The Network for Public Health Law

COVID-19 Vaccine Distribution: Legal Issues and Challenges

December 10, 2020 | 2:00 – 3:00 PM ET

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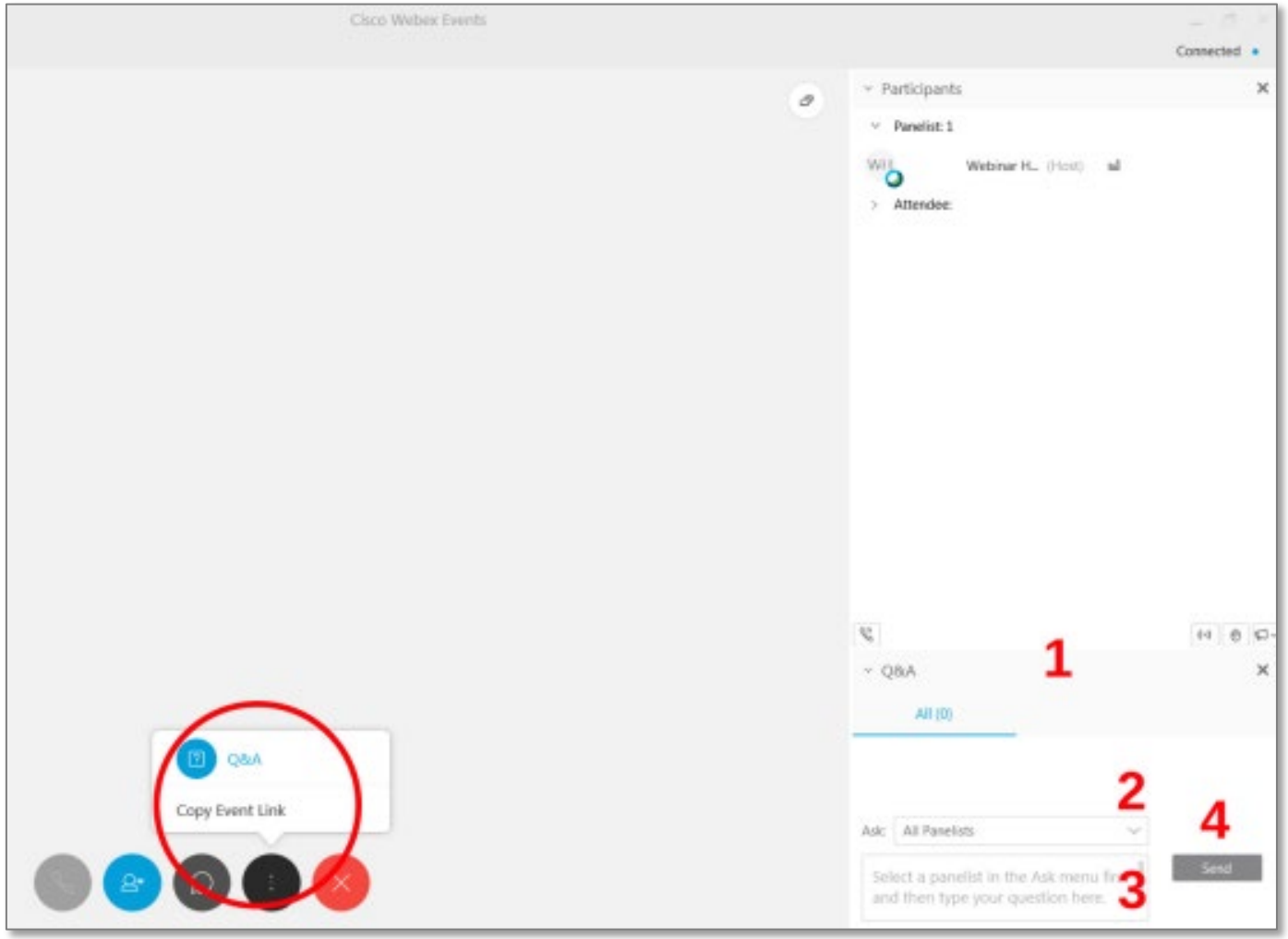
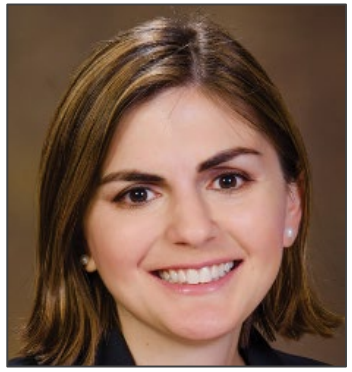


Moderator/Presenter



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COVID-19 Vaccine Distribution: Legal Issues and Challenges

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COVID-19 Vaccine

"We are committed to expediting the development of COVID-19 vaccines, but not at the expense of sound science and decision making. We will not jeopardize the public's trust in our science-based, independent review of these or any vaccines. There's too much at stake."

Stephen M. Hahn, M.D., FDA Commissioner, and Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

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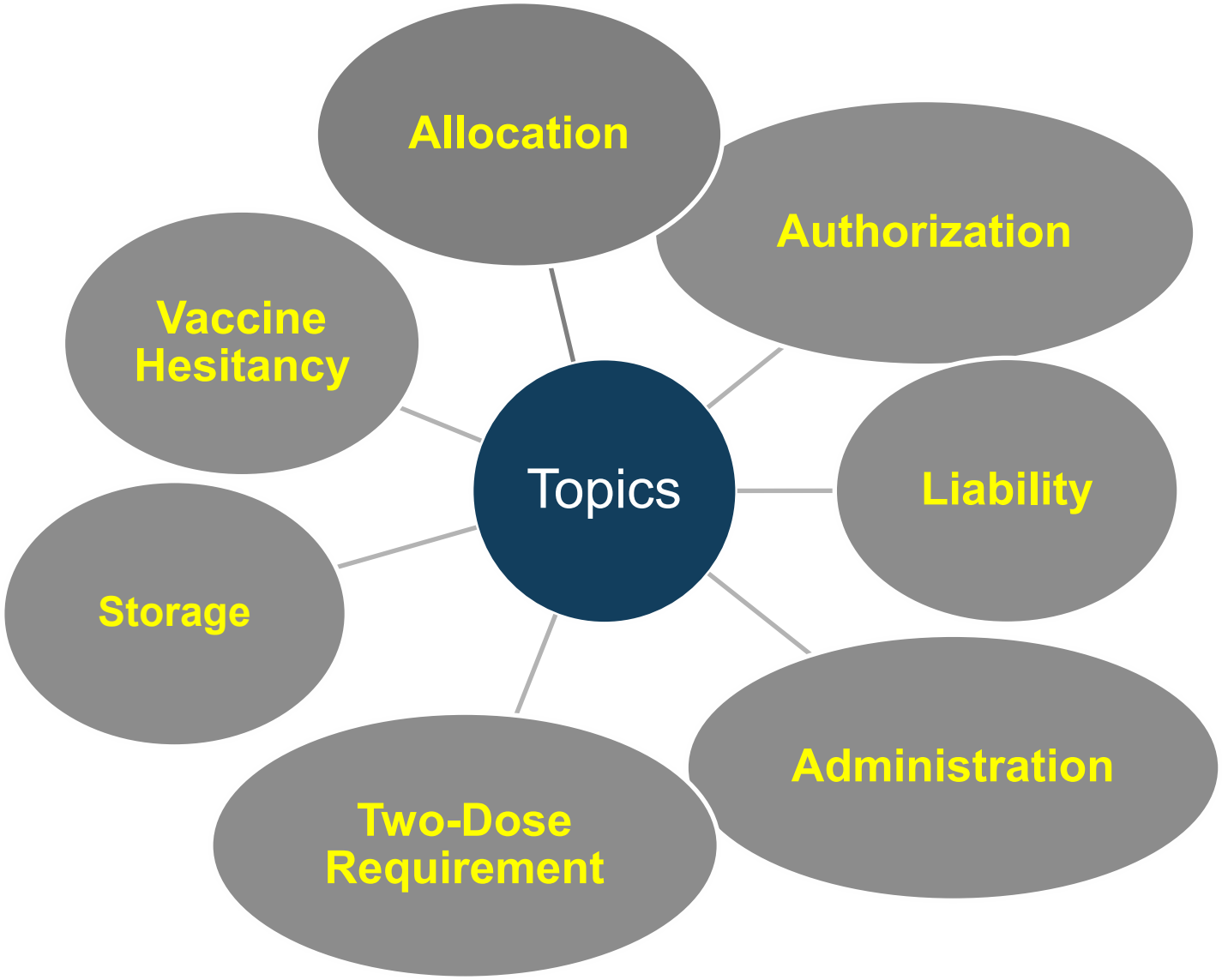
Current & Emerging Challenges



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COVID-19 Vaccine: Legal Implications

A “Top Ten” List of Legal Issues

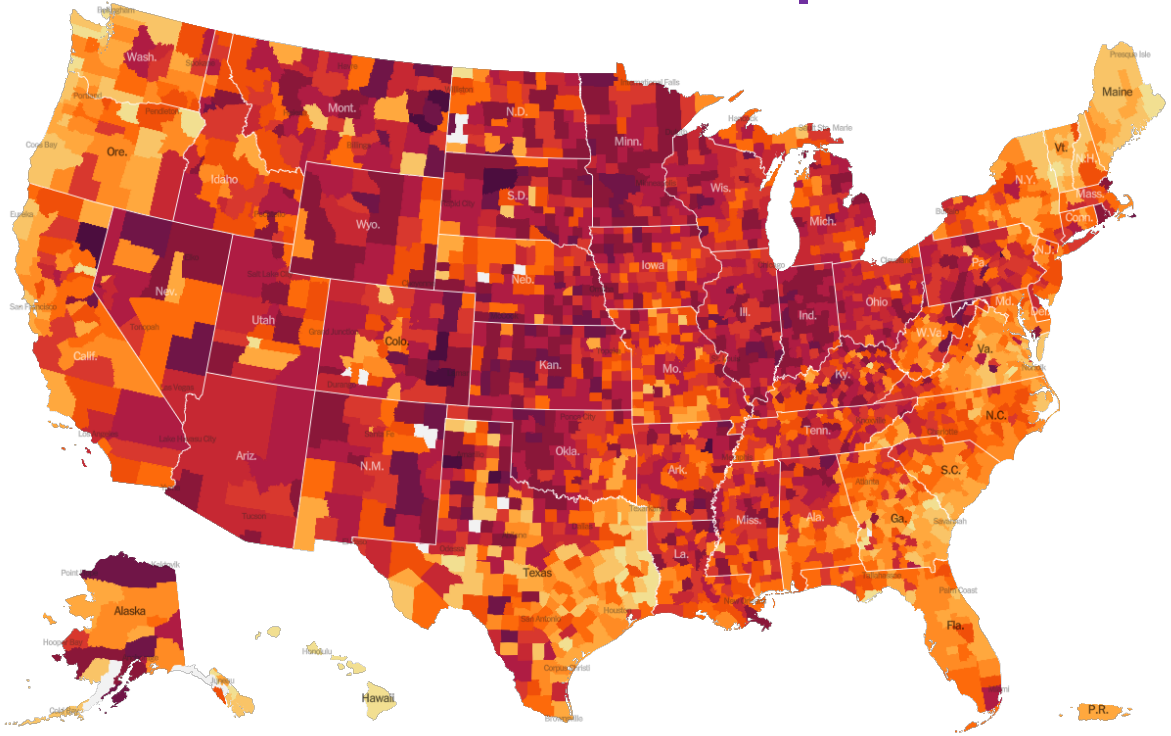
Jennifer L. Piatt, JD

COVID-19 Confirmed Cases & Deaths

Global Cases 68.3 million | Deaths: 1.5 million

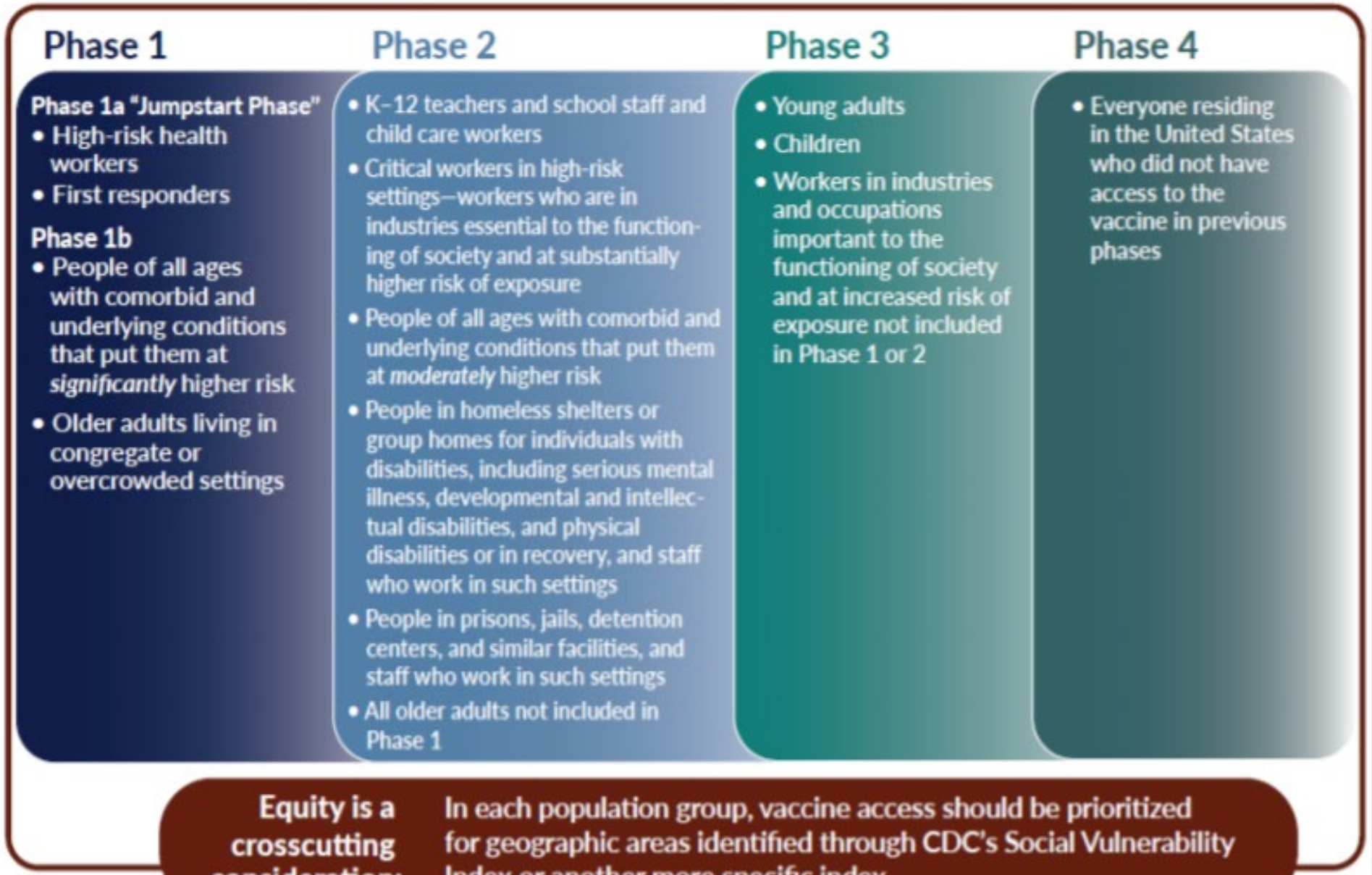
U.S. Cases 15.2 million | Deaths: 286,443

U.S. Stats 22% all cases | 19% all deaths



Source: https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html

Once a vaccine is authorized, how is it allocated, and what legal issues result?


Phase 1
Phase 1a "Jumpstart Phase"
• High-risk health workers
• First responders
Phase 1b
• People of all ages with comorbid and underlying conditions that put them at *significantly* higher risk
• Older adults living in congregate or overcrowded settings
Phase 2
• K–12 teachers and school staff and child care workers
• Critical workers in high-risk settings—workers who are in industries essential to the functioning of society and at substantially higher risk of exposure
• People of all ages with comorbid and underlying conditions that put them at *moderately* higher risk
• People in homeless shelters or group homes for individuals with disabilities, including serious mental illness, developmental and intellectual disabilities, and physical disabilities or in recovery, and staff who work in such settings
• People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings
• All older adults not included in Phase 1
Phase 3
• Young adults
• Children
• Workers in industries and occupations important to the functioning of society and at increased risk of exposure not included in Phase 1 or 2
Phase 4
• Everyone residing in the United States who did not have access to the vaccine in previous phases
Equity is a crosscutting consideration:
In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index.
NATIONAL ACADEMY OF MEDICINE
The National Academies of
SCIENCES • ENGINEERING • MEDICINE

ACIP Interim Recommendation

Health care personnel are defined as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials.

"When a COVID-19 vaccine ***is authorized by FDA and recommended by ACIP***, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both (1) health care personnel and (2) residents of long-term care facilities."

Long-term care facility residents are defined as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

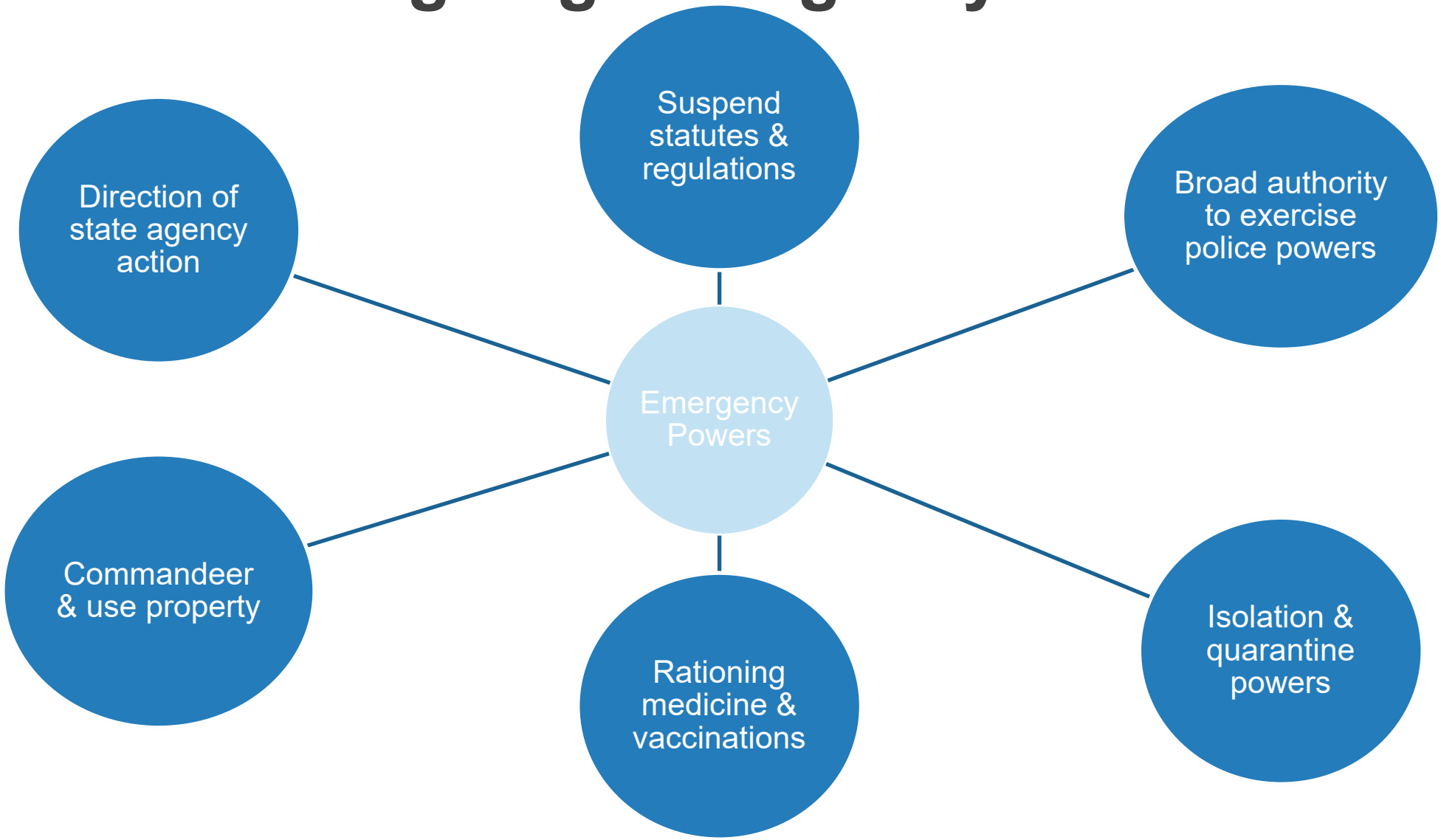
December 1, 2020 Interim Recommendation

The Network for Public Health Law

10 Core Legal Issues Regarding COVID-19 Vaccine Allocation

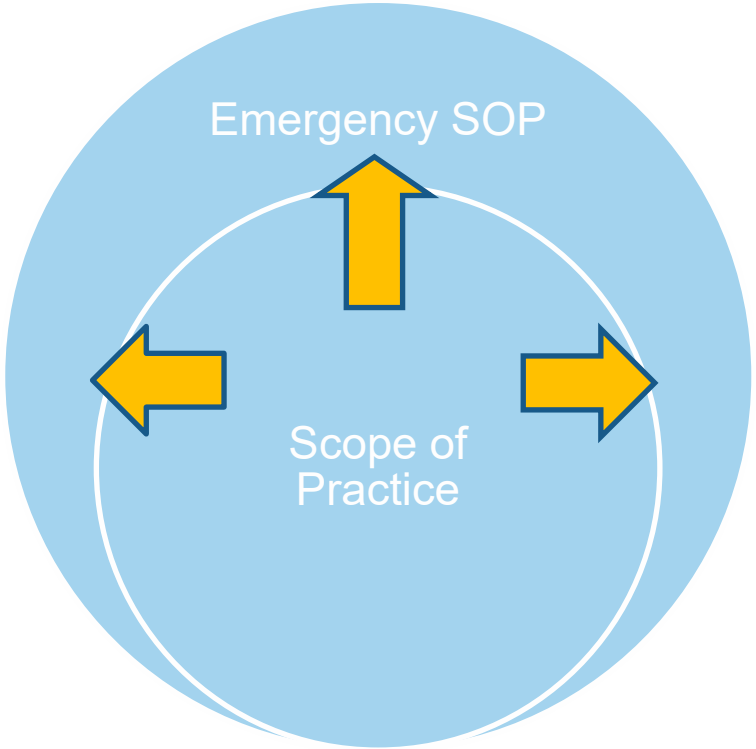
1. Relevance of Ongoing Emergency Declarations at all Governmental Levels
2. Legal Challenges to the Allocation Scheme
3. FDA Approval and EUA Authorization Process
4. Federal Agency Authority over State, Tribal, & Local Governments
5. State Mandates to Vaccinate
6. Employer Mandates
7. Vaccine Exemptions
8. Informed Consent
9. Liability Protections for Providers & Entities
10. Compensation for Injuries Resulting from Vaccination

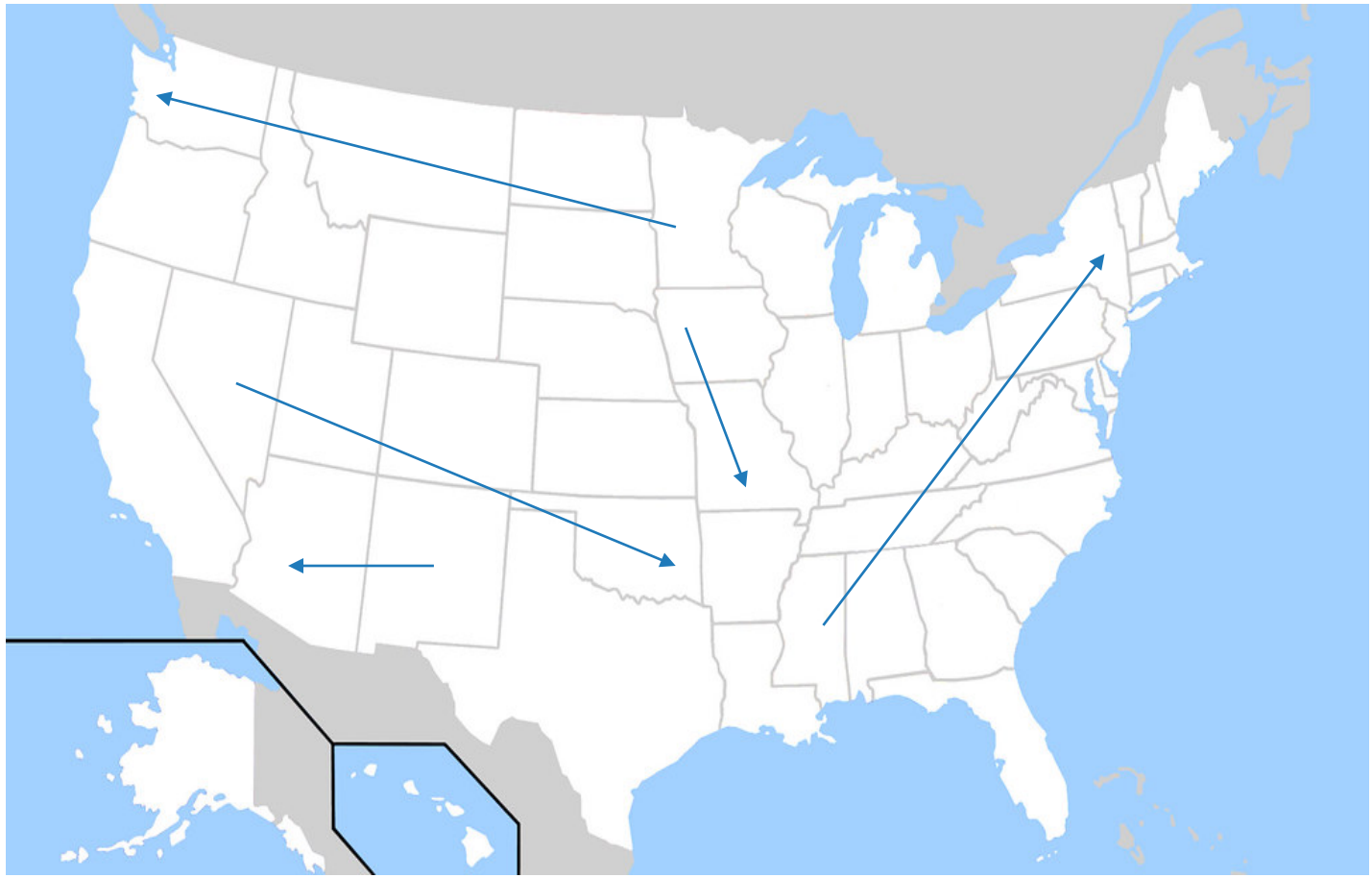
Relevance of Ongoing Emergency Declarations



Relevance of Ongoing Emergency Declarations

Who can provide vaccines?

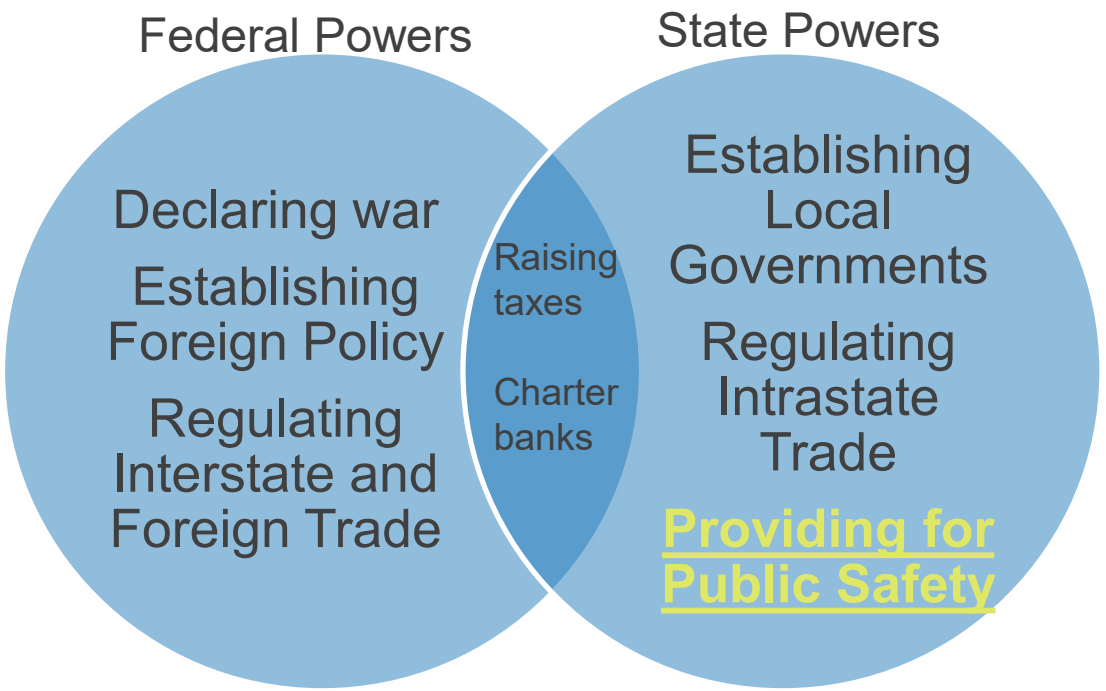




Legal Challenges to the Allocation Scheme Itself

STATE CHALLENGES

Federalism

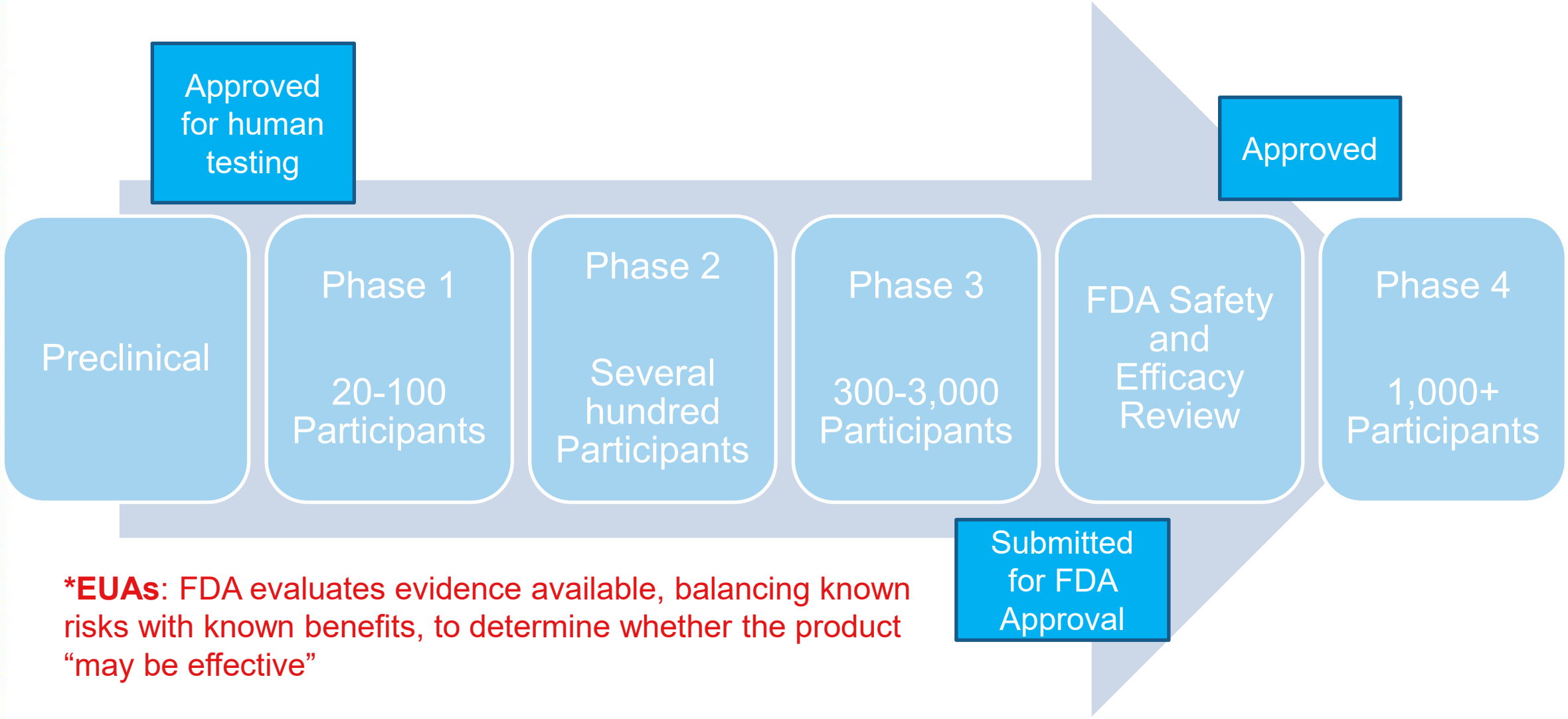


INDIVIDUAL CHALLENGES

Equal Protection Clause

No state shall deny to any person “equal protection of the law”

FDA Approval and EUA Authorization Process



***EUAs**: FDA evaluates evidence available, balancing known risks with known benefits, to determine whether the product "may be effective"

FDA Approval and EUA Authorization Process

White House Blocks New Coronavirus Vaccine Guidelines

The F.D.A. proposed stricter guidelines for emergency approval of a coronavirus vaccine, but the White House chief of staff objected to provisions that would push approval past Election Day.

The New York Times

Health

White House clears Food and Drug Administration coronavirus vaccine standards it tried to derail

The action comes after the FDA unilaterally published the criteria Tuesday morning.

The Washington Post
Democracy Dies in Darkness

Federal Authority over State, Tribal & Local Governments

Some states plan to vet Covid-19 vaccines themselves. Bad idea, experts say.

California and at least five other states have said they may independently vet any vaccines, but experts warn that could needlessly confuse the public.

NEWS

Federal Approval ≠ State Acceptance

HEALTHCARE & PHARMA AUGUST 28, 2020 / 1:35 PM / UPDATED A MONTH AGO

REUTERS

Exclusive: Most U.S. states reject Trump administration's new COVID-19 testing guidance

State Mandates to Vaccinate

State Police Powers

Allow states to legislate and regulate to protect, preserve, and promote health, safety, morals, and general welfare

Example:

Attendance at schools conditioned on vaccination completion

Employer Mandates

PRIVATE SECTOR MANDATES

Example:

Vaccination of health care workers in order to provide services at a hospital workplace

Equal Employment Opportunity Commission

- Religious/Disability Accommodations

Occupational Safety & Health Administration

- Provide a safe workplace

Vaccine Exemptions

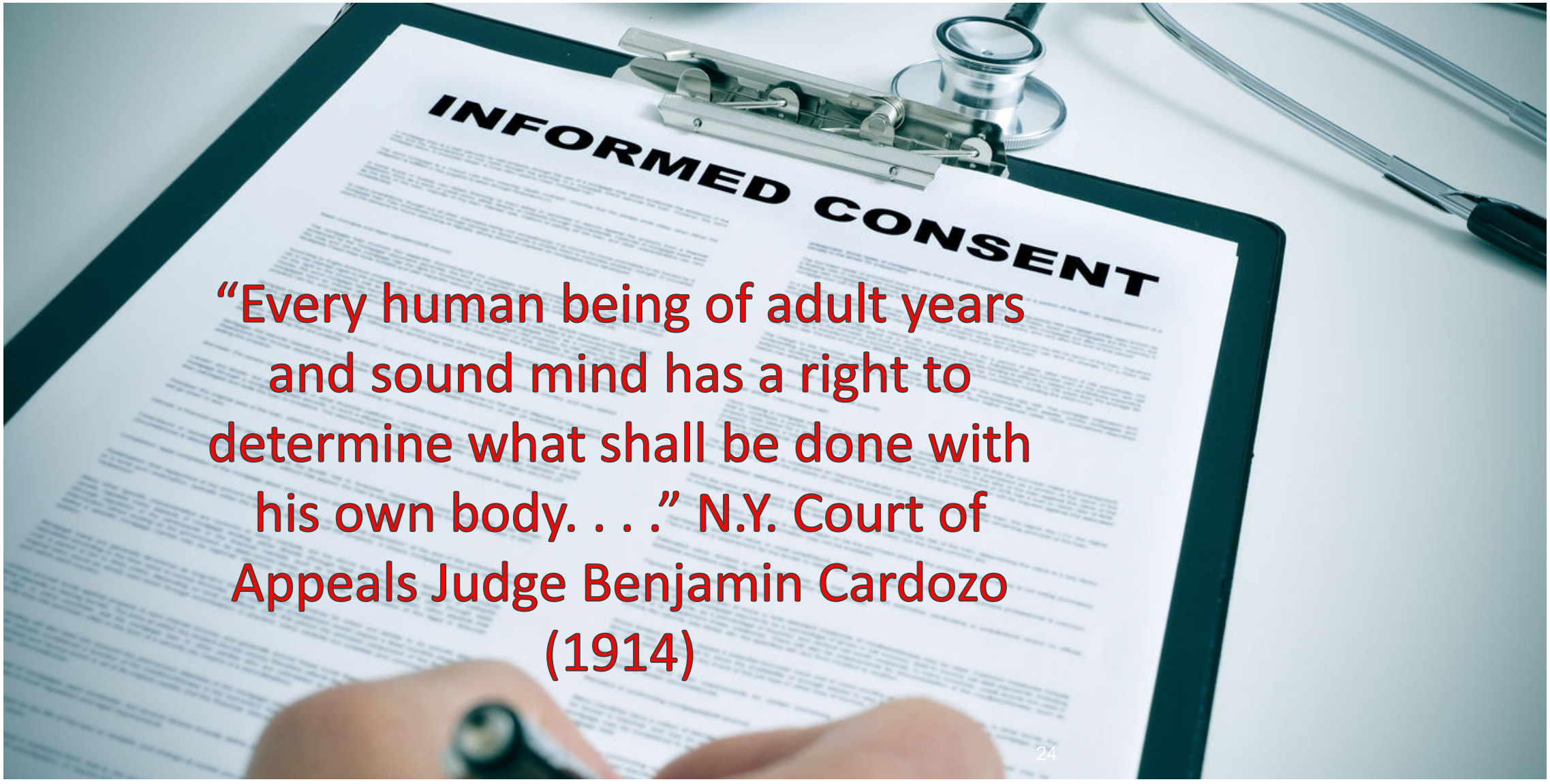
EXEMPTIONS

Exemptions to mandated vaccinations vary widely across states; **medical exemptions** exist in all states, **religious exemptions** exist in most, and **moral exemptions** exist in several

Roman Catholic Diocese of Brooklyn v. Cuomo (U.S. Supreme Court, November 25, 2020)

- Potential implications regarding religious exemptions

Informed Consent Provisions



Liability Protections for Providers and Entities

CARES ACT

"Good Samaritan" provision protects from civil liability interstate volunteer HCWs responding to the COVID-19 public health emergency

Explicitly overrides all state laws except those that provide even greater protection from liability

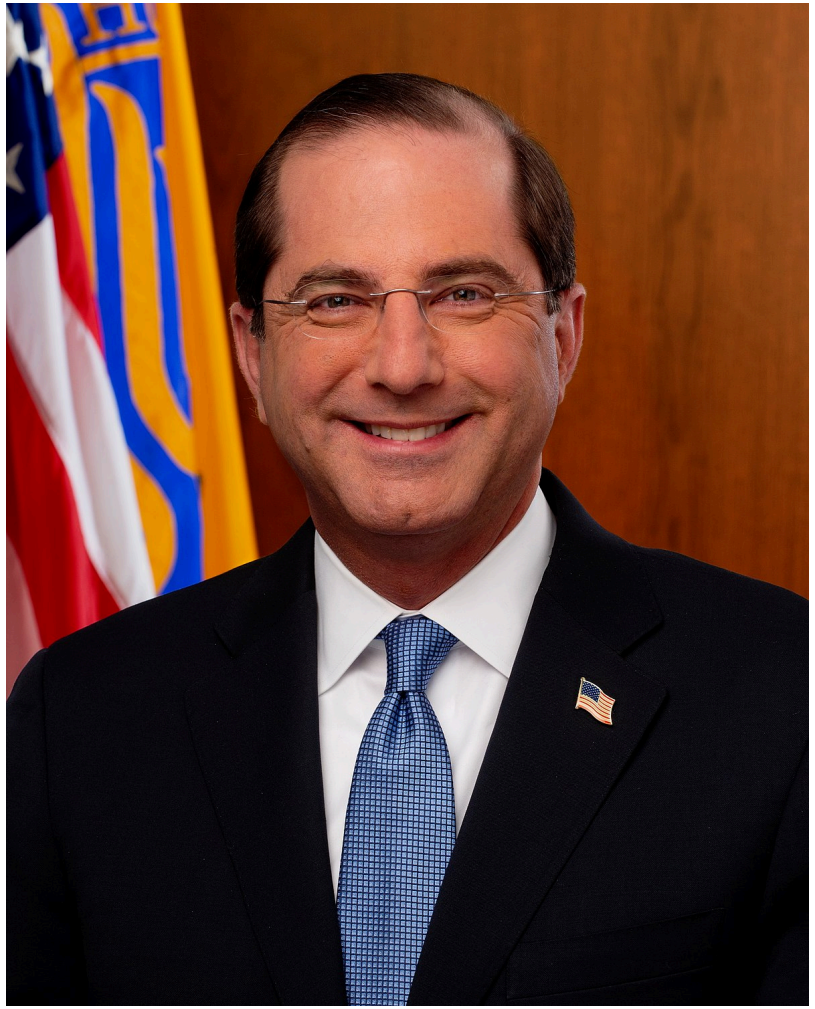
(Applies to volunteers ONLY; does not cover willful or criminal conduct)

PREP ACT

Authorizes HHS Secretary to provide immunity to certain individuals and entities against loss claims arising out of the manufacture, distribution, administration, or use of a "covered countermeasure" in response to a public health emergency

(Applies to all covered HCWs; does not cover willful misconduct)

Liability Protections for Providers and Entities



"Covered Persons who are afforded liability protections under this Declaration [include] . . . '***qualified persons***,' as . . . defined in the PREP Act; their officials, agents, and employees; and the United States.

In addition, I have determined that the following additional persons are qualified persons: . . .

A State-licensed pharmacist who orders and administers, and ***pharmacy interns*** who administer . . . (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA-authorized or FDA-licensed COVID-19 vaccines to persons ages three or older. . . .

Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice."

December 3, 2020 amendment to PREP Act Declaration

Compensation for Injuries

National Vaccine Injury Compensation Program provides compensation for injuries caused by routinely-administered vaccinations

Countermeasures Injury Compensation Program* (CICP)** provides reimbursement of reasonable medical expenses, loss of income, or survivor benefits for individuals *seriously* injured/killed ***by countermeasures implemented under PREP Act

Vaccines

How We Assure Safety and Effectiveness in the Age of COVID

Doug Campos-Outcalt MD, MPA

Disclosures

- Former member of the ACIP
  - 5 years as liaison
  - 4 years as voting member
- Current Consultant to the ACIP on GRADE assessments and ETR process.

Learning Objectives

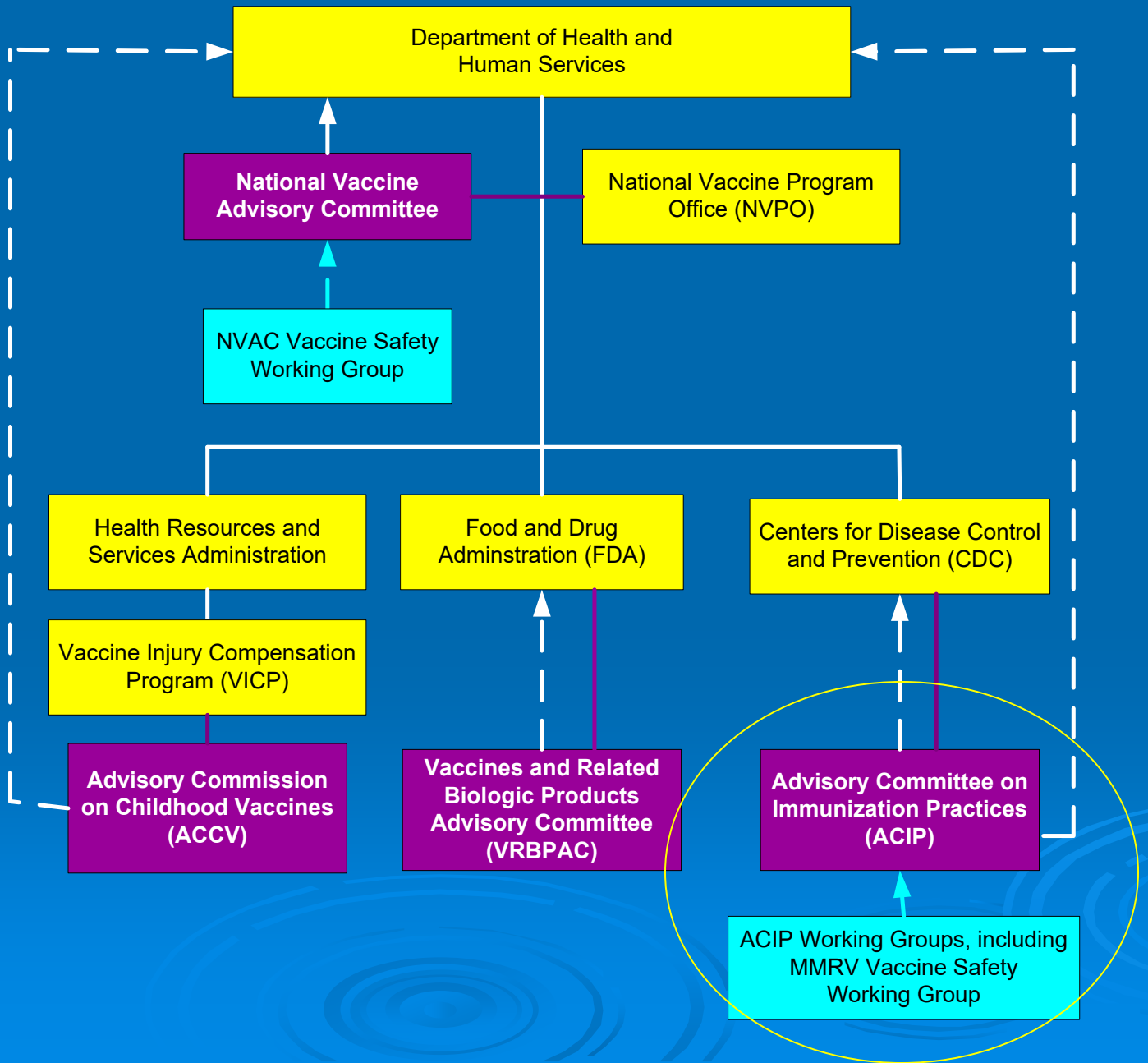
- Describe:
  - The FDA process for approving vaccines
  - The Federal Structure for assessing vaccine safety.
  - How vaccine recommendations are made and where they can be located.
  - The federal system for compensating those affected by rare, serious, vaccine- related adverse events.
  - How this system will relate to the pending COVID vaccines.

COVID-19 vaccines in human clinical trials – United States*

Candidate	Manufacturer	Type	Phase	Trial characteristics	Trial #	Recruiting
mRNA-1273	Moderna TX, Inc.	mRNA	III	• 2 doses (0, 28d) • IM administration • 18-55, 56+ years	NCT04470427	Enrollment complete
mRNA-BNT162	Pfizer, Inc./BioNTech	mRNA	II/III	• 2 doses (0, 21d) • IM administration • 18-85 years	NCT04368728	✓
AZD1222	University of Oxford/AstraZeneca consortium**	Viral vector (NR)	III	• 2 doses (0, 28d) • IM administration • ≥18 years	NCT04516746	✓
Ad26COVS1	Janssen Pharmaceutical Companies	Viral vector (NR)	III	• 1 dose • IM administration • 18-55, 65+	NCT04436276	✓
--	Sanofi/GSK	Protein Subunit	I/II	• Single or 2 doses • IM administration • 18-49, 50+	NCT04537208	✓
NVX-CoV2373	Novavax	Protein Subunit	I/II	• 2 doses (0, 21d) • IM administration • 18-84	NCT04368988	Enrollment complete
V591	Merck	Viral Vector	I/II	• 2 doses (1, 57d) • IM administration • 18-55	NCT04498247	✓

*As of October 27, 2020
**Currently on hold in US
Sources: https://milkeninstitute.org/covid-19-tracker; https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines; https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ ; https://clinicaltrials.gov/; https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html

Federal Advisory Committees Involved with Vaccine Oversight



FDA Approval

- Vaccines and Related Biological Products Advisory Committee (VRBPAC)
  - Reviews effectiveness and safety data
  - Makes recommendation to FDA
- Ways to speed up the process
  - Expedite
  - Emergency use authorization
  - Extended use authorization
- EUA requires regular approval for ongoing use

EUA

- Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

EUA Requirements

- The chemical, biological, radiological, or nuclear (CBRN) agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition
- Based on the totality of scientific evidence available, including data from adequate and well controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.

Criteria Set for EUA for COVID Vaccines

- An EUA for a COVID-19 vaccine may be requested to allow for the vaccine's rapid and widespread deployment for administration to millions of individuals, including healthy people, following a planned interim analysis in an ongoing Phase 3 trial
- A favorable benefit/risk determination to support issuance of an EUA in this scenario would require, in addition to adequate manufacturing information:
  - Efficacy data showing protection against SARS-CoV-2 infection or disease with a point estimate of least 50% vs. placebo comparator and an appropriately alpha-adjusted confidence interval lower bound >30%
  - At least half of Phase 3 study subjects followed for both safety and efficacy for at least 2 months following completion of the full vaccination regimen
  - Safety data from throughout clinical development (including well over 3,000 Phase 3 vaccine recipients) to evaluate reactogenicity, serious AEs, and AEs of special interest
  - Sufficient cases of severe COVID-19 to assess for signals of enhanced disease

After FDA Approval

Who Makes Vaccine Recommendations?

- Advisory Committee on Immunization Practices
  - CDC administered
  - DHHS appointments members
  - Public can attend and speak
  - Agendas, presentations and minutes are posted

ACIP Structure

- 15 voting members (including Chair)
  - **Non-governmental members**
  - 4 year terms - overlapping
  - ACIP Steering Committee nominates, OS DHHS selects
  - Chair - selected from current members
  - One consumer representative
  - Voting members screened for conflicts of interest
- 8 *ex officio* members – representing other government agencies (CMS, DOD, DVA, FDA, HRSA, IHS, NIH, NVPO); nonvoting *
- 30+ liaison organizations – representatives of professional societies and organizations responsible for vaccine development and immunization programs; nonvoting

ACIP Processes

- FACA committee
- Public meetings, 3 times a year, webcast
- Work groups meet between meetings
- CDC staff support

Factors Considered

- Burden of disease
  - Epidemiology
  - Morbidity
  - Mortality
- Evidence is assessed using GRADE
  - Evidence of effectiveness
  - Evidence of safety
- Cost effectiveness
- Implementation logistics
- Values and perceptions of providers and stakeholders

Location
CDC Headquarters, Atlanta, GA

- Safety Monitoring After Approval

CDC Immunization Safety Office: Research and Surveillance Infrastructure

- Vaccine Adverse Event Reporting System (VAERS)
- Vaccine Safety Datalink (VSD) Project
- Clinical Immunization Clinical Assessment (CISA)
  - Consultation to clinicians on safety concerns'
  - Research on clinical vaccine safety
  - 8 academic research center collaborative
- FDA influenza safety
- Military
- General medical literature on vaccine safety

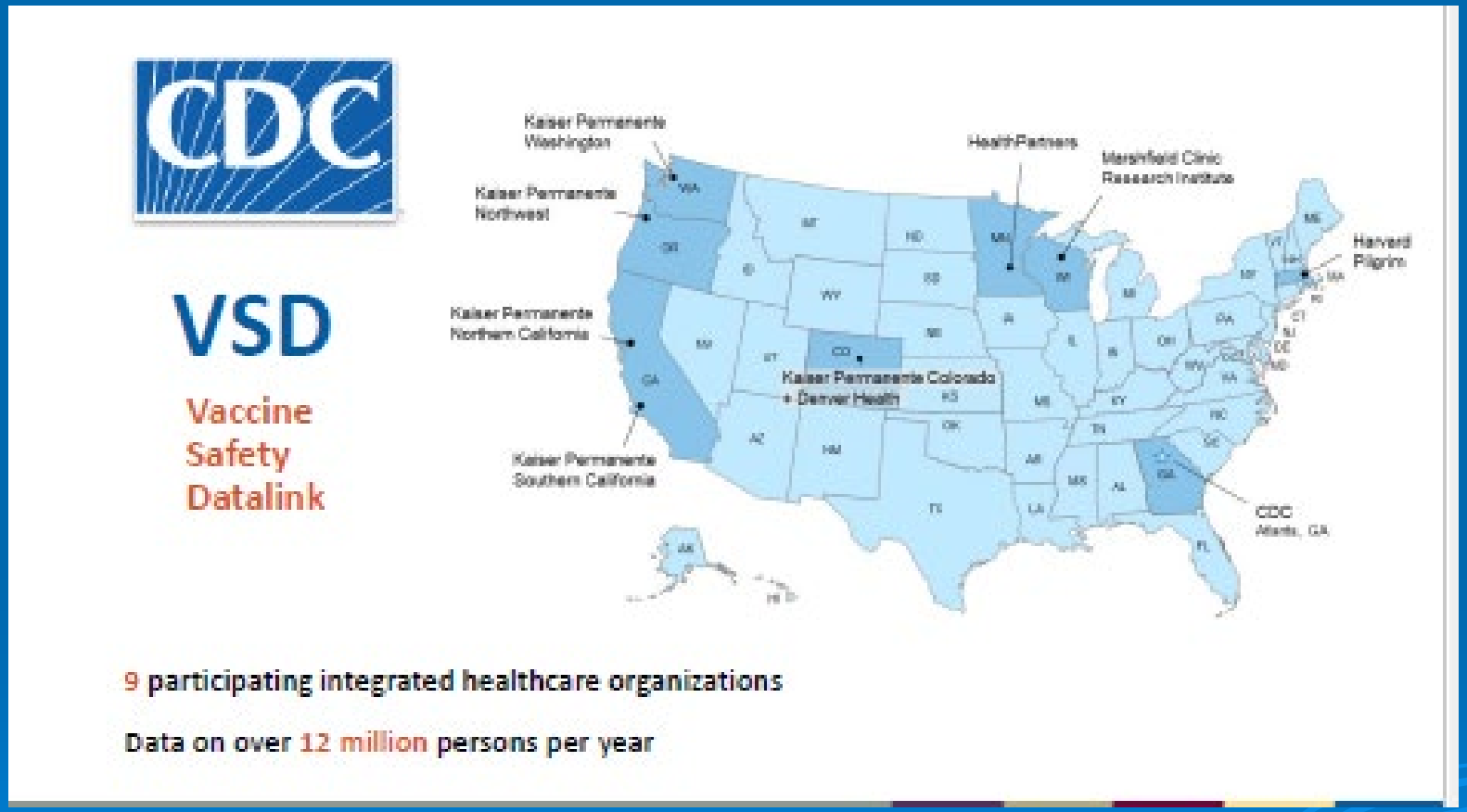
The Vaccine Adverse Event Reporting System (VAERS)

- The “early warning system” of vaccine safety surveillance
- A national passive surveillance system jointly operated by the CDC and the FDA; established in 1990
- Accepts reports from physicians, other health care providers, vaccine manufacturers, health departments, and the public
  - Some reporting legally mandated but most reports voluntary
- “Hypothesis generating”; seeking signals of potential concern regarding rare adverse events not detected in pre-licensure studies and/or occurring in special populations
- Subject to over and under reporting

Vaccine Safety Datalink

- Collaboration between CDC and 8 managed care organizations.
- Provides comprehensive medical and immunization histories for 8.8 million people annually .
- Tests hypotheses suggested by signals from VAERS or other sources and conducts vaccine safety surveillance in near real-time.

VSD


CDC
VSD
Vaccine
Safety
Datalink
Kaiser Permanente Washington
Kaiser Permanente Northwest
Kaiser Permanente Northern California
Kaiser Permanente Southern California
Kaiser Permanente Colorado + Denver Health
HealthPartners
Marshfield Clinic Research Institute
Harvard Pilgrim
CDC Atlanta, GA
9 participating integrated healthcare organizations
Data on over 12 million persons per year

COVID Vaccine Surveillance Enhancements

- VAERS
  - Addition of smart phone app reporting
  - List of adverse events of interest
  - COVID related SAE monitoring
- VSD
  - Rapid cycle analysis
- Additional agencies
  - FDA (BEST)
  - CMS (Medicare)
  - DOD
  - Indian Health Services

2a. FDA Biologics Effectiveness and Safety (BEST) System

- Several partners – Acumen, IBM Watson, IQVIA, OHDSI, HealthCore, Humana, Optum, Healthagen, MedStar, OneFlorida, and Academic organizations
- Represents variety of healthcare settings – inpatient, emergency department, outpatient, etc.
- Emphasis on inclusion of Electronic Health Record (EHR) data, some claims data and linked Claims-EHR data

National Vaccine Injury Compensation Program

VICP

- Covers child vaccines even if used for an adult
- DHHS, DOJ and courts
- No fault system of compensation for vaccine related injuries proven to be caused by vaccines
  - Table of known SAE's developed by the NAM
- The system favors plaintiffs
  - Burden of proof less
  - Government concedes cases that are even possible

Countermeasure Injury Compensation Program

- Same concept as VICP
- A countermeasure is a vaccination, medication, device, or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat.
- See Countermeasures Injury Compensation Program (CICP) | Official web site of the U.S. Health Resources & Services Administration (hrsa.gov)

Summary

- In the U.S. we have:
  - a secure supply of safe vaccines;
  - a transparent method of making vaccine recommendations;
  - a robust system to monitor vaccine safety;
  - an efficient system to compensate those who experience a rare, serious adverse reaction to a vaccine.

Questions?

Questions, Thoughts, Comments

Thank you!

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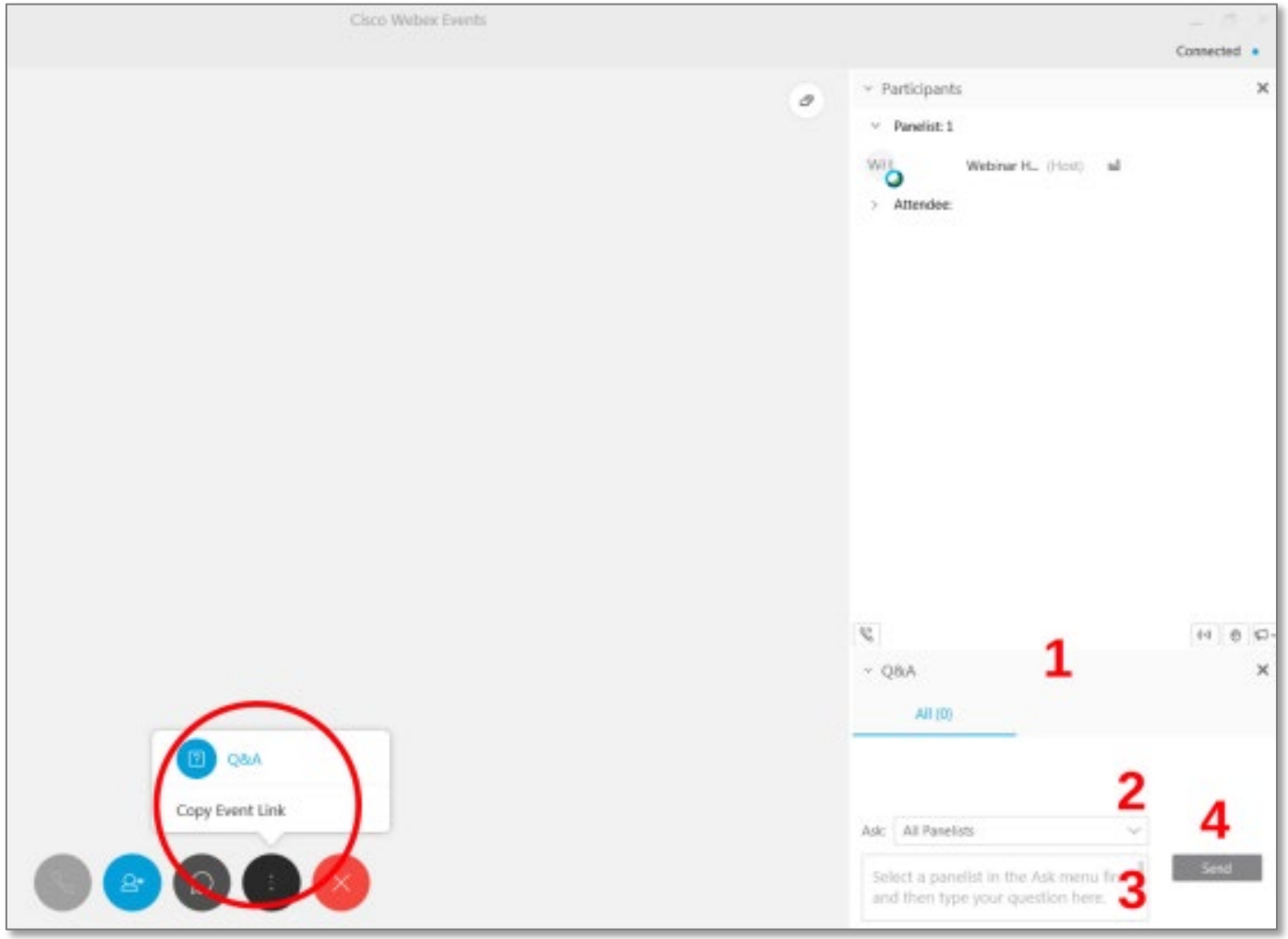

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COVID-19: Real-Time Guidance, Resources and Information
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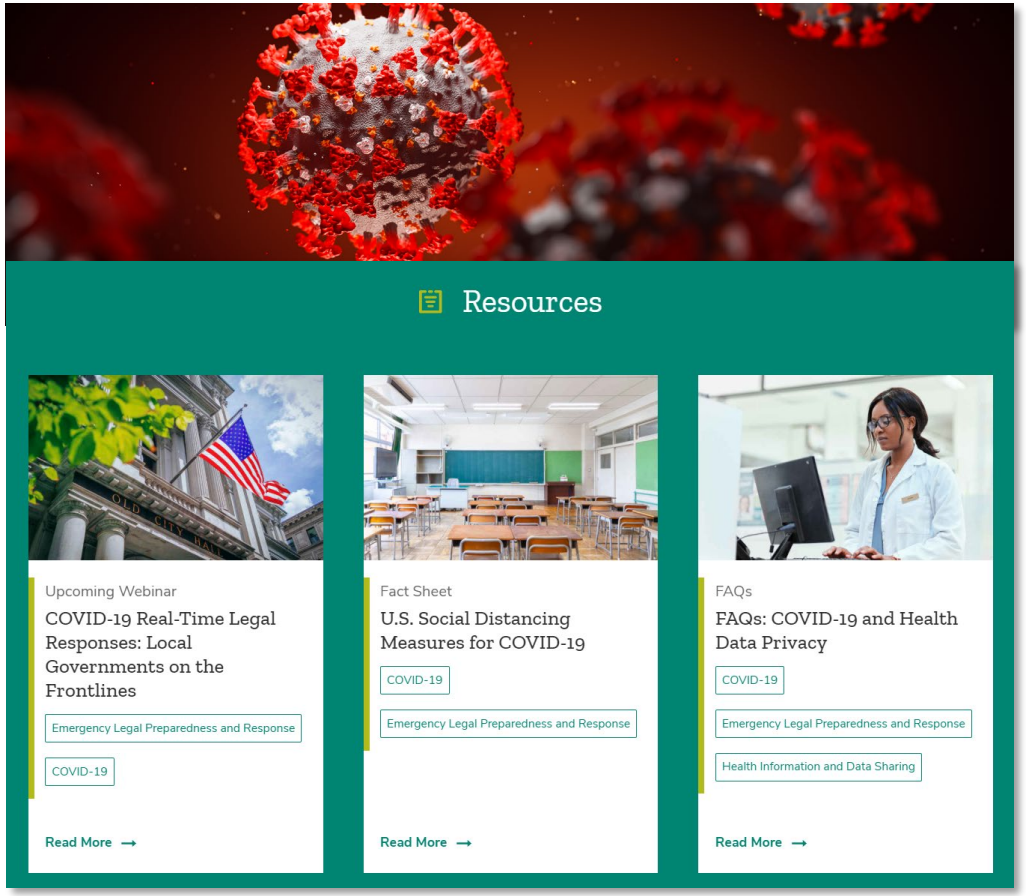

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