How the FDA Regulates Industry

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http://bit.ly/PharmaPolicy

#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, #GAALaw, #DrugLaw, #Epzoids,
  #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

#PharmaPolicy

Anti-vaccine protesters temporarily shut down major coronavirus vaccine site at Dodger Stadium in Los Angeles
Midterm Assignment:
— 600 to 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.

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.

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.
Review of Questions

Question 5
What is a "premarket notification" system?

- A drug approval system in which the FDA individually approves each manufacturer's marketing materials.
- A drug approval system in which the FDA informally notifies manufacturers whether it believes a drug will gain approval before officially announcing the drug's approval status.
- A drug approval system in which drugs are automatically approved unless the FDA affirmatively acts within a specified duration of time to prevent marketing.
- A drug approval system in which FDA notifies the market about its evaluation of drug at some point after the manufacturer starts selling it.

Review of Questions

Question 11
In which of the following branches of government is the FDA located?

- Legislative
- Executive
- Judicial

Question 12
The FDA is located within which department or agency?

- Department of Commerce
- Department of Health and Human Services
- Department of the Interior
- Department of Agriculture
- Centers for Medicare and Medicaid Services
- National Institutes of Health

Review of Questions

Question 17
Because the FDA is composed of expert scientists and physicians, it has the power to create regulations that override statutes enacted by Congress.

- True
- False

Question 18
FDA guidance documents have the force of law.

- True
- False

CDER
Center for Drug Evaluation and Research

- Led by Dr. Janet Woodcock up until COVID-19
- CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs.
- This is more than just medicines
  - Fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens are all considered drugs
Approval of Drugs

- All drugs marketed prior to 1938 were grandfathered in
  - Never required a showing of safety or efficacy
- All drugs marketed prior to 1962 allowed most existing drugs to be grandfathered in as long as they were Generally Regarded As Safe (GRAS)
- FDA believes that there are few, if any, marketed drugs that are actually entitled to grandfather status, because the drugs currently on the market likely differ from the previous versions in some respect:
  - Formulation, dosage form, strength, method of manufacture, route of administration, indications or intended patient population

Prescription Drugs: 505(b)(1) or 505(b)(2):
- (b)(1) for new chemical entities
- (b)(2) for derivatives of already-marketed products

Over-the-Counter Drugs:
- Fall into several large categories and are regulated by class:
  - Antacids, antiperspirants, cold remedies
- Occasionally, prescription drugs will switch to over-the-counter:
  - Generally Regarded As Safe and Effective (GRASE)
  - Often switch for financial reasons (brand loyalty, etc.)

CBER
Center for Biologics Evaluation and Research
- Led by Dr. Peter Marks
- Ensures that biological products are safe, effective, and available
- Provides the public with information to promote the safe and appropriate use of biological products
- Biological products include vaccines, allergens, blood and blood products, and cells, tissues, and gene therapies

CDRH
Center for Devices and Radiological Health
- Led by Dr. Jeff Shuren
- Evaluate medical devices and radiation-emitting products
- Provide understandable and accessible science-based information
- Facilitate medical device innovation by:
  - advancing regulatory science
  - providing industry with predictable, consistent, transparent, and efficient regulatory pathways
  - assuring consumer confidence in devices marketed in the U.S.

Medical Device Approvals
- FDA’s 510(k) process relies on similarity to existing products
- Class I, Class II, and Class III
- Most Class I devices are exempt from Premarket Notification 510(k)
- Most Class II devices require Premarket Notification 510(k)
- Most Class III devices require Premarket Approval

Some PPE during COVID-19 falls into medical devices:
- Most PPE is Class I exempt, some PPE (e.g., ventilators) are Class II
- EUAs apply to medical devices as well

User Fees and PDUFA

Figure 2. User Fees Collected by the FDA, According to Category and Year. Data are from annual financial reports with respect to each user fee act.
User Fees and PDUFA

![Graph showing contributions of PDUF fees to total costs](image1)

**Figure 1.** Contributions of Net PDUFA Fees to Total Evaluation Costs of the FDA Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research. Data are from annual Prescription Drug User Fee Act (PDUFA) financial reports.

**How would you fund the FDA?**

![Graph showing FDA review times for priority and standard new drug applications](image2)

**Figure 2.** FDA Review Times for Priority and Standard New Drug Applications and Biologics License Applications. Data are from the Food and Drug Administration (FDA). Shown is the average review time by the FDA Center for Drug Evaluation and Research. The peak in 2002 for priority applications coincided with an increase in approvals after the first review cycle to 47%, from 15% the previous year.

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*Harvard-MIT Center for Regulatory Science*