FDA History and Legal Framework

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Zoom Etiquette

- All participants will be muted during class.
- You will not be required to have your video on for the entirety of the class. However, I will assume you are paying attention even if your video is off. Use the raise hand feature when possible.
- We will try to take a 5-minute break each day. Please mute yourself and turn your video off during this time.
- Make sure your name appears in Zoom as you'd like to be called.
- The chat function will be disabled for this class.

#PharmaPolicy on Twitter

- Engage with course materials and current topics in drug law and policy by joining the conversation on Twitter!
- Counts toward participation!
- Be sure to tag the following in your tweets:
  - @DrSinhaEsq
  - #PharmaPolicy
- Optional additional tags: @US_FDA, #FDA, #FDALaw, #DrugLaw, #Opioids, #MedTwitter, #LawTwitter, #HealthPolicyTwitter
- Student tweets will be highlighted at the beginning of each class

Zoom Etiquette

- Attendance is required for all sessions.
- The sessions will not be recorded. Slides will be posted after class.
- Unless it is an emergency, a request for an excused absence must come 48 hours before class starts. If you miss the presentation class session, you will not receive credit for that section of the grade.
- If you are having technical issues, please use the Zoom application on your smartphone or call into the class in the meantime:
  - Phone number: +1 669 900 6833
  - Meeting ID: 319 992 2577
  - Permanently posted on Slack: #zoom-info

#PharmaPolicy
Course Overview

- Updated syllabus will be available online
  - SUBJECT TO CHANGE! Always consult the online syllabus!
    - I will inform you in advance about major changes to the syllabus
    - All details will be posted on the respective Slack channel

http://bit.ly/PharmaPolicy

Slack Workspace

- We will be using Slack for the course (not BlackBoard)
  - https://2219-1513-hsc.slack.com/

Add yourself to these channels NOW if you haven’t already:

- #general
- #weekly-questions
- #weekly-videos
- #weekly-readings
- #discussion
- #careers
- #syllabus

You will MISS important information if you are not in these channels!

Course Expectations

Attendance and Engagement: 15%
- Attendance is always required
- No attendance sheet, but Zoom will record when you log on and off the class session
- Be sure that your screen name is accurate, or you will not receive credit for attendance!

Engagement:
- Be ready to participate in class.
- Open-ended questions, breakout group discussions
Course Expectations

**Attendance and Engagement:**
This component of the evaluation is based on:
A. class attendance and punctuality (5%),
B. contribution to in-class discussion and #discussion channel (10%); and
C. posting at least twice weekly on Twitter (at #PharmaPolicy [optional but encouraged]) (5% extra credit).

**Readings and Videos:**
—Readings and videos are always required
—Assigned readings and videos should be done before class

**Question Sets:**
—Each week’s videos have an associated question set.
—Answers must be submitted prior to the start of class.
—Late assignments will count against your score.
—All students should complete all question sets before the semester ends.

STRONG SUGGESTION: watch videos side-by-side with questions! Watch them multiple times!

**#discussion on Slack:**
—Many questions on the weekly assignments are open-ended and require written responses
—You must cut/paste those responses into the #discussion channel AND respond to 2 classmates (for EACH question) by midnight PT on Friday
Course Expectations

**Midterm Assignment:**
— 800-word op-ed on a topic of your choosing.
— The topic must relate to the course or course materials.
— The topic must be pre-approved by Dr. Sinha by September 16th.
— The op-ed is due on October 22nd at midnight PT.

Course Expectations

**Presentation:**
— You will give a short presentation based on your op-ed
— Length/format to be determined (most likely 3-5 minutes)
— More details to come

Pharma Law and Policy

• Societally important
  • Overdose crisis
  • Pharmaceutical costs
  • COVID-19

• Key constitutional and policy debates involve drugs

• Rapidly evolving and cross-cutting
  • ACA and healthcare reform, aging population
  • Personalized medicine and pharmacogenetics
  • Controlled substances policy: supervised consumption facilities
  • COVID-19

• Jobs
  • Pharmaceutical, healthcare, biomedical, industries
  • Public interest: government and advocacy sectors

Historical Background

• Pure Food and Drug Act of 1906
  • Established the FDA
  • Response to "snake oil" medicine

• Food, Drug, and Cosmetics Act (FDCA)
  • Enacted in 1938 after years of debates
  • Focuses on consumer information
  • Congress often updates FDA standards in response to crisis (reactive)
    • 1938: sulfanilamide elixir kills children (FDCA)
    • 1962: thalidomide in pregnancy results in phocomelia abroad (amendments)
    • 2007: Vioxx results in greater post-market surveillance of drugs
Historical Background

- Congress now has a chance to update FDA laws every 5 years, after the 1992 creation of prescription drug user fees
- Other key aspects of FDA regulation often amended at the same time
- Statutes:
  - Prescription Drug User Fee Act (PDUFA, 1992)
  - FDA Modernization Act (FDAMA, 1997)
  - Public Health Safety and Bioterrorism Preparedness and Response Act (2002)
  - FDA Amendments Act (FDAAA, 2007)
  - FDA Safety and Innovation Act (FDASIA, 2012)
  - FDA Reauthorization Act (FDARA or PDUFA VI, 2017)

Current Landscape of Drug Regulation

- Food and Drug Administration (FDA)
  - ¼ of all US consumer products sold in US (FDCA: food, drugs, and cosmetics!)
  - Regulations occupy 250 CFR pages in 1948; 2006: 3800
  - Budget: 72M in 1970; 2.5B in 2011
  - Increasingly global operation to follow supply chains
  - Enforces laws other than what is contained in FDCA

Course Themes: Regulation

- Individual freedom vs corporate freedom vs public health
  - “Occupy” viewpoint: government regulation to control corporate interests
  - Libertarian viewpoint: control of government is problematic
  - Theoretical and constitutional questions, e.g.
    - First amendment issues related to advertising and labeling,
    - Fourth amendment issues related to search and seizure
  - Role of citizen united, commercial free speech, right to privacy
  - Law and economics: is law needed to regulate the free market in drugs?
  - What is the most economically-efficient method of regulation?

Course Themes: Stakeholders

- Pharmaceutical Industry
- FDA
- Consumers/users
- Consumer advocate groups: national and international context
- Governments: international/federal, state and local
- Producers/Manufacturers
- Healthcare providers
- Pharmacists/retailers
- Investors
- Third party payers: government and private
- Lawyers

Course Themes: Balancing Interests

- Right to health, right to access to medications, human rights
- What is the role of intellectual property protections in the patent regime vs. the needs of terminally ill patients? Valuation of life, fairness and profits, economic incentives?
- What is the role of morality in regulation?
Course Themes: Role of Science

- Successes and limitations of science-based regulation
- Not enough data
- Even if enough data, no agreement about the scientific meaning of significance (statistical vs. clinical)
- Even if scientific agreement, no agreement on balance of values like public health, risks, and benefits, or the level of uncertainty acceptable
- Always: Limited resources

Course Themes: State Rights

- Pre-emption
- Standardization vs. experimentation
- Influence of state laws on federal policymaking, even if pre-empted
- What are the competing interests? What can the FDA take into account when making regulatory decisions?
Laws and Regulations

- The Constitution grants Congress the sole authority to enact legislation
- Bills are passed by Congress and signed into law by the President
- A new law often does not include all the details needed to explain how an individual, business, state or local government, or others might follow the law
- The Executive Branch of the Federal Government is responsible for the day-to-day enforcement and administration of federal laws

FDA — Laws and Regulations

- The Federal Food, Drug, and Cosmetic Act (FDCA) is a federal law enacted by Congress
- FDCA and other federal laws establish the legal statutory framework within which FDA operates
- Over 200 laws since 1906 that authorize and direct the regulatory activities of the FDA

FDA — Important Laws

- Pure Food and Drug Act (1906) – “snake oil salesmen”
- Food Drug and Cosmetic Act (1938) – elixir sulfanilamide
- Kefauver-Harris Amendment (1962) – thalidomide
- Orphan Drug Act (1983) – rare diseases
- Prescription Drug User Fee Act (1992) – “regulatory capture”
- FDA Modernization Act (1997) – pediatric research
- FDA Amendments Act (2007) – postmarket research (Vioxx)
- Biologics Price Competition and Innovation Act (2009) – biologics

FDA Rules/Regulations

- Rule - issued pursuant to statutory authority, implements a law, and has the force and effect of law
- Some rules are purely informational
- “Regulation” is the common name for a rule that imposes regulatory requirements
- FDA develops regulations based on the laws set forth in the FD&C Act or other laws under which FDA operates

Administrative Process

- The Administrative Procedure Act (APA) of 1946
- Law that governs the way in which agencies of the Federal Government (like the FDA) may propose and establish regulations
- Notice-and-comment rulemaking
  - Period where public may comment on interim rules before finalizing
  - Agencies like the FDA must read and consider all public comments before finalizing
- All rules are published in the Code of Federal regulations
- All rules are subject to judicial scrutiny
### FDA Regulations
- Violation of a validly adopted regulation can result in a sanction just as severe as one received for violation of a statute passed by Congress
  - Example: FDA can force products off the market for “misbranding”
- To have the force of law a regulation must be issued under a delegation of authority from Congress and according to appropriate rulemaking requirements

### Guidance Documents
- Statements of policy on a regulatory issue or an interpretation of a statute or regulation
- Represents the Agency’s current thinking on a regulatory issue
- Guidance documents are prepared to establish clarity and consistency in FDA policies, regulatory activities, and inspection and enforcement procedures
- Guidance documents provide industry with specific recommendations on how to comply with the statutes and regulations and avoid enforcement actions
- Guidance documents do not have the force of law and are not mandatory

### Guidance Development
- Public can comment on guidance at any time
  - Draft guidances have stated periods for public comment prior to finalizing the guidance, but the docket remains open for future updates and revisions
- Guidance can be revised at any time
  - Advances in science or technology
  - New information
  - New policy

### FDA Advisory Committees
- FDA seeks input from advisory committees on a broad scope of complex issues related to the products it regulates
- Advisory committee meetings also facilitate public discussion of important topics and provide a means for the public to provide comments to the Agency
- Every advisory committee meeting includes an open public hearing (OPH) session, during which interested persons may present relevant information or views orally or in writing
- FDA’s advisory committees provide independent expert advice and recommendations to the Agency on scientific, technical, and policy matters related to FDA-regulated products

### FDA and EUAs
- Once Secretary of Health and Human Services Alex Azar declared a public health emergency concerning COVID-19, the FDA was given the authority to issue “Emergency Use Authorizations” or EUAs
- EUAs can apply to many things:
  - Approved and experimental drugs
  - Medical devices (including PPE)
  - Vaccines
  - Diagnostic tests for COVID-19
  - Etc.

*Note: this is different than the National Strategic Stockpile*