

Law and Policy: Navigating the Post- Pandemic Legal Landscape for Vaccines

December 11, 2024



Association of
Immunization
Managers

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UNIVERSITY OF CALIFORNIA
HASTINGS SCHOOL OF LAW

Compensation Programs and Religion: Vaccines and the Law

Dorit R. Reiss



Disclosures:

- The family owns stock (regular) in GSK.
- Served as a volunteer (unpaid) advisor on Moderna's ethics advisory group

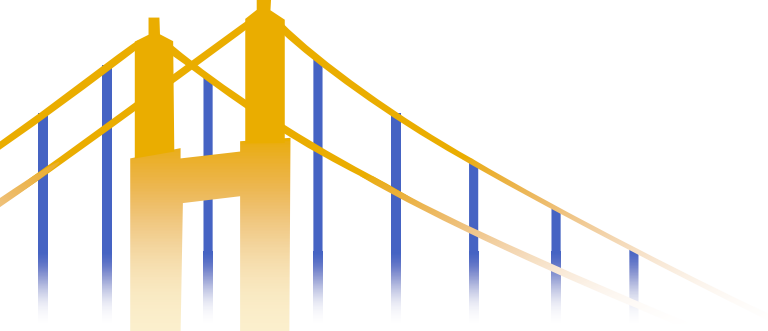
Presentation Plan:

Structure

- Compensation and the new administration
- Religion:
 - The First Amendment jurisprudence.
 - The Civil Rights Act of 1964 and its developments
- Misinformation:
 - Ongoing *Murthy v. Missouri*.



<https://www.tennessean.com/story/news/health/2021/02/03/COVID-19-vaccine-distribution-sign-up-tennessee/4358791001/>



“Wayne Rohde has performed a valuable public service.”
—Robert J. Krakow, Attorney-at-Law

THE
**VACCINE
COURT**
2.0
REVISED AND UPDATED

The Dark Truth
of America's
Vaccine Injury
Compensation
Program



**WAYNE
ROHDE**
Foreword by
ROBERT F. KENNEDY, JR.

COMPENSATION PROGRAMS AND VACCINES



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)



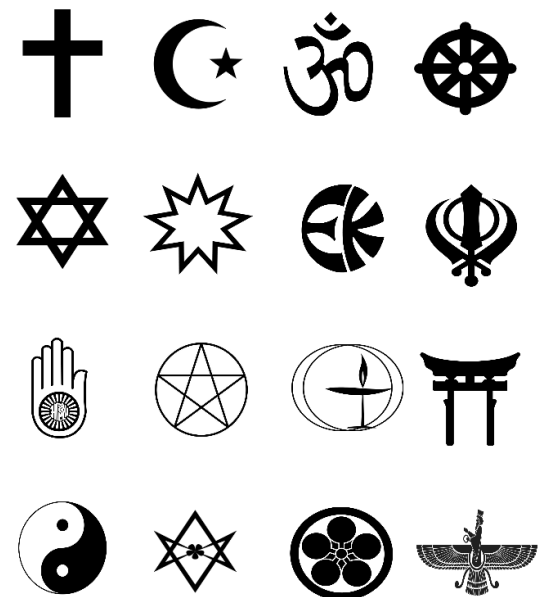
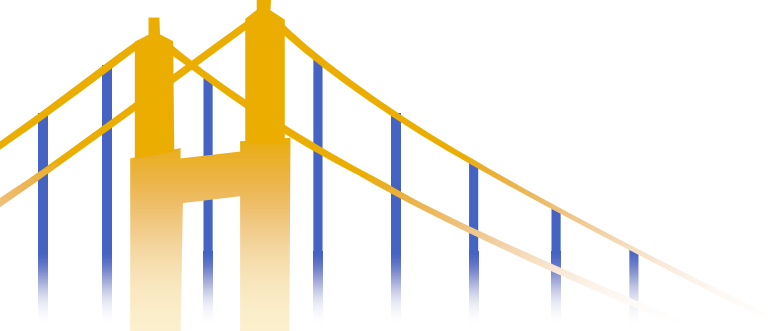
Note:

- How broad liability is under a PREP act declaration is being litigated:
 - For plaintiffs claiming vaccine injury, most federal circuits found liability protections should be limited.
 - For plaintiffs claiming non-consented vaccine application, most state courts found claims preempted.



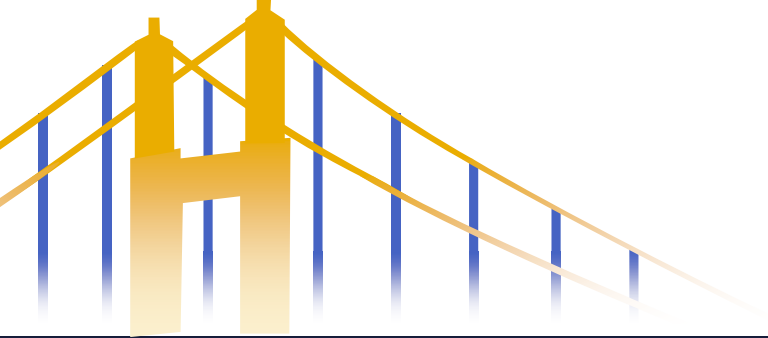
Under new administration:

- Bill to overturn National Childhood Vaccine Injury Compensation Act and VICP by Rep. Gosar likely to be reintroduced.
- Removing vaccines from table? But:
 - Requires rulemaking procedures.
 - Subject to judicial review.
- Potential overturning of PREP declaration for COVID-19 and flu vaccines.

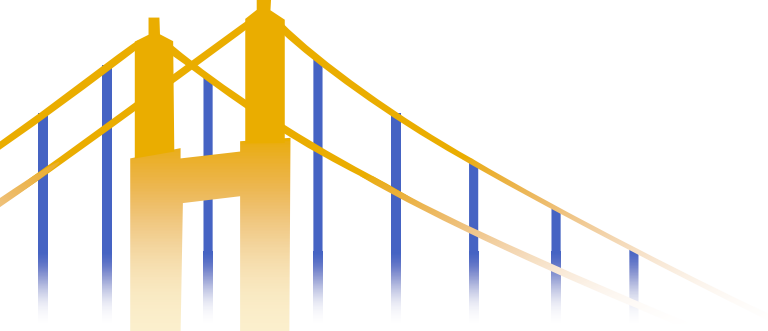


By Pass a Method - Own work, CC BY-SA 3.0,
<https://commons.wikimedia.org/w/index.php?curid=25255735>

FREEDOM OF RELIGION



THE FIRST AMENDMENT'S FREE EXERCISE CLAUSE



Do you need to offer a religious exemption?

Maybe



The Federal Framework:

RCD v.
Cuomo

2020

Tandon v.
Newsom

2021

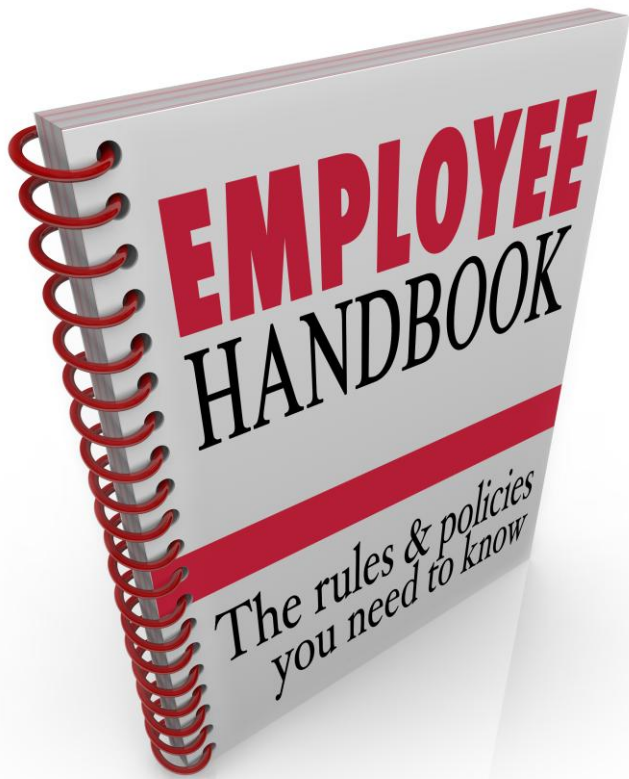
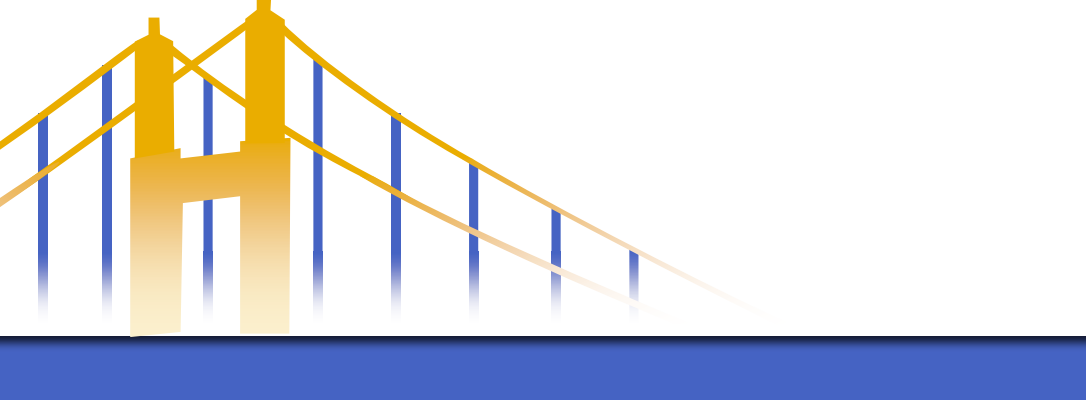
Fulton v. City
of
Philadelphia

2021



Free exercise clause, bottom line:

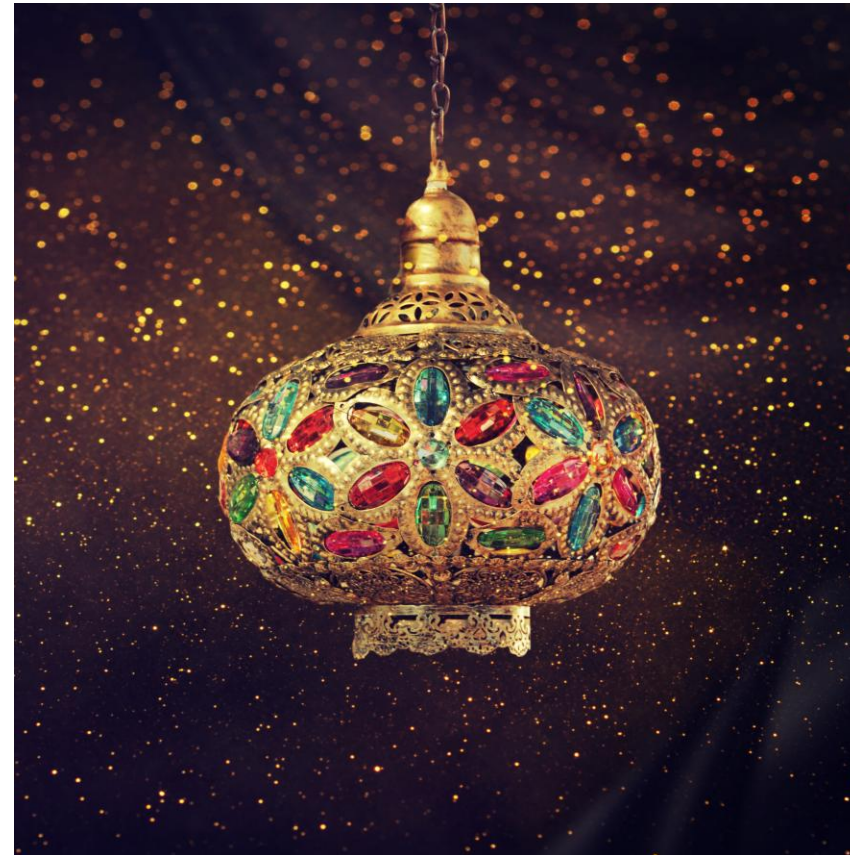
- If you have no exemptions, you're probably fine.
- If there's evidence of hostility to religion or if you target religious practices, you need to meet strict scrutiny.
- If you offer a secular exemption, you need to offer a religious exemption.
 - Question: Medical exemption? Bosarge – but qualification.



MANDATES 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...”





It has to be religious:

- *Fallon v. Mercy Catholic Center: Three-part test:*
 1. Religion addresses fundamental and ultimate questions.
 2. Religion requires a comprehensive belief system, not isolated teaching.
 3. Religion is often recognized by formal and external signs.
- *But – Ringhofer v. Mayo Clinic:*
 - Claims
 - Testing and masking
 - Very mixed jurisprudence right now.

It has to be sincere; pitfalls in evaluating – you:

- Cannot require letter from clergy.
- Cannot refuse just because official religion pro-vaccine.
- Should not try to assess rationality.
- Can you reject if also safety arguments?



Undue Burden:

- Groff v. Dejoy.
- “...an employer must show that the burden of granting an accommodation would result in substantial increased costs in relation to the conduct of its particular business.”
- “courts must apply the test in a manner that takes into account all relevant factors in the case at hand, including the particular accommodations at issue and their practical impact in light of the nature, ‘size and operating cost of [an] employer’.”



Jury decisions:

- Tennessee

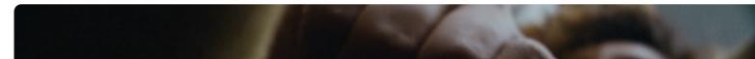
- CA – BART

- Michigan

Michigan jury awards millions to a woman fired after refusing to get a COVID-19 vaccine

A jury has awarded more than \$12 million to a woman who lost her job at a Michigan insurance company after declining to get a COVID-19 vaccination

By ED WHITE Associated Press
November 8, 2024, 2:35 PM



The First Trump Administration:

- Tightened protection of religious freedom in the healthcare sector:
 - The Conscience Freedom rule.
 - Amended to remove vaccines.
 - <https://www.regulations.gov/document/HHS-OCR-2018-0002-0001>

The screenshot displays the Regulations.gov website interface. At the top, the logo "Regulations.gov" is visible with the tagline "Your Voice in Federal Decision Making" and a "Data" link. Navigation buttons for "SUPPORT" and "FEEDBACK" are on the right. Below the header, the breadcrumb "Docket (HHS-OCR-2018-0002) / Document" is shown. The main content area features a "PROPOSED RULE" label and the title "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority", posted by the Department of Health and Human Services on Jan 25, 2018. A "Share" button is present. Below the title, there are two tabs: "Document Details" (selected) and "Browse Comments" (72.41K). The "Document Details" tab shows a green checkmark icon, the document ID "HHS-OCR-2018-0002-0001", and "Comments Received" of 72,417. The "Content" section shows the "Action" as "Proposed rule."



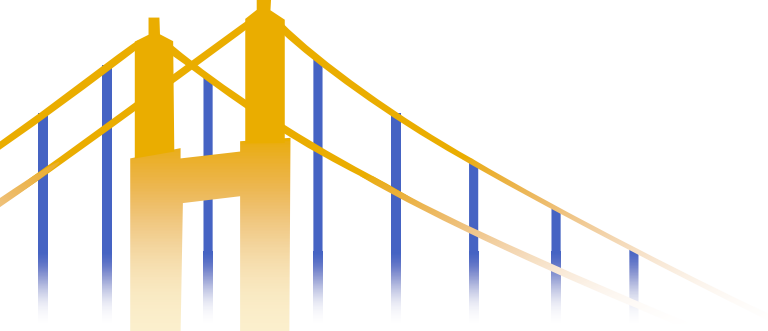
Found arbitrary and capricious:

- Why?
- “HHS also stated that, beginning in November 2016, there had been a **“significant increase” in the number of complaints** that OCR received relating to the Conscience Provisions. *Id.* HHS expressed hope that the new Rule would give it “the proper enforcement tools” to “enforce all Federal conscience and anti- discrimination laws.””



Actual facts...



- 358 complaints were filed with OCR between November 2016 and the end of fiscal year 2018
- Of these 336, 266—or 79%—relate to vaccinations, which HHS admits fall outside the scope of the Conscience Provisions and the Rule.
- additional 49 complaints that are unrelated to the Conscience Provisions because they, *inter alia*, oppose the Rule, involve entities not covered by the Rule, or do not allege conduct covered by the Rule...
- This leaves 21—or a mere 6% of the 336 unique complaints—that are *potentially* related to the Conscience Provisions



Thousands of religious exemptions have been approved!
For anyone else who is mandated...

Religious Exemption Workshop 12/07 @ 7pm EST

In this three hour workshop, Cait Corrigan will provide you with everything you need to write a successful religious exemption with conviction. (Including scriptures & example religious exemption letters in a powerpoint presentation) The following faiths will be covered: Catholic, Christian, Baptist, Greek and Russian Orthodox, Protestant, Lutheran, Unitarian Universalist, Quaker, Mormon, Jewish, Buddhist, Taoist, Hindu, Muslim, Pagan/Wiccan.

 **TRINITY THREE MINISTRY** 
PRIVATE MINISTERIAL ASSOCIATION AND SPIRITUAL MINISTRY

MANAGING EXEMPTIONS: WHAT CAN YOU DO?

Have a process:

26

- Who is covered?
- Who decides?
- How do people apply?
 - Timeline.
 - Format.
- How to appeal denial?
- Consequences of accepting?
- Consequences of denial?

The image shows a digital form titled "Iowa Department of Public Health Certificate of Immunization Exemption Religious Exemption". The form includes a header with the IDPH logo and title. Below the title, there are fields for "Name Last:", "First:", "Middle:", and "Date of Birth:". The main body of the form contains a paragraph explaining the purpose of the exemption and a section titled "By signing this form, I acknowledge the Iowa Department of Public Health has published information regarding immunizations on the Department's website, including:" followed by two bullet points. At the bottom, there are fields for "Signature:" and "Date:", and "State of" and "County of".

Iowa Department of Public Health
Certificate of Immunization Exemption
Religious Exemption

Name Last: _____ First: _____ Middle: _____ Date of Birth: _____

A religious exemption may be granted to an applicant only if immunization conflicts with a genuine and sincere religious belief. A Certificate of Immunization Exemption for religious reasons shall be signed by the applicant or, if the applicant is a minor, by the parent or guardian or legally authorized representative. By signing this certificate you are attesting that the immunization conflicts with a genuine and sincere religious belief and that the belief is in fact religious, and not based merely on philosophical, scientific, moral, personal, or medical opposition to immunizations. The Certificate of Immunization Exemption for religious reasons is valid only when notarized. A child granted a religious exemption may be excluded from child care or school during a disease outbreak. The length of time a child is excluded from child care or school will vary depending on the type of disease and the circumstances surrounding the outbreak, and could range from several days to over a month.

By signing this form, I acknowledge the Iowa Department of Public Health has published information regarding immunizations on the Department's website, including:

- Information that failure to complete the required immunizations increases the risk to my child and others of contracting, carrying, and spreading a vaccine-preventable disease; and
- Information that there are children with special health needs attending schools and child care who are unable to be vaccinated or who are at a heightened risk of contracting a vaccine-preventable disease and for whom such a disease could be life-threatening.

Signature: _____ Date: _____
Applicant, Parent or Guardian

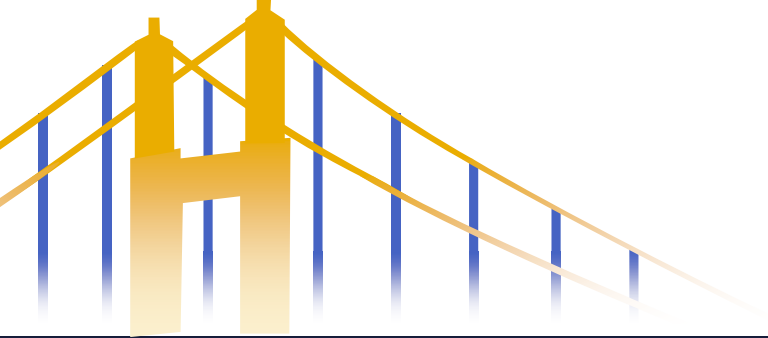
State of _____ County of _____

This instrument was electronically signed before me.

Avoid:

- Appearance of bad faith.
- Focus on organized religion.
- Arbitrary yes or nos.
- Wholesale approaches.





MISINFORMATION AND MURTHY V. MISSOURI



Missouri v. Biden:

- In 2020, social media platforms started more actively combatting misinformation.
- The Biden administration tried to get social media to step this up even more.
- Two state Attorney Generals and anti-vaccine activists sued.
- District Court and Fifth Circuit.



Murthy v. Missouri

- Coercion and social media:
“To distinguish such “attempts to coerce” from “attempts to convince,” courts look to four factors:
(1) the speaker’s “word choice and tone”;
(2) “whether the speech was perceived as a threat”;
(3) “the existence of regulatory authority”; and,
“perhaps most importantly,
(4) whether the speech refers to adverse consequences.””



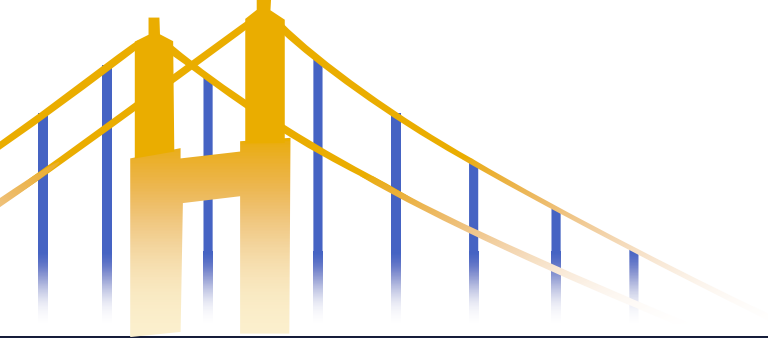
Murthy v. Missouri

- Significant encouragement:
 - ❖ ...there must be such a “close nexus” between the parties that the government is practically “*responsible*” for the challenged decision. *Blum*, 457 U.S. at 1004 (emphasis in original).
 - ❖ ...the government must exercise some active, meaningful control over the private party’s decision.

Murthy v. Missouri:

- Supreme Court overturned, finding no standing.
- Follow up cases:
 - Kennedy v. Biden
 - Berenson v. Biden
 - Dressen v. Flaherty
- Case still open – judge just ordered discovery...





Thank you!

Questions? Comments?

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EPSTEIN
BECKER
GREEN

Anticipated Impact of the Election on the Future of U.S. Health Policy

December 11, 2024

Announced and Potential Nominees for Key Leadership Positions

Major HHS Leadership Appointments



Robert F. Kennedy Jr.
HHS Secretary



Dr. Mehmet Oz
CMS Administrator



Dr. Marty Makary
FDA Commissioner



Dr. Janette Nesheiwat
Surgeon General



Dr. Dave Weldon
CDC Director

In its search process, the Trump transition team has identified loyalists known for vocalizing contrarian views or for antagonizing public health



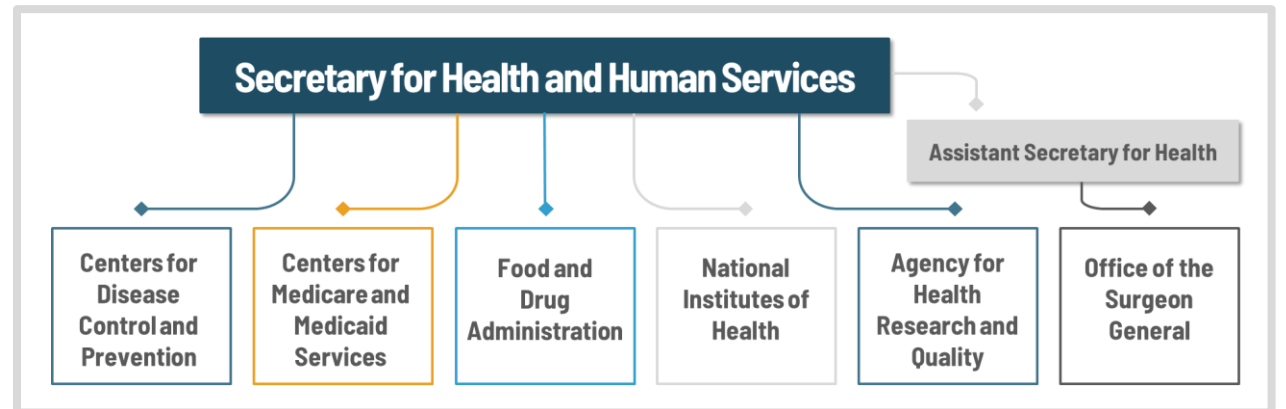
Russ Vought
OMB Director



Dr. Jay Bhattacharya
NIH Director

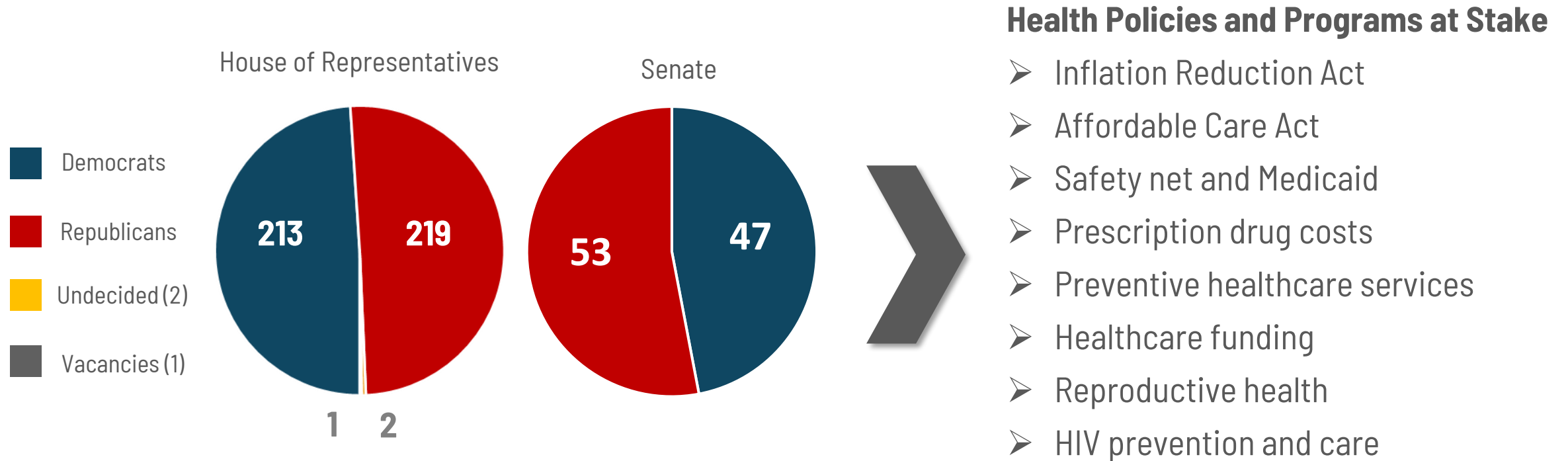


Assistant
Secretary for Health



The New Administration Could Vastly Reshape Health Policy

The 2024 congressional elections delivered a trifecta but with close margins that may not guarantee Trump wins



The Trump administration's success in accomplishing health policy goals will be dependent on the willingness of moderate members to side with his policy goals



Scope of Authority for Presumptive Nominees

Kennedy's Scope of Influence as HHS Secretary

As Secretary of Health and Human Services, RFK would have substantial authority to promote alternative health views

What is "Set in Stone"

- HHS subagencies operate under **specific legal mandates** set by Congress
- Major **regulatory changes must go through public comment periods**, stakeholder input, and comprehensive legal review
- HHS's **budget is determined by Congress**
- HHS's **collaborations with international organizations** like the WHO or through global health treaties are **overseen by the State Department**

What Could RFK Influence

- Choose **like-minded leaders** for CDC, FDA, NIH
- **Shift NIH and CDC funding**, potentially deprioritizing vaccine research or focusing on unproven health risks
- Prioritize certain public health areas, possibly **favoring funding for chronic disease or environmental health** over infectious disease
- Shape HHS operations, including **how health guidance and evidence-based information are communicated**

“

“Our big priority will be to clean up the public health agencies like the CDC, NIH, FDA, and the U.S. Department of Agriculture.”

– RFK

”

Dr. Oz's Influence at CMS Will Likely Prioritize Medicare Advantage

Dr. Oz will likely message support for Medicare Advantage (MA) and may push manufacturers to demonstrate stronger cost-effectiveness of their products

What is "Set in Stone"

- CMS's core duties in administering Medicare, Medicaid, the Child Health Insurance Program (CHIP), and the marketplace are **defined by federal law**
- Medicare and Medicaid coverage standards and others requirements are **set in CMS regulations**, beyond the Commissioner's unilateral control
- Major **regulatory changes require public comments**, stakeholder input, and legal review
- CMS's **budget is set by Congress**, and significant funding changes need Congressional approval

What Could Dr. Oz Influence

- Push manufacturers to engage in more challenging price negotiations
- Force manufacturers to demonstrate stronger cost-effectiveness and improved outcomes in order to be covered in federal programs
- **Loosen marketing requirements** to put forth **broader safe-harbors for MA marketing activity** in order to promote MA growth
- **Overhaul Medicare's payment formula and diminish the influence of the AMA's RUC** in order to pay specialists lower rates and primary care providers higher rates
- As head of CMS, Dr. Oz will be able to influence which services and products are covered by Medicare, which has a downstream effect on private plans and which **influences the medical standard of care**

“

“These plans [Medicare Advantage] are popular among seniors, consistently provide quality care and have a needed incentive to keep costs low.”

– Dr. Oz

”

Dr. Makary's Scope of Influence at FDA

Dr. Makary could promote alternative health views, potentially weakening public trust in drug, vaccine and food safety standards

What is "Set in Stone"

- FDA's core duties in drug, vaccine and food safety are **defined by federal law**
- Drug and vaccine approval standards are **set in FDA regulations**, beyond the Commissioner's unilateral control
- Major **regulatory changes require public comments**, stakeholder input, and legal review
- FDA's **budget is set by Congress**, and significant funding changes need Congressional approval

What Could Dr. Makary Influence

- Allow **marketing of "unapproved"** drugs or interventions he favors
- **Revoke licensure** for certain products
- Advocate for **stricter vaccine studies**, labeling, and **ingredient disclosure**
- Push for **more regulation of pharmaceutical companies**
- **Adjust funding, education, and regulatory guidance** as allowed

“

*"If you work for the FDA and are part of this corrupt system, I have two messages for you:
1. Preserve your records, and 2. Pack your bags."*

– RFK

”

Dr. Weldon's Scope of Influence at CDC

Dr. Weldon could eliminate bodies like ACIP, strengthening the anti-vaxx movement and undermining vaccine recommendations

What is "Set in Stone"

- The CDC's authority is established under Section 361 of the Public Health Service Act (PHSA)
- The CDC's statutory mission is focused on the "control of communicable diseases"
- Federal laws and statutes mandate the CDC's primary roles in disease surveillance, vaccine recommendations, and outbreak response
- As a sub-agency of HHS, any major policy or priority changes require HHS leadership approval
- CDC funding distribution is closely overseen by HHS, ensuring adherence to federal guidelines

What Could Dr. Weldon Influence

- Retract existing measures for disease control
- Potential changes, including the restructuring of the entire agency
- Elimination of centers, divisions, branches and committees, including the National Center for Immunization and Respiratory Diseases (NCIRD) or the Advisory Committee on Immunization Practices (ACIP)
- Section 317 of the PHSA authorizes the Secretary to negotiate the purchase of vaccines and provide grants to states - withholding of discretionary funds from states could trigger public health crises at state and local levels

“

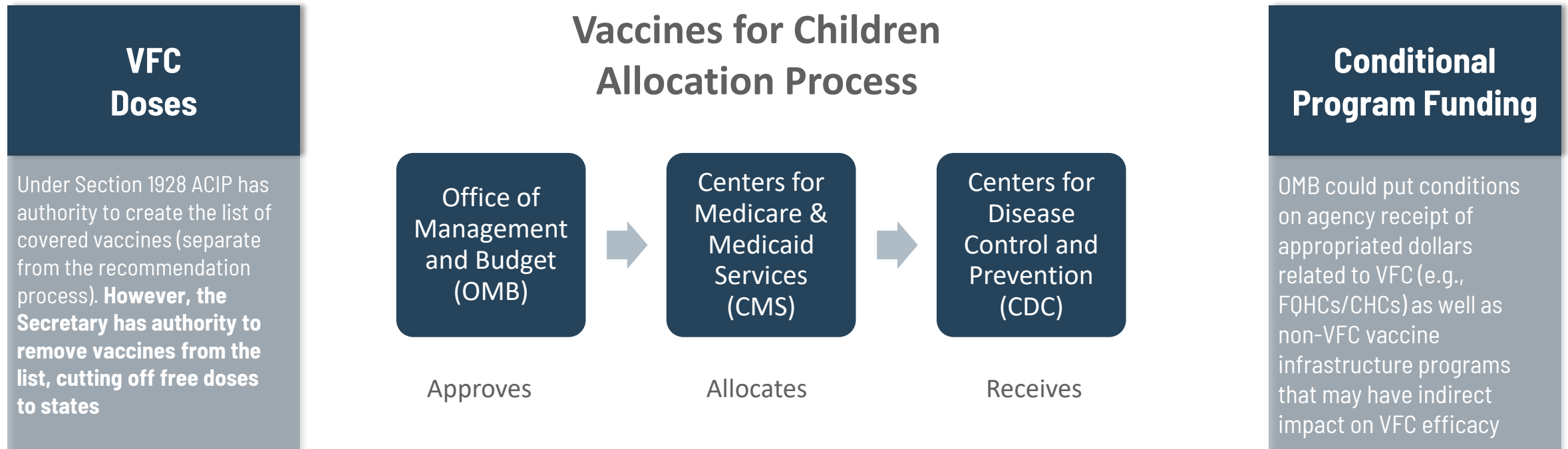
"I will clean up the cesspool of corruption at CDC and force the public health agencies to come clean about COVID vaccines."

– RFK

”

The Vaccines for Children Program

- The Vaccines For Children (VFC) program is a federal program established under Section 1928 of the Social Security Act that allows the CDC to purchase discounted vaccines and distribute them to state and local health agencies.
- Vaccines are delivered through participating physician offices and clinics to eligible children – those under age 19 who are Medicaid-eligible, uninsured, underinsured or American Indian or Alaska Native.
- All ACIP-recommended vaccines are covered at no cost to eligible children.



The CDC Administers the 317 Program, Which Serves as an Important Source of Immunization Infrastructure Funding

- ACA Section 4002 created the Prevention and Public Health Fund (PPHF), which supports core public health programs in disease prevention and health promotion activities
- The PPHF has previously been the subject of appropriation changes and reallocation, including budget sequestration and reductions to offset tax cuts and funding for the 21st Century Cures Act
- The PPHF contribution made up more than half of Section 317 funding in FY2023
- Section 317 of the Public Health Services Act (PHSA) authorizes the Secretary to negotiate the purchase of vaccines and provide grants to states annually via discretionary appropriations
- The Secretary also has authority to delist vaccines from the program, which would deprive states of free doses
- The program allows states to provide vaccines to underinsured children not eligible for the VFC program and uninsured adults

Risks to the 317 Program

Unequal bargaining power between the states and federal government may easily coerce states to eliminate school entry requirements

Fewer vaccines will be purchased by the CDC and may lead to reduced vaccination rates and demand for vaccines

Federal funds may be allocated to states that support policies to discourage vaccination

President-elect Trump has selected Elon Musk and Vivek Ramaswamy to lead a new entity, The Department of Government Efficiency

Musk and Ramaswamy are expected to make “changes to the federal bureaucracy,” “slash excess regulations, cut wasteful expenditures, and restructure federal agencies.”



Vivek Ramaswamy, and entrepreneur, and Elon Musk, CEO of Tesla will identify issues and make recommendations to the White House, agency leaders and Congress for action.

- DOGE will not have government powers. DOGE cannot issue or rescind rules and regulations or enforce federal laws. Despite this, DOGE is expected to be powerful.
- Musk and Ramaswamy have indicated support for requiring federal employees to work from the office five days per week. Ramaswamy has stated that an in-office mandate could lead to a “25 percent thinning out of the federal bureaucracy”
- Schedule F, a proposed reform to the federal civil service that would reclassify many federal employees from “competitive service” (protected by civil service rules) to “excepted service,” would allow the president and political appointees to more easily fire and hire employees. Schedule F could impact vaccine-related functions and the broader government response to health crises

“

“We are entrepreneurs, not politicians. We will serve as outside volunteers, not federal officials or employees. Unlike government commissions or advisory committees, we won’t just write reports or cut ribbons. We’ll cut costs.”

- Musk and Ramaswamy

”

DOGE and Proposed Schedule F Actions Could Have Significant Impacts on Public Health and Preventive Services

Musk and Ramaswamy are expected to make “changes to the federal bureaucracy,” “slash excess regulations, cut wasteful expenditures, and restructure federal agencies.”

Loss of Expertise

If seasoned scientists, public health officials, or regulatory professionals leave or are pushed out, it could undermine the government’s ability to manage vaccine rollouts effectively, review and approve vaccines, and address public health concerns with trusted experts

Undermining Public Confidence in Health Agencies

Without the expertise of long-serving professionals who understand the complexities of public health policy and vaccine distribution, misinformation could spread more easily, further complicating efforts to achieve widespread vaccination

Increased Burden on Remaining Employees

There may be a disruption of key functions, as there would be a shortage of knowledgeable personnel to manage critical vaccine-related tasks like monitoring vaccine distribution, ensuring compliance with health guidelines, and responding to health crises



Vaccine Liability Protections and Injury Compensation

Kennedy May Remove Manufacturer Liability Protections

As Secretary, Kennedy may impact the injury table on vaccine manufacturers and public health

What RFK Could Influence

- The Vaccine Injury Compensation Program (VICP) is a federal program that resolves vaccine-related injuries outside the court systems. It provides compensation to individuals injured by vaccines and limited manufacturers' liability for vaccine-related claims
- The Secretary of HHS has the authority to determine which vaccines and which injuries are included in the VICP
- If a vaccine is removed from the VICP, the manufacturer may face significant legal liability. The removal of routine childhood vaccines from the VICP could have disastrous consequences for vaccine manufacturers. It would expose them to the risk of massive litigation costs and undermine public confidence in vaccination programs
- Plaintiffs' attorneys who focus on mass tort litigation see an opportunity to be "bullish" for the next four years, and Kennedy could open the door

Possible Significant Vaccine Market Disruption

- The vaccine market is an incredibly volatile and low-margin market for manufacturers. Prior to the implementation of the VICP, the number of manufacturers producing the pertussis vaccine dropped from four to one, after a discredited claim linking the vaccine to brain damage exposed manufacturers to mass liability and significant legal defense costs
- **Even the risk of exposure to liability for adverse events from vaccines could be significant enough for some manufacturers to exit the market entirely**
- **The risk of vaccine injury liability will likely vary amongst manufacturers,** with producers of high-volume pediatric and seasonal influenza vaccines likely facing the most significant risk of liability
- Manufacturer market exits will likely lead to **significant disruption of supply of certain vaccines**, both in the short and long term

“

“There is no vaccine that is safe and effective.”

- RFK, HHS Secretary Nominee

”

Public Health Consequences

Past Evidence On Vaccine Hesitancy Research Suggests Hesitancy Has a Quantifiable Impact on Vaccine Uptake

Vaccine Limiting Policies

- The elimination of school immunization entry requirements
- Increase in medical and non-medical exemptions to such requirements

Misinformation, Disinformation, and Anti-Vaccine Rhetoric

Sentinel Events Will Decrease Vaccine Uptake

A 2013 flu school entry immunization requirement increased vaccination rates by 3.7% within two years; a pandemic suspension led to a 6.7% drop and a subsequent surge by 22.2% when the requirement was reinstated in 2021 ([Metroka](#); 2024).

Vaccine-skeptical content lowered vaccination rates by 2.28% per U.S. Facebook user, compared with a reduction by 0.05 percentage points for misinformation ([Allen](#); 2024).

In 2010 in California, areas with high non-medical exemption rates were 2.5 times more likely to have pertussis cases than areas with lower non-medical exemption rates ([Wang](#); 2023; [Atwell](#); 2013).

Nationally, exemptions to school immunization policies increased to 3.3% (the highest ever reported) compared with those during the 2022–23 (3.0%) and 2021–22 school years (2.6%). ([Seither](#); 2024).



Communicating the Value of Vaccines Post-Election

The Electorate's Perspective on Vaccines and Public Health Significantly Impacted the Results of the 2024 Presidential Election

“Attitudes towards COVID-19 vaccines may have “spilled over” to other, unrelated vaccines along party lines in the United States”

“Trump voters were significantly more concerned about vaccines than other Americans”

“Political identity plays a significant role in shaping a legislator's vote and decisions. Public health issues are not an exception to this rule”

57% of Republicans support requiring children to be vaccinated to attend public schools (down from 79% in 2019)

85% of Democrats support requiring children to be vaccinated to attend public schools

The Outcome of Elections Can Be Attributed to Well-Intended, Aggressive and Misunderstood Public Health Measures

Pandemic Fatigue. The pandemic, and the government's response to it, created a deep divide among voters. For many, issues such as vaccine mandates, lockdowns, and mask requirements became key political flashpoints. Some candidates supported strict public health measures and were seen as aligning with the need for science-based policies while other candidates opposed such measures or criticized the handling of the pandemic and gained traction among voters who viewed these actions as government overreach

Vaccine Mandates and Personal Liberties. For some, the government's response to COVID-19, including lockdowns and vaccine requirements, fueled distrust in federal authority and public health measures. Candidates who aligned with more relaxed policies or opposed strict mandates appealed to this segment of voters.

Understanding of Public Health Expertise. Scientists work on the best information they have at the time, which can result in evolving, and seemingly "changing" or "conflicting" guidance. However, many people do not see things that way or don't understand the process.

The government's response to the COVID-19 pandemic and related health measures has had a lasting impact on political dynamics and future responses will similarly have long-lasting impacts

Significant Efforts Are Needed to Shift the Approach to Promoting Vaccine Uptake

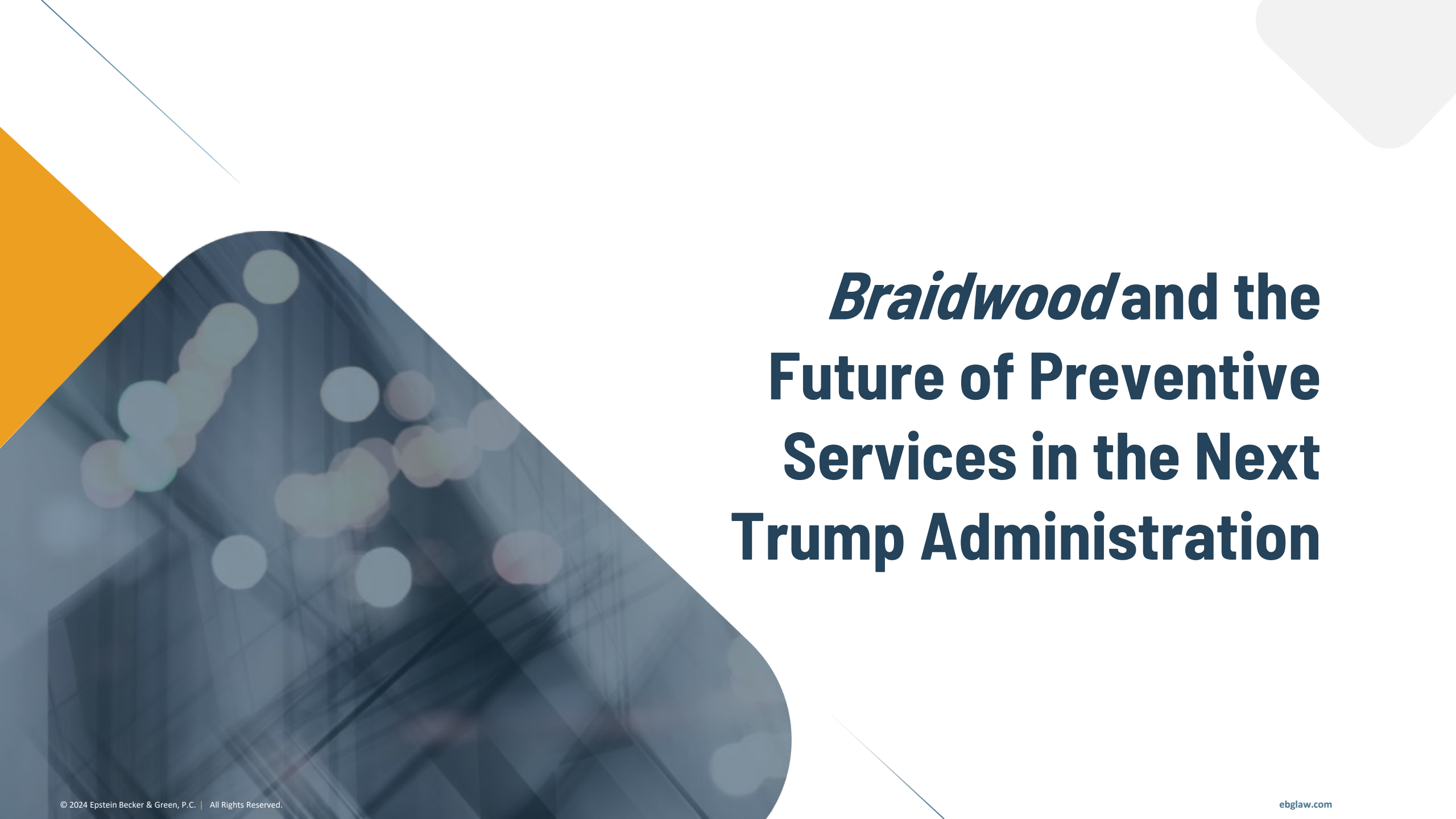
What We Have Been Doing to Promote Vaccine Uptake

- Referring to vaccines as the greatest public health intervention
- Using numbers to show that vaccines have eliminated diseases
- Overemphasizing epidemiology and vaccine science
- Dismissing misinformation
- Refusing to adjust communications strategies



What We Need to Do to Promote Vaccine Uptake

- Compensate the vaccine injured adequately and in a timely manner
- Communicate more effectively to the American people by making vaccine science more understandable to the lay public and lawmakers
- Continuously monitor public sentiment and vaccine coverage, adapting strategies as needed to address emerging issues or challenges
- Work cooperatively across all levels of government to improve vaccination rates



Braidwood and the
**Future of Preventive
Services in the Next
Trump Administration**

Braidwood v. Becerra Could Further Reshape Preventive Services

The Supreme Court may consider appeals challenging the ACA's preventive services coverage requirements

- Two recent filings urge the Supreme Court to review Braidwood, potentially disrupting the current structure of preventive health services
 - **Petition 1:** Concerning the constitutionality of the US Preventive Services Task Force's (USPSTF's) role under the ACA
 - **Petition 2:** Invoking the non-delegation doctrine, calling for SCOTUS to overturn the roles of the Health Resources and Services Administration (HRSA) and ACIP in setting coverage requirements for women's preventive services and immunizations
- At this stage, the Supreme Court is very likely to take up the question as to the USPSTF's role under the ACA but appears unlikely that the Supreme Court will take up the question as to the constitutionality of ACIP and HRSA, given that on November 16, 2024 the Supreme Court granted cert in two separate non-delegation doctrine cases
- Decision on whether SCOTUS will hear these cases is expected by January, with possible amicus brief strategies under discussion

If SCOTUS grants certiorari, the role of advisory bodies like USPSTF, HRSA, and ACIP under the ACA could be fundamentally altered, impacting access to preventive services



Post-Election Advocacy Strategies are Necessary

Agile and Strategic Responses Will Be Necessary

The prior Trump Administration's actions indicate unpredictability may be the norm

- **Scenario Planning is Essential:** Prepare for major potential policy and regulatory changes
- **Public Awareness Campaigns:** Counter misinformation with proactive public affairs strategies
- **Create a "Plan B" in Case of Agency Reconfigurations:** Strategize alternative ways to engage with agencies
- **State Government Engagement:** Although the Federal government will be impacted first, downstream state-level impacts are imminent
- **Internal Coordination:** Share information across medical, public, legal, and regulatory affairs teams for rapid response to potential changes

Unified, proactive efforts are essential to safeguard policies, mitigate misinformation and respond to detrimental impacts over the course of the next four years

Q&A



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Thank you!



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