

Course Introduction, Expectations, and Themes

Michael S. Sinha, MD, JD, MPH

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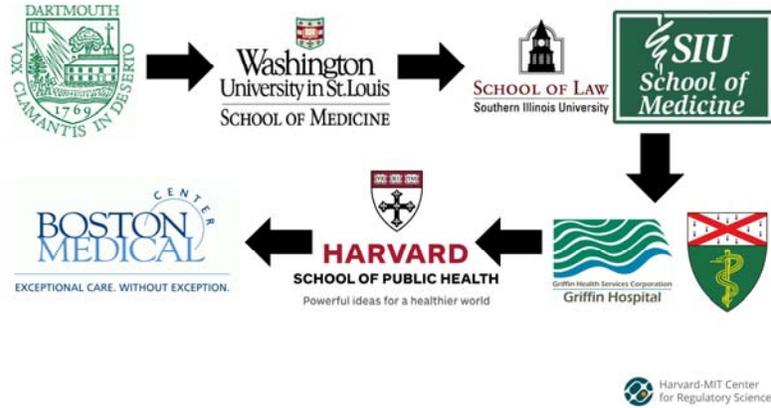
Visiting Scholar, NUSL Center for Health Policy and Law

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Teaching Faculty, Harvard Medical School Center for Bioethics

Lecturer, Department of Health Sciences, California State University, East Bay





N Northeastern University School of Law



Michael S. Sinha
Dartmouth College, BA 2009
Southern Illinois University School of Medicine, MD 2012
Southern Illinois University School of Law, JD 2012
Harvard T.H. Chan School of Public Health, MPH 2015

Dr. Michael Sinha is a Regulatory Science Fellow in the new Harvard-MIT Center for Regulatory Science, within the Harvard Program in Therapeutic Science (HiTS) at Harvard Medical School. He is also affiliated with the Program On Regulation, Therapeutics, and Law (PORTAL), within the Division of Pharmacoeconomics and Pharmacoeconomics, Department of Medicine at Brigham and Women's Hospital. His legal scholarship includes articles in the *American Journal of Legal Medicine*, the *American Journal of Law and Medicine*, the *Journal of Law, Medicine & Ethics*, the *Harvard Law & Policy Review*, the *Food & Drug Law Journal*, the *Stanford Law & Policy Review* and the *Hastings Law Journal* (forthcoming). Medical publications have appeared in *JAMA*, *JAMA Internal Medicine*, *CHEST*, *PLOS Medicine*, the *American Journal of Bioethics*, *Drug Safety*, *Mayo Clinic Proceedings* (forthcoming), and the *Health Affairs Blog*. Research interests include FDA and pharmaceutical law, intellectual property law and antitrust law.



American Journal of Law & Medicine, 42 (2016): 223-255
American Society of Law, Medicine & Ethics, © 2016 The Author(s)
Boston University School of Law
DOI: 10.1177/0098558116658269

THE PERILS OF PANIC: EBOLA, HIV, AND THE INTERSECTION OF GLOBAL HEALTH AND LAW

Michael S. Sinha¹ & Wendy E. Parmet²

Ameet Sarpatwari, Michael S. Sinha,** Aaron S. Kesselheim****

CRITICAL PUBLIC HEALTH 2016
<http://dx.doi.org/10.1089/cph.2016.115028>

COMMENTARY

A panic foretold: Ebola in the United States

Wendy E. Parmet* and Michael S. Sinha²

DOI: 10.1089/cph.2016.115028

COVID-19: State and Local Responses to PPE Shortages

Michael S. Sinha, MD, JD, MPH, Harvard Medical School Harvard-PIT Center for Regulatory Science

Perspective

Covid-19 — The Law and Limits of Quarantine

Wendy E. Parmet, J.D., and Michael S. Sinha, M.D., J.D., M.P.H.



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



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

- Attendance is required for all sessions.
- Permanent Zoom link: <https://northeastern.zoom.us/my/publichealthlaw>
- 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 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, but since this is a small class, I prefer that you have your video on during in-class activities and discussions.

 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 Canvas or ask questions during class.



Canvas

- Syllabus will not be updated on Canvas
- Updated syllabus (permanent link): <http://bit.ly/PublicHealthLaw>
- TBD: We may use Canvas for discussion, submitting assignments, grades, etc.



Michael S. Sinha MD, JD, MPH
@DrSinhaEsq
IP/FDA law @HarvardMIT_CRS @PanFabBoston @HITSatHarvard @PORTAL_Research @NUSLHealth @HMSBioethics @CalStateEastBay • #HeForShe • Tweets • 📧/📧
advice
📍 Boston, MA 🌐 scholar.harvard.edu/sinha 📅 Joined May 2012
5,281 Following 5,256 Followers

Let's talk about Twitter...

Harvard Program in Therapeutic Science
 HarvardMIT_CSIS · Follow you

Center within @HITSatHarvard @HarvardMed • Drug development, translational science & @USFDA #FDAinformed • Tweets by @DrSinhaEsq

📍 Boston, MA • hits.harvard.edu/the-program/ce... • Joined May 2018

221 Following · 335 Followers

Program On Regulation, Therapeutics, And Law
 @PORTAL_Research · Follow you

PORTAL, Division of Pharmacoepidemiology, @BrighamWomens @HarvardMed • Faculty @akesselheim @AmeesSarpateari @JonathanDannou • Tweets by @DrSinhaEsq

📍 Boston, Massachusetts • PORTALresearch.org • Joined October 2014

820 Following · 1,632 Followers



Susan Bailey MD
 @sbailey · Follow you

Director, Center for Health Policy and Law & Matthews University Distinguished Professor of Law and Prof. of Public Policy and Urban Affairs, Northeastern Univ.

📍 Boston, MA • northeastern.edu/centerforhealthpolicy • Joined April 2015

517 Following · 963 Followers

Jessica Silbey
 @jsilbey · Follow you

Law & Innovation and Intellectual Property Institute, Critical Decision, partner of the MIT & a long time in start-up on your last unit & am happy for it

📍 Boston, MA • northeastern.edu • Joined January 2014

Center for Health Policy and Law
 @CenterforHealthPolicyandLaw · Follow you

U.S. News & World Report
 #11 Health Care Law

The Center for Health Policy and Law at Northeastern University School of Law focuses on public health, health and human rights, global health, drug law, etc.

📍 Boston, MA • northeastern.edu/centerforhealthpolicy • Joined November 2016

Leo Balesky
 @LBalesky · Follow you

Public Health expert of law and politics (Semin, blogs, panels and teaching) @MIT @BostonUniversity @ColumbiaUniversity @Harvard @MIT2

📍 Boston, MA • northeastern.edu/centerforhealthpolicy • Joined May 2012

NUSL CLIC
 @NUSLCLIC · Follow you

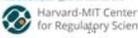
Technology and intellectual property with a public health lens. Based at @NUSL Health Science, @BrighamWomens @HarvardMed

📍 Boston, MA • northeastern.edu • Joined December 2016

Kara Swanson
 @KaraSwanson · Follow you

Harvard and Northeastern professor (IP & property and @NUSL) author (Banking on the Body) and @northeastern.edu/centerforhealthpolicy

📍 Boston, MA • northeastern.edu/centerforhealthpolicy • Joined November 2012



#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, @PHLR_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

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq

Teaching "Problems in Public Health Law" at @NUSL @NUSLHealth starting tomorrow!

Students will be engaging on Twitter using the hashtag #PHLaw -- follow along, or better yet, join the conversation!

10:25 PM · Feb 16, 2021 · Twitter Web App



#NUSLDrugLaw #NUSLPatentLaw #PharmaPolicy

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq

#NUSLDrugLaw starts tomorrow! Looking forward to meeting @NUSL students, exploring Drug Law and Policy in greater depth, and contributing to @NUSLHealth as a Visiting Scholar

4:12 PM · Aug 21, 2019 · Twitter Web App

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq

Looking forward to teaching Pharmaceutical, Biotechnology and Medical Device Policy to undergraduate Health Science students at @CataState@Bay! We will be using the #PharmaPolicy hashtag in class -- follow along for key insights! cc: @Profession@ @DrMikeSantoro

11:28 PM · Aug 21, 2019 · Twitter Web App

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq · Nov 17, 2020

@NUSLHealth Students will be engaging on #LawTwitter @PharmLaw #PHLaw

@BetsyMiklow is a national treasure -- she is also older than Woodstock!

U.S. Pat. No. 1,816,339 (Sildenafil brand package)

July 26, 1951 · U.S. PATENT AND TRADEMARK OFFICE · 1,816,339

Northeastern and 1 others



Using Twitter to Amplify Your Own Work

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq · Aug 18

My newest law article with @fraser_tessema & @akesselheim @PORTAL_Research (pre-publication, accepted at @HastingsLJ) is now up on @SSRN

View the abstract and download here: papers.ssrn.com/sol3/papers.cfm?abstract_id=418888

Generic But Expensive: Why Prices Can Remain High for Off-Patent Drugs

Hastings Law Journal, Environment/Volume 71, Issue 4, May 2019

23 Pages · Posted

Fraser Tessema
 Program On Regulation, Therapeutics, and Law (PORTAL), Brigham and Women's Hospital and Harvard Medical School

Amees Sarpateari
 Program On Regulation, Therapeutics, and Law (PORTAL), Brigham and Women's Hospital and Harvard Medical School

Michael S. Sinha
 Harvard MIT Center for Regulatory Science, Harvard Medical School, Program On Regulation, Therapeutics, and Law (PORTAL), Brigham and Women's Hospital and Harvard Medical School

Date Written: July 25, 2019

11 · 24

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq

Looking forward to joining @LSEHealthPolicy and @LSEGlobalHealth for a great conversation on antibiotics and innovation!

Huseyin Nad
 @HuseyinNad2 · Aug 22

Looking forward to hosting @DrSinhaEsq from @PORTAL_Research on September 5th @LSEHealthPolicy @LSEGlobalHealth for his talk: "Incentivizing the Development of Novel Antibiotics: New Paradigm Needed?"

Register here: eventbrite.com.uk/e/incentiviz...

1:43 PM · Aug 22, 2019 · Twitter for Android



Amplification is a Two-Way Street

Susan Bailey MD
 @sbailey

Thanks to @ABAesq for this opportunity to collaborate in the fight against opioid use disorder. @AmerMedicalAssn and to @DrSinhaEsq for the tweet!

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq · Aug 24

AMA to ABA: Let's work together to fight the opioid epidemic! americanbar.org/news/abanews/... via @AmerMedicalAssn @ABAesq @sbailey #MembersMoveMedicine

8:58 PM · Aug 24, 2019 · Twitter for iPhone

Michael S. Sinha MD, JD, MPH
 @DrSinhaEsq · 34m

#NUSLDrugLaw starts tomorrow! Looking forward to meeting @NUSL students, exploring Drug Law and Policy in greater depth, and contributing to @NUSLHealth as a Visiting Scholar

Susan Bailey MD
 @sbailey · Follow you

President-Elect, American Medical Association Regent Emerita, Texas A&M University System Aggie allergist Proud mom and grandmom



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
 - Major changes will be posted on Canvas as announcements

<http://bit.ly/PublicHealthLaw>



Course Expectations

Attendance and Engagement	25%
Midterm Assignment	25%
Final Paper	50%



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



Course Expectations

Attendance and Engagement: (25% of grade)

- Class attendance and punctuality
- Participation during class
- Engagement during office hours
- Participation on the Canvas discussion board
- At least twice weekly engagement on Twitter (using the hashtag #PHLaw [optional but encouraged])



Public Comment Brief

- Review the 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.
- A structured “public comment” brief (5-7 pages) will be due before the start of class on Monday, March 22, 2021 **(25% of grade)**
- 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)**
- A proposal outlining the topic significance, key questions, expected outcomes and preliminary sources will be due before class on Monday, March 8, 2021. Please clear the topic with Dr. Sinha prior to beginning the proposal. Use the Mariner casebook as a resource for project ideas.
- *The final paper will be due on Friday, May 7, 2021.*



Core Functions of Public Health

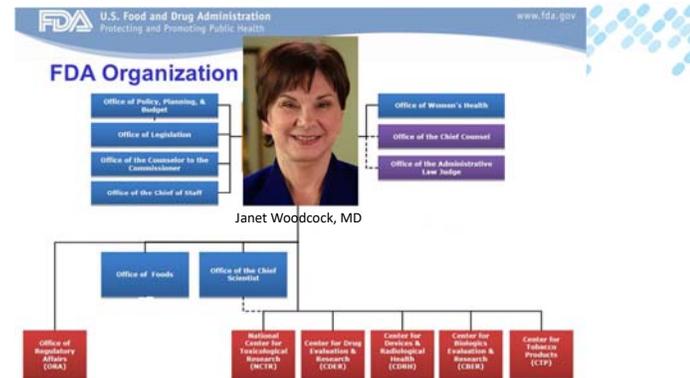
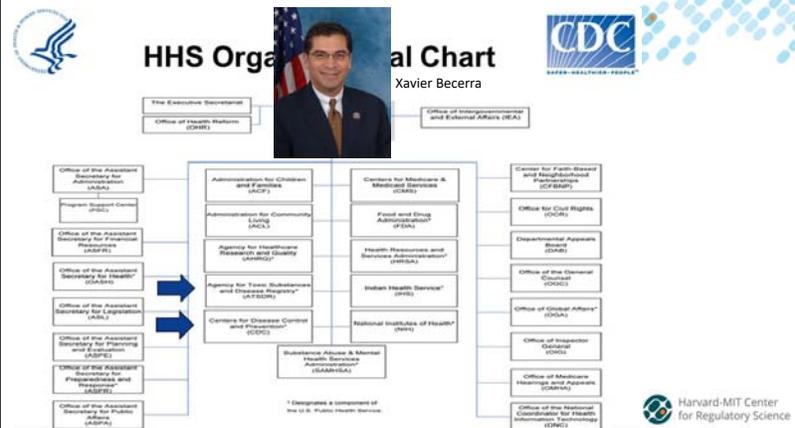
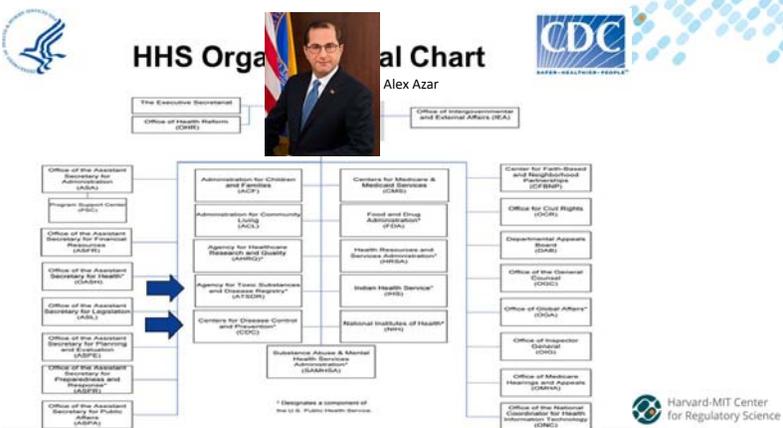


Where does law come in?

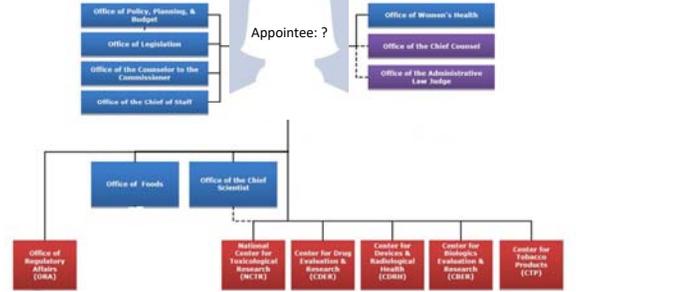


Health-Related Statutes & Regulations

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



FDA Organization



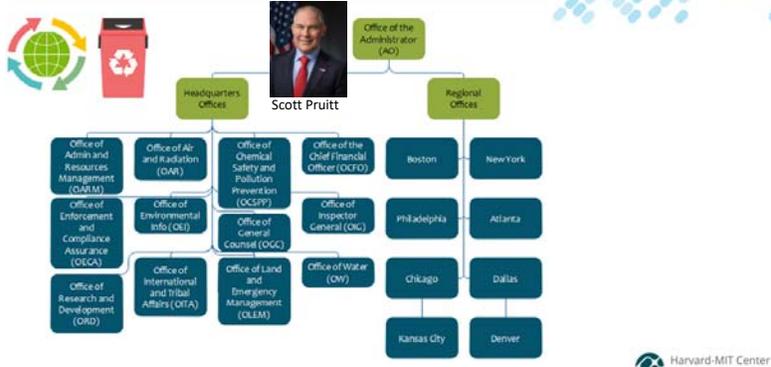
DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)



DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)



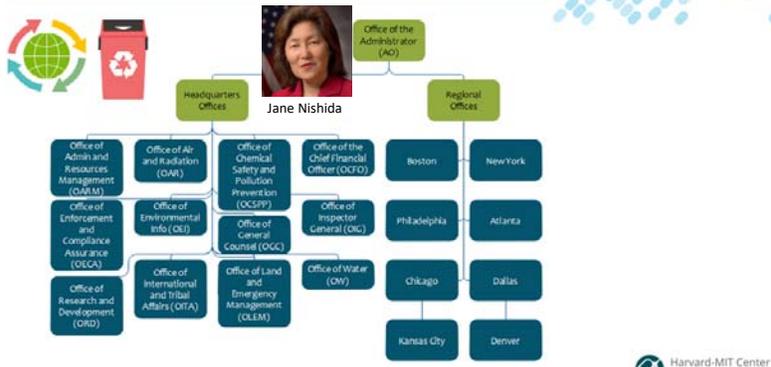
EPA Organization Chart



EPA Organization Chart



EPA Organization Chart



EPA Organizational Chart



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

State Legislative Authority: “The Police Power”

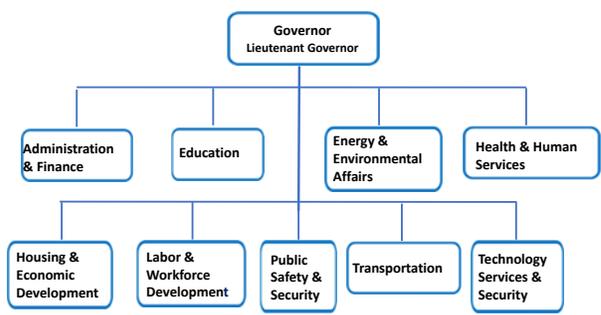


- authority of a state to enact laws to protect the **health, safety & welfare** of its population
- retained by states when they gave up some power to allow creation of a more powerful central (federal) government in ratifying the US Constitution

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)

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



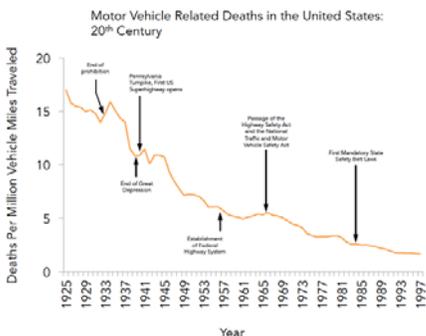
Immunization

- 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

