

Law & Policy Barriers to Vaccination

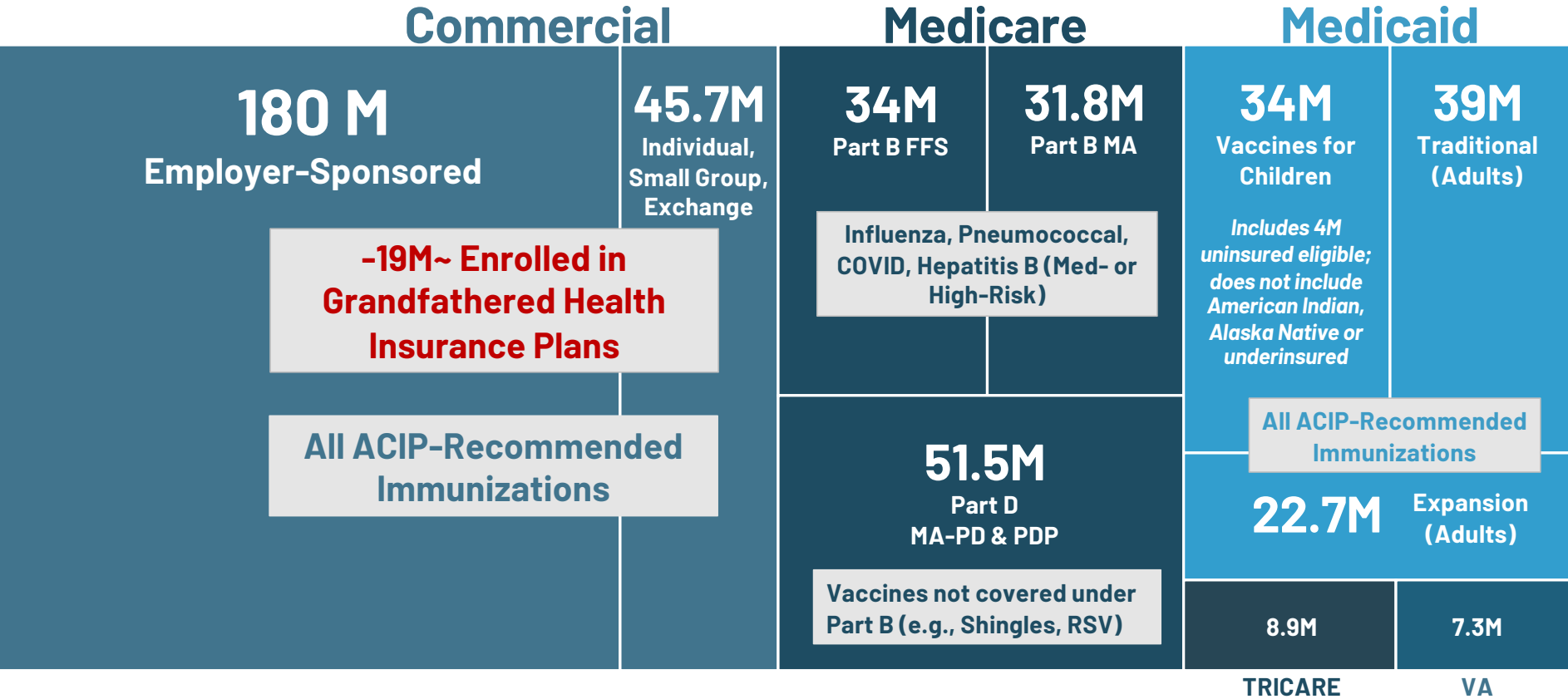
April 2024

Agenda

- Overview
- Vaccine Access
 - Overview of vaccine access issues
- Judicial Threats and Liability
 - Overview of *Braidwood v. Becerra*
 - Vaccine mandates and misinformation

Immunization Coverage in the United States

More than 21 million Americans do not have a source of coverage for vaccines



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Braidwood v Becerra

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**



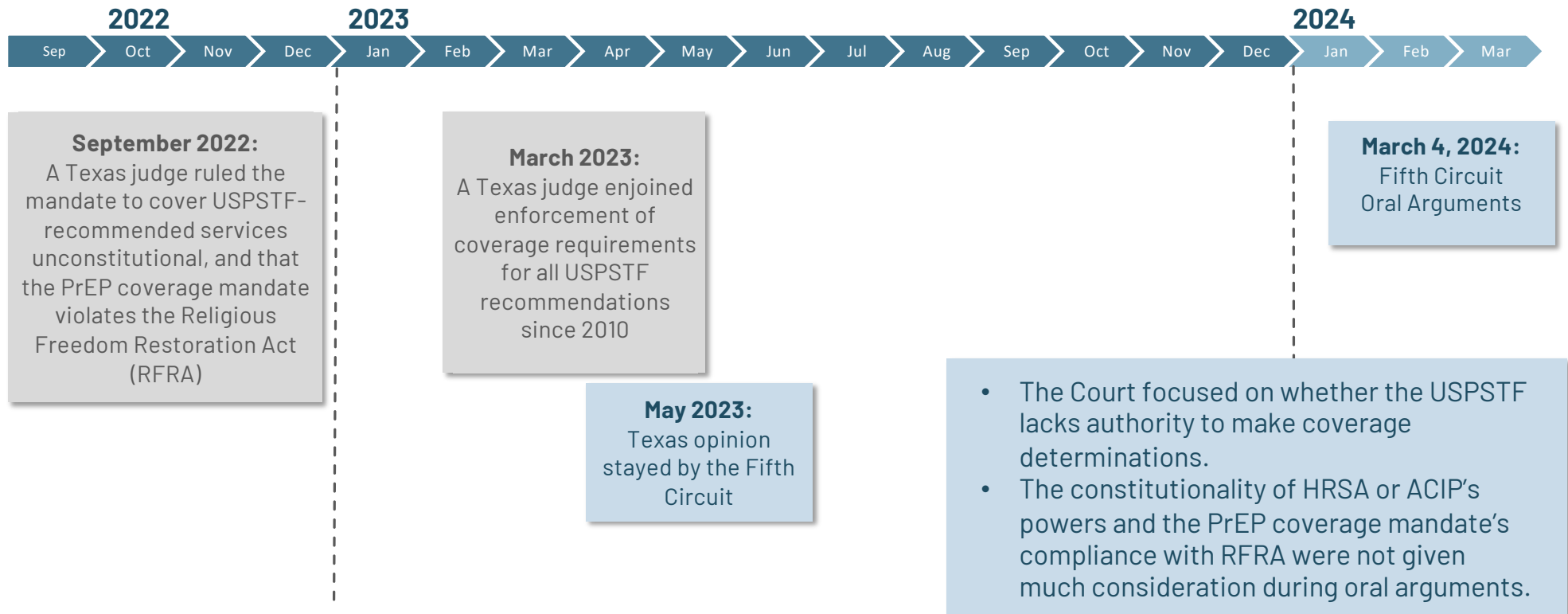
**Women's Services Such as
Contraceptives**

***Braidwood* may impact preventive coverage for over 150M Americans with private insurance, nearly 23M with Medicaid expansion coverage**

Braidwood v. Becerra Threatens Preventive Coverage, Including for PrEP and Vaccinations

Who are the <i>Braidwood</i> plaintiffs?	What are the plaintiffs claiming?	What does this mean for preventive coverage?
Employers who have religious objections to covering certain preventive recommendations, believing it makes them complicit in encouraging behaviors they disagree with (e.g. sex outside of heterosexual marriage, drug use)	<p>That recommending bodies' authority to determine coverage requirements under the ACA is unconstitutional under the Appointments Clause</p> <p>That the requirement to cover PrEP violates the Religious Freedom Restoration Act (RFRA) and that they should be allowed an exemption similar to the contraceptive mandate exemption</p>	<p>Requirements to cover PrEP, vaccines, screenings and other preventive interventions are at stake in the case</p> <p>While USPSTF and PrEP has been a focal point in the case, the current appeal involves all recommending bodies and all preventive interventions</p>

Braidwood v. Becerra: Case Timeline



Coverage of key recommendations will remain in effect until a decision is made by the Fifth Circuit

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What Happens Next?

Several Potential Fifth Circuit Outcomes are Possible

Scenario 1: Fifth Circuit *upholds* lower court decision

- Requirement to cover USPSTF recommendations is enjoined or invalidated
- Subsumes any remaining RFRA challenge at the lower court level

There is **high risk** that commercial payers and Medicaid expansion plans will no longer be obligated to cover PrEP

There is **high risk** that commercial payers and Medicaid expansion plans will no longer be obligated to cover recommended screenings

Scenario 2: Fifth Circuit *overturns* lower court decision

- Requirement to cover USPSTF recommendations is left intact
- The plaintiffs may seek a remedy from the lower court on its RFRA claims, including injunctive or declaratory relief
- The ruling may compel the Biden administration to either **halt enforcement** of the mandate or to establish an **exemption process** akin to that for the contraceptive mandate.

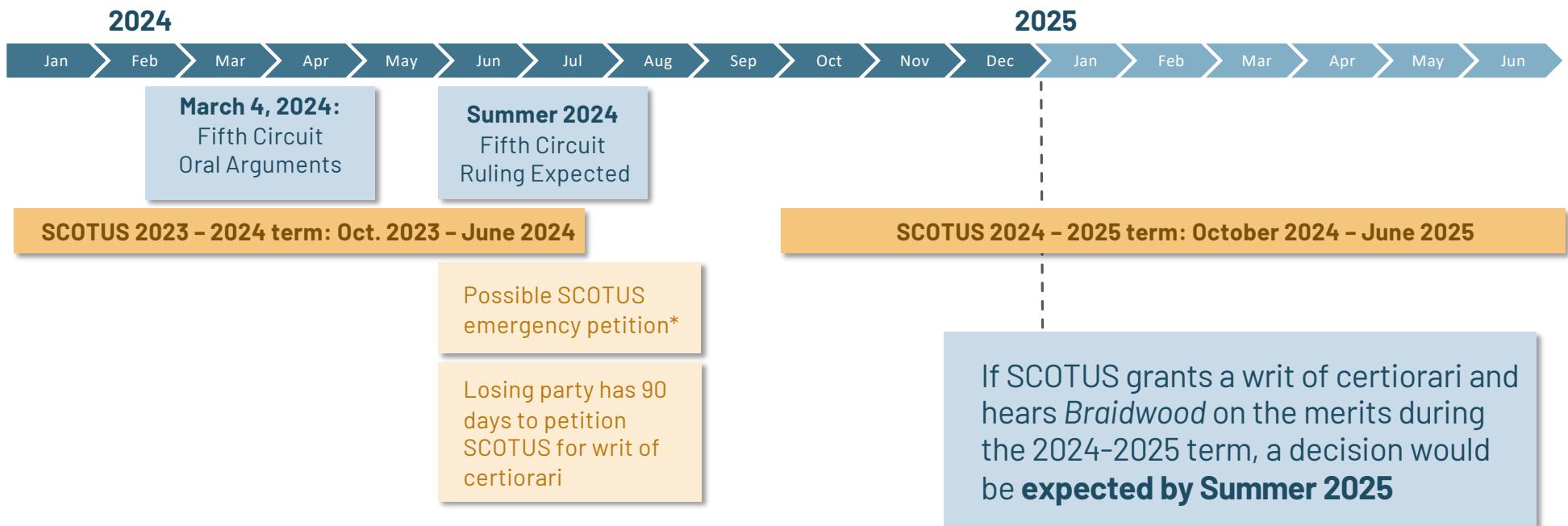
Scenario 3: Fifth Circuit *accepts* the plaintiffs' arguments with respect to the USPSTF, HRSA, and ACIP

- Requirement to cover all recommendations is enjoined or invalidated in its entirety
- Subsumes any remaining RFRA challenge at the lower court level

There is **low/moderate risk** that payers will no longer be required to cover any recommended preventive services

Braidwood v. Becerra: Anticipated Appeal Timeline

After the Fifth Circuit's decision, an appeal to the Supreme Court of the United States is likely



The Fifth Circuit is likely to uphold the lower court decision, followed by appeal to SCOTUS

*An emergency petition to SCOTUS is filed outside of the regular docket and seeks temporary relief if a party believes it will face irreparable harm from a lower court's decision, allowing the Court to decide without a full hearing

Even if Coverage Requirements Remain Intact, Religious Exemptions to PrEP, Some Vaccines Are Likely in the Future

- Initially, the *Braidwood* plaintiffs raised religious objections to a wider range of recommended interventions, including:
 - “Abortifacient contraception”
 - HPV vaccine
 - Screenings and behavioral counseling for sexually transmitted disease and drug use
- Only the claim that the PrEP coverage mandate violates RFRA was decided by the lower court, which sided with the plaintiffs

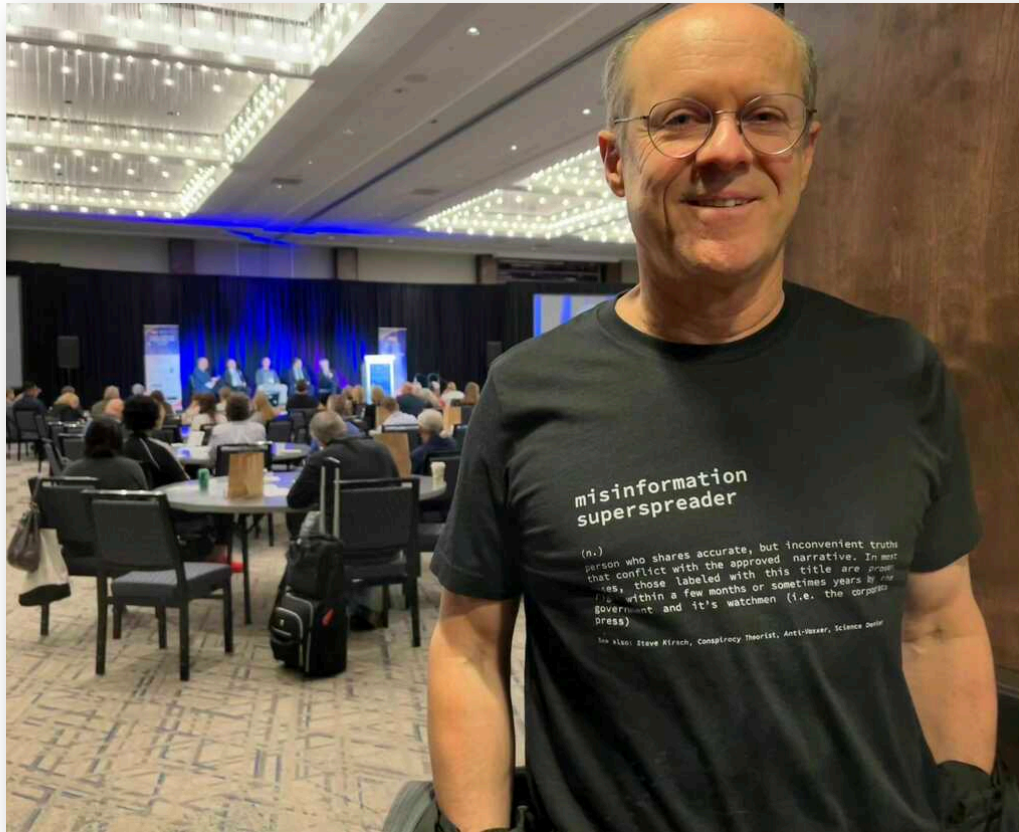
Several future RFRA developments are likely:

- Additional RFRA claims against various recommended services
- If the USPSTF survives constitutional claims, the Texas court may order the Biden administration to create an exemption process for PrEP coverage similar to the current contraceptive mandate exemption
- The administration may create this process on its own to mitigate opposition
- Additional future litigation and advocacy for further RFRA exemptions is likely for certain vaccines and screenings

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Judicial Threats

Anti-Vaccine Advocates Have Entered the Courts



Manufacturers are a target

"Their proposed targets include hospitals, school systems, medical licensing boards and, **the holy grail, pharmaceutical companies that make vaccines.**"

A major benefactor and organizer stated, "My goal is to expose every single one of these a**holes" and was met with "uproarious applause."

NPR, As the pandemic winds down, anti-vaccine activists are building a legal network (May 4, 2023), <https://www.npr.org/2023/05/04/1173697394/as-the-pandemic-winds-down-anti-vaccine-activists-are-building-a-legal-network>

The New Frontier: The COVID-19 Pandemic Has Resulted in an Unprecedented Influx in Vaccine Related Litigation

Lawsuits over military vaccine mandate to continue despite DOD rescinding it

Lawsuits still piling up over hospital vaccine mandates

Blue Cross faces flurry of new lawsuits over vaccine mandate

NY vaccine mandate for healthcare workers 'null, void' following judge ruling

Challenges Against Employer COVID-19 Vaccine Mandates Show No Sign of Slowing

Politico, Anti-vaxxers are now a modern political force (September 24, 2023),
<https://www.politico.com/news/2023/09/24/anti-vaxxers-political-power-00116527>

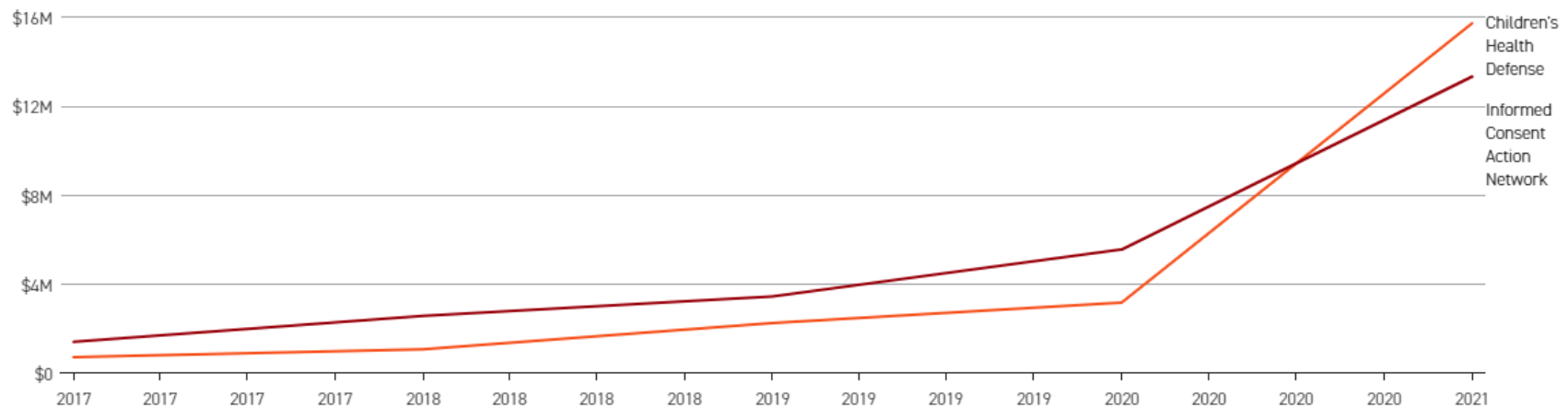


“Del Bigtree said Informed Consent Action Network had been able to hire more lawyers and scientists, with its staff more than doubling compared to pre-pandemic levels.”

Politico, Anti-vaxxers are now a modern political force (September 24, 2023),
<https://www.politico.com/news/2023/09/24/anti-vaxxers-political-power-00116527>

Anti-Vaccine Nonprofits Saw Revenues Spike During the COVID-19 Pandemic

Total revenues for Children's Health Defense and the Informed Consent Action Network from 2017-2021



Source: POLITICO analysis of nonprofit tax filings
Jessica Piper/POLITICO

Politico, Anti-vaxxers are now a modern political force (September 24, 2023),
<https://www.politico.com/news/2023/09/24/anti-vaxxers-political-power-00116527>

Anti-Vaccine Litigants Have Clear Objectives

■ Following the model that led to *Dobbs*

- "And I think like we saw with *Roe v Wade*, you had a case that was passed 50 years ago and then had various chips away at it until the ground crumbled"

■ "Winning" even if not on legal grounds

- "Cases don't even have to succeed in court to have an impact . . . Influencers and headlines can frame settlements, technical legal outcomes or compelling, emotional testimony as victories for one side or another"

■ Taking advantage of SCOTUS focus

- "She said these lawsuits also come at a time when the Supreme Court is weakening the powers of many regulators."

■ Leveraging COVID fatigue and frustration

- "keeping COVID-related grievances alive in the courts may also help sustain the larger movement against vaccines"

NPR, As the pandemic winds down, anti-vaccine activists are building a legal network (May 4, 2023),
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Vaccine Mandates at SCOTUS After A Century Hiatus



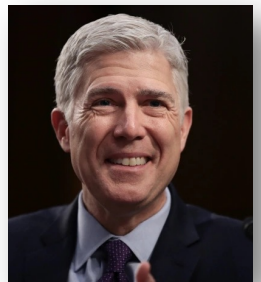
"Three Courts of Appeals and one State Supreme Court agree that such requirements are not neutral or generally applicable and therefore trigger strict scrutiny."

- Justice Clarence Thomas (dissenting opinion, *Dr. A. v. Hochul*, re: health care work vaccination requirements)



"Slice it how you will, medical exemptions and religious exemptions are on comparable footing when it comes to state asserted interests."

- Justice Neil Gorsuch (dissenting opinion, *Does v. Mills*)



Vaccine Litigation Undermines Public Health Authority, Vaccine Confidence

Some decisions have misconstrued vaccine evidence, delivering fodder for vaccine disinformationists.

“It is clear such expertise was not utilized as the COVID-19 shots do not prevent transmission”

– Judge Gerard Neri, New York State Supreme Court, Onondaga County



Several Supreme Court justices and circuit courts of appeal have indicated a willingness to revisit well-settled public health authority.

“Nothing in *Jacobson* purported to address, let alone approve, such serious and long-lasting intrusions into settled constitutional rights.”

– Justice Neil Gorsuch (dissenting opinion, *Roman Catholic Diocese v. Cuomo*, re: social distancing measures)

Norris v. Stanley Could Turn Back the Clock on Over 120 Years of Public Health Law

1905: *Jacobson v. Massachusetts*



Allowed States to enforce vaccination under police powers under “rational basis scrutiny”

There are policies in all 50 states designed to safeguard children, healthcare workers, daycare employees, college students, and particularly vulnerable patients from vaccine-preventable illnesses

These policies help protect vaccinated individuals and build herd immunity

2024: *Norris, et al. v. Stanley, et al.*



May essentially overturn *Jacobson*, upending public health law and requiring more stringent scrutiny of vaccine mandates

Heightened judicial standards may weaken state mandates, threatening herd immunity and allowing suppressed diseases to resurface