Course Introduction, Expectations, and Themes

Michael S. Sinha, MD, JD, MPH
Adjunct, Department of Health Sciences, California State University, East Bay
Research Fellow, Harvard-MIT Center for Regulatory Science
Affiliated Researcher, Program On Regulation, Therapeutics, And Law (PORTAL)
Teaching Faculty, Harvard Medical School Center for Bioethics
Adjunct, Northeastern University School of Law
Visiting Scholar, NUSL Center for Health Policy and Law
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

• 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

Introductions

1. Preferred name
2. Preferred pronouns
3. Hometown (city, state, country)
4. Year (e.g., junior, senior) and major
5. Any pharmaceutical policy interest/experience
6. Career goals/plans

Let’s talk about Twitter...
#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

Some Recent Posts:

**Using Twitter to Amplify Your Own Work**

**Amplification is a Two-Way Street**

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)

Course Expectations

Readings and Videos:
- Readings and videos are always required.
- Assigned readings and videos should be completed before class.

YouTube Channel
Course Expectations

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!

---

Question Sets for Videos:

1. Which one of the following did the Federal Food, Drug, and Cosmetic Act of 1938 expand?
   - Preventative evaluation of new drugs for side-effects
   - Preclinical testing of new drugs for safety
   - Phase 1, 2, and 3 testing for drug efficacy
   - Preventative setting of patient acceptance (such as taste)

Question Sets for Videos:

2. Which three of the following proposed legislative actions that eventually led to the 1938 U.S. Federal Food, Drug, and Cosmetic Act? (select all that apply)
   - Restrictions on advertising
   - Requirements for more effective prescription drug packaging
   - Removal of medications causing lung cancer from the market
   - Removal of medications causing kidney stones from the market

---

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

---

Course Expectations

**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.
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.

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.

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
• 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

Current Landscape of Drug Regulation

Food and Drug Administration (FDA)
• 1/3 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
Current Landscape of Drug Regulation

- Controlled Substances Act (CSA)
  - Enacted 1970 with subsequent amendments
  - Schedules controlled substances
  - Schedule for marijuana in Schedule I most controversial
  - Creates DEA

- Drug Enforcement Administration (DEA)
  - 2.5B budget, including license fees from practitioners
  - Law enforcement agency
  - Global reach (interdiction, investigation, training, etc.)

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 citizens 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?