

Legal Challenges Underlying COVID-19 Vaccinations

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Abstract: Immunizing hundreds of millions against COVID-19 through the most extensive national vaccine campaign ever undertaken in the United States has generated significant law and policy challenges.

In response to the most impactful and costly public health event in U.S. history, federal authorities and pharmaceutical companies including Pfizer, Moderna, and Johnson & Johnson have collaborated to produce multiple safe and efficacious COVID-19 vaccines.¹ Pervasive allocation and monitoring of these vaccines are key to preventing further morbidity and mortality. Through his revitalized national COVID-19 strategy, President Biden emphasized the need for widespread access, uptake, and equity in distributing vaccines to assure Americans' health and economic prosperity.²

Immunizing 70% of eligible Americans against COVID-19 by mid-summer 2021 was the goal.³ Achieving herd immunity, however, is complicated by substantial logistical, informational, political and, notably, legal challenges. Primary among legal issues are divergent approaches to the use of employer-based vaccine mandates and “pass-

ports.” The Biden Administration has not endorsed either concept even as international and state governments implement them.⁴ Determining who and when persons should be vaccinated raises legal concerns among schools and universities considering immunization measures. As younger populations (ages 0-17) become eligible for vaccines, informed consent issues surface. Engrained notions of vaccine hesitancy among Americans have rekindled battles over perceived safety risks and personal liberty. Governmentally-supported “lotteries” designed to incentivize more Americans to get vaccinated are legally-suspect.⁵ Persons of faith seeking religious exemptions from COVID-19 vaccines face contrary state policies and variable judicial responses. Health information privacy concerns underlie public health surveillance activities using personally-identifiable information. Omnipresent anxieties over potential liability for vaccine-related injuries may be dispelled via strong federal emergency liability protections. As explored below, addressing these legal and policy issues is pivotal to the success of the national COVID-19 vaccine campaign.

Employer-Based Vaccine Mandates

Employers across the country considered the legality of COVID-19 vaccine mandates long before the first vaccine received Food and Drug Administration (FDA) emergency use authorization (EUA). Public-sector vaccination mandates are con-

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stitutional under the U.S. Supreme Court's seminal 1905 decision, *Jacobson v. Massachusetts*.⁶ In the private sector, the Equal Employment Opportunity Commission (EEOC) and Occupational Safety and Health Administration (OSHA) have previously approved workplace vaccine requirements.⁷ Yet, employer-based vaccine mandates in the health care sector, schools, or other settings are controversial, principally because of the unique status of COVID-19 vaccines as FDA "authorized," but not fully "approved." The Food, Drug, and Cosmetic Act indicates Americans may refuse EUA vaccines.⁸ Pending lawsuits argue that the Act prevents mandates.⁹ While employer-based requirements impose conditions as

ance with specific country's vaccination schedules.¹³ That COVID-19 vaccine passports may be required in other situations is logical. New York has already enrolled millions in an online vaccine "pass."¹⁴ However, debates over autonomy and personal liberty have led other states (e.g., AL, FL, MT, TX) to legislatively prohibit passports.¹⁵ Widespread objections to passport requirements under the HIPAA Privacy Rule are unwarranted since only certain entities, namely health care providers, are covered by the Rule.¹⁶

School/University-Based Vaccine Requirements

No states currently require COVID-19 vaccination for K-12 students as a

Arizona have legislatively proposed limits on universities to mandate COVID-19 vaccines.²³ A "patchwork" approach to COVID-19 vaccination requirements across higher education may inevitably lead to preventable outbreaks in select locales.

Consent Among Minors

On May 10, FDA authorized Pfizer's COVID-19 2021 vaccine for use in minors (ages 12-17), immediately raising questions of consent among parents/guardians. According to the Kaiser Family Foundation, 41 states require adult consent for minors' vaccinations, while only four states (AL, OR, RI, SC) and DC allow children (of certain ages) to self-consent. Five other states (AR, ID, NC, TN, WA) grant medical providers some discretion in administering vaccines to children deemed sufficiently mature.²⁴ Though purposeful in assuring the safety of minors, consent laws may slow vaccine uptake nationally. Vaccination centers initially lacked procedures for securing consent. Marginalized children in foster care, juvenile institutions, or unaccompanied at the U.S. southern border may be compromised in securing consent.²⁵ Conflicts may also arise between minors seeking vaccination contrary to guardians' wishes.²⁶ In response, some localities have broadened minor self-consent provisions. On April 28, San Francisco's health officer ordered that minors 12 and older may consent to receive the COVID-19 vaccine and that healthcare providers may rely on such consent (with certain limitations).²⁷

Vaccine Hesitancy

In 2019, the World Health Organization classified vaccine hesitancy as a major threat to global health.²⁸ Fueled by false or misleading messaging largely by anti-vax entities via social media, widespread resistance to COVID-19 vaccines poses direct threats.²⁹ Millions of Americans express concern about the long-term safety of vaccines unapproved by FDA, resist efforts assimilating mandates, promote their personal liberty over communal interests, and raise religious freedoms against their own

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incentives to participate, they do not legally compel employees to get vaccinated. Consequently, in May 2021, EEOC updated prior COVID-19 guidance, generally approving employer mandates that comply with civil rights protections and state/local laws.¹⁰ In June 2021, OSHA encouraged workplace COVID-19 vaccination by requiring paid leave for immunizations and resulting side effects.¹¹

Vaccine Passports

As COVID-19 vaccination rates increase nationally, public- and private-sector entities (e.g., entertainment venues, airlines, and other businesses) are considering whether to require proof of vaccination as a prerequisite, or "passport," to provision of services.¹² Vaccination verification is standard in certain settings. For example, international travelers must typically demonstrate compli-

condition of their attendance, in part because children younger than 12 are not yet authorized to receive the vaccine. However, at least one state (Arkansas) has legislatively forbidden COVID-19 vaccine requirements as a condition of education;¹⁷ other states may follow. In May 2021, the Superintendent of the Los Angeles Unified School District stated it is "likely" COVID-19 vaccines will be required once vaccines receive full FDA approval.¹⁸ Among institutes of higher education, disputes over vaccine requirements are raging. Unlike for K-12 schools, state laws rarely dictate which vaccines universities and colleges may require among their students.¹⁹ The American College Health Association recommends COVID-19 vaccine requirements for on-campus students, subject to certain exemptions.²⁰ While numerous universities plan to comply,²¹ others are flatly refusing.²² Some states like

vaccinations. Each of these positions is legally specious. To date COVID-19 vaccines are proving highly-effective and safe. No autonomous adult may be compelled to be vaccinated despite contrary allegations.³⁰ Constitutionally-protected liberty interests do not include actions that place others at direct harm. Further, First Amendment free exercise rights (as noted below) do not currently require vaccine exemptions, although most states allow them.

Vaccine Lotteries

In part to counter hesitancy, innovations encouraging COVID-19 vaccination have emerged including dispensing marijuana joints (AZ, WA), liquor (LA, NJ), and raffles for college scholarships (NY).³¹ Among other states (e.g., CA, CO, OR), Ohio has established a vaccine lottery offering several \$1 million payouts or full-ride in-state college scholarships to individuals newly seeking COVID-19 immunizations.³² Persuading undecided persons to be vaccinated is the aim. Early results suggest lotteries provide ample incentives. Since the launch of Ohio's lottery, Governor Mike DeWine claims a 49% increase in vaccinations among individuals aged 16+, a 36% increase among minorities, and a 65% rise among rural populations.³³ Still, controversies swirl. Ohio lottery payouts are taken from federal coronavirus relief funds, suggesting a misuse of public resources. Federal authorities, however, have approved lottery funds if they are "reasonably expected" to increase vaccine rates.³⁴ Some hesitant individuals question the safety of COVID-19 vaccines if government must resort to lottery incentives to get public buy-in. Whether vaccine lotteries become commonplace after the pandemic (e.g., annual flu vaccine campaigns) depends on forthcoming public health assessments of their efficacy.³⁵

Religious Exemptions

Further contributing to widespread vaccine refusal and hesitancy are specific exemptions to immunization requirements. Constitutionally, no one who is medically at-risk of harm

may be required to be vaccinated.³⁶ Vaccine mandates often include as well religious or philosophical exemptions that vary across states.³⁷ Failures to respect religious exemptions may engender constitutional challenges under First Amendment free exercise principles. Currently, governments do not constitutionally have to respect religious exemptions to generally-applied vaccine requirements.³⁸ However, during the throes of the pandemic, the U.S. Supreme Court upheld several First Amendment religious freedom challenges to social distancing and closure orders.³⁹ Consequently, even arguably neutral public health laws may be closely scrutinized if they implicate free exercise principles. In future cases, the Court could determine that faith-based exemptions to vaccine mandates are required by the First Amendment, fundamentally altering the legal landscape.

Privacy Repercussions Related to Surveillance

Public health reporting and surveillance efforts involving sensitive conditions like COVID-19 heighten information privacy fears. Americans are quick to raise privacy concerns even though laws regularly permit disclosures of identifiable health information to public health agencies to prevent or control infectious diseases.⁴⁰ Other privacy concerns surface. Beginning in 2020, the Centers for Disease Control and Prevention (CDC) executed data sharing agreements with states to monitor COVID-19 vaccination status nationally.⁴¹ Some states seek to limit information sharing, citing state privacy laws. New York will not disclose data to CDC that could be used to document citizenship.⁴² California refuses to share potentially identifiable information.⁴³ CDC requests for specific vaccine data categorized by race and ethnicity help ensure equitable allocation of resources but may deter some communities from seeking vaccination.⁴⁴ Properly balancing access to identifiable health data and individual or communal privacy expectations is synergistic with accomplishing public health objectives.

Liability for Vaccine-Related Injuries

Despite numerous reports verifying the safety of FDA-authorized COVID-19 vaccines, the specter of liability pervades their production, allocation, and administration. The federal Public Readiness and Emergency Preparedness (PREP) Act⁴⁵ provides strong liability protections to persons or entities related to the manufacture or administration of vaccines and other medical countermeasures, absent claims of willful misconduct. Former U.S. Secretary of Health and Human Services Alex Azar issued a PREP Act declaration,⁴⁶ effective February 4, 2020, initiating these protections. This declaration helps insulate clinics, pharmacies, or other entities administering COVID-19 vaccines from claims of injury involving ordinary negligence. Americans suffering a serious physical injury or death as a direct result of their vaccination may be eligible for benefits through the federal Countermeasures Injury Compensation Program.⁴⁷ Benefits include compensation for unreimbursed medical expenses, lost wages, or survivor death payouts,⁴⁸ provided requests are filed within 1 year of receiving the vaccine.⁴⁹

With the looming threat of additional variants of coronavirus impacting Americans in subsequent waves of disease,⁵⁰ rapidly achieving vaccination milestones and herd immunity is urgent. Identifying and resolving legal and policy challenges is essential toward accomplishing not only these immediate goals, but also the long-term viability of public health protections for the twenty-first century.

Note

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