FDA History and Legal Framework

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Learning During a Pandemic

• COVID-19 has affected all of us in one way or another
• I am committed to helping you learn
  • Ask for accommodations if needed!
  • I will be as lenient/flexible as possible under the circumstances
• Never feel obligated to share any details of your health status with me
  • I will never require any medical information or doctor’s notes
• My (virtual) door is always open – you are welcome to discuss anything with me.
• I want you all to stay healthy, balanced, and grounded through this crisis.

Zoom Etiquette

• The sessions will not be recorded.
• Attendance is required for all sessions.
• 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

Zoom Etiquette

• All participants will be muted during class. You may unmute yourself in order to speak or ask questions.
• 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 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 class. Save discussions for posting on the Slack channel or ask questions during class.

Slack Workspace

• We will be using Slack for the course (not BlackBoard)
• http://2209-4347-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!
#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
- If you want help getting started on Twitter, schedule time during office hours
Course Overview

• Reminder: always consult the online syllabus!
• Videos and questions for next week will be posted shortly
• Readings will be posted shortly

http://bit.ly/PharmaPolicy

Course Expectations

Attendance and Engagement 15%
Question Sets 25%
Midterm Assignment 25%
Presentation 10%
Final Exam 25%

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 (including Slack) and policy debates (10%); and
C. posting at least twice weekly on Twitter (at #PharmaPolicy [optional but encouraged]) (5% extra credit).

Course Expectations

Readings and Videos:
— Readings and videos are always required.
— Assigned readings and videos should be completed before class.
Question Sets:
—Each week’s videos have an associated question set.
—Answers must be submitted prior to the start of class.
—Each quiz will be worth 3 points, with 1 point deducted for late assignments and 1 point deducted for scores less than 70%. No points will be awarded if the quiz is not submitted by Friday night at 9:00 pm PST.
STRONG SUGGESTION: watch videos side-by-side with questions!
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 February 18th, and the op-ed is due by March 26th.

Course Expectations

Presentation:
— You will give a short presentation based on your op-ed.
— Length will be determined by number of students in class (most likely 3-5 minutes).
— More details to come.

Course Expectations

Final Exam:
— This will be a take-home exam consisting of a 2-page formatted policy memo.
— On May 6th, I will give you instructions.
— The policy memo will be due in one week (May 13th).
— More information to come.

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
  • 1962: thalidomide in pregnancy results in phocomelia abroad
  • 2007: Vioxx results in greater post-market surveillance of drugs

Current Landscape of Drug Regulation

Food and Drug Administration (FDA)
• ¾ of all US consumer products sold in US (FDCA: food, drugs, and cosmetics!)
• Regulations occupy 250 CFR pages in 1948; 2006: 3800
• Budget: $2.7B in 1970; $2.5B in 2011
• Increasingly global operation to follow supply chains
• Enforces laws other than what is contained in FDCA
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 – Important Laws

- 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)

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 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

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