Course Introduction, Themes, and Expectations

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Dr. Michael Sinha is a Regulatory Science Fellow in the Harvard-MIT Center for Regulatory Science, within the Harvard Program in Health Care Sciences (HPHC), at Harvard Medical School. He is also affiliated with the Program On Regulation, Therapeutics, And Law (PORTAL), within the Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine at Brigham and Women's Hospital. His legal scholarship includes articles in the American Journal of Law and Medicine, the Journal of Law, Medicine & Ethics, and Harv. Law & Pol'y Rev. He is a design editorial board member, Jotwell Law; the Stanford Law & Policy Review; and the Stanford Law & Policy Journal. His recent work has appeared in, 2013 Am J Public Health, 2014 Pub Health, 2015 Jtpt Medicine; the American Journal of Orthopsych, Drug Safety, Regen Clin Rsrch for Biobehav. Sci, and the Health Affairs Mag. Research interests include HHC, and pharmaceutical law, intellectual property law, and antitrust law.

Harvard-MIT Center for Regulatory Science

Program On Regulation, Therapeutics, And Law

Hasting Medical School and Brigham and Women's Hospital

The goal of regulatory science is to make innovations that get to patients faster, safer and cheaper.

Harvard-MIT Center for Regulatory Science
Introductions

1. Preferred name
2. Preferred pronouns
3. Hometown
4. Undergraduate institution and major
5. Co-op experience
6. Any drug law or policy interest/experience

Let’s talk about Twitter...

I want a gender neutral world.

Michael A. Sinha MD, JD, MPH

[Image] 

Let’s talk about Twitter...

#NUSLDrugLaw 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
  - #NUSLDrugLaw
- Optional additional tags: @US_FDA, #FDA, #FDALaw, #DrugLaw, #Naloxone, #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

#NUSLDrugLaw on Twitter
Some Recent Drug Law Posts

Dr. Reiley (2015) *Drug Policy* • Aug 13


Using Twitter to Amplify Your Own Work

Social and Biological Context

• Use of mind-altering substances exists in most animal species and human societies
• Indigenous societies utilized “drugs” for ceremonial, medicinal, and recreational purposes
• We use many of the same substances in same ways (caffeine, sugar, opium)
• Current law prohibits certain substances, and tightly regulates many other drugs

Drugs Law and Policy

• Societally important
  • Overdose crisis
  • Pharmaceutical costs
• Key constitutional and policy debates involve drugs
  • First Amendment: Sorrell, Caronia
  • Commerce Clause: Reich
• Rapidly evolving and cross-cutting
  • ACA and healthcare reform, aging population
  • Personalized medicine and pharmacogenetics
  • Controlled substances policy: supervised consumption facilities
• Jobs
  • Pharmaceutical, healthcare, biomedical, industries
  • Public interest: government and advocacy sectors
Drugs, Defined

• Broadly characterized, a drug is a substance that alters the body
• Food, Drug, and Cosmetic Act (FDCA): a chemical substance intended in the treatment, cure, prevention, or diagnosis of disease
• Controlled Substances Act: substance with abuse potential and medical use

Key Questions

• How are drugs currently regulated?
• What forces/stakeholders shape drug regulation?
• What rationales justify drug laws?
• Do the drug laws and policies meet their stated goals?
• What are the gaps between theory and reality?
• How can those gaps be filled?

Historical Background

• Bayer Pharmaceuticals of Germany began to market heroin in 1898 as a cough medicine
• Several manufacturers sold elixirs containing alcohol, cannabis, morphine, chloroform, ether, and other dangerous ingredients

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

Evolution of Medical Drug Regulation

- Growth of FDA: Responsive regulation
  - Multiple scandals involving spoilt or poisoned food, dangerous drugs
  - Many of the medicines sold in the free market caused harm (e.g. blindness)
  - Partly as a result of Prohibition
  - Use of Commerce Clause to establish jurisdiction

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
  - Hyperlinks to all readings and videos can be found on the syllabus


Course Textbook

Food and Drug Law: Cases and Materials, Fourth Edition
Hutt, Merrill, Grossman (West Academic, 2013)

Online Resources

- For the Opioids sessions, videos are available from the HarvardX MOOC, “The Opioid Crisis in America,” http://bit.ly/OpioidX.
Course Expectations

- Participation (20%)
  - Attendance
  - Participation (policy debates, current events)
  - Engagement (in-class, outside of class, e.g. office hours, Twitter)
- Midterm Assignment: Public Comment Brief (20%)
- Final Paper (60%)
  - Topic (clear with Dr. Sinha before beginning the proposal)
  - Draft
  - Presentation
  - Final
- All assignments should be e-mailed in editable format (e.g., Microsoft Word) to both Dr. Sinha and TA Abigail Fletes

Readings and Videos: Readings from Hutt and all videos are always required. Optional readings are noted within the syllabus. Assigned readings should be completed before class. Copies of Hutt are available for purchase in NUSL Bookstore and on reserve at the law library.
Course Expectations

- **Attendance and Engagement**: This component of the evaluation is based on:
  - Class attendance and punctuality (5%)
  - Contribution to in-class structured policy debates (10%)
  - Participation and demonstrated engagement with the subject matter as evidenced by participation during class, during office hours, and at least twice weekly on Twitter (at #NUSLDrugLaw [optional but encouraged]) (5%)

Debates

- Debate 1: Prescription Drug User Fees (September 11, 2019)
- Debate 2: Off-Label Promotion (September 23, 2019)
- Debate 3: OTC Naloxone (October 16, 2019)
- Debate 4: Should the FDA be independent? (October 28, 2019)

  - All students should come to class prepared to debate if called upon

Debates

- Opening statement: Position 1 (90 sec)
- Opening statement: Position 2 (90 sec)
- Rebuttals and discussion: open floor for entire class (6-8 min)
- Closing statement Position 2 (90 sec)
- Closing statement Position 1 (90 sec)
- Timer/judge evaluates debate performance

Public Comment Brief

- A structured “public comment” brief (4-5 pages) will be due before the start of class on Wednesday, October 2, 2019. An assignment document containing the pertinent guidelines is on the Syllabus page.

Public Comment Brief

- Consult relevant legal, regulatory, and public health material to educate yourself about the context and implications for the proposed action.
- Write a 5-6 page public comment brief (framework in assignment document)

Public Comment Brief

- The assignment is worth 20% of your final grade and will be evaluated based on the following criteria:
  - Clear and cogent positions and arguments
  - Grammar and style
  - Adherence to format guidelines
  - Credible and well-cited sources
  - Timely submission
Public Comment Brief

• After one round of edits, you will upload your public comment to the Federal Register here:

• A statement that the document was prepared for a law school class will be added to the final comment prior to submission (I will provide the statement). This document can go on your CV!
• Docket closes on October 15, 2019 at 11:59 p.m. EST; please e-mail submission confirmation to both Dr. Sinha and TA Abigail Fletes.

Final Paper

• The final paper on a pre-approved topic should be 18-24 pages in length and contain appropriately formatted BlueBook references.

• A proposal outlining the topic significance, key questions, expected outcomes and preliminary sources will be due before class on Thursday, September 12, 2019. Please clear the topic with Dr. Sinha prior to beginning the proposal. Use the Hutt book as a resource for project ideas—a lot of great topics not covered in this class.

• An assignment document containing the pertinent guidelines is on the Syllabus page. For questions about format of proposal or final paper, refer to this document.

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Course Overview

Sep. 4:
3. OVERVIEW OF ADMINISTRATIVE LAW, DRUG AND MEDICAL DEVICE REGULATION

- Hutt: bottom 29-33, 43-46, 47-49, 55-56, 60-75 (skim); 89-101, 119-1223 (skim)

Course Overview

Sep. 9:
4. INVESTIGATIONAL, NEW DRUGS, CLINICAL TESTING AND EXPANDED ACCESS RIGHTS TO TRY

- Hutt: 134-186, 263-266, 762-775
- Videos: HarvardSPDA video clips
  - Clinical Trial Design: Strengths and Limitations of Clinical Trials: Many Drugs from Trial to Clinic: Ethical Challenges with Crossline Solutions
  - Expanded Access: Where to Trial Later and Synthesis

Course Overview

Sep. 11:
5. NEW DRUG APPROVAL PROCESS: EXPEDITED PATHWAYS, LABELING, POSTMARKETING SURVEILLANCE

- Hutt: 370-710, 721-739, 735-739, 751-759
- Videos: HarvardSPDA video clips
  - FDA: Benefits and Risks of Alternative Approval Pathways: Orphan Drugs, Fast Track, and Accelerated Approval Pathways: Priority Review and Breakthrough Therapy Designations, Use and Consequences of Alternative Approaches to Regulatory Submissions

Course Overview

Sep. 12:
6. ORPHAN DRUGS, HATCH-WAXMAN AND GENERIC DRUGS

- Hutt: 730-793, 906-1015
- History of Orphan Drug Regulation: United States and Beyond. 100 Clinical Pharmacology & Therapeutics 342 (2016).

Course Overview

Sep. 16:
7. BIOLOGICS AND BIOSIMILARS

- Hutt: 1123-1137
- Videos: HarvardSPDA video clips

Course Overview

Sep. 16:
8. PHARMACEUTICAL COSTS

- Hutt: 1023-1035

  - Guest Lecturer: Aaron S. Kesselheim, MD, MPH; Professor of Medicine, Harvard Medical School
Course Overview

Sep 23: 5. MARKETING AND FIRST AMENDMENT ISSUES
- Guest: Professor of Health Law
- Videos: Harvard TDP video clips
- "Effect & Significance of OTC-Label Marketing: Marketing as Commercial Speech: Recent Cases"
- U.S. v. Caro: 769 F.3d 140 (2d Cir. 2012)
- Guest speaker: Liz Lu, JD, MPH, Postdoctoral Fellow, Program on Regulation, Therapeutics, And Law (PORTAL), Brigham and Women’s Hospital

DEBATE 2: Off-Label Promotion

Course Overview

Oct 2: 11. PUBLIC HEALTH & HARM REDUCTION
- Videos: Harvard video clips
- "Harm reduction strategies: The role of law enforcement and the criminal justice system."
- "The role of law enforcement and the criminal justice system."
- "Harm Reduction: Does it Work?" 21 Addictive Behaviors 779 (1996)
- "Harm reduction in the USA: the research perspective." 14 Harm Reduction J. 51 (2011)
- Guest Lecture: Leo Beletsky, JD, MPH, Professor of Law, Northeastern University School of Law (via videoconference)

ASSIGNMENT DUE: MIDTERM PUBLIC COMMENT BRIEF

Course Overview

Oct 7: 12. OPIOID LITIGATION: PARALLELS TO TOBACCO
- Public Health Law Watch brief (to the National Prescription Opiate Litigation)
- Guest Lecture: Faith Khall, JD, Legal Fellow, Public Health Law Watch and the NUSL Center for Health Policy and Law

Course Overview

Oct 21: 14. CSA and DEA: COLLATERAL IMPACT, CIVIL RIGHTS, HEALTH AND ECONOMY
- Excerpts from Controlled Substances: Crime, Regulation, and Policy (pp. 51-5, 52-5, 113-125)
- Guest Lecture: Ayana Jordan, MD, MPH, Assistant Professor of Psychiatry, Yale School of Medicine and Medical Director, Recognizing and Eliminating disparities in Addiction through Culturally-informed Healthcare (REACH) Program (via videoconference)
Course Overview

Oct 23: 15. IMPLEMENTATION CAPS: THE POLICY TRANSFORMATION PROCESS

- RESOLUTION 1 - Massachusetts Medical Society
- Fear, Loathing and Tobacco Exposure. N.Y. Times (2019)
- RESOLUTION 2 - American Medical Association

Guest Lecture: Jesse Gaeta, MD, Chief Medical Officer, Boston Health Care for the Homeless Program.

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
- Pharmacist/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?

Dec 6: Should the FDA be independent?
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?

Any questions?

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