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SUMMARY

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State and Federal Authority to Mandate COVID-19 Vaccination

The Coronavirus Disease 2019 (COVID-19) vaccines recently authorized by the U.S. Food and Drug Administration (FDA) are a critical tool to address the pandemic. After determining that these vaccines meet the applicable statutory standards and the Agency's specific safety and efficacy standards, FDA issued Emergency Use Authorizations (EUAs) under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In particular, data supporting the EUA requests show that the vaccines are effective at preventing symptomatic COVID-19 in vaccinated individuals. Given this data, many public health experts believe that promoting COVID-19 vaccination—along with continued engagement in community mitigation activities that prevent transmission, such as mask wearing and social distancing—should be a key component of the United States' pandemic response.

One available legal tool for increasing vaccination rates is for governments to require vaccination. Under the United States' federalist system, states and the federal government share regulatory authority over public health matters, with states traditionally exercising the bulk of the authority in this area pursuant to their general police power. This power authorizes states, within constitutional limits, to enact laws "to provide for the public health, safety, and morals" of the states' inhabitants. In contrast to this general power, the federal government's powers are confined to those enumerated in the Constitution.

This report provides an overview of state and federal authority to mandate vaccination. The first part of the report provides background on state and local authority to mandate vaccination under states' general police power. It discusses the Supreme Court's long-standing recognition of state and local authority to mandate vaccination as an exercise of their police power, as well as modern courts' analyses of more recent challenges to state vaccination mandates based on the First Amendment's Free Exercise Clause. The first part of the report closes with a look at how the COVID-19 vaccines' EUA status may affect a court's analysis of a potential mandate.

The second part of the report provides an overview of federal authority to mandate vaccination. It discusses one possible source of existing federal authority, Section 361 of the Public Health Service Act (PHSA), and reviews the extent of Congress's constitutional authority under the Constitution's Spending and Commerce Clauses to potentially mandate vaccination.

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The Coronavirus Disease 2019 (COVID-19) vaccines recently authorized by the U.S. Food and Drug Administration (FDA) are a critical tool to address the pandemic.[1] After determining that these vaccines meet the applicable statutory standards and the Agency's specific safety and efficacy standards, FDA issued Emergency Use Authorizations (EUAs) for the vaccines under Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[2] In particular, data supporting the EUA requests show that the vaccines are effective at preventing symptomatic COVID-19 in vaccinated individuals.[3] Given this data, many public health experts believe that promoting COVID-19 vaccination—along with continued engagement in community mitigation activities that prevent transmission, such as mask wearing and social distancing—should be a key component of the United States' pandemic response.[4]

One available legal tool for increasing vaccination rates is for governments to require vaccination.[5] Under the United States' federalist system, states and the federal government share regulatory authority over public health matters, with states traditionally exercising the bulk of the authority in this area pursuant to their general police power.[6] This power authorizes states, within constitutional limits, to enact laws "to provide for the public health, safety, and morals" of the states' inhabitants.[7] In contrast to this general power, the federal government's powers are confined to those enumerated in the Constitution.[8]

This report provides an overview of state and federal authority to mandate vaccination. The first part of the report provides background on state and local authority to mandate vaccination under

[1] To date, FDA has issued EUAs for three COVID-19 vaccines. *See FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Dec. 11, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; *FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN. (Dec. 18, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine*, U.S. FOOD & DRUG ADMIN, (Feb. 27, 2021), https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine [hereinafter, and collectively, FDA EUA Press Releases].

[2] FDA EUA Press Releases, *supra* note 1. *See also* CRS Report R46399, *Legal Issues in COVID-19 Vaccine Development and Deployment*, by Kevin J. Hickey, Wen W. Shen, and Erin H. Ward, at 12–14.

[3] FDA EUA Press Releases, *supra* note 1. The vaccines authorized to date are at least 67% effective at preventing symptomatic COVID-19. *See id.* Data relating to the vaccine's ability to prevent asymptomatic COVID-19—or the transmission of SAR-CoV-2 (the virus that causes COVID-19)—are not yet available as of the date of this report's publication. *See id.*

[4] *See, e.g.*, Stacy Wood & Kevin Schulman, *Beyond Politics—Promoting Covid-19 Vaccination in the United States*, NEW ENG. J. MED. (Feb. 18, 2021), https://www.nejm.org/doi/full/10.1056/NEJMms2033790; Mary Van Beusekom, *Experts Propose Steps to Promote, Distribute COVID Vaccine*, CIDRAP NEWS (Dec. 15, 2020), https://www.cidrap.umn.edu/news-perspective/2020/12/experts-propose-steps-promote-distribute-covid-vaccine.

[5] While it is beyond the scope of this report, there are also a range of public policy and other legal tools available (such as education, accessibility, and outreach efforts) to increase vaccine uptake short of a mandate. *See* Kevin G. Volpp et al., *Behaviorally Informed Strategies for a National COVID-19 Vaccine Promotion Program*, JAMA (Dec. 14, 2020), https://jamanetwork.com/journals/jama/fullarticle/2774381; Matt Motta et al., *Encouraging COVID-19 Vaccine Uptake Through Effective Health Communication*, FRONTIER IN POL. SCI. (Jan. 28, 2021), https://www.frontiersin.org/articles/10.3389/fpos.2021.630133/full. *See also* Dorit Rubinstein Reiss & Lois A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, 63 BUFF. L. REV. 881, 958–79 (2015) (describing a continuum of legal tools to increase vaccination rates).

[6] *See* Elizabeth Y. McCuskey, *Body of Preemption: Health Law Traditions and the Presumption Against Preemption*, 89 TEMPLE L. REV. 95, 113–20 (2016).

[7] Barnes v. Glen Theatre, Inc., 501 U.S. 560, 569 (1991).

[8] *See* CRS Report R45323, *Federalism-Based Limitations on Congressional Power: An Overview*, coordinated by Andrew Nolan and Kevin M. Lewis, at 1.

states' general police power. It discusses the Supreme Court's long-standing recognition of state and local authority to mandate vaccination as an exercise of their police power, as well as modern courts' analyses of more recent challenges to state vaccination mandates based on the First Amendment's Free Exercise Clause. The first part of the report closes with a look at how the COVID-19 vaccines' EUA status may affect a court's analysis of a potential mandate.

The second part of the report provides an overview of federal authority to mandate vaccination. It discusses one possible source of existing federal authority, Section 361 of the Public Health Service Act (PHSA), and reviews the extent of Congress's constitutional authority under the Constitution's Spending and Commerce Clauses to potentially mandate vaccination.

State and Local Authority to Mandate Vaccination

The states' general police power to promote public health and safety encompasses authority to mandate vaccination.[9] In the early part of the 20th Century, the Supreme Court twice considered constitutional challenges to state vaccination mandates.[10] Each time, the Court rejected the challenges and recognized such laws as falling squarely within the states' police power.[11] In 1905, the Supreme Court in *Jacobson v. Massachusetts* upheld a state law that gave municipal boards of health authority to require the vaccination of persons over the age of 21 against smallpox, determining the vaccination program had a "real [and] substantial relation to the protection of the public health and safety."[12] In doing so, the Court rejected an argument that such a program violated a liberty interest that, under more modern jurisprudence, the plaintiff might have asserted as a substantive due process right.[13]

Less than two decades later, in *Zucht v. King*, parents of a child who was excluded from school due to her unvaccinated status challenged the local ordinance requiring vaccination for schoolchildren, arguing that the ordinance violated the Fourteenth Amendment's Equal Protection and Due Process Clauses.[14] Relying on *Jacobson*, the Supreme Court rejected the constitutional challenges, concluding that "it is within the police power of a State to provide for compulsory vaccination" and that the ordinance did not bestow "arbitrary power, but only that broad discretion required for the protection of the public health."[15]

Based on the Supreme Court's recognition of this authority, states and localities have enacted vaccination mandates for certain populations and circumstances. All fifty states and the District of Columbia, for instance, currently have laws requiring students to receive specified vaccines as a condition of school entry.[16] With respect to adults, states—to the extent they have mandated vaccination—have limited the mandates to health care workers, who are required to be vaccinated

[9] *See* Jacobson v. Massachusetts, 197 U.S. 11, 39 (1905).

[10] *Id.*; Zucht v. King, 260 U.S. 174 (1922).

[11] *Jacobson*, 197 U.S. at 39; *Zucht*, 260 U.S. at 175–77.

[12] *Jacobson*, 197 U.S. at 31.

[13] *See* Reiss & Weithorn, *supra* note 5, at 897–98. Since *Jacobson*, for instance, the Supreme Court has recognized that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment" under the Fourteenth Amendment. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 278 (1990).

[14] *Zucht*, 260 U.S. at 175–77.

[15] *Id.* at 176–77.

[16] *States with Religious and Philosophical Exemptions From School Immunization Requirements*, NAT'L CONF. OF STATE LEGISLATURES (NCSL) (June 26, 2020), https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx.

against certain vaccine-preventable diseases as a condition of their employment.[17] These vaccination requirements are generally subject to certain exemptions, which vary from state to state.[18] While most vaccination mandates generally provide for some degree of medical exemption (e.g., if one is allergic to vaccines or is immunocompromised), some mandates also include religious exemptions for those whose beliefs counsel against immunization.[19] In the case of student vaccination mandates, several states also provide a broader philosophical exemption for those who object to immunizations because of personal, moral, or other beliefs.[20]

State and local vaccination mandates—including ones that do not provide a religious exemption—have withstood more recent legal challenges.[21] While the Supreme Court's constitutional jurisprudence has evolved substantially since *Jacobson* and *Zucht*,[22] modern courts have continued to rely on these cases to reject due process and equal protection claims against vaccination mandates, giving considerable deference to the states' use of their police power to require immunizations to protect public health.[23] In cases that also challenge a mandate's lack of religious exemption, plaintiffs have typically asserted a claim under the First Amendment's Free Exercise Clause.[24] Courts have generally rejected this claim—which was not available to the plaintiffs in *Jacobson* or *Zucht* because the Supreme Court had not yet held that the First Amendment applied to the states[25]—and concluded that a state is not constitutionally required to provide a religious exemption.[26] The courts reasoned that under *Employment Division,*

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[17] *See* Brian Dean Abramson, *Vaccine Law in the Health Care Workplace*, 12 J. HEALTH & LIFE SCI. L. 22, 24–27 (2019) (describing different approaches states have taken to impose vaccination requirements on health care workers: some states require health care workers to receive annual flu vaccines; several others require hospitals or other health care facilities to ensure their employees have been vaccinated against certain vaccine-preventable diseases, including hepatitis B, rubella, and mumps; and still others require hospital employees to provide proof of immunization against certain vaccine-preventable diseases).

[18] *See id.* at 28–31 (describing scope of medical and religious exemptions for vaccination mandates for health care workers); NCSL, *supra* note 16 (describing exemptions for student vaccination mandates).

[19] Abramson, *supra* note 17, at 28–31; NCSL, *supra* note 16.

[20] NCSL, *supra* note 16.

[21] *See, e.g.*, Phillips v. City of New York, 775 F.3d 538, 542–44 (2d Cir. 2015); Workman v. Mingo Cty. Bd. of Edu. 419 F. App'x 348 (4th Cir. 2011); Whitlow v. California, 203 F. Supp. 3d 1079, 1085–89 (S.D. Cal. 2016); Boone v. Boozman, 217 F. Supp. 2d 938, 952–57 (E.D. Ark. 2002). Challenges against state vaccination mandates have primarily occurred in the context of student vaccination requirements. However, in 2009, following the emergence of a new strain of type A influenza (H1N1), New York State issued a regulation that made vaccination against seasonal and H1N1 influenza a condition of employment for health care workers who have direct contact with patients, or who may expose patients to disease. This directive drew several legal challenges from local health care workers, who argued that the regulation violated the Fourteenth Amendment's Due Process Clause, the First Amendment's Free Exercise Clause, and the right to "freedom of contract" guaranteed by the Fifth and Fourteenth Amendments. *See* Alexander M. Stewart, *Mandatory Vaccination of Health Care Workers*, NEW ENG. J. OF MED. (Nov. 19, 2009), https://www.nejm.org/doi/full/10.1056/nejmp0910151. The litigation, however, was mooted in its early stages after the governor suspended the regulation due to a vaccine shortage. *See* Joe Nocera, *When New York Mandated Vaccinations, Nurses Sued*, BLOOMBERG BUSINESSWEEK (Mar. 23, 2020), https://www.bloomberg.com/news/articles/2020-03-23/can-states-mandate-vaccinations-for-health-care-workers.

[22] Commentators have observed, for instance, that the Supreme Court decided *Jacobson* and *Zucht* before the advent of tiered scrutiny, which subjects regulations that infringe upon certain fundamental liberty interests to heightened scrutiny. Reiss & Weithorn, *supra* note 5, at 896–97. A regulation survives this heightened scrutiny only if it is narrowly tailored to serve a compelling government interest. *See* Reno v. Flores, 507 U.S. 292, 301–02 (1993).

[23] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87.

[24] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87; *Boone*, 217 F. Supp. 2d at 952–55.

[25] *See Phillips*, 775 F.3d at 543.

[26] *See, e.g.*, *id.* at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87; *Boone*, 217 F. Supp.

Department of Human Resources of Oregon v. Smith and its progeny, a vaccination mandate is a neutral, generally applicable law (i.e., one that does not target specific religious groups) that is not subject to heightened scrutiny.[27] Under the lenient rational basis review, courts have held that "the right to free exercise of religion . . . [is] subordinated to society's interest in protecting against the spread of disease."[28]

The vaccines that are currently subject to governmental mandates were licensed under a biological license application (BLA), the standard regulatory framework under which vaccines are typically introduced into interstate commerce.[29] By contrast, FDA has not yet licensed the COVID-19 vaccines under BLAs. Instead (as discussed in detail in other CRS products), the COVID-19 vaccines are authorized for emergency use under the FD&C Act's EUA provision, which allows the HHS Secretary to permit patient access to an unlicensed vaccine for emergency use under specified conditions.[30]

Some commentators have argued that Section 564(e)(1) of the EUA provision precludes states and private employers from mandating the COVID-19 vaccines.[31] Section 564(e)(1) directs the HHS Secretary, when issuing an EUA for a medical product, to impose such necessary conditions to protect the public health, including appropriate conditions designed to inform individuals "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."[32] Because each individual must be provided with "the option to accept or refuse," some commentators assert that this provision "suggests that mandates are categorically prohibited."[33]

While no court has interpreted this provision, making it difficult to predict how one might consider this argument, Section 564(e)(1) might not address the permissibility of a vaccination mandate. As these commentators acknowledge, the provision essentially directs the HHS Secretary to require health care professionals administering an EUA product to provide informed

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2d at 952–55.

[27] *See, e.g.*, *Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87; *Boone*, 217 F. Supp. 2d at 952–55. The Supreme Court heard oral arguments on November 4, 2020 in *Fulton v. City of Philadelphia*, a case in which the petitioners have asked the Court to, among other things, revisit *Smith*. *See* Pet. for a Writ of Cert. 31, Fulton v. City of Philadelphia, No. 19-123 (2020).

[28] *Boone*, 217 F. Supp. 2d at 954; *see also Phillips*, 775 F.3d at 543; *Workman*, 419 F. App'x at 352–54; *Whitlow*, 203 F. Supp. 3d at 1085–87. In cases where a vaccination mandate includes a religious exemption, plaintiffs have also filed suit to challenge their unsuccessful invocation of the exemption. In these cases, courts, applying the relevant state law, typically considered whether the plaintiffs' objections to vaccination are based on a sincere religious belief. *See, e.g.*, N.M. v. Hebrew Acad. Long Beach, 155 F. Supp. 3d 247, 257–58 (E.D.N.Y. 2016) (finding that plaintiff failed to establish her objections to vaccination were religious in nature); *In re* Christine M., 157 Misc. 2d 4, 21 (N.Y. 1992) (finding that plaintiff's objections to vaccination were based on plaintiff's personal and medical, rather than religious, beliefs); Lewis v. Sobol, 710 F. Supp. 506, 516 (S.D.N.Y. 1989) (finding that plaintiffs' objections to vaccination stemmed from their religious beliefs, which entailed "views of spiritual perfection" that they apply in their dietary and medical practices).

[29] *See, e.g.*, CRS Report R46593, *Vaccine Safety in the United States: Overview and Considerations for COVID-19 Vaccines*, by Kavya Sekar and Agata Bodie, at 15, 34–35.

[30] *See id.*; *see also* Hickey et al., *supra* note 2, at 12–14.

[31] *See* Efthimios Parasidis & Aaron S. Kesselheim, *Assessing the Legality of Mandates for Vaccines Authorized Via an Emergency Use Authorization*, HEALTH AFFAIRS (Feb. 16, 2021), https://www.healthaffairs.org/do/10.1377/hblog20210212.410237/full/.

[32] 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

[33] Parasidis & Kesselheim, *supra* note 31.

consent as part of the medical procedure, and to provide an "option to refuse" in that context.[34] As discussed above, existing vaccination mandates—as they are typically structured—generally do not interfere with the medical informed consent process and an individual's right to refuse in that context.[35] Rather, they impose secondary consequences—often in the form of exclusion from certain desirable activities, such as schools or employment—in the event of refusal.[36] Put another way, mandates generally do not require involuntary vaccination, but instead impose consequences on individuals who refuse to get vaccinated.[37] Thus, to the extent a state vaccination mandate for an EUA-authorized vaccine is so structured, Section 564(e)(1) may not address the mandate's permissibility.[38]

If a state mandates COVID-19 vaccination in a neutral, generally applicable manner while the vaccines are still authorized under an EUA,[39] courts are likely to factor the vaccines' EUA status into their rational-basis review.[40] In particular, courts will likely consider whether requiring vaccines subject to an EUA—including the specific steps taken by FDA in issuing the EUA[41]—under the specified conditions of the mandate is reasonably related to a legitimate government interest given the nature of the pandemic.[42]

Federal Authority to Mandate Vaccination

Executive Branch Authority to Mandate Vaccination

Except in certain limited circumstances, including in the immigration[43] and military[44] contexts, no existing federal law expressly imposes vaccination requirements on the general population.

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[34] *See id.*

[35] *See supra* notes 16–17 and accompanying text.

[36] *See id.*

[37] *Cf.* Zucht v. King, 260 U.S. 174, 175–77 (1922).

[38] Section 564(e)(1) may more directly limit mandates that require involuntary vaccination without consent. *Cf.* Doe v. Rumsfeld, 341 F. Supp. 2d 1 (D.D.C. 2004) (enjoining Department of Defense's anthrax vaccination program under 10 U.S.C. § 1107—which permits the Secretary of Defense to require service members to receive an investigatory new drug or drug unapproved for its intended use without their informed consent only upon a waiver from the President—after concluding that FDA improperly licensed the vaccine for inhalation anthrax and no presidential waiver had been sought).

[39] FDA's guidance states that sponsors of the EUA-authorized vaccines are expected to continue to collect data to support eventual submission of a BLA to obtain full licensure. U.S. FOOD & DRUG ADMIN., EMERGENCY USE AUTHORIZATION FOR VACCINES TO PREVENT COVID-19: GUIDANCE FOR INDUSTRY 11 (Feb. 2021), https://www.fda.gov/media/142749/download.

[40] *See, e.g.*, Whitlow v. California, 203 F. Supp. 3d 1079, 1086 n.4 (S.D. Cal. 2016).

[41] Sekar & Bodie, *supra* note 29, at 34 (noting that FDA officials have stated that the amount of safety and effectiveness data needed to support EUA-authorized vaccines is similar to the data that is appropriate for a BLA).

[42] *See* Roman Catholic Diocese of Brooklyn v. Cuomo, 141 S. Ct. 63 (2020) (Gorsuch, J., concurring) (stating that the Court in *Jacobson* "essentially applied rational basis review" to the vaccination mandate in question, determining that the law was "reasonable" in light of an ongoing smallpox pandemic).

[43] Under 8 U.S.C. § 1182(a)(1)(A), for instance, immigrants seeking permanent residence in the United States must present documentation showing they have been vaccinated against certain specified vaccine-preventable diseases.

[44] The Department of Defense's Immunization Program, for instance, requires all health care personnel working in the Department's medical treatment facilities, as well as all active duty and selected reserve personnel, to receive annual seasonal influenza vaccines or to obtain a medical or administrative exemption. DEP'T OF DEFENSE INSTRUCTION 6205.02 § 1.2b (July 23, 2019), https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620502p.pdf?ver=2019-07-23-085404-617.

Certain existing authorities, however, could potentially form the basis of executive action in the context of the COVID-19 pandemic. One such law could be Section 361 of the PHSA.[45] Subsection (a) of this provision, which one court has characterized as "broad [and] flexible,"[46] grants the Secretary of HHS the authority—delegated in part to the Centers for Disease Control and Prevention (CDC)[47]—to make and enforce regulations necessary "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession."[48] A broad construction of this authority may permit CDC to issue regulations requiring vaccination in circumstances that would prevent the foreign or interstate transmission of COVID-19.[49] The Constitution and other generally applicable statutory requirements, such as the Administrative Procedure Act[50] and the Religious Freedom Restoration Act of 1993 (RFRA),[51] would nevertheless constrain CDC's exercise of this authority. RFRA, for example, requires courts to recognize certain religious exemptions from a generally applicable rule that imposes a substantial burden on a regulated person's religious exercise.[52]

On the other hand, Section 361's statutory text and context may be ambiguous as to the scope of CDC's subsection (a) authority to issue "necessary" regulations, possibly suggesting a narrower construction. Following the broad statement of authority identified above, Section 361(a) provides: "For purposes of carrying and enforcing such regulations," the Agency "may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in [its] judgment may be necessary."[53] The remaining subsections of Section 361 primarily set forth CDC's foreign and interstate quarantine and isolation authority, including the authority to apprehend, examine, and detain any individual reasonably believed to be infected with certain communicable diseases.[54] The text of these subsections frame this quarantine authority as another example of possible regulations issued under "this section,"[55] while imposing certain additional safeguards to which these regulations are subject, such as limiting the exercise of this authority to certain specified communicable diseases.[56]

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[45] 42 U.S.C. § 264.

[46] Louisiana v. Matthews, 427 F. Supp. 174, 176 (E.D. La. 1977).

[47] *See Legal Authorities for Isolation and Quarantine*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 24, 2020), https://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html.

[48] 42 U.S.C. § 264(a).

[49] *See* Christopher T. Robertson, *Vaccines and Airline Travel: A Federal Role to Protect the Public Health*, 42 AM. J.L. & MED. 543, 566 (2016) (suggesting CDC has authority under Section 361 "to require vaccinations as a condition of airline travel"); *cf.* CRS Legal Sidebar LSB10572, *Mask Mandate: Does the Federal Aviation Administration Have Authority to Require Masks on Flights?*, by Bryan L. Adkins.

[50] *See, e.g.*, CRS Legal Sidebar LSB10523, *Administrative Law Reform Legislation in the 116th Congress*, by Daniel J. Sheffner.

[51] *See, e.g.*, CRS In Focus IF11490, *The Religious Freedom Restoration Act: A Primer*, by Whitney K. Novak.

[52] 42 U.S.C. § 2000bb-1.

[53] *Id.* § 264(a).

[54] *Id.* § 264(b)–(d).

[55] *Id.*

[56] *See id.* § 264(b) (limiting the use of foreign and interstate quarantine and isolation authority only to prevent the spread of communicable diseases designated by an executive order); § 264(d) (limiting the application of interstate quarantine and isolation authority only to individuals "reasonably believed to be infected with a communicable disease in a qualifying stage").

In the context of Section 361's focus on quarantine authority and its parameters, the enumerated list under subsection (a) could potentially be understood as a list of measures that facilitate or supplement quarantine efforts.[57] These considerations could suggest a narrower reading of Section 361(a) that limits the authority to issue "necessary" regulations to measures related to quarantine or other similar public health measures. The larger context of the related PHSA provisions may also highlight the ambiguity in Section 361's scope.[58]

To the extent Section 361's text is ambiguous as to the scope of delegated authority, certain canons of construction may apply to support a narrower construction.[59] On several occasions when assessing an agency's statutory authority, for instance, the Supreme Court has cautioned that courts must "be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of [significant] economic and political magnitude to an administrative agency."[60] Thus, to the extent a federal vaccination mandate involves significant economic and political considerations, there may be an interpretative question as to whether Congress intended to empower the CDC with such authority through Section 361(a).[61]

In addition, a practical consideration in the federal government's use of Section 361 authority is the applicable enforcement scheme. Under Section 368 of the PHSA, violators of regulations issued under Section 361 are subject to statutory penalties of up to one year in jail or a fine of $1,000, or both.[62] Generally applicable criminal statutes on sentencing, however, authorize higher

[57] *See id.* §§ 264–272 (codified under the subheading "Part G – Quarantine and Inspection"); *id.* § 268(b) (directing U.S. Customs officers and Coast Guard officers to aid only "in the enforcement of quarantine rules and regulations"). *But see id.* § 264 (codified under the section heading "control of communicable disease" and not limited to quarantine and related measures).

[58] *See* Hearing before a Subcomm. on Interstate and Foreign Commerce on H.R. 3379: A Bill to Codify the Laws Relating to the Public Health Service, and for Other Purposes, 78th Cong. 64 (1944) (noting that the second sentence of Section 361(a) "would expressly authorize the Public Health Service to make inspections and take other steps necessary in the enforcement of quarantine"). *But see id.* at 140 (also noting that the Section 361 provisions were "written in broader terms in order to make it possible to cope with emergency situations which we cannot now foresee").

[59] *See* United States v. Turkette, 452 U.S. 576, 581 (1981) (explaining that canons of statutory construction "come[ ] into play only when there is some uncertainty as to the meaning of a particular clause in a statute").

[60] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000). More recently, Justice Neil Gorsuch has characterized this doctrine as a canon of statutory construction that presumes Congress, absent express and specific delegation, does not intend to grant agencies the power to fill in statutory gaps concerning "a question of deep economic and political significance that is central to [a] statutory scheme." Gundy v. United States, 139 S. Ct. 2116, 2141–42 (2019) (Gorsuch, J., dissenting); *see also* Paul v. United States, 140 S. Ct. 342 (2019) (statement of Kavanaugh, J.) (noting the Court has applied a "statutory interpretation doctrine" related to "major questions" that requires Congress to either "(i) expressly and specifically decide the major policy question itself and delegate to the agency the authority to regulate and enforce; or (ii) expressly and specifically delegate to the agency the authority both to decide the major policy question and to regulate and enforce").

[61] For instance, large-scale vaccination campaigns can implicate costly and complex issues of supply and distribution that have required congressional action. *See, e.g.*, Nat'l Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113 (1976) (authorizing the Secretary to conduct necessary activities to carry out a national swine flu immunization program); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. M, tit. III (2020) (authorizing appropriations for activities "to plan, prepare for, promote, distribute, administer, monitor, and track coronavirus vaccines to ensure broad-based distribution, access, and vaccine coverage"). They can also implicate issues of vaccine hesitancy stemming in part from prior governmental vaccine campaigns. *See* discussion *supra* note 21; Wendy E. Parmet, *Pandemics, Populism and the Role of Law in the H1N1 Vaccine Campaign*, 4 ST. LOUIS UNIV. L.J. 113, 115–24 (2010) (describing the history of pandemic influenza responses in the United States and issues related to the 2009 H1N1 vaccine campaign); Kat Eschner, *The Long Shadow of the 1976 Swine Flu Vaccine 'Fiasco'*, SMITHSONIAN MAG. (Feb. 6, 2017), https://www.smithsonianmag.com/smart-news/long-shadow-1976-swine-flu-vaccine-fiasco-180961994/.

[62] 42 U.S.C. § 271(a).

fines.[63] CDC has incorporated the higher fines into applicable regulations, which subject violating individuals to a fine up to $100,000 if the violation does not result in death, or a fine of up to $250,000 if the violation results in a death.[64] Violations by organizations are subject to a fine of up to $200,000 per event if the violation does not result in a death, or $500,000 per event if the violation results in a death.[65] Given the significant potential penalties, any mandate issued under the provision—assuming that it falls within the Agency's delegated authority—may be more appropriately structured as requirements on entities in interstate commerce, such as a requirement on entities to verify vaccination status.[66]

Congress's Authority to Mandate Vaccination

Although states have traditionally exercised the bulk of authority over public health matters, including vaccination, Congress shares certain concurrent authority in this area emanating from its enumerated powers in the Constitution.[67] This authority derives from, among other sources, the Constitution's Spending and Commerce Clauses.[68]

The Spending Clause empowers Congress to tax and spend for the general welfare.[69] Under this authority, which is subject to several limitations, Congress may offer federal funds to nonfederal entities and prescribe the terms and conditions under which the funds are accepted and used by recipients.[70] Over the past century, Congress has frequently invoked this authority in the public health context, including for purposes of controlling specified diseases, establishing neighborhood or community health centers, and creating federal health insurance programs, including Medicare and Medicaid.[71]

Applying its authority in the context of a vaccination mandate, Congress could encourage states to enact a vaccination mandate meeting certain federal requirements by imposing it as a condition of receiving certain federal funds.[72] This use of the Spending Clause authority, assuming it falls within the broad parameters of being for the "general welfare," would be permissible so long as (1) Congress provides clear notice of the vaccination mandate that states must enact; (2) the mandate is related to the purpose of the federal funds; (3) this conditional grant of funds is not

[63] *See* 18 U.S.C. §§ 3559, 3571(b)(5), 3571(c)(5).

[64] *See* 42 C.F.R. § 70.18(a).

[65] *See id.* § 70.18(b).

[66] For instance, CDC's public transit mask mandate was issued under Section 361 and includes an obligation on conveyance operators to require passengers to wear masks while also contemplating "widespread voluntary compliance" and enforcement support from other federal agencies with access to civil enforcement schemes. *See* 86 Fed. Reg. 8025, 8026, 8030 n.33 (Feb. 3, 2021). *See also* Abramson, *supra* note 17, at 24–27 (noting that some state vaccination mandates for health care workers are structured as a requirement on hospitals and health care facilities to ensure that their employees are vaccinated against specified vaccine-preventable diseases).

[67] McCuskey, *supra* note 6, at 113–20.

[68] *See id.* at 116–19.

[69] U.S. CONST. art. I, § 8, cl. 1.

[70] *See* Nolan & Lewis, *supra* note 8, at 29–31 (discussing South Dakota v. Dole, 483 U.S. 203, 207–08 (1987)).

[71] *See* James G. Hodge, Jr., *The Role of New Federalism and Public Health Law*, 12 J.L. & HEALTH 309, 335–37 (1998); McCuskey, *supra* note 6, at 118–19.

[72] *See Dole*, 483 U.S. at 211–12 (holding that 23 U.S.C. § 158, which conditioned the provision of certain federal highway funds upon a state's enactment of a minimum drinking age of twenty-one, was a valid exercise of Congress's spending clause authority).

otherwise barred by the Constitution; and (4) the amount of federal funds offered is not "so coercive as to pass the point at which pressure turns into compulsion."[73]

In addition, the Commerce Clause grants Congress the power "[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."[74] This authority empowers Congress to regulate "three broad categories of activities": (1) "channels of interstate commerce," like roads and canals; (2) instrumentalities of, or persons or things in, interstate commerce; and (3) activities that substantially affect interstate commerce.[75] Congress relied on the Commerce Clause to enact some of the earliest federal health laws aimed at protecting the public from contagion and products posing health concerns.[76] As the federal government increased its role in public health, Congress relied on the Commerce Clause to pass more comprehensive national health regulations, beginning with the Food and Drug Act of 1906.[77]

While Congress's authority under the Commerce Clause is expansive, a majority of the Supreme Court in *National Federation of Independent Business (NFIB) v. Sebelius* agreed that there is a discrete limit to this authority—it cannot *compel* individuals to engage in commercial activity.[78] According to Chief Justice John Roberts, in a portion of the opinion not joined by other Justices but largely echoed in the view of the four dissenting Justices, the Commerce Clause did not empower Congress "to regulate individuals precisely because they are doing nothing."[79] While it is uncertain whether this conclusion constitutes binding precedent,[80] it suggests that a direct federal mandate on individuals to receive a vaccine may be susceptible to challenge because such mandates could be construed as compelling individuals who are "doing nothing" to engage in the commercial activity of receiving a specified health care service.[81] On the other hand, a federal mandate that requires vaccination as a condition to engage in existing economic activities, such as employment or interstate travel, may raise fewer constitutional concerns.[82]

Even if a vaccine mandate falls within Congress's enumerated powers, other constitutional provisions may constrain governmental action.[83] In the context of public health regulations, the key constraints are those grounded in federalism and the protection of individual rights.[84] For example, the Supreme Court has interpreted the Tenth Amendment to prevent the federal government from commandeering or requiring states or localities to adopt or enforce federal

[73] *See id.* at 207–08, 211 (internal quotations omitted).

[74] U.S. CONST. art. I, § 8, cl. 3.

[75] United States v. Lopez, 514 U.S. 549, 558–59 (1995).

[76] McCuskey, *supra* note 6, at 116–19 (noting that the Commerce Clause enabled several early federal health laws, including a law that authorized the quarantine of diseased livestock and people, and a law that regulated certain drugs and food products posing health concerns).

[77] *See id.*; *see also* Medtronic, Inc. v. Lohr, 518 U.S. 470, 475 (1996); Hodge, *supra* note 71, at 335–36 (noting that "[f]ederal regulation now reaches broad aspects of public health such as air and water quality, food and drug safety, tobacco advertising, pesticide production and sales, consumer product safety, occupational health and safety, and medical care").

[78] *See* Nolan & Lewis, *supra* note 8, at 10.

[79] *See id.* at 10–11 (quoting NFIB v. Sebelius, 567 U.S. 519, 551 (2012) (opinion of Roberts, C.J.)).

[80] S*ee id.* at 11.

[81] *See NFIB*, 567 U.S. at 551.

[82] *See* Liberty Univ., Inc. v. Lew, 773 F.3d 72, 93 (4th Cir. 2013) (rejecting a Commerce Clause challenge to an Affordable Care Act requirement that certain employers offer a minimum level of health insurance coverage to their employees and dependents on the grounds that the requirement merely regulates an existing commercial activity).

[83] *See* Nolan & Lewis, *supra* note 8, at 24–25.

[84] *See id.* at 19, 24–25.

policies.[85] In the context of vaccination, this principle prevents Congress from directly requiring states or localities to pass mandatory vaccination laws or implement federal vaccination laws.[86] It does not, however, impede Congress from using its Spending Clause authority to incentivize states to do so, as long as the amount offered is not so significant as to effectively coerce, or functionally commandeer, states into enacting the mandate.[87]

As to protection of individual rights, courts have recognized few rights-based constraints on the ability to impose mandatory vaccination requirements.[88] As noted above, courts have largely rejected due process and equal protection challenges to compulsory vaccination under *Jacobson* and *Zucht*, and potential free exercise concerns are limited under *Smith* and its progeny.[89]

To date, the federal government has generally limited its role with respect to vaccination to promoting, facilitating, or monitoring the use and manufacture of vaccines. For instance, federal laws and agencies require insurance coverage for recommended vaccinations[90] and the purchase of certain vaccines,[91] provide clinical guidance on vaccinations,[92] and ensure vaccine safety.[93]

Consideration for Congress

A vaccination mandate is one available legal tool that governments could use to increase COVID-19 vaccine uptake. As discussed above, whether the federal government has existing statutory authority to mandate vaccination in the context of COVID-19 is subject to debate.[94] Thus, inasmuch as Congress determines that a federal vaccination mandate may be necessary to address the pandemic, legislative action may be required to implement such a mandate. Congress could, for instance, update Section 361 of the PHSA—which has remained largely unchanged since its enactment in 1944—to articulate this authority more clearly and provide a more flexible enforcement mechanism. Congress could also impose a mandate through other legislative actions, if grounded in Congress's enumerated constitutional authority and structured consistently with constitutional due process and religious freedom guarantees.

[85] *Id.* at 25.

[86] *See id.*

[87] *See id.*

[88] *See supra* notes 21–28 and accompanying text.

[89] *See id.*

[90] *See* 42 U.S.C. § 300gg-13(a) (requiring private health insurance plans to cover certain recommended immunizations); *id.* § 1396s(a) (requiring coverage of certain recommended pediatric vaccines under a state Medicaid plan).

[91] *See* CRS Insight IN11560, *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials*, by Simi V. Siddalingaiah. *See also Vaccines for Children Program (VFC)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 18, 2016), https://www.cdc.gov/vaccines/programs/vfc/index.html (describing the Vaccines for Children program, under which federally purchased childhood vaccines are provided at no cost to certain children).

[92] *See Advisory Committee on Immunization Practices (ACIP) Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/acip/committee/charter.html.

[93] *See, e.g.*, Sekar & Bodie, *supra* note 29, at 4–11.

[94] *See* discussion *supra* in "Executive Branch Authority to Mandate Vaccination."

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