Law and Policy: Navigating the Legal Landscape

December 10, 2025

AIM
Association of Immunization Managers

Agenda

- Introductions
- Presentations
  - Richard Hughes IV, JD, MPH
  - Dorit Reiss, LLB, Ph.D.
- Q&A
- AIM Resources

Richard H. Hughes IV, JD, MPH

Partner

Epstein, Becker & Green

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EPSTEIN BECKER GREEN

The State of Vaccine Law and Policy in 2025

Presentation for Association of Immunization Managers

December 10-11, 2025

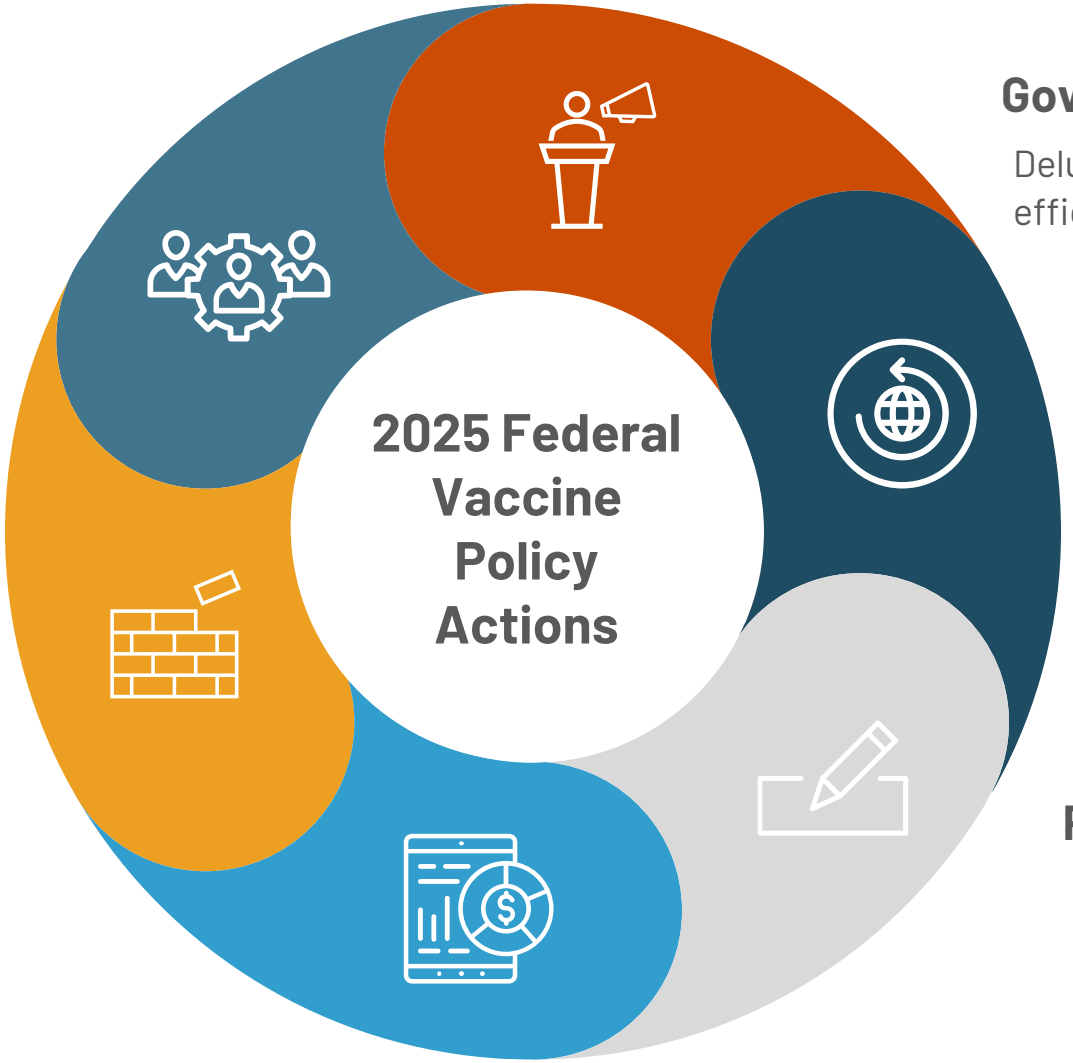
We Have Entered A New Era of Government Policies That Are Meant to Undermine Vaccine Coverage, Access and Innovation

Governance Changes

Firing and replacement of ACIP members, policy by X post

Government-Led Misinformation

Deluge of misleading claims on safety, efficacy, ingredients



Infrastructure Cuts

Funding cuts for state/local health, mass reductions in force

Global Retreat

Withdrawal from WHO and cuts to Gavi, posing health security risks

Research Cuts

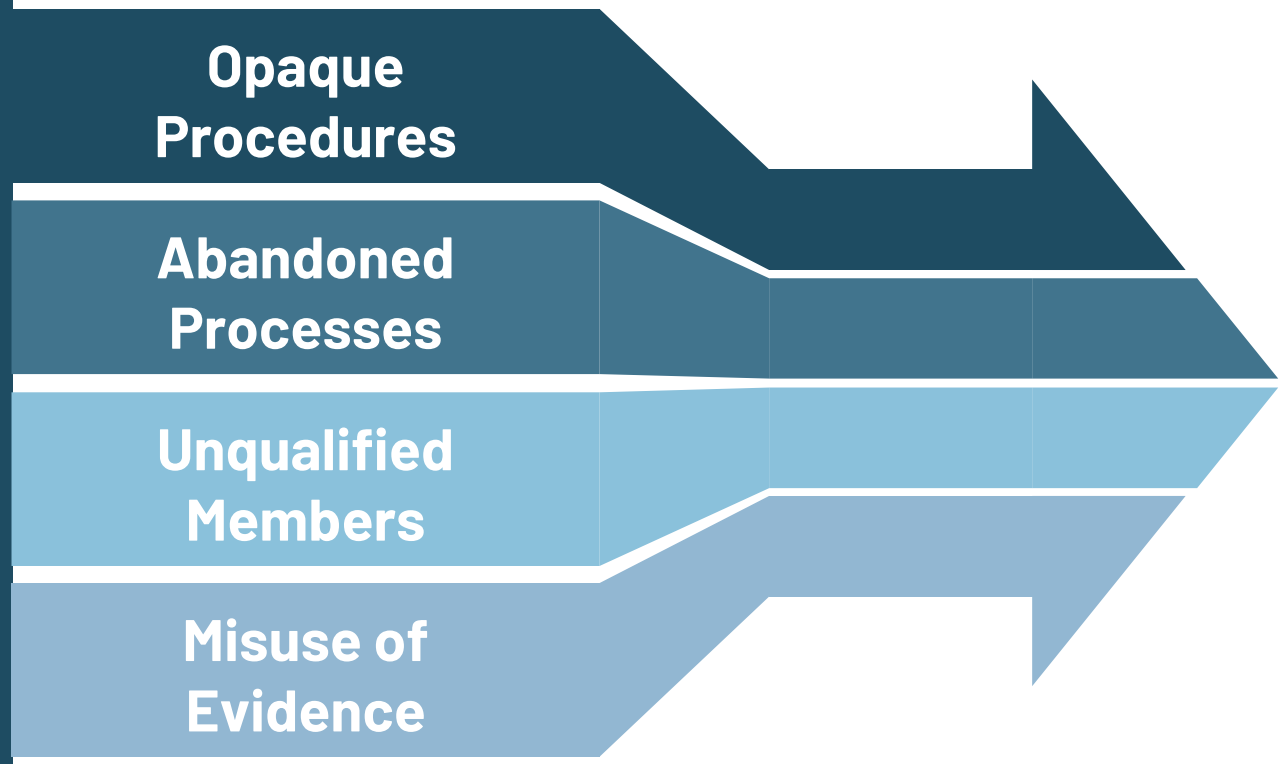
Cancellation of federal vaccine grants on hesitancy and mRNA

Policy and Regulatory Shifts

Recommendation changes, narrowed FDA label, new vaccine frameworks

5

A New, Co-Opted ACIP Poses an Existential Threat to Vaccines



Loss of Scientific Integrity

Decisions lacked transparency and rigor, eroding ACIP's credibility and trust in federal vaccine policy

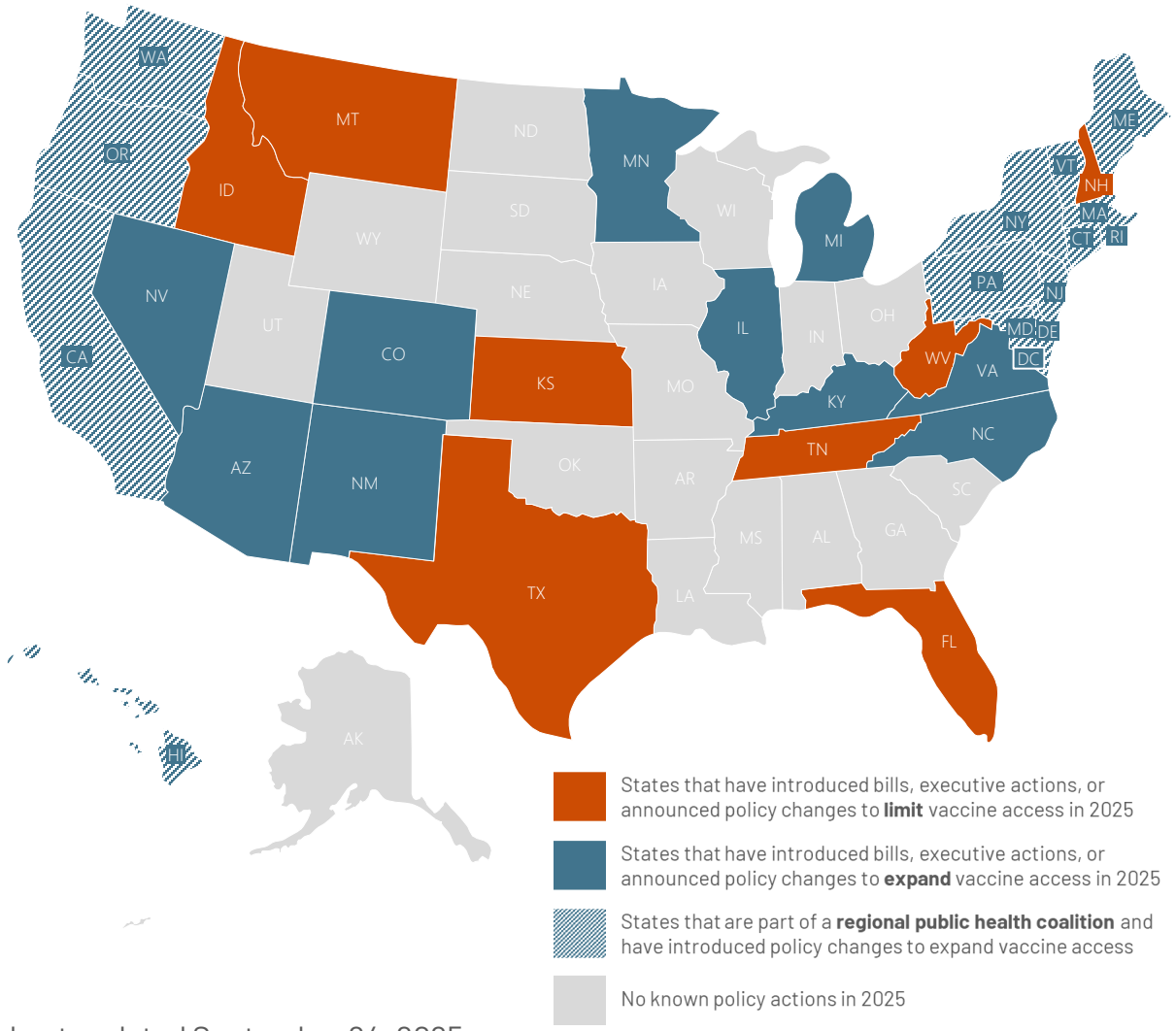
A Platform for Mis- and Disinformation

Anti-vaccine rhetoric is given equal or greater footing with scientific evidence during deliberations

Access and Delivery Issues

The compromised nature of recommendations has fractured standards of care and raised liability concerns

In Today's Polarizing Vaccine Environment, We're Seeing a Shift in Vaccine Federalism, For Better and For Worse



Last updated September 24, 2025.

A Patchwork of Expansions and Limitations in 2025

- In response to downward pressure on federal vaccine policy, 26 states have moved to **allow pharmacists to administer COVID-19 vaccines without a prescription**, and 4 states have extended this to include other vaccines.
- To help ensure coverage, 13 states have moved to **require state-regulated health insurers to cover COVID-19 vaccines at no cost**, and 4 states have expanded this policy to include all vaccines recommended by the state.
- Twenty-two states have specified **non-federal entities** (e.g. AAP, ACOG, and AAFP) **as sources for vaccine recommendations**, either in addition to or instead of CDC/ACIP.
- At the same time, red states are limiting vaccine access by **expanding exemptions, weakening entry requirements**, shifting authority from health agencies to legislatures, and simplifying opt-out processes for parents.

Sources: (1) KFF, Tracking State Actions on Vaccine Policy and Access, September 24, 2025. (2) KFF, State Vaccine Requirements for Children, 2025.

Vaccines Are At a Judicial Inflection Point

1

Federal leadership is pushing an anti-vaccine agenda

Medical societies have challenged recent actions by HHS Secretary Kennedy, NIH Director Bhattacharya and FDA Commissioner Makary

2

VICP is facing an existential threat

The Vaccine Injury Compensation Program (VICP) and broader liability protections are at risk

3

Recent decisions could be a harbinger for what's coming

Describing vaccines as "forced medical treatment" and considering medical and religious exemptions comparable are just some of the recent examples

4

Challenges to further limit vaccine policy are unchecked

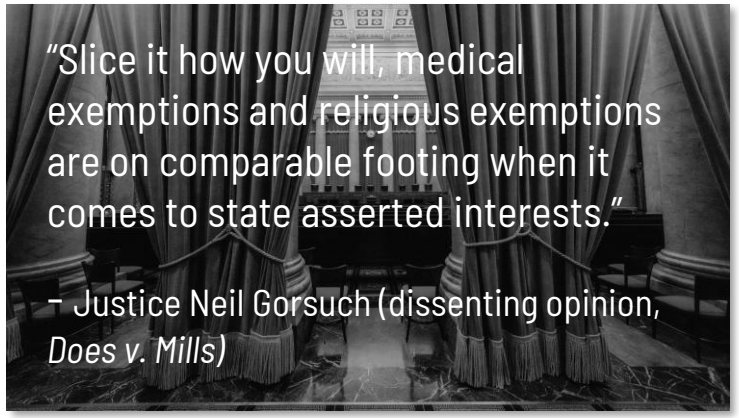
Lawsuits that could advance anti-vaccine viewpoints may not be defended by the administration

The Washington Post
Democracy Dies in Darkness

Public health groups file lawsuit to stop RFK Jr.'s vaccine changes

The lawsuit seeks to overturn Kennedy's decision in May to end the government's long-standing blanket recommendation for children and pregnant women to receive coronavirus shots.

Updated July 7, 2025



UNIVERSITY OF CALIFORNIA LAW
SAN FRANCISCO

Vaccines Legal Update AIM 2025

Dorit R. Reiss

Disclosures:

- The family owns stock (regular) in GSK.

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

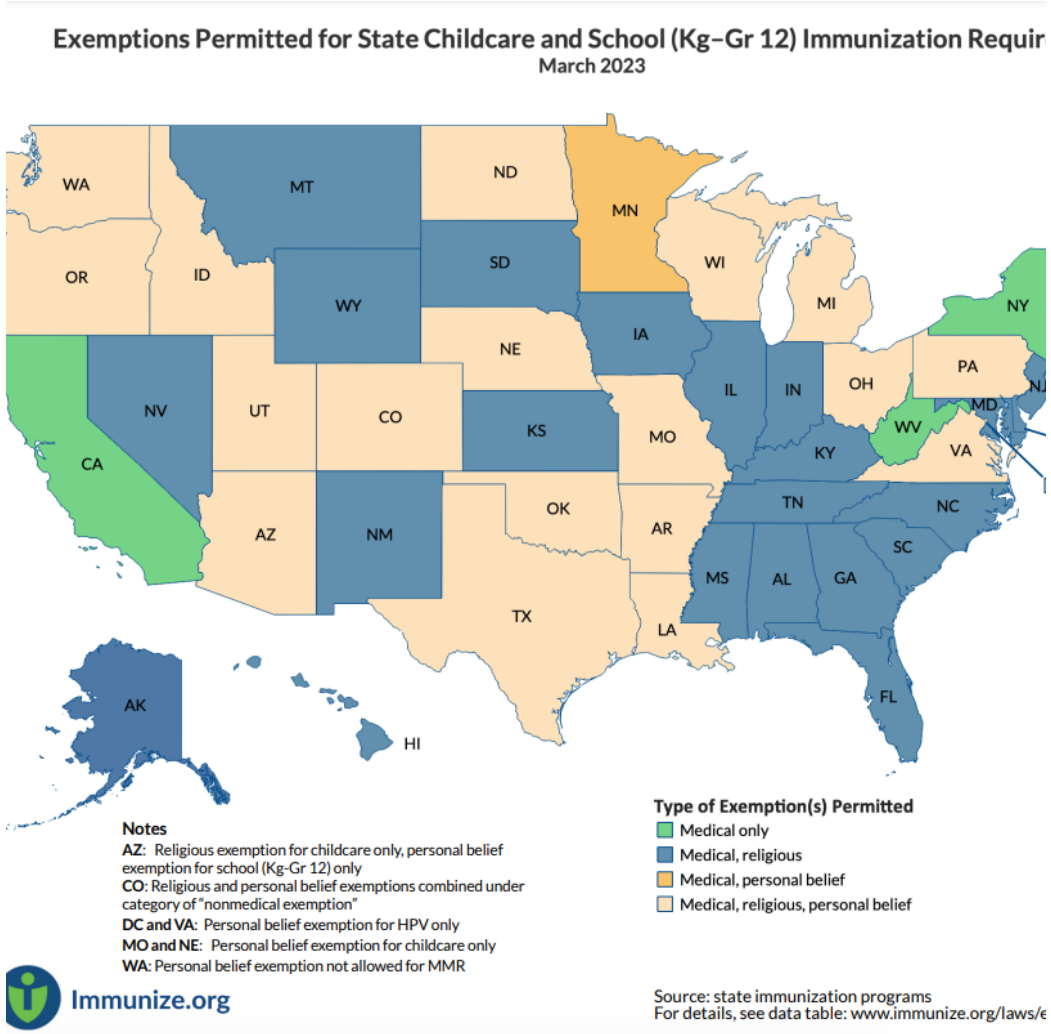
Presentation Plan:

Structure

- School vaccine mandates generally.
- Exemption struggles update.
- VICP.
- Other litigation.

SCHOOL MANDATE STRUGGLES

School Immunization Requirements



State legislation:

- Idaho (more below)
- Florida
- Other states
- GRACE act.

Idaho's School Mandate Generally

- § 39-4801-4804 of the Idaho Code.
- Requires DTaP, Hepatitis A and B, Meningococcal, MMR, Polio, varicella.
- Medical and "religious or other grounds" exemptions.
- Providers need to notify parents of exemptions before administering vaccines.
- Schools/daycares need to notify parents of exemptions.

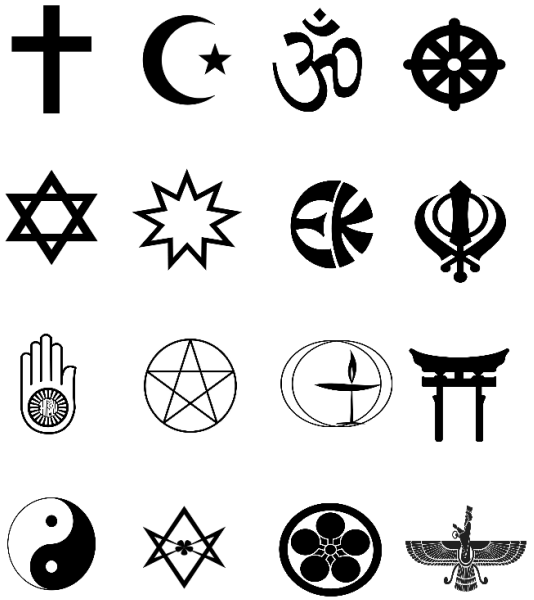
New legislation:

- Enacted – SB1210.
- Still removed workplace mandates.
- Presented by media and activists as removing school mandates.
- In reality, bill preserved existing school mandates.

Key provision in Idaho:

“(4) A school operating in the state or a business subject to chapter 11, title 39, Idaho Code, operating in the state shall not mandate a medical intervention for any person to attend, enter campus or buildings, or be employed, subject to the requirements of the Idaho parental rights act, sections 32-1010 through 32-1015, Idaho Code; sections 39-4801 through 39-4804, Idaho Code; and sections 33-205 and 33-512(7), Idaho Code.”

https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2025/legislation/S1210E2.pdf



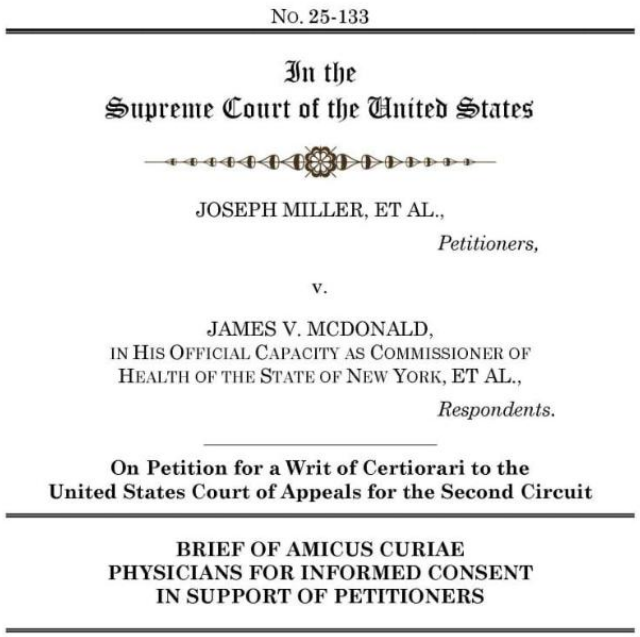
RELIGION AND VACCINES

Generally: a recap

- For decades, religious exemptions from vaccine mandates not required.
- 2020-21: Supreme Court tightened protection of religious freedom.
- Question: is religious exemption required?
- Mixed jurisprudence.
- Also: increased pressure against denying religious exemptions.

Struggles:

- Mississippi
- Connecticut
- California
- New York
- Kansas



No. 25-133

In the
Supreme Court of the United States

JOSEPH MILLER, ET AL.,
Petitioners,

v.

JAMES V. MCDONALD,
IN HIS OFFICIAL CAPACITY AS COMMISSIONER OF
HEALTH OF THE STATE OF NEW YORK, ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

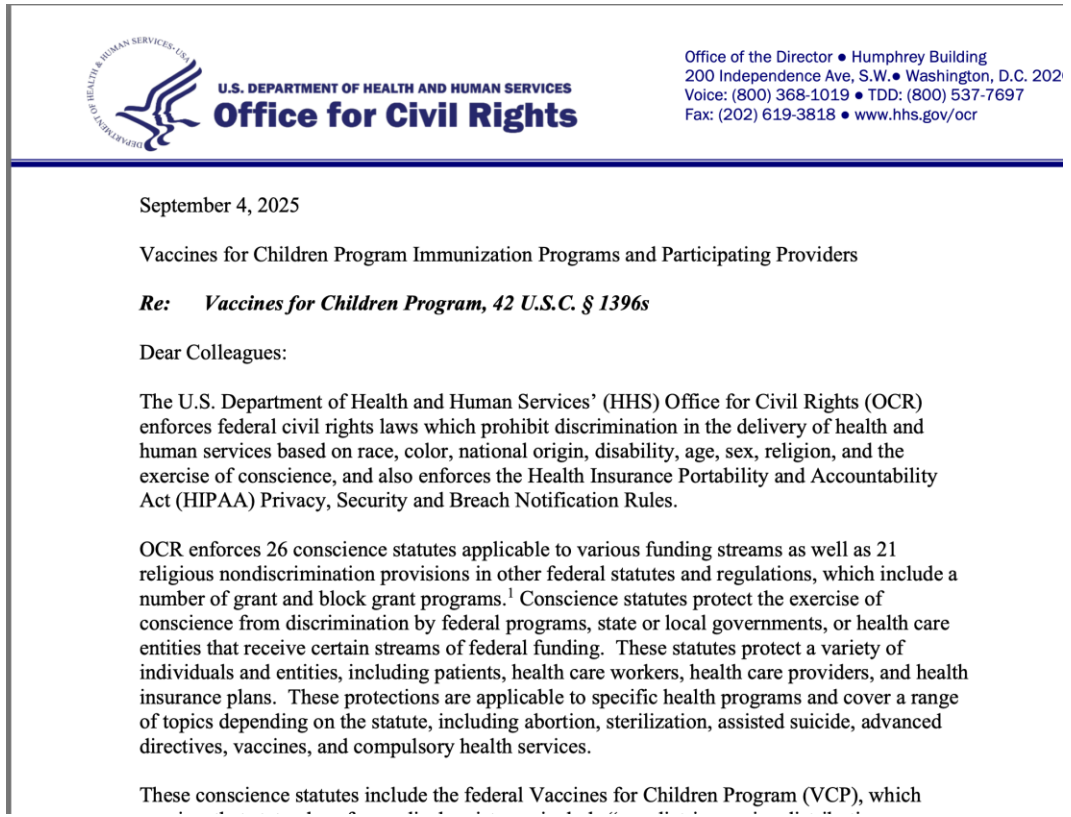
BRIEF OF AMICUS CURIAE
PHYSICIANS FOR INFORMED CONSENT
IN SUPPORT OF PETITIONERS

West Virginia

- Never had a religious exemption.
- Legislative battles.
- Governor Morrisey's E.O.
- Litigation & where we are.

The federal government steps in

- Letter to West Virgina providers.
- Letter to providers in all states.
- Issues:
  - Overreach.
  - Misuse.



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

Office of the Director • Humphrey Building
200 Independence Ave, S.W.• Washington, D.C. 202
Voice: (800) 368-1019 • TDD: (800) 537-7697
Fax: (202) 619-3818 • www.hhs.gov/ocr

September 4, 2025

Vaccines for Children Program Immunization Programs and Participating Providers

Re: Vaccines for Children Program, 42 U.S.C. § 1396s

Dear Colleagues:

The U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) enforces federal civil rights laws which prohibit discrimination in the delivery of health and human services based on race, color, national origin, disability, age, sex, religion, and the exercise of conscience, and also enforces the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security and Breach Notification Rules.

OCR enforces 26 conscience statutes applicable to various funding streams as well as 21 religious nondiscrimination provisions in other federal statutes and regulations, which include a number of grant and block grant programs.[1] Conscience statutes protect the exercise of conscience from discrimination by federal programs, state or local governments, or health care entities that receive certain streams of federal funding. These statutes protect a variety of individuals and entities, including patients, health care workers, health care providers, and health insurance plans. These protections are applicable to specific health programs and cover a range of topics depending on the statute, including abortion, sterilization, assisted suicide, advanced directives, vaccines, and compulsory health services.

These conscience statutes include the federal Vaccines for Children Program (VCP), which

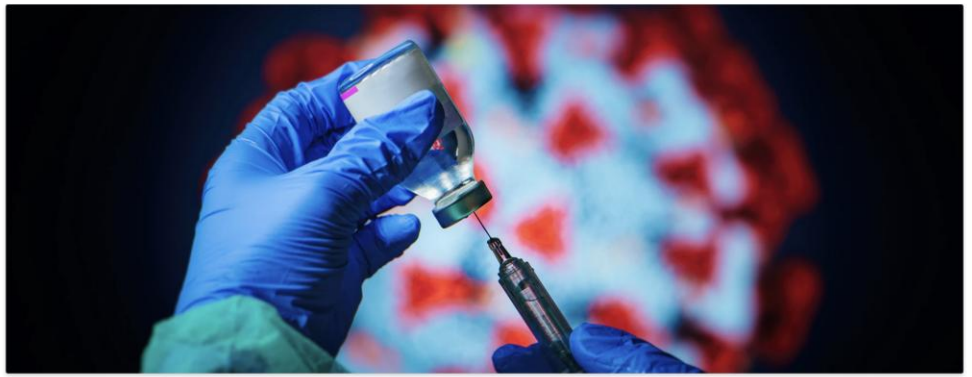
Medical exemptions in New York

- State instituted a supervision process
- Challenges.
- Doe v. Oceanside.
- Anti-vaccine letter.
- Other developments.

National Vaccine Injury Program Needs Modernizing

March 8, 2022, 1:00 AM PST

Renée J. Gentry
George Washington University Law School



Getty Images

The federal program established to compensate Americans for vaccine injuries needs amending, says Renée J. Gentry, director of the Vaccine Injury Litigation Clinic at George Washington Law School. The National Vaccine

Bloomberg

COMPENSATION AND ITS CHALLENGES

No fault systems:

- **Do not show:**
  - Negligence
  - Product defect
  - Other fault
- **Show:**
  - Causation
  - Damages

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

Reminder: Two Programs -

- VICP:
  - Vaccines recommended for children and pregnant people.
  - Relatively easy standard.
  - Limited liability protections
- CICP:
  - For emergency countermeasures.
  - Hard to meet standard.
  - Strong liability protections (PREP)

VICP Process:

https://www.myvaccinelawyer.com/vaccine-injury-lawyer/resources/vaccine/vicp/?utm_source=adwords&utm_medium=ppc&utm_term=vicp&utm_campaign=2019-2020+Vaccine+Campaign&hsa_acc=6279629756&hsa_kw=vicp&hsa_grp=179622247634&hsa_net=adwords&hsa_src=g&hsa_ad=739458714957&hsa_mt=b&hsa_ver=3&hsa_cam=6548094361&hsa_tgt=kwd-341440681&gad_source=1&gad_campaignid=22352095387&gbraid=0AAAADLwlw9aV19kmIM7QJ_M7dhhnBG69&gclid=Cj0KCQjwzOvEBhDVARIsADHfJJR7fNvQIiY4m3_07HYDJ36yTLJKD3ciH_mpnviOCVyJyCVzaUesZNEaArFMEALw_wcB

An individual files a petition with the U.S. Court of Federal Claims.

The U.S. Department of Health and Human Services (HHS) medical staff reviews the petition, determines if it meets the medical criteria for compensation and makes a preliminary recommendation.

The parties may begin settlement discussions at this time, or HHS could choose to defend the case if they believe it does not qualify for compensation.

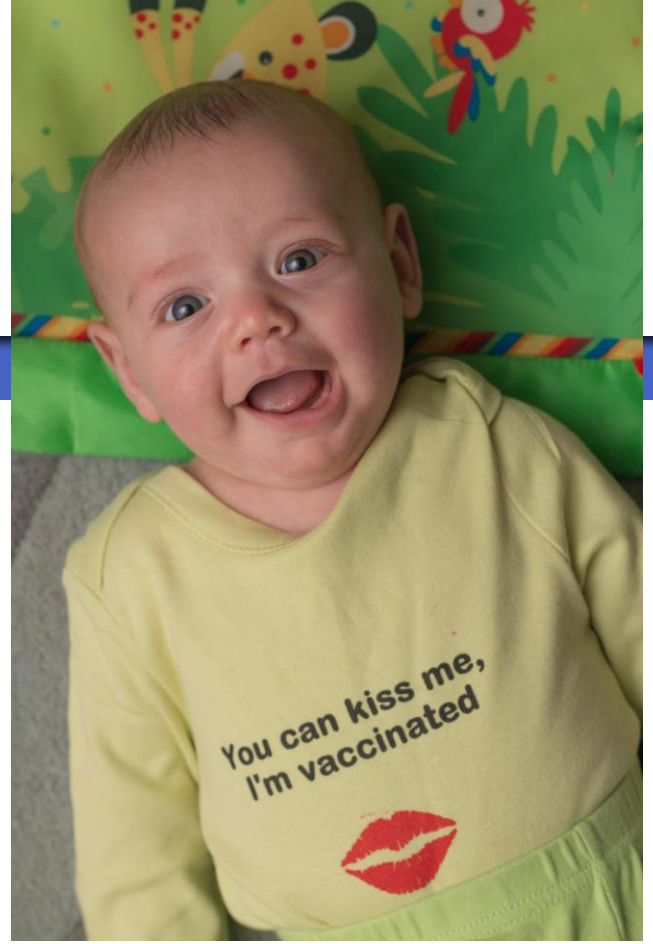
If HHS chooses to defend the case, sometimes the parties will retain medical experts to support their side, and in a rare case, petitioners can go to a hearing in front of a Special Master.

If the case is decided in favor of the petitioner, the Court orders the U.S. Department of Health and Human Services to award compensation.

The special master's decision may be appealed and petitioners who reject the decision of the court (or withdraw their petitions within certain timelines) may file a claim in civil court against the vaccine company and/or the health care provider who administered the vaccine.

Under new administration:

- Representative Paul Gosar: bill to remove immunity/statute of limitations.
- States bills on liability.
- Kennedy's steps:
  - Changes to ACIP relevant.
  - Looking to reform systems – details hidden.
  - Rumor: will add autism to table somehow.
  - Question: COVID-19 vaccines.
    - Lawsuit dismissed.

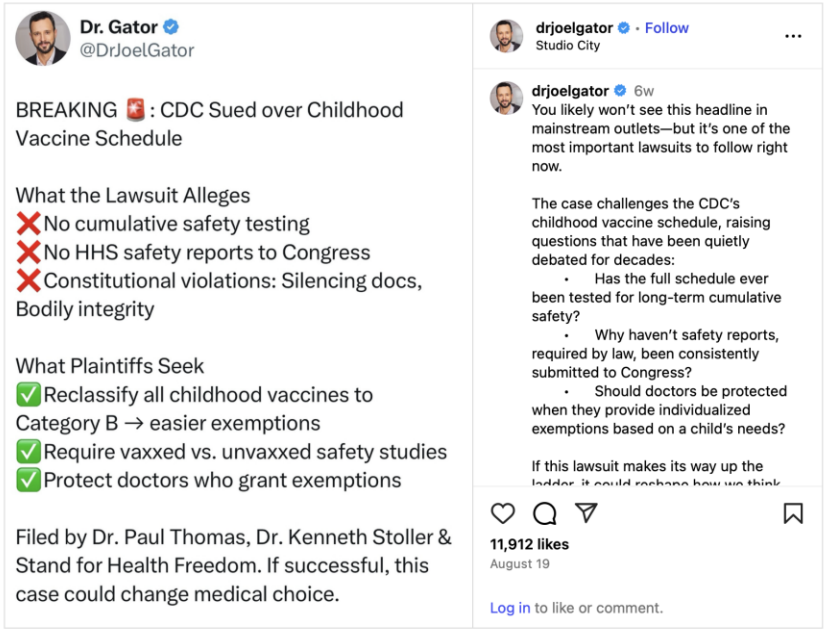


OTHER LAWSUITS

The Thomas/Stoller litigation

- Who are they?
- What are they claiming?

- Early days yet.
- One concern: government may conceded.



Dr. Gator
@DrJoelGator

BREAKING 🚨: CDC Sued over Childhood Vaccine Schedule

What the Lawsuit Alleges
❌No cumulative safety testing
❌No HHS safety reports to Congress
❌Constitutional violations: Silencing docs, Bodily integrity

What Plaintiffs Seek
✅Reclassify all childhood vaccines to Category B → easier exemptions
✅Require vaxxed vs. unvaxxed safety studies
✅Protect doctors who grant exemptions

Filed by Dr. Paul Thomas, Dr. Kenneth Stoller & Stand for Health Freedom. If successful, this case could change medical choice.

drjoelgator · Follow
Studio City

drjoelgator 6w
You likely won't see this headline in mainstream outlets—but it's one of the most important lawsuits to follow right now.

The case challenges the CDC's childhood vaccine schedule, raising questions that have been quietly debated for decades:

- Has the full schedule ever been tested for long-term cumulative safety?
- Why haven't safety reports, required by law, been consistently submitted to Congress?
- Should doctors be protected when they provide individualized exemptions based on a child's needs?

If this lawsuit makes its way up the

11,912 likes
August 19

Log in to like or comment.

Thank you!

Questions? Comments?

reissd@uclawsf.edu
415-5654844

Q&A

immunizationmanagers.org

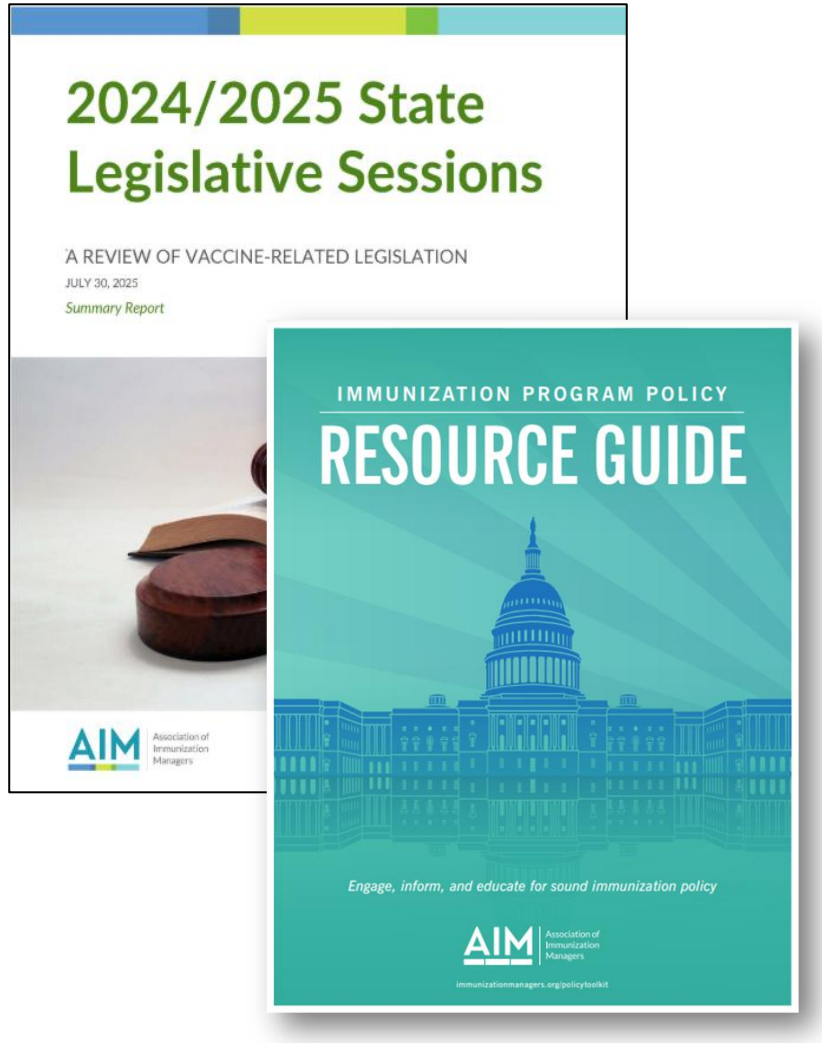
@AIMimmunization

Association of Immunization Managers

AIM Association of Immunization Managers

AIM Legislative Resources

- Legislative Analysis & Individual Consultation
- Pre-Legislative Session Webinar
- Talking Points and Infographics
- Advocacy Resources
- Resource Guide



2025 AIM Leadership in Action Conference
Palm Springs, CA
December 9-11

Please Complete: Evaluation

- The AIM Leadership in Action conference aims to serve our members and partners by facilitating idea sharing, leadership training, and connection.
- Please complete the session specific evaluation in the conference app now and be sure to complete the full conference survey on Thursday.
- Our goal is to make next year's conference even better. Thank you!

Complete the evaluation for this session in the **conference app.**

Thank you!

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