Course Introduction, Expectations, and Themes

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Introductions

1. Preferred name
2. Preferred pronouns
3. Hometown (city, state, country)
4. Year/degree (e.g., 2L, 3L, LLM)
5. Public health law interest/experience
6. Career goals/plans

Poll Questions

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 I can be under the circumstances
• Never feel obligated to share any details of your health status with me
  • I will never require any 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 Information

https://northeastern.zoom.us/my/publichealthlaw

- Attendance is required for all sessions.
- Sessions will not be recorded. Slides will generally be posted after class.
- Unless it is an emergency, a request for an excused absence must come 48 hours before class starts.
- If you are having technical issues, please use the Zoom application on your smartphone or call into the class in the meantime:
  - Phone number: +1 312 626 6799 (one of many phone numbers, international numbers also available)
  - Meeting ID: 340 372 2397

Zoom Etiquette

- All participants will be muted during class. You may unmute yourself in order to speak or ask questions. Use the raise hand feature when possible.
- Video on during lectures is optional. Class runs through dinner time, so eating/drinking off-camera is fine.
- Make sure your name appears in Zoom as you’d like to be called.
- The chat function will be disabled for class. Ask questions during class or stay on after class to discuss.

We will use Canvas minimally

• I may send class e-mails via Canvas
• We will not use other Canvas features
• Syllabus will not be updated on Canvas

• Updated syllabus (permanent link): http://bit.ly/PublicHealthLaw (case sensitive)
#PHLaw on Twitter

- Engage with course materials and current topics in patent law and policy by joining the conversation on Twitter!
- Counts toward participation!
- Be sure to tag the following in your tweets:
  - @DrSinhaEsq
  - #PHLaw
  - Optional additional tags: @PHLawWatch, @PHUR_Temple, @NetworkForPHL, #PublicHealthLaw, #LawTwitter
- Student tweets will be highlighted at the beginning of each class
- If you want help getting started on Twitter, schedule time during office hours

#PHLaw

#NUSLDrugLaw #NUSLPatentLaw #PharmaPolicy
Using Twitter to Amplify Your Own Work

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


Course Expectations

- Readings and Videos:
  - Readings from Mariner are always required
  - Assignments should be completed before class
  - Casebook may be supplemented with articles, videos, podcasts, and other content

Amplification is a Two-Way Street

Course Expectations

- Attendance and Engagement: 25% of grade
  - Class attendance and punctuality
  - Participation during class (VOLUNTEER case presentations!)
  - Engagement during office hours
  - At least twice weekly engagement on Twitter (using the hashtag #PHLaw [optional but highly encouraged!])
  - 5-minute in-class presentation of your final paper (last class session)
Public Comment Brief

- Review docket announcement and related materials for a Proposed Rule
- Consult relevant legal, regulatory, and public health material to educate yourself about the context and implications for the proposed action.
- Structured “public comment” brief (6-8 pages) will be due before the start of class on Wednesday, June 30, 2021 (25% of grade)
- You are required to submit a draft to me by June 16th for review/feedback
- Topic(s) TBD: Ideally, we will respond to a live docket and you will formally submit your public comment to the appropriate agency. A great way to add a line to the resume!

Final Paper

- The final paper on a pre-approved topic should be 16-18 pages in length and contain appropriately formatted BlueBook references. (50% of grade)
- Please clear the topic with Dr. Sinha prior to beginning the proposal. Use the Mariner casebook as a resource for project ideas. Topic must be cleared AS EARLY AS POSSIBLE, but no later than May 26, 2021.
- A proposal outlining the topic significance, key questions, expected outcomes and preliminary sources will be due before class on June 9, 2021.
- The final paper will be due on Tuesday, August 24, 2021.

Health-Related Statutes & Regulations

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<tr>
<th>Type of Statute or Regulation</th>
<th>Federal</th>
<th>State</th>
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<tbody>
<tr>
<td>Requirements</td>
<td>Internal Revenue Code</td>
<td>State Revenue Code (taxation)</td>
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<td>Prohibitions</td>
<td>Controlled Substances Act</td>
<td>Most criminal offenses</td>
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<td>Food, Drug &amp; Cosmetic Act</td>
<td>Alcohol, tobacco sales</td>
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<td>Standard Setting</td>
<td>Clean Air Act</td>
<td>Professional licensure</td>
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<td>Clean Water Act</td>
<td>Insurance licensure</td>
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<td>Occupational Health &amp; Safety Act</td>
<td>Local environmental protection</td>
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<td>Direct Service Provision</td>
<td>Veterans Affairs</td>
<td>Government health care facilities (e.g., mental health; substance use)</td>
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<td>Funding for Private Entities</td>
<td>Medicare &amp; Medicaid</td>
<td>Medicaid</td>
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<td></td>
<td>Affordable Care Act</td>
<td>Non-profit health, social service organizations</td>
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<td>National Institutes of Health</td>
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<td>Non-profit service organizations</td>
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<td>Funding for State &amp; Local Government</td>
<td>Medicaid, TANF</td>
<td>Municipal health agencies</td>
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<td>Disease surveillance</td>
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<td>Highway, traffic, pipeline safety</td>
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<td>Emergency preparedness</td>
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Core Functions of Public Health

Where does law come in?

HHS Organizational Chart

Xavier Becerra

FDA Organization

Janet Woodcock, MD
Federal vs. State Authority

Congressional Authority: Enumerated Powers

"Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States."

"To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes"

"To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof."

US Constitution, Article I, Section 8, Clauses 1, 3, and 18

How does a state exercise police power?

• Enact legislation
  • Legislature passes a law, Governor signs it
  • Legislation creates administrative agencies with specific powers (or assigns new tasks to existing agencies)
  • adopt regulations to carry out the purpose of the legislation (both interpret and enforce)

State Legislative Authority: “The Police Power”

• authority of a state to enact laws to protect the health, safety & welfare of its population
• retained by states when they gave up some power to allow creation of a more powerful central (federal) government in ratifying the US Constitution

Massachusetts Executive Agencies
What is Health?

• Health
  • Oxford English Dictionary: “soundness of body; that condition in which its functions are duly and efficiently discharged.”
  • World Health Organization: “state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.”

• Health care
  • individual medical care

• Public health
  • Institute of Medicine: “what we, as a society, do collectively to assure the conditions for people to be healthy.”

Public Health, Broadly

“Public health is the science and art of preventing disease, prolonging life, and promoting physical health and efficiency through organized community effort for the sanitation of the environment, the control of communicable infections, the education of the individual in personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of disease, and the development of the social machinery to insure everyone a standard of living adequate for the maintenance of health, so organizing these benefits as to enable every citizen to realize his birthright of health and longevity.”

Charles E.A. Winslow
American bacteriologist/public health expert
(1877-1957)

What do you think are the two most important public health achievements of the past 100 years?

What do you think are the two most important public health problems today?

CDC’s top 10 public health achievements from 1900 to 1999 (responsible for adding 25 years to life expectancy of Americans)

1. Immunizations
2. Motor vehicle safety
3. Workplace safety
4. Control of infectious diseases
5. Declines in deaths from heart attacks & strokes
6. Safer and healthier foods
7. Healthier mothers and babies
8. Family planning
9. Fluoridation of drinking water
10. Tobacco as a health hazard

Immunization

• Science
  • Polio and smallpox eliminated
  • Childhood vax rates > 90%

• Law and policy
  • Individual rights
  • State law requires for school entry
  • Federal research policy
  • Private and governmental funding (insurance)

Not to mention the myriad issues raised by COVID-19 vaccines!

Motor vehicle injuries and deaths

Relationship to law and policy
• Law enforcement led to behavior change
• Natl Highway Safety Act
• Seat belt requirements
• Car and highway design changes
• State licensing requirements
Motor vehicle safety

Those affected:
- Drivers, passengers, and their family members, some pedestrians
- Traffic engineers
- Owners and employees at car dealers and manufacturers
- First responders
- Health care providers

Those having an impact:
- National Automobile Dealers Association
- American Automobile Association
- Association of Trauma Surgeons
- Mothers Against Drunk Driving
- Alliance of Automobile Manufacturers

15 Minute Break