UNIVERSITY OF CALIFORNIA LAW
SAN FRANCISCO

Vaccines and the Law: An Overview

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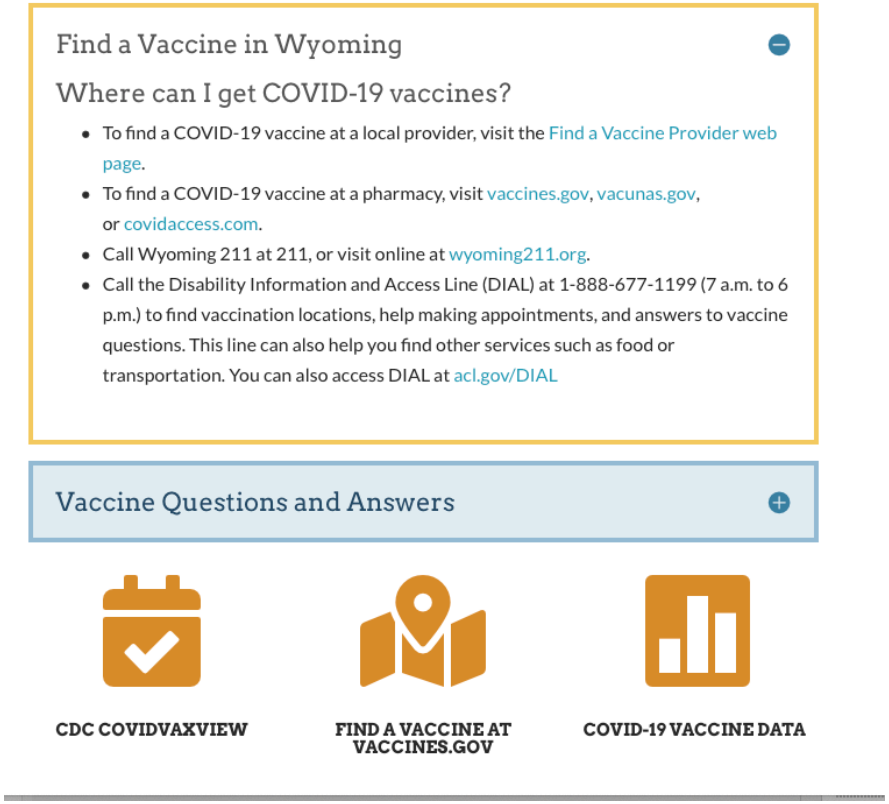
Lesson plan

Introduction

- A roadmap
- Getting to market and monitoring.
- Access.
- Mandates.
- Compensation for vaccine harms.



Disclosures:

- The family owns stock (regular) in GSK.

- Served as a volunteer (unpaid) advisor on Moderna's ethics advisory group

A roadmap:

Getting to market	• Licensing • Authorization
Safety monitoring	• Systems • Committees
Access	• The ACA • VFC • Issues
Mandates	• General • School • Workplace
Compensation	• VICP • CICP

Not covered:

Intellectual Property	Mandates	Some access
• Patents • Global Access	• Federal mandates • EUA	• In depth reimbursement • Details Medicaid/medicare

Vaccine Development – 101

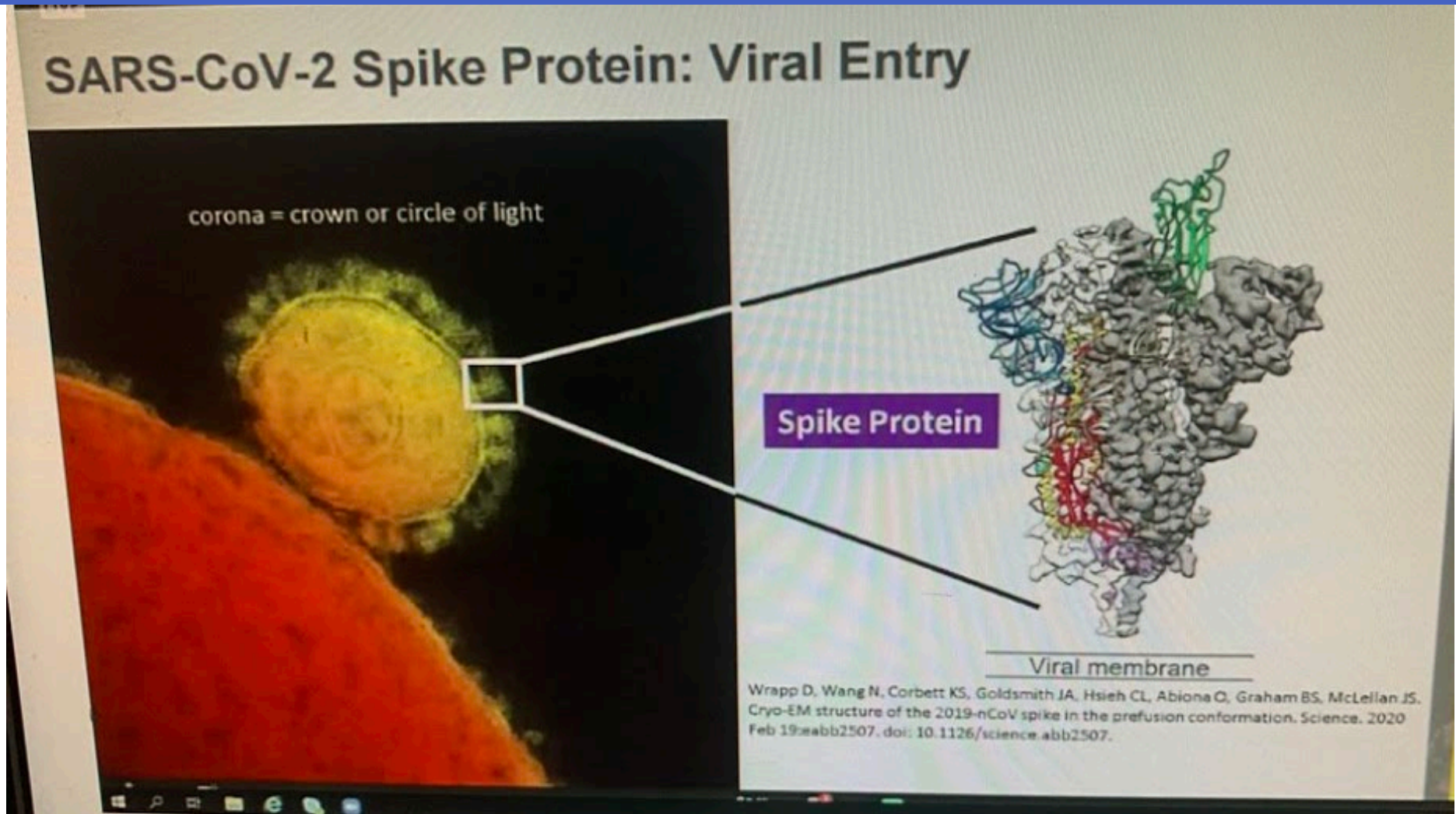
GETTING TO MARKET & MONITORING SAFETY

Vaccine regulation – two frameworks:

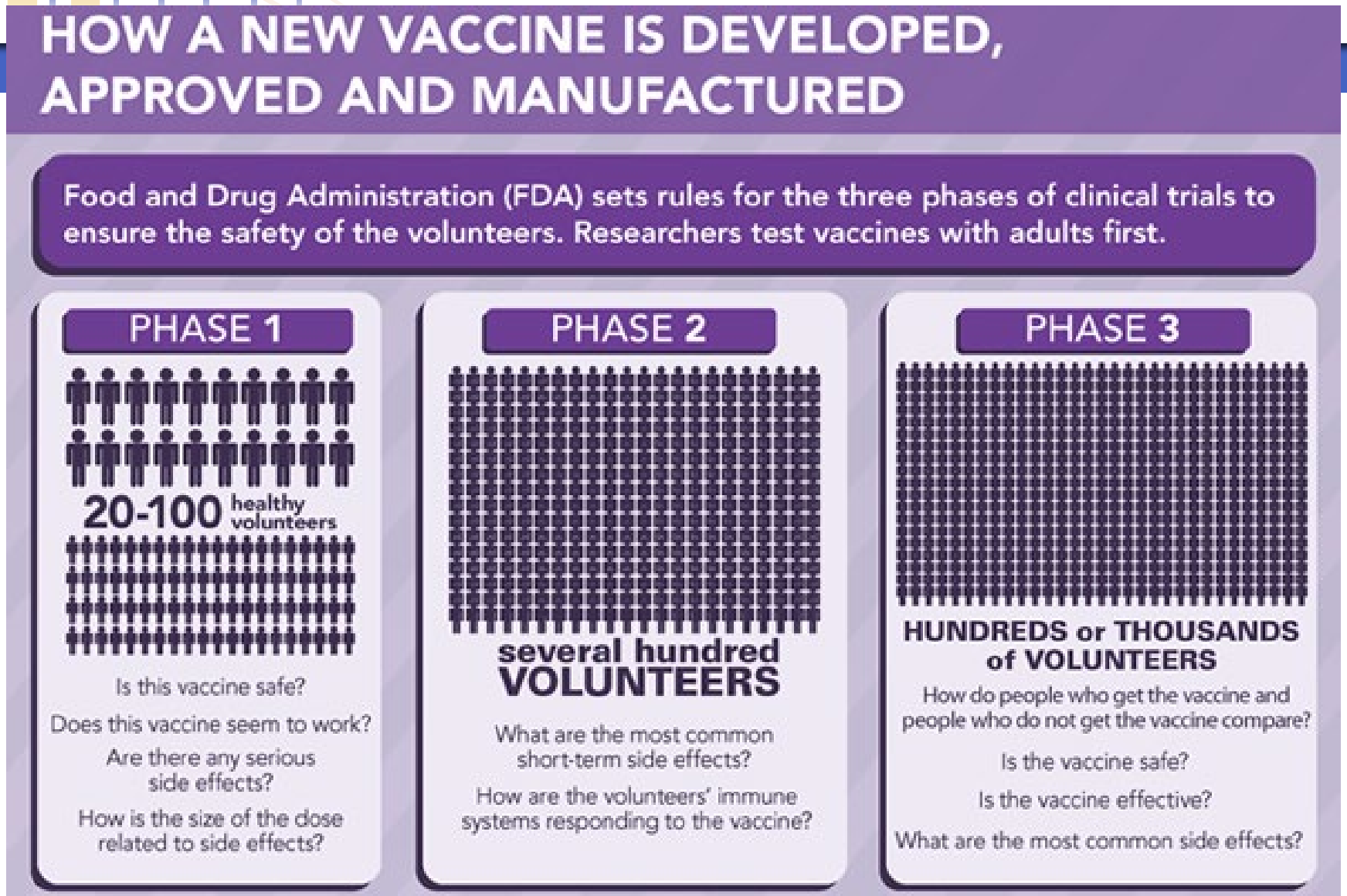
- Public Health Service Act:
  - "safe, pure, potent and effective."
  - Building licensing.
  - Lot testing.
- Food, Drug and Cosmetics Act.

Toddler receiving a vaccine in his arm
Photographer: Heather Hazzan; Wardrobe: Ronald Burton; Props: Campbell Pearson; Hair: Hide Suzuki; Makeup: Deanna Melluso at See Management. Shot on location at One Medical.

Vaccine Development Process, zero



FDA Licensing Process



Emergency Use Authorization:

- § 564 of Food, Drugs and Cosmetics Act.
- Show:

1) Cause of the emergency (the pathogen)—"can cause a serious or life-threatening condition."

2) The totality of evidence, "including data from adequate well-controlled clinical trials, if available," provides reasonable grounds to believe that the medical product "may be effective in diagnosing, treating or preventing" the disease or condition.

Conditions for granting an EUA –

- § 564 of Food, Drugs and Cosmetics Act.
- Show:

3) The known and potential benefits of the product outweigh its risks.

4) No “adequate, approved, alternative medical product is available.”

COVID-19 EUAs and Licenses

- 50% or more reduction in infections.
- [E]stablish safety and efficacy with “large, diverse, controlled Phase 3 trials with tens of thousands of [volunteers]"
- A median of two months of safety data and a full data set.
- Minimum of cases.

Vaccines EUA process: "EUA Plus"

- Pfizer:
  - approximately 43,000 participants
  - 95% effective v. disease
  - No serious safety concerns at trial.
- Moderna:
  - Approximately 30,000
  - 94% effective v. disease
  - No serious safety issues at trial.

Safety Monitoring: Systems

VAERS

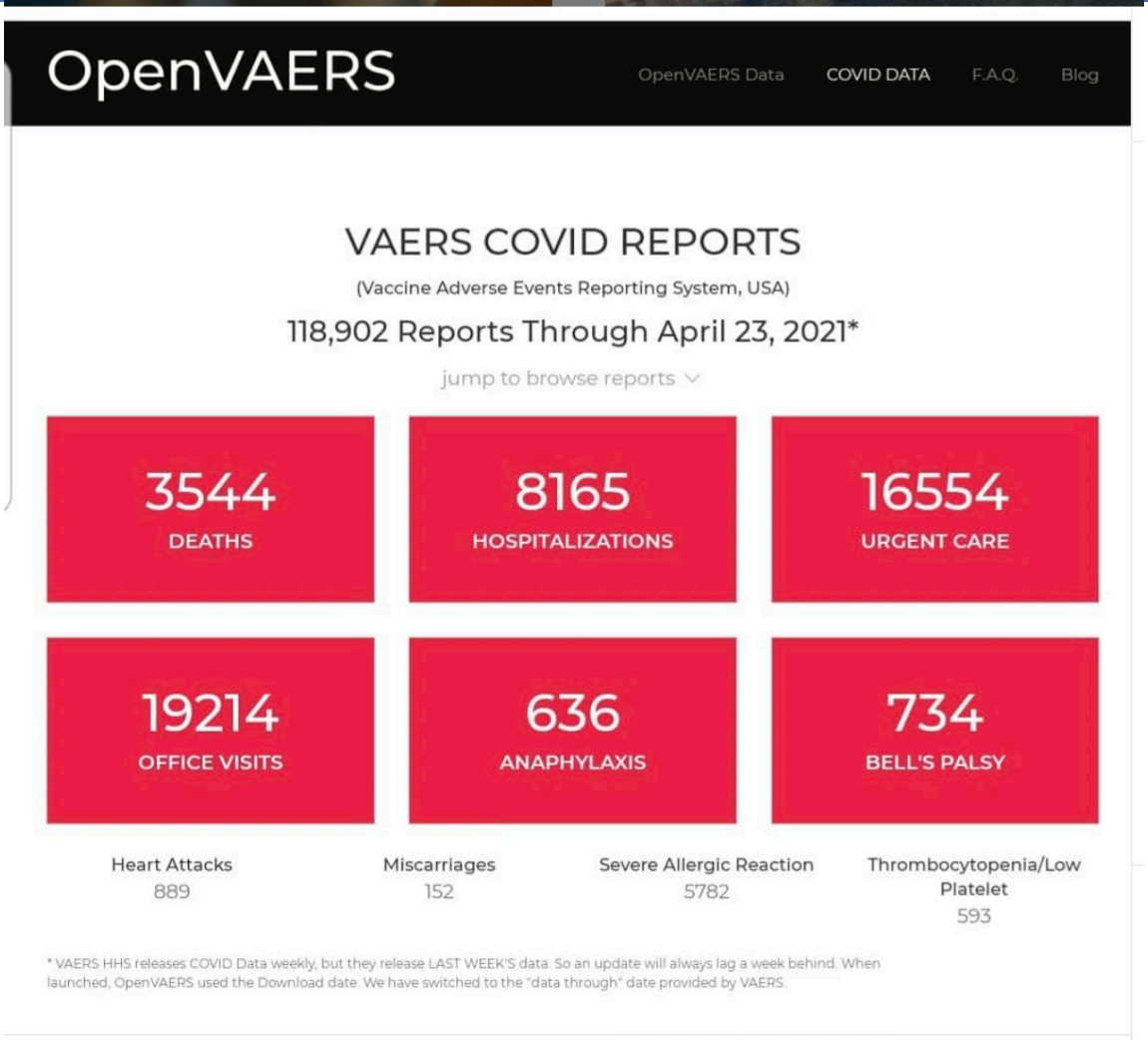
V-SAFE

VSD

CISA

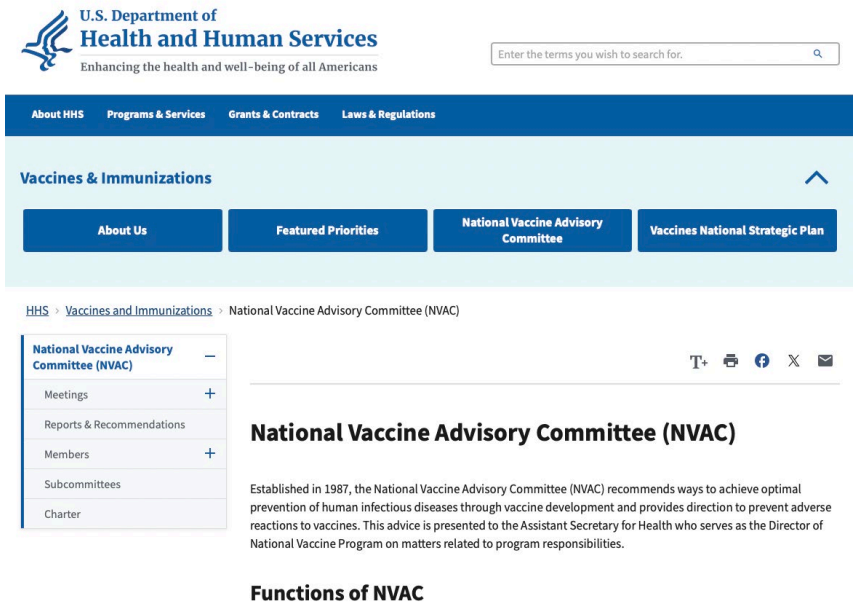
PRISM

Misuse of VAERS



Safety Monitoring: Institutions

- Agencies:
  - FDA
  - CDC
- Committees:
  - VRBPAC
  - ACIP
  - NVAC
  - ACCA

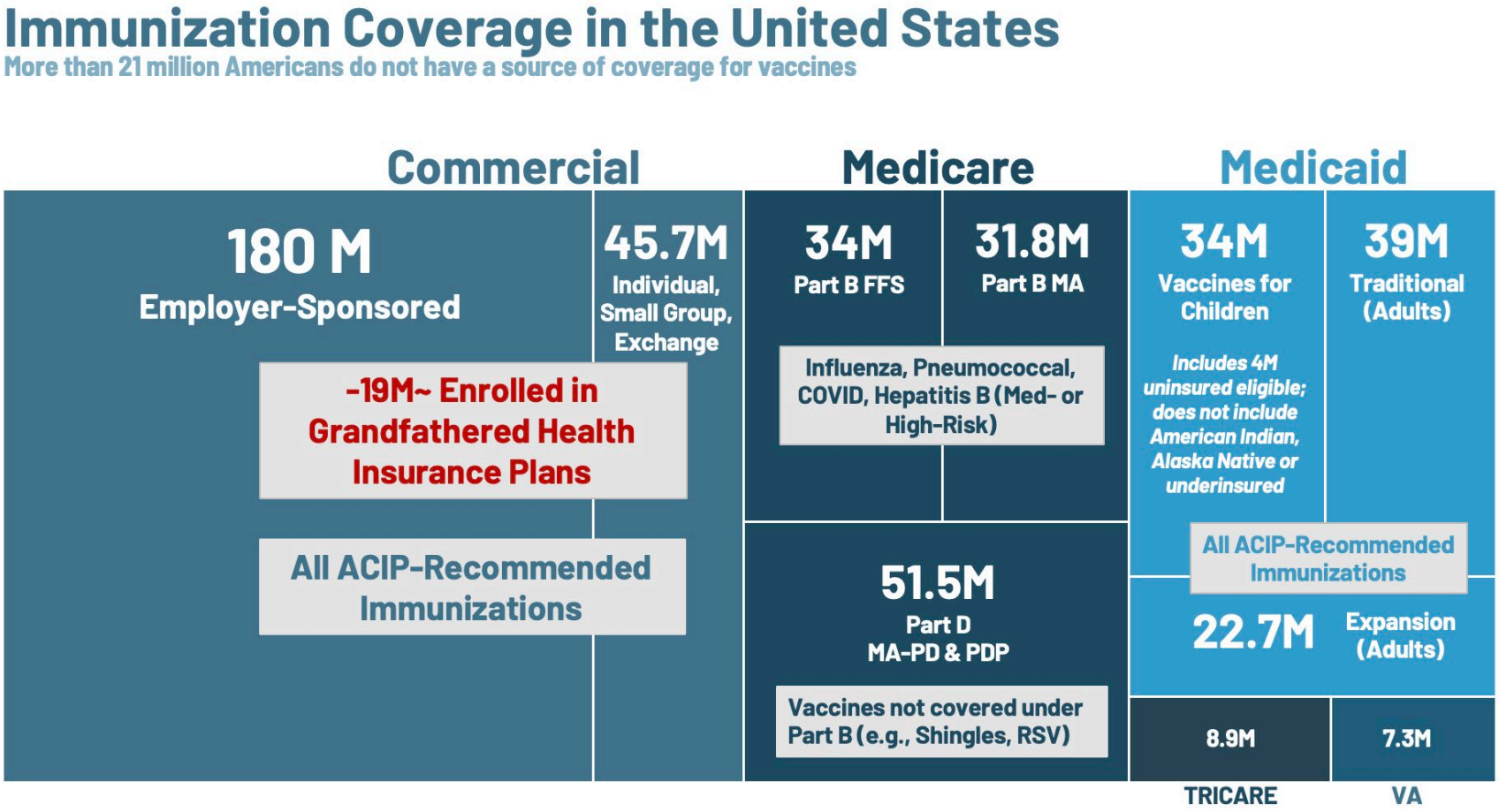


Heather Hazzan vaccine photo
https///www.flickr.com/photos/selfmagazine/48545962716/in/album-72157710332198661/

ACCESS TO VACCINES

Access: Affordable Care act

Slide from Richard Hughes IV



Access: Affordable Care act

Slide from Richard Hughes IV

The Affordable Care Act Requires Preventive Coverage

Certain evidence-based recommendations must be covered without cost sharing by private health plans and Medicaid expansion programs

Advisory Committee on Immunization Practices	Recommended Immunizations
United States Preventive Services Task Force	Recommended Disease Screenings and Products Such as PrEP for HIV, Statins
Health Resources and Services Administration	Women's Services Such as Contraceptives

Access: Braidwood v. Becerra

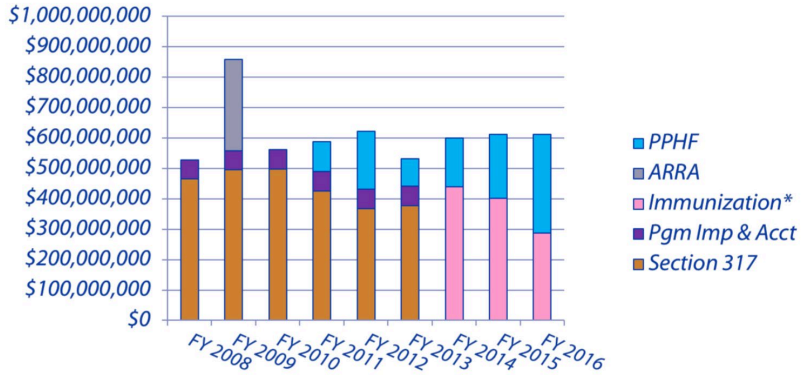
- Challenges preventive services provision of ACA.
- Challenging constitutionality of ACIP and other preventive services advisory bodies.
- District Court accepted part of argument.
  - But not on ACIP/Vaccines.
- Oral argument heard before Fifth Circuit in March 2024.

Access: Vaccine for Children

Access Issues:

- Vaccines for adults?
- VFC issues?
- Other access issues?

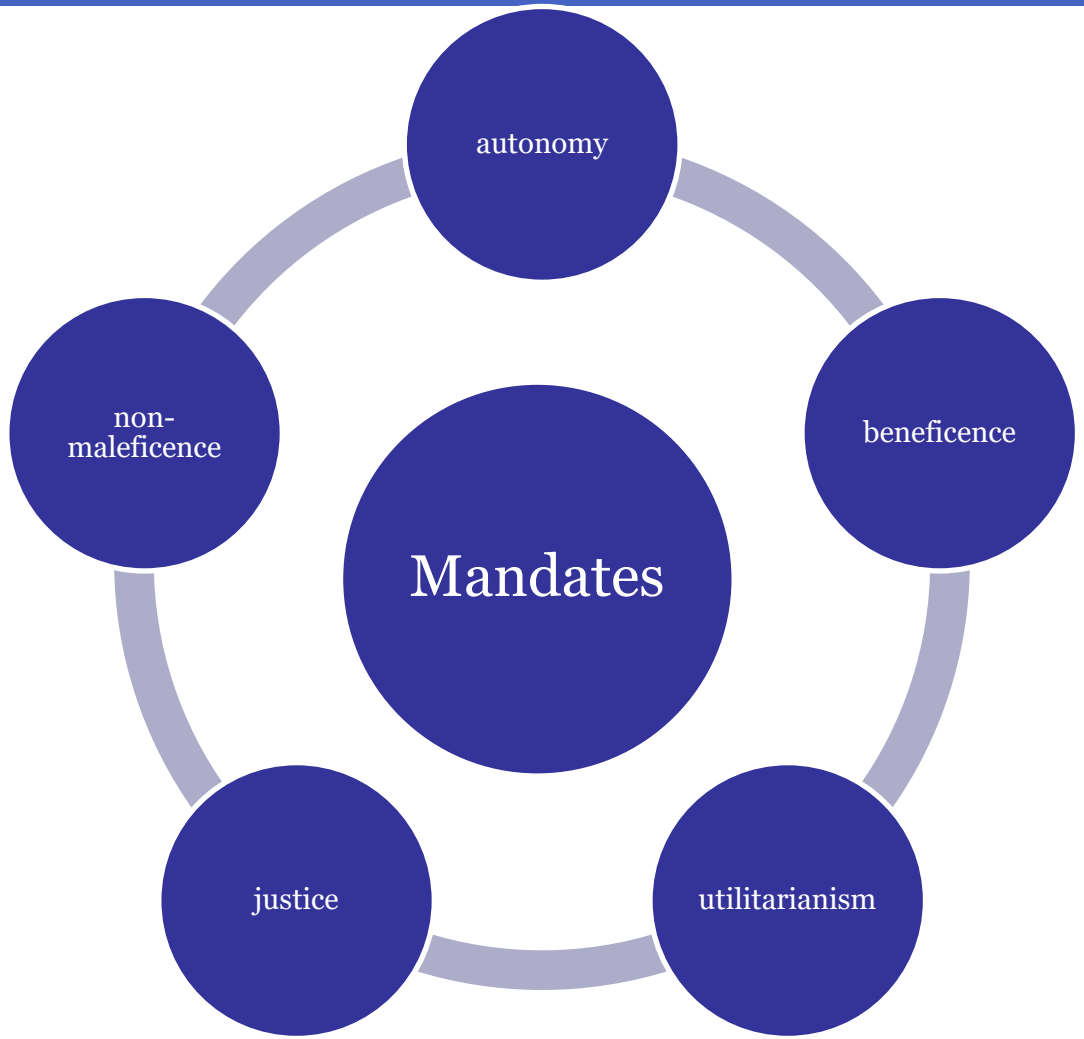
ve Figure 1. **Discretionary Immunization Funding: FY 2008 - FY 2016**



*FY 2014 Omnibus establishes an Immunization line and eliminates the Section 317 and Program Implementation and Accountability sublines; activities in the former sublines are expected to continue.

VACCINE MANDATES

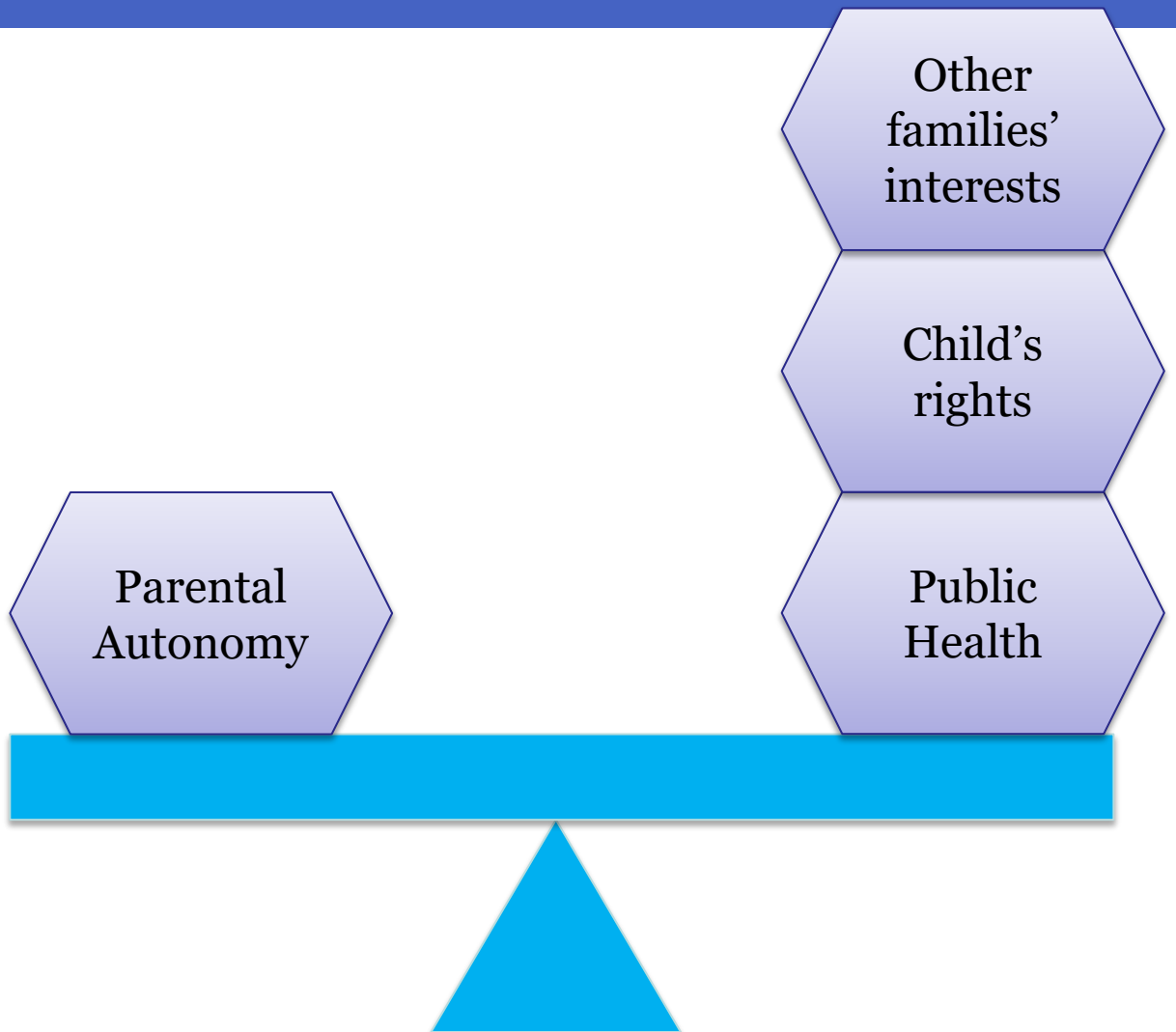
Mandates: balance of values.



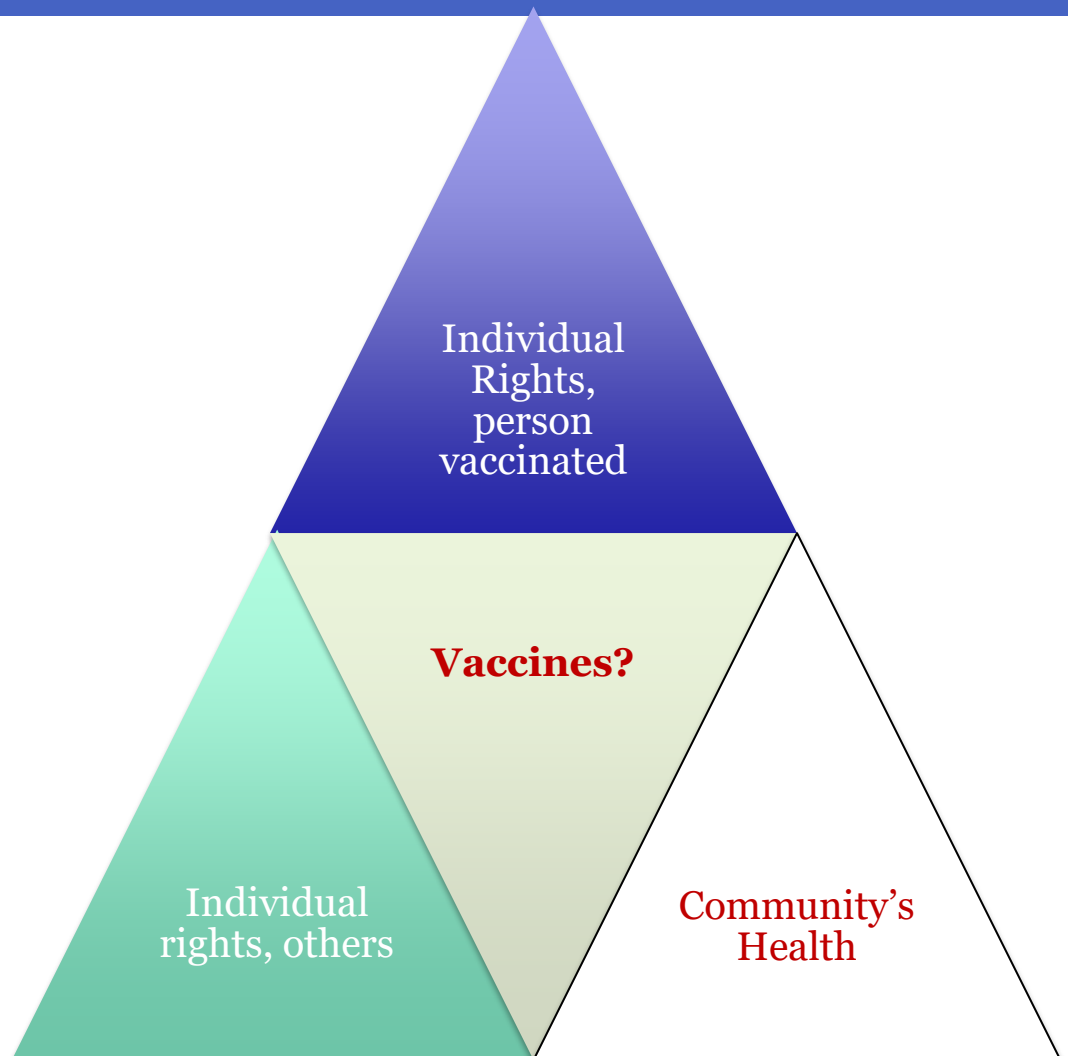
Dorit R. Reiss and Arthur J. Caplan, *Considerations in Mandating a New Covid-19 Vaccine in the USA for Children and Adults*, 7 *J. L. & Biosci.* 1 (2020).

Framework: Childhood Vaccines and Rights

Balance of Interests, Vaccines:

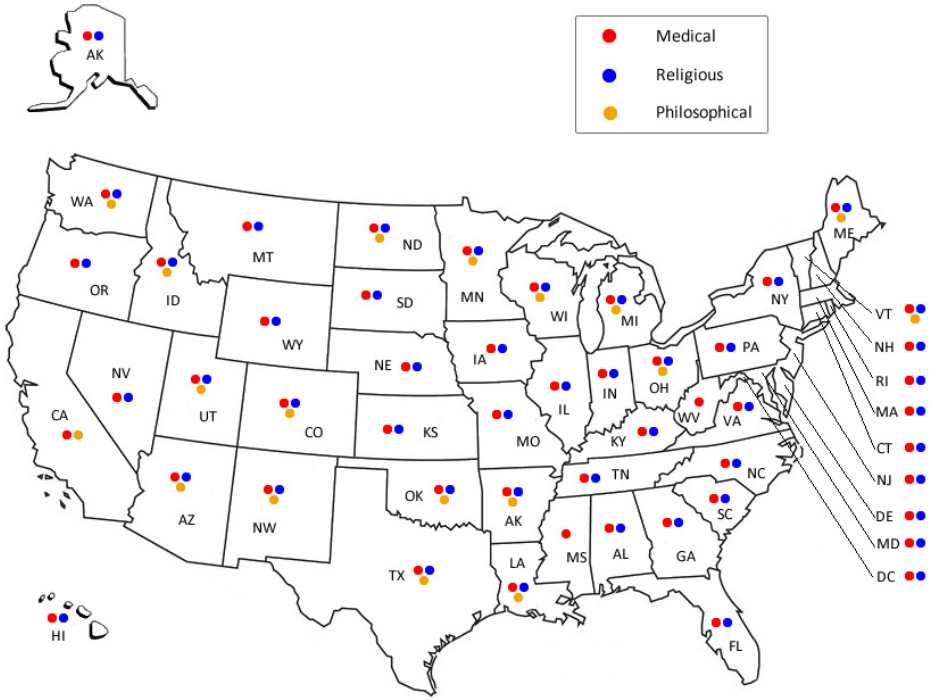


Framework: Adult Vaccines and Rights:



School mandates in the United States:

- First: 1855, Massachusetts.
- By 1980, all states and D.C. had school mandates.
- Exemptions vary.
- No court, state or federal, struck a school mandate for violating rights.
  - Yet.



Workplace mandates, overview:

- Employment in the United States is generally at-will.
- Vaccine mandates: a work safety rule.
- Some limits.

Justification of workplace mandates:

- Employers owes employees a safe workplace.
- Employer has personal interest in healthy workforce.
- Workplace already comes with rules: part of agreement – follow rules.
- But: workers need protection – power difference.

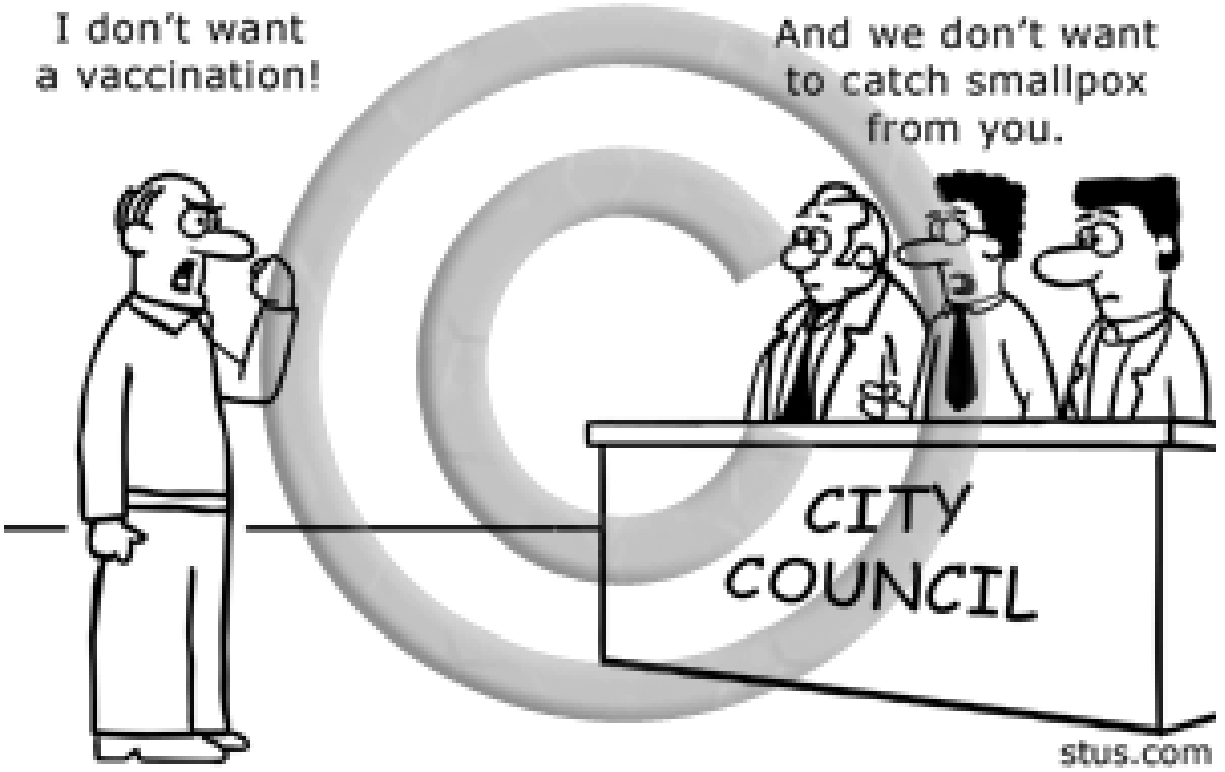
Other mandates?

- University mandates.
- Travel mandates: Long history.
- New York, 2019: neighborhood mandate.
- Vaccine passport, access: cities.

CONSTITUTIONAL AND LEGAL LIMITS

Constitutional assessment, reasonableness

- Jacobson v. Massachusetts (1905):



Jacobson's arguments:

- Constitutional: mandate interfered with his rights.

- On the science: vaccines are dangerous and don't work.

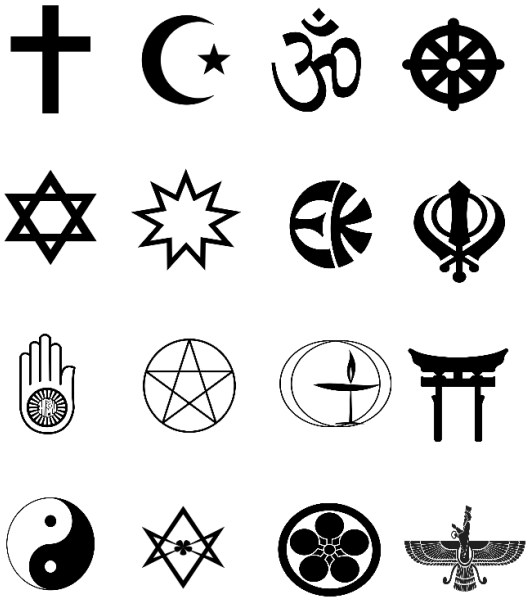
Heather Hazzan vaccine photo
https///www.flickr.com/photos/selfmagazine/48545962716/in/album-72157710332198661/

Jacobson on Police Power

"[T]he police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety."

Take homes:

- A reasonableness standard.
- Not unlimited license to limit rights.
- High deference on science.
- High deference on policy.
- Revival during the pandemic.
  - Some Supreme Court Justices have doubts.



FREEDOM OF RELIGION

First Amendment Free Exercise Clause:

"Congress shall make no law respecting an establishment of religion, or **prohibiting the free exercise thereof**..."

Levels of Scrutiny:

Rational Basis	Intermediate Scrutiny	Strict Scrutiny
Rationally related	Substantially Related	Narrowly Tailored
Legitimate purpose	Important interest	Compelling interest

The Federal Framework:

Jacobson v. Mass.

1905

Zucht v. King

1922

Cantwell v. Connecticut

1940

Christian Scientists

“ Rather than **quarrel** over **vaccination**, I recommend, if the law demand, that an individual submit to this process, that he obey the law, and then appeal to the gospel to save him from bad physical results.”

Mary Baker Eddy, Prose Works, Miscellanious, pp. 219-220

Lies:

[redacted] am sure there will be exemptions allowed:
Medical and Religious for sure!
There has to be!!!!
Note hard to find Bible verses to prohibit immunizations.
Check out the verses that Christian Scientist use.
I am not a CS but I used these verses to qualify for religiou
exemption for my 3 sons ..... grade school thru college.
No problem!!!

If not .... expect to see a spike in adverse reactions.
Yesterday at 5:00pm via mobile · Like · 1

[redacted]

Lies:

Lik

"My sister is living in NM and needs to get a vaccine waiver for her 2 children. Her son has some shots but due to his backtracking after a series of vaccines she is not wanting to do anymore at this time. She needs to get him enrolled in school but they only accept medical or religious exemptions. She has to right the reason for her "religious beliefs" against the kids being vaccinated and then it has to be approved. What is the best wording for her to use for this?"--Anonymous

Lies:

[redacted] I lied also.
3 hours ago · Like

Great Mothers (and others) Questioning Vaccines Be careful what you put here. This is a public site
3 hours ago · Like · 5

[redacted] my kids are adults now. So I don't have lie.
3 hours ago · Like · 1

Fake churches:

TENETS OF BELIEF

Universal Wisdom

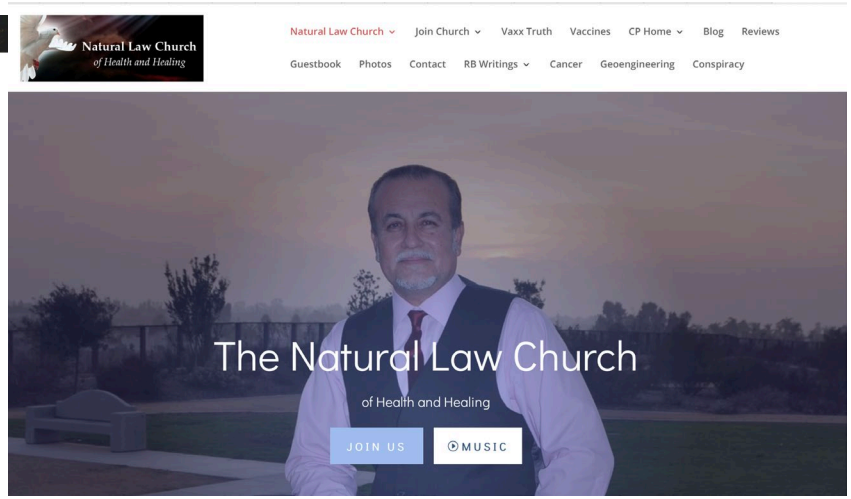
Purpose

As Universal Wisdom is the Supreme Master of all levels in creation and all life of the universe, it shall, therefore, be the guide or principle by which all mankind shall aspire to live.

The healing of mind, body and spirit is but one and is governed by this Universal Wisdom.

It is the belief of the members of the Congregation that upheaval of the morals and inferiority of human values have been the results of a departure of mankind from the ideals expressed by Universal Wisdom. This, we believe, has resulted in a sick and decaying society whose redemption can only be brought about by a blending of Universal Intelligence with man's innate mind. This blending must be initiated by correction of all interference of the brain and central nervous system by forces physical or otherwise that would prevent a free flow of life to all human parts.

https://seekwisdom.life/beliefs/



https://thenaturallawchurch.com

The Federal Framework:

RDC v. Cuomo

Tandon v. Newsom

Fulton v. City of Phil

2020 2021 2021

Bosarge:

- Issue: does the existence of a medical exemption mean you have to have a religious exemption?
  - Raising Tandon.
- Court found that religious exemption required. Change?
  - Maybe, but…
    - MRFRA
    - AG collousion
    - But – re medical exemption…
  - Current case in West Virginia: no preliminary injunction.

Limits on Religious Exemptions:

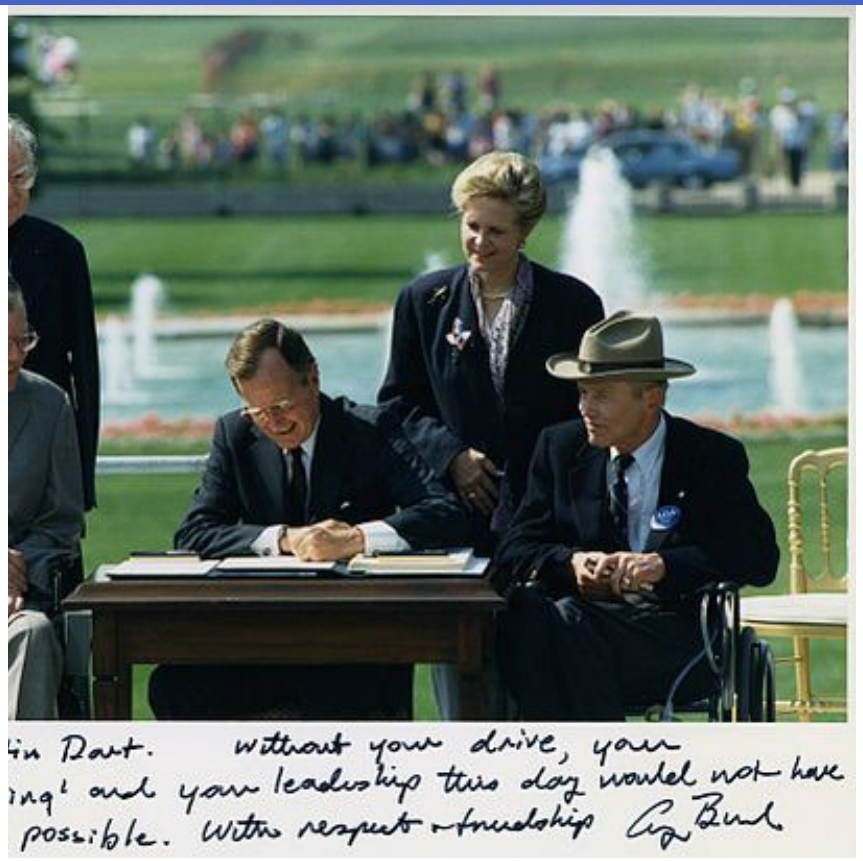
- Cannot be limited to organized religions:
  - *Dalli v. Board of Ed.* 358 Mass. 753 (1971).
- Your religion does not have to oppose vaccines.
  - *Berg v. Glen Cove City School Dist.*, 853 F. Supp. 651, 655 (E.D.N.Y. 1994)
- Unless legislature required it, cannot evaluate sincerity.
  - *LePage v. State of Wyoming Department of Health*, 18 P.3d 1177, 1180 (2001)

In the workplace: Civil Rights Act of 1964:

- Title VII
- Employers with 15 or more employees..
- Cannot “discriminate against, any individual because of his race, color, religion, sex, or national origin…”

Medical exemptions?

- Americans with Disabilities Act: protects medical exemptions.
- Evaluating medical exemptions.
- Accommodations.



Compensation: the issue

- Vaccines benefit:
  - Individual
  - Public
- Nothing is without risks.
- How to compensate rare harms?


Chronicle / Penni Gladstone

https://www.sfgate.com/health/article/When-polio-vaccine-backfired-Tainted-batches-2677525.php

Why no fault for vaccines?

- Easier compensation.
- Fairness: public benefit.
- Increase vaccine confidence.
- Concerns: accountability and legal tools.

Global no fault compensation systems

Global landscape analysis of no-fault compensation programmes for vaccine injuries: A review and survey of implementing countries

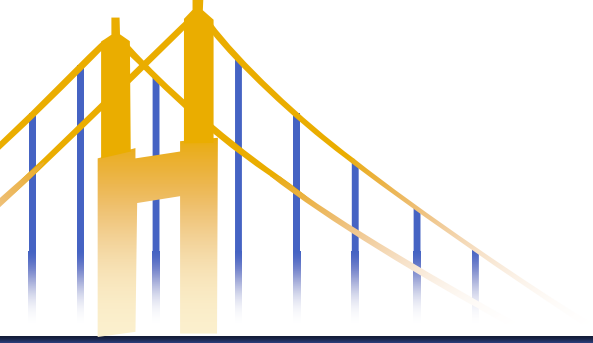
Randy G. Mungwira, Christine Guillard, Adiela Saldaña, Nobuhiko Okabe, Helen Petousis-Harris, Edinam Agbenu, Lance Rodewald, Patrick L. F. Zuber

Published: May 21, 2020 • https://doi.org/10.1371/journal.pone.0233334

National Childhood Vaccine Injury Act of 1986

- "The Vaccine Act;"

- Created the no-fault compensation program for specific vaccines;
- Intended to provide individuals an exclusive, swift, flexible, and less adversarial alternative to traditional civil tort litigation;
- Original focus was children (6 covered vaccines).



Althen v. Secretary of Health and Human Services (2005)

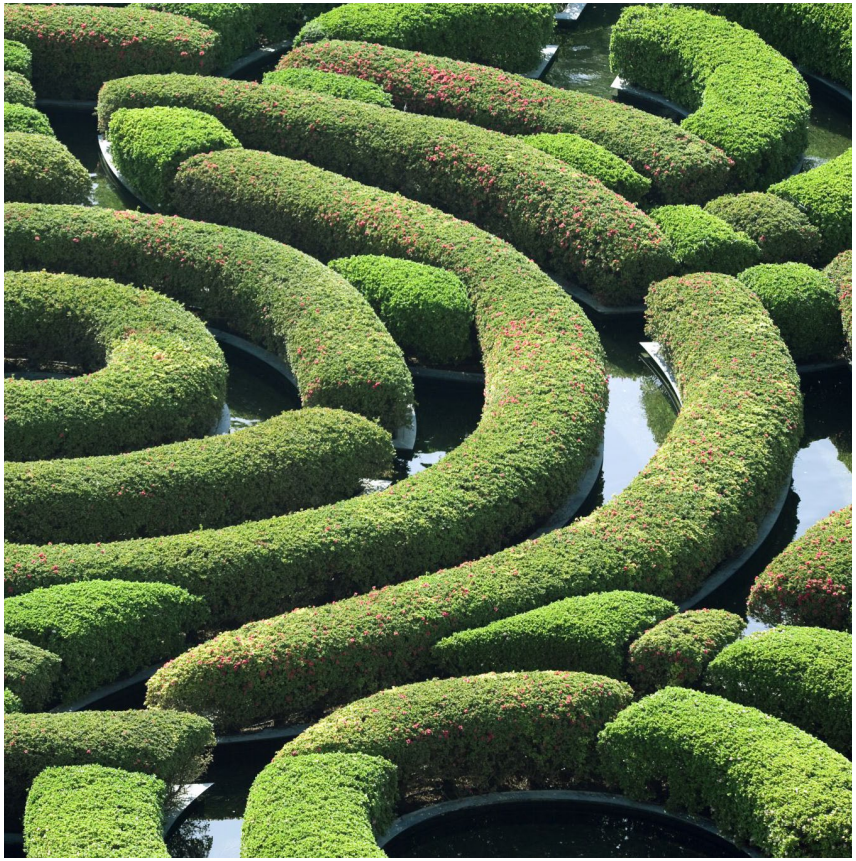
"[show] by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury "

Access to Courts?

- After going through the program.
- Or: If decision not made within 240 days.
- Limit: cannot bring design defect claims (Bruesewitz v. Wyeth).
- Can bring other claims (MDL Gardasil litigation).

Problems with VICP:

- Caps need to be raised.
- Statute of limitations.
- Delays?
- Reducing adversarialism?



Public Readiness and Emergency Preparedness Act of 2005 (PREP Act)

- Authorizes the Secretary of U.S. Department of Health and Human Services to issue PREP Act Declarations

- Declarations provide immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency.

CICP Process

1. Submit a Request for Benefits Package.

2. CICP medical staff reviews to determine whether the requester is eligible for program benefits.

3. If eligible, the requester is asked to submit additional documentation to determine the type and amount of compensation the requester may be entitled to receive.

4. The requester may ask the Associate Administrator of the Healthcare Systems Bureau of HRSA to reconsider the program's eligibility or benefits determination. A qualified panel, independent of the program, is convened to review the program's determination.
5. The panel makes its recommendation to the Associate Administrator who makes a final determination. Requesters may not seek review of a decision made on reconsideration.

CICP Criteria for Compensation

- A covered injury is a direct result of a covered countermeasure;
- Causation standard: "compelling, reliable, valid, medical and scientific evidence" that the injury:
  - Meets the requirement of an injury table; or
  - Is the direct result of administering a covered countermeasure (including aggravation).
- Statute of limitation: one year.
- Cannot go to state courts, except:
  - Willful injury.

Issues:

- CICP standard is hard to meet.
- No alternative.
- No review.
- Need to find an alternative for COVID-19 vaccines.

Thank you!

Questions? Comments?

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