respond thoughtfully to others' contributions.
2. Professional Conduct
    - Use professional language, tone, and etiquette in all communications.
    - Dress appropriately when attending live video sessions.
    - Maintain academic honesty in all assignments and discussions.
3. Preparedness and Engagement
    - Complete readings and assignments on time to contribute meaningfully to class discussions.

- Be present and attentive in synchronous sessions; avoid multitasking.
- Participate regularly in discussion boards and collaborative activities.

4. Constructive Participation
   - Offer evidence-based opinions and support arguments with course materials or credible sources.
   - Encourage inclusive dialogue and be mindful of different perspectives.
5. Timely and Appropriate Communication
   - Check your email and Canvas regularly for updates.
   - Contact the instructor promptly with questions or concerns using professional email etiquette.
6. Confidentiality and Academic Integrity
   - Respect the confidentiality of shared personal experiences and course discussions.
   - Do not record or share course content without permission.

CLASS ATTENDANCE & MAKEUP POLICIES:

Observance of Religious Holidays:

UF Law respects students' observance of religious holidays. Students, upon prior notification to their instructors, shall be excused from class or other scheduled academic activity to observe a religious holy day of their faith. Students shall be permitted a reasonable amount of time to make up the material or activities covered in their absence. Students shall not be penalized due to absence from class or other scheduled academic activities because of religious observances.

Absence Due to Illness:

A student who is absent from class or misses any required class-related activity because of illness should contact their instructor, if feasible, as early as possible before the missed class or activity. Students shall be permitted a reasonable amount of time to make up the material or activities covered during an excused absence. Students should contact their college by the deadline to drop a course for medical reasons. Students can petition the Dean of Students' Office to drop a course for medical reasons. The university's policy regarding medical excuses from classes is maintained by the Student Health Care Center.

EVALUATION METHODS & GRADING POLICY:

[If a portion of the grade is tied to participation, please provide specific details on how you will determine an individual student's participation grade.]

Grade Scale & Grading Policies:

Grade	Points
A	4.0
A-	3.67
B+	3.33
B	3.00
B-	2.67
C+	2.33

C	2.00
C-	1.67
D+	1.33
D	1.00
D-	0.67
E	0.00

The law school grading policy is available at https://www.law.ufl.edu/uf-law-student-handbook-and-academic-policies. Note that the mandatory mean does not apply to MSL or LLM students.

EXAM DELAYS AND ACCOMMODATIONS:

The law school policy on exam delays and accommodations can be found here.

STATEMENT RELATED TO ACCOMMODATIONS FOR STUDENTS WITH DISABILITIES:

Students requesting accommodations for disabilities must first register with the Disability Resource Center (https://disability.ufl.edu/). Once registered, students will receive an accommodation letter, which must be presented to the Assistant Dean Brian Mitchell. Students with disabilities should follow this procedure as early as possible in the semester. It is important for students to share their accommodation letter with their instructor and discuss their access needs as early as possible in the semester. Students may access information about various resources on the UF Law Student Resources Canvas page, available at https://ufl.instructure.com/courses/427635.

STUDENT COURSE EVALUATIONS:

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Click here for guidance on how to give feedback in a professional and respectful manner. Students will be notified when the evaluation period opens and may complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students here.

COMPLIANCE WITH UF HONOR CODE:

Academic honesty and integrity are fundamental values of the University community. Students should be sure that they understand the UF Law Honor Code located here. The UF Law Honor Code also prohibits the use of artificial intelligence, including, but not limited to, ChatGPT and Harvey, to assist in completing quizzes, exams, papers, or other assessments.

UF students are also bound by The Honor Pledge, which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards

of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: 'On my honor, I have neither given nor received unauthorized aid in doing this assignment.'" The Conduct Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Click here to read the University Conduct Code. If you have any questions or concerns, please consult with the instructor in this class.

RECORDINGS:

Students are allowed to record video or audio of class lectures. However, the purposes for which these recordings may be used are strictly controlled. The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding. All other purposes are prohibited. Specifically, students may not publish recorded lectures without the written consent of the instructor.

A "class lecture" is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a University of Florida course. A class lecture does not include lab sessions, student presentations, clinical presentations such as patient history, academic exercises involving solely student participation, assessments (quizzes, tests, exams), field trips, private conversations between students in the class, or between a student and the faculty or guest lecturer during a class session.

Publication without permission from the instructor is prohibited. To "publish" means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons), including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third-party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under UF Regulation 4.040 Student.

RESOURCES:

Wellness:

U Matter, We Care: If you or someone you know is in distress, please contact umatter@ufl.edu, 352-392-1575, or visit U Matter, We Care website to refer or report a concern, and a team member will reach out to the student in distress.

Counseling and Wellness Center: Visit the Counseling and Wellness Center website or call 352-392-1575 for information on crisis services as well as non-crisis services.

Student Health Care Center: Call 352-392-1161 for 24/7 information to help you find the care you need, or visit the Student Health Care Center website.

GatorWell Health Promotion Services: For prevention services focused on optimal wellbeing, including Wellness Coaching for Academic Success, visit the GatorWell website or call 352-273-4450.

Academic & Tech Support Resources:

E-learning technical support: Contact the UF Computing Help Desk at 352-392-4357 or via e-mail at helpdesk@ufl.edu.

Online Student Complaints: View the Distance Learning Student Complaint Process.