THE FIRST GENERAL FEDERAL VACCINATION REQUIREMENT: THE OSHA EMERGENCY TEMPORARY STANDARD FOR COVID-19 VACCINATIONS

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I. A POTENTIAL FEDERAL COVID-19 VACCINATION REQUIREMENT

Since late in the summer of 2020, three pharmaceutical companies have developed different vaccines to combat the effects of the SARS-CoV-2 virus and prevent additional people from succumbing to the disease it causes, COVID-19, in the United States.[1] The response has been favorable. The

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1. The Secretary of Health and Human Services may find that "an actual or potential emergenc[y]" exists justifying a "drug" or "biological product" (the COVID-19 vaccines are

U.S. Centers for Disease Control and Prevention (CDC) reports that, as of January 24, 2021, 250 million people in the United States (75.5% of the population) received at least one vaccination, 210 million received two doses (63.4% of the population), and more than 83 million (39.9% of the population) also received a booster dose.[2] In addition, the U.S. Food and Drug Administration (FDA) granted emergency use approval for a third dose of one vaccine (manufactured by Pfizer-BioNTech), the CDC has recommended boosters for select groups, and more than 68 million people (36.3% of the population) have received boosters.[3] Accordingly, the nation

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both, see *infra* note 80 and accompanying text) to be distributed in interstate commerce if (*inter alia*) he or she finds **"**that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents[.]" 21 U.S.C. § 360bbb–3(a)(2), (b)(1) (2018). In 2020, the Food and Drug Administration (FDA) granted "emergency use authorization" to three vaccines manufactured by Pfizer BioNTech, Moderna TX, Inc., and Janssen Biotech, Inc. (a component of Johnson & Johnson, *see* Janssen Global, *About Us – Our Heritage*, https://www.janssen.com/emea/our-company/our-heritage), respectively. *See* Letter from the FDA to BioNTech Mfg. GmbH re: Biologics License Application (BLA) Approval [of the Pfizer COVID-19 Vaccine], Aug. 23, 2021, https://www.fda.gov/media/151710/download (last visited Jan. 24, 2022); Letter from the FDA to Moderna TX, Inc. [re: Moderna COVID-19 Vaccine], reissued Oct. 20, 2021, https://www.fda.gov/media/144636/download (last visited Jan. 24, 2022); Letter from the FDA to Janssen Biotech, Inc. [re: Johnson & Johnson COVID-19 Vaccine], Reissued Oct. 20, 2021, https://www.fda.gov/media/146303/download. *See generally* Food & Drug Admin., COVID-19 Vaccines, Sept. 17, 2021, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines (last visited Jan. 24, 2022). On August 23, 2021, the FDA granted final approval for the Pfizer vaccine, now known as the Comirnaty vaccine. *See* Letter from the FDA to BioNTech Mfg. GmbH re: BLA Approval [of the Pfizer COVID-19 Vaccine], Aug. 23, 2021, https://www.fda.gov/media/151710/download (last visited Jan. 24, 2022).

2. *See* U.S. Cntrs. for Disease Control & Prevention (CDC), COVID Data Tracker, COVID-19 Vaccinations in the United States, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (last visited Jan. 24, 2022) [hereinafter, CDC COVID Vaccinations]. The number of people who received a vaccination is even higher for people 12 or 18 years of age and older. *Id.* For example, 85.5% of the population 12 and older have received one dose (242 million people), and 72,2% are fully vaccinated (204 million people). *Id*. Similarly, 87.4% of the population 18 and older received one dose (225 million people), 73.8% are fully vaccinated (190 million people), and 43% have also received a booster (82 million). *Id.* For the population 65 and older, 56 million have received one dose (95%), 48 million are fully vaccinated (88.2%), and 29 million have received a booster (63%). *Id.*

3. On September 22, 2021, the FDA authorized a booster dose of the Pfizer-BioNTech vaccine for people aged 65 and older and certain other individuals who had received two

is steadily increasing the number of people vaccinated against COVID-19.[4]

Historically, the United States did not have a general federal vaccination requirement,[5] and until recently, President Joe Biden opposed adopting one.[6] Instead, he took numerous opportunities to encourage or incentivize public vaccination[7]—in effect to "nudge" people toward that result, rather than order

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doses of that vaccine. U.S. Food & Drug Adm'n, FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations, Sept. 22, 2021, https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations (last visited Jan. 24, 2022). Two days later, the CDC outlined its recommendations for booster shots for individuals who had received two doses of the Pfizer BioNTech vaccine at least six months previously. It recommended boosters for those aged 65 and older, along with people aged 50-64 with underlying medical conditions. It also said that adults under 50 "may" receive a booster dose "based on their individual benefits and risks." It made a similar recommendation with respect to people "at increased risk … because of occupational or institutional setting." U.S. Cntrs. for Disease Control & Prevention, CDC Statement on ACIP Booster Recommendations (Sept. 24, 2021), https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations-.html.

4. *See* CDC, COVID Data Tracker, COVID-19 Vaccinations in the United States, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (last visited Jan. 24, 2022). Moreover, on December 22, 2021, the FDA issued an emergency use authorization for Pfizer's Paxlovid for use in treatment of mild to moderate cases of COVID-19. *See* Letter from FDA to Pfizer, Inc. [re: Emergency Use Authorization 105] (Dec. 22, 2021), https://www.fda.gov/media/155049/download; U.S. Food & Drug Admin., FDA News Release: Coronavirus (COVID-19) Update: FDA Authorizes First Antiviral for Treatment of COVID-19, Dec. 22, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19 (last accessed Dec. 22, 2021).

5. Mandatory vaccination requirements inapplicable to civilians have existed for members of the armed forces. *See*, *e.g.*, Army Reg. 40-562, Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases, (Oct. 7, 2013), https://media.defense.gov/2017/Mar/16/2001717444/-1/-1/0/CIM_6230_4G.PDF; John D. Grabenstein & William Winkenweder, Jr., *US Military Smallpox Vaccination Program Experience*, 289 JAMA 3278 (2003); Khaldeea Rahman, *Full List of Vaccines Mandates by the U.S. Military*, NEWSWEEK, (Oct. 21, 2021), https://www.newsweek.com/list-vaccines-mandated-us-military-covid-1641228.

6. Robby Soave, *Biden's Vaccine Mandate Is a Big Mistake*, N.Y. TIMES (Sept. 10, 2021), https://www.nytimes.com/2021/09/10/opinion/politics/biden-vaccine-mandate.html?searchResultPosition=7 (explaining that "[i]n December 2020, as the prospect of imminent mass vaccination against COVID-19 was finally becoming a reality, Mr. Biden leveled with the American people: He said he would not force anyone to get the jab. 'No, I don't think it should be mandatory,' he told reporters. 'I wouldn't demand it be mandatory.' Jen Psaki, the White House press secretary, recently reiterated Mr. Biden's position. 'That's not the role of the federal government,' she declared on July 23, referring to the idea of a government mandate. Rochelle Walensky, the director of the Centers for Disease Control and Prevention, said the same thing a week later: 'There will be no nationwide mandate.'").

7. *See*, *e.g.*, Allen Rappeport, *The Biden Administration Wants States and Cities to Pay People*

them to do so.[8] On September 9, 2021, however, he switched gears. Expressing frustration that an insufficient number of Americans had received the vaccine,[9] President Biden directed the Occupational Safety and Health Administration (OSHA), for the first time in American history, to promulgate a federal "emergency temporary standard" (ETS) requiring all private businesses[10] with 100 or more employees to ensure that every employee is vaccinated against the virus or presents a negative test result on a weekly basis.[11] The White House predicted that the OSHA standard would apply to at least 80 million people.[12]

OSHA published the vaccination mandate in the Federal Register on November 5, 2021.[13] As authority, the agency relied on § 6 of the

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$100 to Get Vaccinated, N.Y. TIMES (July 29, 2021), https://www.nytimes.com/2021/07/29/us/politics/100-dollars-covid-vaccine-biden.html; Zolan Kanno-Youngs, *As the Pace of Vaccination Slows, Biden Makes a Personal Appeal*, N.Y. TIMES (June 24, 2021, updated Aug. 25, 2021), https://www.nytimes.com/2021/06/24/us/politics/biden-vaccines.html ("President Biden implored Americans on Thursday to 'knock on doors and talk to friends and neighbors' about getting vaccinated, as the White House opened a campaign-like blitz to persuade people around the country to get their shots.").

8. *Cf.* RICHARD H. THALER & CASS R. SUNSTEIN, NUDGE: THE FINAL EDITION (2021) (advocating in favor of often encouraging, rather than requiring, people to make decisions that are in their own and society's best interests).

9. *See*, *e.g.*, The White House, Remarks by President Biden on Fighting the COVID-19 Pandemic, (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ ("We've been patient, but our patience is wearing thin.") [hereinafter Biden's COVID-19 Remarks].

10. ETSs do not apply to state or local government agencies or units (e.g., public hospitals, fire departments, jails, etc.). 29 U.S.C. § 655(c)(1) (2018). Nor does this ETS apply to healthcare facilities or government contractors; separate mandates cover them. *See* 86 Fed. Reg. 61,555 (Nov. 5, 2021); 86 Fed. Reg. 63,418 (Nov. 16, 2021).

11. *See* The White House, Path Out of the Pandemic: President Biden's COVID-19 Action Plan (Sept. 2021), https://www.whitehouse.gov/covidplan/ ("Requiring All Employers with 100+ Employees to Ensure their Workers are Vaccinated or Tested Weekly. The Department of Labor's Occupational Safety and Health Administration (OSHA) is developing a rule that will require all employers with 100 or more employees to ensure their workforce is fully vaccinated or require any workers who remain unvaccinated to produce a negative test result on at least a weekly basis before coming to work. OSHA will issue an ETS to implement this requirement. This requirement will impact over 80 million workers in private sector businesses with 100+ employees.") (emphasis deleted) [hereinafter Biden's COVID-19 Action Plan].

12. *Id*.

13. Dep't of Labor, OSHA, COVID-19 Vaccination and Testing: Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917-18, 1926, and 1928) [hereinafter OSHA Vaccination Mandate]. The government had informally published the mandate on November 4. *See* Sarah Chaney Cambon, *OSHA Covid-19 Mandate: What to Know*, WALL ST. J., (Nov. 5, 2021),

Occupational Safety and Health Act (OSH Act) of 1970.[14] Entitled "Emergency Temporary Standards," § 6 empowers the Labor Secretary to issue workplace standards on an emergency basis when doing so is "necessary" to protect employees against "grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards."[15] In OSHA's opinion, the OSH Act required the ETS because the OSH Act provides that the agency "'shall'" promulgate such a standard if it makes the findings specified in the statute.[16] OSHA concluded that, under its regulations, the agency has the authority to regulate "'any . . . biological agent'"[17] such as the SARS-Cov-2 virus because its regulations define a virus as a "'[t]oxic substance or harmful physical agent'" for purposes of the OSH Act.[18] The ETS vaccination requirements fell "well

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https://www.wsj.com/articles/vaccine-mandate-for-private-sector-is-here-what-to-know-11636031354?mod=article_inline.

14. Pub. L. No. 91-596, 84 Stat. 1590, 1593 (codified as amended at 29 U.S.C. §§ 651–678 (2018)); *see* 86 Fed. Reg. at 61,402 (citing Section 601(c)(1) of the OSH Act as authority for the ETS), 86 Fed. Reg. at 61,404–07 (discussing OSHA's claimed authority for the mandate). We will refer to the Occupational Safety and Health Act as the "OSH Act" and to the Occupational Safety and Health Administration as "OSHA."

15. 29 U.S.C. § 655(c)(1); *see also* Pub. Citizen Health Rsch. Grp. v. Auchter, 702 F.2d 1150, 1156 (D.C. Cir. 1983); *infra* text accompanying notes 44–46 (explaining the relevant components of the OSH Act).

16. OSHA Vaccination Mandate, 86 Fed. Reg. at 61,405 (citing 29 U.S.C. § 655(c)).

17. OSHA Vaccination Mandate, 86 Fed. Reg. at 61,406 (citing 29 C.F.R. § 1910.1020(c)(13)).

18. *Id.* As a threshold matter, OSHA's authority to regulate workplace exposure to biological hazards like SARS–CoV–2 is well-established. Section 6(b)(5) of the OSH Act uses similar language to section 6(c)(1)(A): The former sets forth requirements for promulgating permanent standards addressing "toxic materials or harmful physical agents," 18· and the latter authorizes OSHA to promulgate an ETS addressing "substances or agents determined to be toxic or physically harmful" (as well as "new hazards"). *See* 29 U.S.C. § 655(b)(5); 29 U.S.C. § 655(c)(1)(A). OSHA has consistently identified biological hazards similar to SARS– CoV–2, as well as SARS–CoV–2 itself, to be "toxic materials or harmful physical agents" under the Act. Indeed, in its exposure and medical records access regulation, OSHA has defined "toxic materials or harmful physical agents" to include "any . . . biological agent (bacteria, virus, fungus, etc.)" for which there is evidence that it poses a chronic or acute health hazard. 29 C.F.R § 1910.1020(c)(13). And in addition to previously regulating exposure to SARS–CoV–2 as a new and physically harmful agent in the Healthcare ETS (*See, e.g.*, Dep't of Labor, Occupational Exposure to COVID-19; Emergency Temporary Standard, 86 Fed. Reg 32,376, 32,381 (June 21, 2021) (to be codified at 29 C.F.R. pt. 1910)), OSHA has also previously regulated biological hazards like SARS–CoV–2 as health hazards under section 6(b)(5), such as in, for example, the Bloodborne Pathogens (BBP) standard, 29 C.F.R. § 1910.1030, which addresses workplace exposure to HIV and Hepatitis B. The BBP

within the bounds of OSHA's authority," the agency concluded, because they "can be a critical tool in the pursuit of health and safety goals, particularly in response to an infectious and highly communicable disease."[19] OSHA even went so far as to argue that "the OSH Act explicitly acknowledges that such treatments might be necessary in some circumstances," because the text of the act expressly states that it neither requires nor authorizes the vaccination of parties over a religious objection unless a vaccination "is necessary for the protection of the health or safety of others."[20] Finally, OSHA concluded that SARS-CoV-2 poses both a

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standard was upheld (except as to application in certain limited industries) in American Dental Association, which observed that "the infectious character" of the regulated bloodborne diseases might warrant "more regulation than would be necessary in the case of a noncommunicable disease." Am. Dental Ass'n v. Martin, 984 F.2d 823, 826 (7th Cir. 1993). In addition, in the preamble to the respiratory protection standard, 29 CFR 1910.134, which was also promulgated under section 6(b)(5), "OSHA emphasize[d] that [the] respiratory protection standard does apply to biological hazards." Dep't of Labor, Respiratory Protection, 63 Fed. Reg. 1152, 1180 (Jan. 8, 1998) (citing Mahone Grain Corp., 10 OSHC 1275, 1981). In addition to being a physically harmful agent covered by section 6(c)(1)(A), SARS–CoV–2 is also, without question, a "new hazard" covered by this provision, as discussed in more detail in Grave Danger (Section III.A. of this preamble). SARS–CoV–2 was not known to exist until January 2020, and since then more than 813,000 people have died from COVID–19 in the U.S. alone (COVID-19 Mortality Overview, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/nchs/covid19/mortality-overview.htm.).

19. *Id.* (citing Jacobson v. Massachusetts, 197 U.S. 11 (1905) and Klaassen v. Trustees of Ind. Univ., 7 F.4th 592, 593 (7th Cir. 2021)), both of which rejected challenges to vaccination requirements).

20. OSHA Vaccination Mandate, 86 Fed. Reg. at 61,406 (citing 29 U.S.C. § 669(a)(5)). That provision of the OSH Act provides in full as follows:

> § 669: Research and related activities
>
> (a) Authority of Secretary of Health and Human Services to conduct research, experiments, and demonstrations, develop plans, establish criteria, promulgate regulations, authorize programs, and publish results and industrywide studies; consultations.
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> * * * * *
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> (5) The Secretary of Health and Human Services, in order to comply with his responsibilities under paragraph (2), and in order to develop needed information regarding potentially toxic substances or harmful physical agents, may prescribe regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which the Secretary of Health and Human Services reasonably believes may endanger the health or safety of employees. The Secretary of Health and Human Services also is authorized to establish such programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the susceptibility of employees to such illnesses.

"significant risk" and "grave danger" of harm that could not be addressed in a less onerous manner.[21]

An ETS can take effect immediately upon publication in the Federal Register, but it expires after six months and must be replaced by a permanent rule.[22] Perhaps for that reason (and possibly others), OSHA has rarely issued ETSs, and few of the ones that it has issued survived a challenge in court.[23] OSHA issued only nine ETSs between 1971 and 1983.[24] Plaintiffs challenged six of them in court, and only one was upheld. In the other cases, courts fully or partially vacated or stayed the ETSs.[25] OSHA's ETS authority has largely lain dormant since the courts invalidated a 1983 asbestos ETS.[26]

> Nothing in this or any other provision of this chapter shall be deemed to authorize or require medical examination, immunization, or treatment for those who object thereto on religious grounds, except where such is necessary for the protection of the health or safety of others. Upon the request of any employer who is required to measure and record exposure of employees to substances or physical agents as provided under this subsection, the Secretary of Health and Human Services shall furnish full financial or other assistance to such employer for the purpose of defraying any additional expense incurred by him in carrying out the measuring and recording as provided in this subsection.

The "paragraph (2)" referred to in the above subsection provides as follows:

> (2) The Secretary of Health and Human Services shall from time to time consult with the Secretary in order to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling the Secretary to meet his responsibility for the formulation of safety and health standards under this chapter; and the Secretary of Health and Human Services, on the basis of such research, demonstrations, and experiments and any other information available to him, shall develop and publish at least annually such criteria as will effectuate the purposes of this chapter.

21. OSHA Vaccination Mandate, 86 Fed. Reg. at 61,403, 61,407–29.

22. 29 U.S.C. §§ 655(c)(2) & (3). An ETS takes effect immediately upon publication in the Federal Register, 29 U.S.C. § 655(c), but OSHA announced that it would not begin enforcement of its mandate until January 4, 2022. *See* Stephanie Armour & Sabrina Siddiqui, *Biden's Vaccine Mandate Means Millions of Workers Must Get Shots by Jan. 4 or Test Weekly*, WALL ST. J. (Nov. 4, 2021), https://www.wsj.com/articles/employer-covid-19-vaccine-and-testing-rules-unveiled-by-biden-administration-11636029900?mod=article_inline.

23. *See* James Sullivan, *Lawsuits Fighting OSHA Covid-19 Vaccine Standard May Not Matter*, BLOOMBERG LAW (Sept. 24, 2021), https://news.bloomberglaw.com/business-and-practice/lawsuits-fighting-osha-covid-19-vaccine-standard-may-not-matter (stating that "OSHA's track record defending the use of this power has not been stellar").

24. *Id.*

25. *See id.*

26. *See* Asbestos Info. Ass'n v. OSHA, 727 F.2d 415, 425–427 (5th Cir. 1984) (ruling that the ETS was invalid because the risk was not grave and the ETS was not necessary, as required by statute). OSHA issued a new ETS in June 2021 regarding COVID-19 workplace safety in

In the short time since the announcement, President Biden's vaccination requirement has already proved controversial.[27] Various parties have said they would file lawsuits to have the OSHA rule invalidated once it was

health care facilities. Unlike the proposed vaccine mandate, however, the June 2021 ETS dealt only with working-condition requirements, such as personal protective equipment (PPE), ventilation standards, and so forth. *See* Scott D. Szymendera, Occupational Safety and Health Administration (OSHA): Emergency Temporary Standards (ETS) and COVID-19, Cong. Res. Serv. R46288 (Sept. 13, 2021); *see also* Occupational Safety & Health Adm'n, *Occupational Exposure to COVID-19; Emergency Temporary Standard*, 86 Fed. Reg. 32,376 (June 21, 2021).

27. *See*, *e.g.*, *Protecting Lives and Livelihoods: Vaccine Requirements and Employee Accommodations*, Hearing Before the Subcomms. on Workforce Protections and on Civil Rights and Human Services of the House Comm. on Education and Labor, 117th Cong. (Oct. 26, 2021) (competing views on the validity of the OSHA vaccination mandate); The Heritage Found., *What's Wrong with President Biden's COVID-19 Mandate* (Nov. 4, 2021), https://www.heritage.org/public-health/event/whats-wrong-president-bidens-covid-19-vaccine-mandate; Sarah Chaney Cambon & Amara Omeokwe, *Covid-19 Safety Fight Heats Up Between Biden Administration and States*, WALL ST. J., Oct. 19, 2021, https://www.wsj.com/articles/federal-government-moves-against-three-states-over-covid-19-worker-safety-11634678976?mod=Searchresults_pos2&page=1 (suggesting that lawsuits claiming an infringement of fundamental liberties will quickly be brought to courts); Bridget Dooling, *What's the Status of the Biden Administration's Workplace Vaccine Mandate?*, LAWFARE (Oct. 21, 2021), https://www.lawfareblog.com/whats-status-biden-administrations-workplace-vaccine-mandate (same); Edit. Bd., *Vaccine Mandate Madness*, WALL ST. J. (Oct. 12, 2021), https://www.wsj.com/articles/greg-abbott-osha-vaccine-mandate-southwest-airlines-joe-biden-11634075349?mod=Searchresults_pos7&page=1 (same); Andrew C. McCarthy, *How Will Courts React to Biden's Increasingly Imperial Presidency?*, NAT'L REV. (Sept. 18, 2021), https://www.nationalreview.com/2021/09/how-will-courts-react-to-bidens-increasingly-imperial-presidency/; Walter Olson, *Where Does Biden Get the Authority to Mandate Vaccination?*, REASON (Sept. 10, 2021), https://reason.com/2021/09/10/where-does-biden-get-the-authority-to-mandate-vaccination/; David B. Rivkin Jr. & Robert Alt, *Biden's Lawless Vaccine Mandate*, WALL ST. J. (Sept. 28, 2021), https://www.wsj.com/articles/biden-lawless-vaccine-mandate-constitution-occupational-safety-11632841737?mod=searchresults_pos1&page=1; Roger Severino & Rachel N. Morrison, *In OSHA We Trust?*, NAT'L REV., Oct. 28, 2021, https://www.nationalreview.com/2021/10/in-osha-we-trust/; Soave, *supra* note 6 ("The president should not—and most likely does not—have the power to unilaterally compel millions of private-sector workers to get vaccinated or risk losing their jobs . . . : [T]he mechanism of enforcement . . . is fundamentally undemocratic. Congress is supposed to make new laws, not an unaccountable bureaucratic agency."); Ilya Somin, *Rights and Wrongs of Biden's New Vaccination Mandate Policies*, VOLOKH CONSPIRACY (Sept. 10, 2021), https://reason.com/volokh/2021/09/10/rights-and-wrongs-of-bidens-new-vaccination-mandate-policies/ ("The really problematic element of Biden's plan is the requirement that all employers with 100 or more workers impose a requirement of vaccination or regular Covid testing on their entire workforce. This affects some 80 million workers . . . and the legal authority for it is dubious, at best.").

published,[28] and numerous states, private organizations, and individuals have already done so.[29] Soon, we will see a new round of litigation like the one that we witnessed in 2021 after the CDC issued a moratorium on tenant evictions for nonpayment of rent.[30] The Biden Administration lost that effort, but only time will tell what will happen with regard to this one.

To date, the OSHA vaccination mandate has been the subject of considerable litigation in the lower federal courts and even in the Supreme Court of the United States. In January 2022 in *National Federation of Independent Business v. OSHA*, the Court stayed the effectiveness of the mandate pending the completion of the litigation over its legality.[31] The Court rejected the government's argument that OSHA may order employees to be vaccinated to protect them against workplace infection by SARS-CoV-2. The OSH Act, the Court reasoned, "empowers [OSHA] to set *workplace* safety standards, not broad public health measures,"[32] the general subject of public health "falls outside of OSHA's sphere of expertise," and employees are at risk of exposure to the virus "at home, in schools, during sporting events, and everywhere else that people gather."[33] In sum, "[a]lthough Congress has

28. *See*, *e.g.*, Gov. Kristi Noem (@govkristinoem), Twitter, (Sept. 9, 2021, 4:14 PM), https://twitter.com/govkristinoem/status/1436060414970892288 ("South Dakota will stand up to defend freedom. @Joe Biden see you in court."); David Shepardson, *Biden Vaccine Mandate Will Test OSHA, U.S. Workplace Regulator*, REUTERS (Sept. 13, 2021), https://www.reuters.com/legal/government/biden-vaccine-mandate-will-test-us-workplace-regulator-2021-09-13/.

29. *See, e.g.*, Joseph Pisani, *States Sue to Stop Biden's Covid-19 Mandate*, WALL ST. J., Nov. 5, 2021, https://www.wsj.com/articles/states-sue-to-stop-bidens-covid-19-vaccine-mandate-11636137439?mod=article_inline. On the day after the mandate's publication, the U.S. Court of Appeals for the Fifth Circuit granted an emergency motion for a stay of the rule's enforcement on the ground that "there are grave statutory and constitutional issues with the Mandate." BST Holdings, L.L.C. v. OSHA, No. 21-60845, slip op. at 3 (5th Cir. Nov. 6, 2021).

30. *See* Ala. Ass'n of Realtors v. HHS, 2021 WL 1779282 (D.D.C. May 5, 2021) (ruling that the CDC lacked authority to issue its eviction moratorium), supplemented, 2021 WL 1946376 (May 14, 2021) (granting a stay pending appeal), on a motion to vacate the district court stay pending appeal, 2021 WL 2221646 (D.C. Cir. June 2, 2021) (denying motion), on a motion to vacate the district court stay pending appeal, 141 S. Ct. 2320 (2021) (denying motion), on remand, 2021 WL 3577367 (D.D.C. Aug. 13, 2021) (No. 20-cv-3377 (DLF)) (denying renewed motion to vacate stay pending appeal), on emergency motion to vacate the stay pending appeal, 2021 WL 3721431 (D.C. Cir. Aug. 20, 2021), vacating stay pending appeal, 141 S. Ct. 2485 (2021), order dismissing appeal, No. 21-5093 (D.C. Cir. Sept. 3, 3021) (order granting government's unopposed motion to dismiss the appeal). *See generally* Paul J. Larkin, *The Sturm und Drang of the CDC Home Eviction Moratorium*, HARV. J.L. & PUB. POL'Y: PER CURIAM (2021).

31. Nat'l Fed'n of Indep. Bus. v. Dep't of Lab, Occupational Safety and Health Admin., Nos. 21A244 & 21A247 (U.S. Jan. 13, 2022) [hereinafter *NFIB*].

32. *Id.* at 6 (emphasis in original).

33. *Id.*

indisputably given OSHA the power to regulate occupational dangers, it has not given that agency the power to regulate public health more generally."[34]

The Court's order, however, only stays the effectiveness of the mandate; the order is not a final decision on the mandate's validity. The government could continue the litigation in the lower courts and eventually ask the Supreme Court to reconsider its order. Accordingly, this Article will address the legality of the OSHA vaccination-or-weekly-test requirement ("vaccination requirement"). Part II will discuss whether OSHA's mandate is "arbitrary" and "capricious" or "unsupported by substantial evidence" for purposes of the Administrative Procedure Act (APA).[35] Part III will address whether OSHA has the statutory authority to adopt its vaccination mandate.[36]

II. THE RATIONALITY OF THE PROPOSED OSHA COVID-19 VACCINATION REQUIREMENT

President Biden directed OSHA to adopt a vaccination requirement as an "emergency" response to the decreasing rate of new immunizations witnessed since the spring of 2021.[37] Some parties challenging the rule are likely to argue that OSHA cannot satisfy the rigorous standard the OSH Act requires to avoid the APA notice-and-comment process before the standard takes effect—viz., proof that "employees are exposed to *grave danger*" from exposure to toxic materials at the workplace and that the standard is "*necessary* to protect employees from such danger."[38] In fact, twenty-four state attorneys general made that argument in a letter they sent to President Biden shortly after he announced his proposal.[39] The state attorneys general argued that the OSH Act does not empower OSHA to require employees to be vaccinated and that a universal employee vaccination requirement is overbroad because numerous people have acquired "a level of natural immunity" from having already suffered through Covid-19.[40] It could also

34. *Id.* at 9.

35. 5 U.S.C. § 706(2)(A) & (E) (2018). In *NFIB*, the Court went out of its way to say that "we express no view on issues not addressed in this opinion," such as whether the ETS was also invalid on other grounds. Slip op. at 8 n.*.

36. 5 U.S.C. § 706(2)(C).

37. *See* Biden's Covid-19 Remarks, *supra* note 9.

38. 29 U.S.C. § 655(c)(1) (emphasis added).

39. *See*, *e.g.*, Letter from Alan Wilson, South Carolina Att'y Gen'l et al. to President Joseph R. Biden 2-3 (Sept. 16, 2021), https://ago.wv.gov/Documents/AGs%27%20letter%20to%20Pres.%20Biden%20on%20vaccine%20mandate%20(FINAL)%20(02715056xD2C78).PDF [hereinafter 24 State AG's Letter].

40. *Id.* at 2; *see also id.* (arguing that "the statistics are clear that young people without co-morbidities have a low risk of hospitalization from" COVID-19); *see also* Letter from Aaron

be argued that OSHA's requirement is irrational because the nation is moving toward an increasing *number* of vaccinated parties, even if the *rate* of vaccinations has slowed.[41] Over time, the argument goes, everyone (or at least a sufficient number to achieve herd immunity) who should be vaccinated will receive one without the need for an intrusive government mandate. Finally, it is unclear precisely what is the "grave" workplace danger against which OSHA purports to be protecting workers. In President Biden's telling, the mandate would protect *vaccinated* workers against contracting Covid-19 from *unvaccinated* workers. But the danger is the *virus itself*, not one's colleagues, and what protects vaccinated workers is the vaccine. Anyone already fully vaccinated has greatly mitigated the "grave danger" posed by the coronavirus, whether or not others in their workplace have been immunized. The vaccine has greatly reduced their risk of contracting the disease and, if they do, their chance of serious illness and death is limited.[42] The mandate thus has a negligible effect on vaccinated workers. The mandate undoubtedly motivates some unvaccinated workers to get jabbed, but in that case, the mandate's chief effect is to protect unvaccinated workers from themselves.[43] Those arguments, however, are unlikely to prevail in court.

Siri et al., to Rochelle Walensky, Director, CDC & Sandra Cashman, Exec. Sec'y, CDC, Reply Regarding Citizen Petition to Lift Restrictions on the Naturally Immune to the Extent Lifted on the Vaccinated (Oct. 21, 2021), https://www.icandecide.org/wp-content/uploads/2021/10/Reply-to-CDC-Re-Natural-Immunity-v-Vaccine-Immunity.pdf.).

President Biden argued that a vaccination requirement is necessary "to protect vaccinated workers from unvaccinated co-workers." *See* Biden's Covid-19 Remarks, *supra* note 7 ("The bottom line: We're going to protect vaccinated workers from unvaccinated co-workers. We're going to reduce the spread of COVID-19 by increasing the share of the workforce that is vaccinated in businesses all across America."). The state attorneys general contended that the proposal was unnecessary because the vaccine itself should prevent vaccinated parties from succumbing to Covid-19. *See* 24 State AG's Letter, *supra* note 35, at 2. Even fully vaccinated people, however, can acquire a "breakthrough" version of Covid-19. That is why the federal government is considering a "booster" shot for fully vaccinated individuals. *See supra* note 3.

41. *See supra* notes 2–3 and accompanying text; *cf.* 5 U.S.C. § 706(2)(A) (2018) (providing that courts should hold invalid an agency's actions that are arbitrary, capricious, or beyond its statutory authority).

42. *See, e.g.*, Johns Hopkins Univ., Coronavirus Resource Cntr., The State of State-Level Breakthrough Case Reporting, (Sept. 7, 2021), https://coronavirus.jhu.edu/pandemic-data-initiative/data-outlook/the-state-of-state-level-breakthrough-case-reporting (last visited Jan. 24, 2022) ("The vaccines work against all current variants of the SARS-CoV-2 virus, including the delta variant. We know this in part due to breakthrough case data reported by the CDC: compared to unvaccinated individuals infected with SARS-CoV-2, vaccinated individuals were much less likely to develop severe disease and much less likely to die from the virus.") (footnotes omitted).

43. *See*, *e.g.*, Severino & Morrison, *supra* note 27.

The APA's arbitrary-and-capricious standard is stricter than the "minimum rationality" standard that legislation must surpass to avoid being held unconstitutional.[44] Nonetheless, that standard would be a difficult one for challengers to surmount here. In several different contexts, the Supreme Court has explained that courts should be most deferential to expert agencies when they make medical or scientific judgments on issues that Congress has assigned them.[45] In fact, Chief Justice John Roberts made that specific point in his separate opinion in *South Bay United Pentecostal Church v. Newsom*, writing that, because "[o]ur Constitution principally entrusts the safety and the health of the people to the politically accountable officials of the States to guard and protect," when they undertake action "in areas fraught with medical and scientific uncertainties," the federal courts must afford them "especially broad" latitude, and "they should not be subject to second-guessing by an unelected federal judiciary" lacking both "the background, competence, and expertise to assess public health" as well as any political accountability for their judgments.[46] Six months later, the full Court endorsed that principle in *Roman Catholic Diocese of Brooklyn v. Cuomo*, confessing that "[m]embers of this Court are not public health experts, and we should respect the judgment of those with special expertise and responsibility in this area."[47]

Perhaps challengers can present a convincing medical case that the ETS is arbitrary and capricious, even under the very deferential standard articulated in *South Bay* and *Catholic Diocese of Brooklyn*, given the availability of

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44. *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 n.9 (1983).

45. *See*, *e.g.*, Kisor v. Wilkie, 139 S. Ct. 2400, 2413 (2019) (lead opinion of Kagan, J.) ("If you are a judge, you probably have no idea of what the FDA's rule means, or whether its policy is implicated when a previously approved moiety is connected to lysine through a non-ester covalent bond. . . . Agencies (unlike courts) have unique expertise, often of a scientific or technical nature, relevant to applying a regulation to complex or changing circumstances.") (punctuation omitted); Indus. Union Dep't v. Am. Petrol. Inst., 448 U.S. 607, 656 (1980) (plurality opinion) (ruling that a deferential standard applies to judicial review of OSHA's safety regulations). *See generally* Paul J. Larkin, Jr. & GianCarlo Canaparo, *Gunfight at the New Deal Corral*, 19 GEO. J.L. & PUB. POL'Y 477, 523 n.234 (2021) (collecting cases).

46. 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring in the denial of application for injunctive relief) (citing Jacobson v. Massachusetts, 197 U.S. 11, 38 (1905), and Marshall v. United States, 414 U.S. 417, 427 (1974), respectively) (internal punctuation omitted).

47. 141 S. Ct. 63, 68 (2020). To be sure, the Court's orders in *South Bay United Pentecostal Church* and *Catholic Diocese of Brooklyn* were only interlocutory orders entered in response to requests to award interim relief pending the final resolution of those cases. Nonetheless, they can offer an authoritative view of how the Court would resolve a case on its merits. *See* Casa de Md., Inc. v. Trump, 971 F.3d 220, 229–30 (4th Cir. 2020) (discussing the effect of rulings on the court's "shadow docket."). *See generally* Trevor N. McFadden & Vetan Kapoor, *The Precedential Effect of the Supreme Court's Emergency Stays*, 44 HARV. J.L. & PUB. POL'Y 827 (2021).

vaccines that had not yet been approved at the time of those decisions, as well as the large number of people who already have been vaccinated. But we doubt it. The Court has been very deferential to expert agencies when Congress has given the latter responsibility over medical or scientific judgments. As then-Associate Justice William Rehnquist wrote for the Court in *Baltimore Gas & Elec. Co. v. Natural Resources Defense Council*, "a reviewing court must generally be at its most deferential" whenever an agency "is making predictions, within its area of special expertise, at the frontiers of science," more deferential than when the court is reviewing "simple findings of fact."[48] If an expert agency's prediction is within the range of permissible medical judgment, the federal courts are unlikely to set it aside.[49]

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48. 462 U.S. 87, 103 (1983).

49. *See, e.g.*, *id.* at 97 ("Resolution of these fundamental policy questions [surrounding nuclear generation facilities] lies . . . with Congress and the agencies to which Congress has delegated authority, as well as with state legislatures and, ultimately, the populace as a whole. Congress has assigned the courts only the limited, albeit important, task of reviewing agency action to determine whether the agency conformed with controlling statutes. . . . [A]dministrative decisions should be set aside in this context, as in every other, only for substantial procedural or substantive reasons as mandated by statute . . . not simply because the court is unhappy with the result reached.") (citations and internal punctuation omitted); *id.* at 105–06 ("In sum, we think that the zero-release assumption—a policy judgment concerning one line in a conservative Table designed for the limited purpose of individual licensing decisions—is within the bounds of reasoned decisionmaking. It is not our task to determine what decision we, as Commissioners, would have reached. Our only task is to determine whether the Commission has considered the relevant factors and articulated a rational connection between the facts found and the choice made. . . . Under this standard, we think the Commission's zero-release assumption . . . was not arbitrary and capricious.") (citations omitted); *Industrial Union Dep't*, 448 U.S. at 655 n. 62 ("[W]hen the question involves determination of the acceptable level of risk, the ultimate decision must necessarily be based on considerations of policy as well as empirically verifiable facts. Factual determinations can at most define the risk in some statistical way; the judgment whether that risk is tolerable cannot be based solely on a resolution of the facts. . . . Thus, while the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognize that its determination that a particular level of risk is significant will be based largely on policy considerations. At this point we have no need to reach the issue of what level of scrutiny a reviewing court should apply to the latter type of determination.") (citation and internal punctuation omitted); *id.* at 656 (plurality opinion) ("OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty. Although the Agency's findings must be supported by substantial evidence, 29 U.S.C. § 655(f), [OSH Act] § 6(b)(5) specifically allows the Secretary to regulate on the basis of the best available evidence. As several Courts of Appeals have held, this provision requires a reviewing court to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge. . . . Thus, so long as they are supported by a body of reputable scientific thought,

In this case, the government's judgment easily fits into that range. The FDA has formally approved one vaccine and granted emergency use authorization for two more.[50] Each vaccine reduces the risk of developing Covid-19 from exposure to SARS-CoV-2 and greatly ameliorates the risk of hospitalization and death.[51] The larger the number of people who receive the vaccine, the smaller the number of people who will suffer death or serious incapacitation from the disease. Increasing the former reduces risks to the latter. [52] Increasing the former also might benefit those people already vaccinated because the vaccines are not an immediate or lifetime guarantee that no recipient will suffer from Covid-19.[53] The law does not demand certainty from agency officials when making medical or scientific judgments, and there is no reason to impose such a requirement here.[54] Rightly or

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the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection."); Asbestos Info. Ass'n/North America v. OSHA, 727 F.2d 415, 425 (5th Cir. 1984) ("OSHA claims that by permanently lowering the present 2.0 f/cc PEL to 0.5 f/cc, it will save sixty-four lives per one thousand workers over a working lifetime of forty-five years. . . . Over six months, this works out to eighty lives out of an estimated worker population of 375,399. . . . As the Supreme Court has noted, the determination of what constitutes a risk worthy of Agency action is a policy consideration that belongs, in the first instance to the Agency. *Industrial Union Dep't*, 448 U.S. at 656, n. 62. 'Some risks are plainly acceptable and others are plainly unacceptable.' *Id.* at 655. The Secretary determined that eighty lives at risk is a grave danger. We are not prepared to say it is not.") (footnotes and some citations omitted).

50. *See supra* note 3.

51. *COVID-19 Vaccines: Get the Facts*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-vaccine/art-20484859 (last visited Jan. 24, 2022).

52. *See id*.

53. *See Coronavirus (COVID-19) Information and Updates*, JOHNS HOPKINS MEDICINE, https://www.hopkinsmedicine.org/coronavirus/covid-19-vaccine/for-patients.html#protection (last visited Jan. 24, 2022) ("When will I be protected from catching COVID-19? According to CDC Guidelines, you are fully vaccinated when it has been two weeks after receiving your second dose in a two-dose series, such as the Pfizer or Moderna vaccines. Two weeks after a single dose of the Johnson & Johnson vaccine. However, data from clinical trials are clear that there is further improvement four weeks after the single-shot vaccine, especially for preventing severe COVID-19 or having asymptomatic infection. For this reason, Johns Hopkins Medicine recommends four weeks after the single-dose vaccine to be considered fully vaccinated. If you don't meet these requirements, you are not fully vaccinated.") ("How long does the COVID-19 vaccine last? This is a question researchers are eager to answer. Data from the vaccine trials show strong immunity for at least several months after vaccination, with some studies indicating possible long-term immunity. People who are infected with the coronavirus show a decline in protection within a few months, but their immunity may last significantly longer than that. (A few people appear to have caught COVID-19 twice, but this is unusual).").

54. *See* 29 U.S.C. § 655(f); Asbestos Info. Ass'n v. Occupational Safety & Health Admin.,

wrongly, medical experts have decided that a vaccination requirement will prevent needless morbidity and mortality.[55] The federal courts are not likely to find that the government's expert medical judgment is an "arbitrary" or "capricious" one under the APA.[56]

III. THE LEGALITY OF THE PROPOSED OSHA COVID-19 VACCINATION REQUIREMENT

At the same time, the Supreme Court has treated differently the task of legal interpretation. Consider the Court's 2020 decision in *Roman Catholic Diocese of Brooklyn*.[57] The Court expressed a need to defer to the judgment of medical experts in how best to respond to the pandemic, but the Court did not defer to the judgment of then-New York Governor Andrew Cuomo regarding the legality of a church attendance restriction. The Court reviewed that matter de novo. That case, however, involved a Free Exercise Clause challenge to a Covid-19 restriction on church attendance, and the Court has been far less reluctant to review de novo an agency's analysis of constitutional issues than scientific judgments. After all, the courts, not physicians, are the experts when it comes to legal analysis, and the "[g]overnment is not free to disregard the First Amendment in times of crisis."[58] *Roman Catholic Diocese of Brooklyn* is evidence that the Court will exercise independent judgment, at least when constitutional issues are in play.[59]

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727 F.2d 415, 425 (5th Cir. 1984) ("The Agency need not support its conclusion with anything approaching scientific certainty. . . . Additionally, so long as the Agency supports its conclusion with a body of reputable scientific thought, it may "use conservative assumptions to support that conclusion. The Agency also has a prerogative to choose between conflicting evidence of equivalent quality, and a court will consider a finding consistent with one authority.").

55. *See supra*, note 51; *Path Out of the Pandemic: President Biden's COVID-19 Action Plan*, THE WHITE HOUSE, https://www.whitehouse.gov/covidplan (last visited Jan. 24, 2022).

56. 5 U.S.C. § 706; Washington v. Harper, 494 U.S. 210, 229 (1990) (quoted *infra* at note 161); Dent v. West Virginia, 129 U.S. 114, 122 (1889) ("Few professions require more careful preparation by one who seeks to enter it than that of medicine. . . . The physician must be able to detect readily the presence of disease, and prescribe appropriate remedies for its removal. Every one may have occasion to consult him, but comparatively few can judge of the qualifications of learning and skill which he possesses.").

57. 141 S. Ct. 63 (2020).

58. *Id.* at 69 (Gorsuch, J., concurring).

59. The Court ruling in *Roman Catholic Diocese of Brooklyn* is consistent with its rulings in cases interpreting other constitutional provisions. *See, e.g.*, Ornelas v. United States, 517 U.S. 690, 697 (1996) (ruling that appellate courts should undertake "independent appellate review of . . . ultimate determinations of reasonable suspicion and probable cause"); Milkovich v. Lorain J. Co., 497 U.S. 1, 17 (1990) (pertaining to cases raising Free Speech Clause issues).

That being said, there is an additional factor to consider. The Supreme Court has been willing to defer to an agency's legal interpretation of ambiguous statutory text. The leading case is *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc*.[60] *Chevron* decided that statutory silence or ambiguity impliedly delegates to an agency the authority to construe acts of Congress in light of the relevant policies that the agency must accommodate to implement that law.[61] I f so, a reviewing court must accept the agency's interpretation even if it would have read the statute differently in the first instance.[62] T hat rule is quite controversial,[63] however, and four Justices have concluded that the *Chevron* deference doctrine is mistaken and should be retired,[64] Chief Justice Roberts is open to that argument,[65] and Justice Amy Coney Barrett has not yet cast a vote on the issue. Whether the Court will jettison *Chevron* is beyond the scope of this Article, but the OSHA ETS could force the Court to address that issue.

In any event, the *Chevron* deference doctrine does not apply when Congress has answered the disputed question. *Chevron* itself made that point, noting that the first step in any statutory construction problem "always" is "whether Congress has directly spoken to the precise question at issue."[66] If Congress did, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[67]

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60. 467 U.S. 837 (1984).

61. *Id*. at 842–43 ("When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.").

62. *Id*. at 843 n.11 ("The court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding.").

63. *See generally* Larkin & Canaparo, *supra* note 41, at 480–82; *id.* at n.8–11; *id.* at 520–28 (summarizing the controversy).

64. *Id*. at 482; *id.* at n.16 (discussing the importance of the separate opinions in Kisor v. Wilkie, 139 S. Ct. 2400 (2019) (Gorsuch, J., joined by Thomas, Alito and Kavanaugh, JJ., concurring in the judgment)).

65. Kisor v. Wilkie, 139 S. Ct. 2400, 2424–25 (2019) (Roberts, C.J., concurring in part).

66. 467 U.S. at 842.

67. *Id.* at 842–43; *see also*, *e.g.*, Utility Air Regulatory Group v. EPA, 573 U.S. 302, 315–34 (2014).

Here, the question is whether Congress has assigned to OSHA the authority to impose a mandatory vaccination or testing requirement. It turns out that the answer is "No." That conclusion follows from the text of the relevant section of the OSH Act,[68] from the text of the entire statute when read as a whole,[69] and from the role that the OSH Act plays in the overall congressional effort to protect employees and the public from harmful viruses.[70]

A. Section 6 of the OSH Act

Start with the text of the OSH Act. The act itself obviously does not contain any reference to "vaccinations" or "immunizations." Yet, state health codes commonly use those terms when addressing this subject. States require students to be vaccinated to attend school, and the state health codes and implementing regulations expressly use terms such as "vaccination," "inoculation," or "immunization" to make that point clearly.[71] States also

68. *See infra* Section III.A.

69. *See infra* Section III.B.

70. *See infra* Section III.C.

71. *See, e.g.*, CONN. GEN. STAT. ANN. § 10-204a (West 2021) ("Each local or regional board of education, or similar body governing a nonpublic school or schools, shall require each child to be protected by adequate immunization against diphtheria, pertussis, tetanus, poliomyelitis, measles, mumps, rubella, haemophilus influenzae type B and any other vaccine required by the schedule for active immunization adopted pursuant to section 19a-7f before being permitted to enroll in any program operated by a public or nonpublic school under its jurisdiction. Before being permitted to enter seventh grade, a child shall receive a second immunization against measles."); KAN. STAT. ANN. § 72-6262 (West 2021) ("In each school year, every pupil enrolling or enrolled in any school for the first time in this state, and each child enrolling or enrolled for the first time in a preschool or day care program operated by a school, and such other pupils as may be designated by the secretary, prior to admission to and attendance at school, shall present to the appropriate school board certification from a physician or local health department that the pupil has received such tests and inoculations as are deemed necessary by the secretary by such means as are approved by the secretary."); S.C. Code § 44-29-180 (West 2021) ("(A) No superintendent of an institution of learning, no school board or principal of a school, and no owner or operator of a public or private childcare facility as defined in Section 63-13-20 may admit as a pupil or enroll or retain a child or person who cannot produce satisfactory evidence of having been vaccinated or immunized so often as directed by the Department of Health and Environmental Control. Records of vaccinations or immunizations must be maintained by the institution, school, or day care facility to which the child or person has been admitted. (B) The Department of Health and Environmental Control shall monitor the immunization status of each child who is enrolled or retained in a licensed child day care facility or a registered church or religious child day care facility. The monitoring of day care facilities shall consist of a review of the immunization or vaccination records to insure that required immunizations are complete as recommended

authorize health officers to administer vaccinations, particularly during a public health emergency (while also distinguishing between voluntary and mandatory vaccination requirements).[72] That is the ordinary way of imposing a vaccination requirement—viz., in the text of the governing statute or regulation. In fact, the state-law smallpox vaccination requirement that the Supreme Court upheld in *Jacobson v. Massachusetts*[73] over a Due Process Clause challenge expressly referred to the "vaccination" of the public.[74] Accordingly,

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and routinely provided by the Department of Health and Environmental Control for all infants and children. (C) South Carolina Department of Health and Environmental Control Regulation 61-8, as amended, "Vaccination, Screening and Immunization Regarding Contagious Diseases", and its exemptions apply to this section."); S.C. Code of Regulations R. 61-8.I.A. (West 2021) ("A. No child or person shall be admitted to or retained in any public, private, or parochial school, grades kindergarten through twelve (K-12), or any public or private childcare facility as defined in Code Section 62-13-20 without a valid South Carolina Certificate of Immunization. To be valid, the South Carolina Certificate of Immunization must be signed by a licensed physician or his/her authorized representative. Exemptions to this requirement are authorized in Section II of this regulation."); Hillel Y. Levin et al., *Stopping the Resurgence of Vaccine-Preventable Childhood Diseases: Policy, Politics, and Law*, 2020 U. Ill. L. Rev. 233, 238 ("All fifty states require children to be vaccinated against a range of diseases in order to attend school.") (footnote omitted). Every state allows exemptions for a limited number of reasons. Levin, *supra*, at 238-39.

72. *See*, *e.g.*, S.C. CODE § 44-4-520 (West 2021) ("(A) During a state of public health emergency, DHEC may exercise the following emergency powers, in addition to its existing powers, over persons as necessary to address the public health emergency: (1) to vaccinate persons as protection against infectious disease and to prevent the spread of contagious or possibly contagious disease; (2) to treat persons exposed to or infected with disease; and (3) to prevent the spread of contagious or possibly contagious disease, DHEC may isolate or quarantine, pursuant to the applicable sections of this act, persons who are unable or unwilling for any reason (including, but not limited to, health, religion, or conscience) to undergo vaccination or treatment pursuant to this section. (B) Vaccinations or treatment, or both, must be provided only to those individuals who agree to the vaccinations or treatment, or both. (C)(1) Vaccination may be performed by any qualified person authorized by DHEC. (2) To be administered pursuant to this section, a vaccine must not be such as is reasonably likely to lead to serious harm to the affected individual. (D)(1) Treatment must be administered by any qualified person authorized to do so by DHEC. (2) Treatment must not be such as is reasonably likely to lead to serious harm to the affected individual.").

73. 197 U.S. 11 (1905).

74. *Id.* at 12–13 ("The Revised Laws of that commonwealth, chap. 75, § 137, provide that 'the board of health of a city or town, if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit $5.' [¶] . . . [¶] Proceeding under the above statutes, the board of health of the city of Cambridge, Massachusetts, on the 27th day of

Congress could easily have drafted the OSH Act to empower OSHA to require that employees be vaccinated against communicable diseases. The text of the statute, however, contains no such referent or authorization.

Now turn to what the OSH Act does contain. Two subsections are relevant here. The first one is Subsection 6(b)(5).[75] It directs the Labor Secretary, when issuing "occupational safety and health standard[s]," [76] to ensure that, "to the extent feasible," no employee will suffer a "material impairment of health or functional capacity" even if he is she is regularly exposed to a hazard for the duration of "his working life." [77] The scope of that directive, however, is limited. It applies only to standards dealing with "toxic materials or harmful physical agents." [78] The other provision is Subsection 6(c)(1). It permits ETS to take effect immediately upon publication in the Federal Register if the Labor Secretary finds that "employees are exposed to grave danger from exposure to substances or agents determined to be toxic

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February, 1902, adopted the following regulation: 'Whereas, smallpox has been prevalent to some extent in the city of Cambridge, and still continues to increase; and whereas, it is necessary for the speedy extermination of the disease that all persons not protected by vaccination should be vaccinated; and whereas, in the opinion of the board, the public health and safety require the vaccination or revaccination of all the inhabitants of Cambridge; be it ordered, that all the inhabitants habitants of the city who have not been successfully vaccinated since March 1st, 1897, be vaccinated or revaccinated.' [¶] Subsequently, the board adopted an additional regulation empowering a named physician to enforce the vaccination of persons as directed by the board at its special meeting of February 27th.").

75. See 29 U.S.C. §§ 655(b)(5) & (c)(1).

76. OSH Act § 3(8) defines an "occupational safety and health standard" as "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 U.S.C. § 652(8).

77. 29 U.S.C. § 655(b)(5) ("The [Labor] Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.").

78. *Id.*

or physically harmful" to employees.[79] Subsection 6(c)(1) achieves that result by exempting ESTs from the APA's notice-and-comment process that a proposed rule must ordinarily satisfy before becoming effective.[80]

Congress obviously intended those two provisions to be read and work together. The substance of each one is directed toward preventing harm to employees from dangerous materials, and they both appear in the same section of the OSH Act.[81] Subsection 6(b)(5) addresses the standards that the Labor Secretary may adopt, while Subsection 6(c)(1) permits certain standards to take effect immediately upon publication.[82] former speaks to *what* certain standards must contain and *why* that is obligatory, while the latter addresses *when* those standards can become law and *how long* they can remain law. Accordingly, it makes sense to construe the two provisions together when interpreting the OSH Act. Not surprisingly, standard rules of statutory interpretation also would require the courts to do just that.[83]

That creates a problem for the Biden Administration. The standards addressed by Subsection 6(b)(5), which can go into effect immediately upon publication under Subsection 6(c)(1) must involve "toxic materials or harmful physical agents." Yet, it is not clear that a "virus" qualifies as either one for purposes of the OSH Act.

A "virus" is a communicable pathogen with a protein coat encapsulating an RNA or DNA genetic material that replicates within a host or dies.[84] A

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79. 29 U.S.C. § 655(c)(1) (emphasis omitted) ("(c) Emergency temporary standards (1) The [Labor] Secretary shall provide, without regard to the requirements of chapter 5 of Title 5, for an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger.").

80. 5 U.S.C. §§ 551, 553 (West 2021). An ETS

81. Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, § 6, 84 Stat. 1590, 1593–97 (1970).

82. Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, § 6(c)(1), 84 Stat. 1590, 1596 (1970).

83. *See*, *e.g.*, Utility Air Regulatory Group v. EPA, 573 U.S. 302, 321 (2014) (internal quotations omitted) ("A statutory provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.").

84. *See*, *e.g.*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/virus ("**1a**: any of a large group of submicroscopic infectious agents that are usually regarded as nonliving extremely complex molecules, that typically contain a protein coat surrounding an RNA or DNA core of genetic material but no semipermeable membrane, that are capable of growth and multiplication only in living cells, and that cause various important diseases in humans, animals, and plants.") (last visited Jan. 24, 2022).

"toxin" is different. The OSH Act does not define that term, so it should receive its ordinary, dictionary meaning.[85] A "toxin" is a "poisonous" substance, which refers to an element or compound such as arsenic or chemical waste that, though often hazardous, does not replicate within a human host.[86] The terms "toxin" and "toxic substance" therefore do not readily serve as synonyms for the terms "contagious"[87] or "communicable disease,"[88] which refer to pathogens spread from person to person, like

85. *See*, *e.g.*, Bostock v. Clayton, Cnty, Ga., 140 S. Ct. 1731, 1738 (2020) ("This Court normally interprets a statute in accord with the ordinary public meaning of its terms at the time of its enactment."); Crawford v. Metro. Gov't of Nashville & Davidson Cnty., Tenn., 555 U.S. 271, 276 (2009) ("The term 'oppose,' being left undefined by the statute, carries its ordinary meaning . . .: '[t]o resist or antagonize . . .; to contend against; to confront; resist; withstand,' Webster's New International Dictionary 1710 (2d ed. 1957.").

86. *See*, *e.g.*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/toxic ("**1:** containing or being poisonous material especially when capable of causing death or serious debilitation //*toxic* waste //a *toxic* radioactive gas //an insecticide highly *toxic* to birds [¶] **2:** exhibiting symptoms of infection or toxicosis //the patient became *toxic* two days later [¶] **3:** extremely harsh, malicious, or harmful //*toxic* sarcasm [¶] **4:** relating to or being an asset that has lost so much value that it cannot be sold on the market.") (last visited Jan. 24, 2022); *id.* (definition of "toxin"), https://www.merriam-webster.com/dictionary/toxin ("a poisonous substance that is a specific product of the metabolic activities of a living organism and is usually very unstable, notably toxic when introduced into the tissues, and typically capable of inducing antibody formation") (last visited Jan. 24, 2022).

87. *See*, *e.g.*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/contagious%20disease#medicalDictionary ("Definition of *contagious disease* [¶]: an infectious disease (such as influenza, measles, or tuberculosis) that is transmitted by contact with an infected individual or infected bodily discharges or fluids (such as respiratory droplets), by contact with a contaminated surface or object, or by ingestion of contaminated food or water [¶] NOTE: The terms *contagious disease* and *communicable disease* are often used interchangeably. However, communicable diseases such as malaria or schistosomiasis that are spread by contact with disease vectors (such as mosquitoes or ticks) are not typically considered to be 'contagious' diseases since they cannot be spread from direct contact with another person.") (last visited Jan. 24, 2022).

88. *See*, *e.g.*, MERRIAM-WEBSTER."), https://www.merriam-webster.com/dictionary/communicable%20disease ("communicable disease [¶] noun [¶] Medical Definition of *communicable disease*: an infectious disease (as cholera, hepatitis, influenza, malaria, measles, or tuberculosis) that is transmissible by contact with infected individuals or their bodily discharges or fluids (as respiratory droplets, blood, or semen), by contact with contaminated surfaces or objects, by ingestion of contaminated food or water, or by direct or indirect contact with disease vectors (as mosquitoes, fleas, or mice) [¶] NOTE: The terms *communicable disease* and *contagious disease* are often used interchangeably. However, communicable diseases (as malaria or schistosomiasis) that are spread by contact with disease vectors are not typically considered to be 'contagious' diseases since they cannot be spread from direct contact with another person.") (last visited Jan. 24, 2022).

Covid-19.[89] A virus like SARS-CoV-2 satisfies the definitions of a "contagious disease,"[90] while arsenic, a known poison and a hazardous waste under federal law today,[91] is not contagious. According to the Agency for

89. *See*, *e.g.*, U.S. Cntrs. for Disease Control & Prevention, *Frequently Asked Questions* (Sept. 13, 2021), https://www.cdc.gov/coronavirus/2019-ncov/faq.html ("COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth. In some circumstances, they may contaminate surfaces they touch. People who are closer than 6 feet from the infected person are most likely to get infected. [¶] COVID-19 is spread in three main ways: • Breathing in air when close to an infected person who is exhaling small droplets and particles that contain the virus. [¶] • Having these small droplets and particles that contain virus land on the eyes, nose, or mouth, especially through splashes and sprays like a cough or sneeze. [¶] •Touching eyes, nose, or mouth with hands that have the virus on them.); MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/infectious ("**1a:** producing or capable of producing infection //bacteria and other *infectious* agents [¶] **b:** caused by or resulting from an infection with one or more pathogenic agents //*infectious* mononucleosis— see also INFECTIOUS DISEASE [¶] **c:** transmitting or capable of transmitting infection **:** containing pathogenic agents which may be transmitted //*infectious* droplets [¶] **2:** spreading or capable of spreading rapidly to others //an *infectious* laugh //Her happiness was *infectious*.").

90. For the difference between the latter two terms, see MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/infectious ("What is the Difference Between *contagious* and *infectious*? [¶] The words contagious and infectious can be confusing because they do not designate wholly distinct categories; something is not *either* contagious or infectious. [¶] Essentially, infectious diseases and contagious diseases are caused by disease-producing agents such as bacteria and viruses, but they differ in that contagious diseases can be spread to other people by direct or indirect contact. [¶] Anything contagious, such as the flu, is always automatically infectious: if you can catch it from someone, it's being passed to you via an infectious agent, which is the thing that gets you sick—usually a virus or a bacteria. [¶] The reverse, however, isn't true. Just because something is infectious does not mean it's contagious. Food poisoning, for example, is infectious but not contagious: food can be contaminated with a bacteria (an infectious agent) that makes you sick, but you can't give your food poisoning to someone else by shaking their hand or even giving them a kiss. [¶]Both *contagious* and *infectious* are also used figuratively, often in much happier contexts: laughter can be contagious; someone's enthusiasm can be infectious. While both words are used figuratively of both pleasant and unpleasant things, *contagious* is more often chosen for the unpleasant, as when it's grumpiness or fear that seems to be spreading.").

91. *See* 42 U.S.C. § 6903(5) (West 2021) ("The term 'hazardous waste' means a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may—(A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."), *id.* § 6924(d)(2)(B)(i) (identifying arsenic and its compounds as a hazardous waste); 40 C.F.R. § 261, App. VII (West 2021).

Toxic Substances and Disease Registry, a component of the Department of Health and Human Services (HHS), inhalation or transdermal contact with arsenic usually does not cause "acute systemic toxicity."[92] Ingestion is the most likely way for arsenic to become hazardous.[93] Moreover, the natural reading of the term "physical agent" does not include viruses.[94] A hazardous waste is dangerous because it is flammable, explosive, or carcinogenic, but it does not replicate itself inside a living organism.[95] Viruses do.

To be sure, the text of Subsections 6(b)(5) and 6(c)(1) do not neatly disclose their congruence; their terminology differs slightly. The former uses the phrase "toxic materials or harmful physical agents," while the latter uses slightly different terms: "substances or agents determined to be toxic or physically harmful or from new hazards."[96] The term "materials" appears in the former subsection but not in the latter, while the terms "substances" and "or from new standards" appear in the latter subsection but not in the former.[97]

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92. Agency for Toxic Substances and Disease Registry (Oct. 21, 2014), https://www.atsdr.cdc.gov/MHMI/mmg2.pdf (last visited Jan. 24, 2022); Agency for Toxic Substances and Disease Registry, Public health Statement, Arsenic CAS#: 7440-38-2, §§ 1.3 to 1.7, at 3-8. (Aug. 2007) [hereinafter ATSDR Statement].

93. ATSDR Statement, § 1.4, at 4 ("If you swallow arsenic in water, soil, or food, most of the arsenic may quickly enter into your body. The amount that enters your body will depend on how much you swallow and the kind of arsenic that you swallow. This is the most likely way for you to be exposed near a waste site. If you breathe air that contains arsenic dusts, many of the dust particles settle onto the lining of the lungs. Most of the arsenic in these particles is then taken up from the lungs into the body. You might be exposed in this way near waste sites where arsenic-contaminated soils are allowed to blow into the air, or if you work with arsenic-containing soil or products. If you get arsenic-contaminated soil or water on your skin, only a small amount will go through your skin into your body, so this is usually not of concern.")

94. MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/agent ("**1 :** one that acts or exerts power [¶] **2a :** something that produces or is capable of producing an effect **:** an active or efficient cause Education proved to be an agent of change in the community. [¶] **b :** a chemically, physically, or biologically active principle an oxidizing agent [¶] **3 :** a means or instrument by which a guiding intelligence achieves a result [¶] **4 :** one who is authorized to act for or in the place of another: such as [¶] **a :** a representative, emissary, or official of a government crown agent federal agent [¶] **b :** one engaged in undercover activities (such as espionage) **:** spy a secret agent [¶] **c :** a business representative (as of an athlete or entertainer) a theatrical agent [¶] **5 :** a computer application designed to automate certain tasks (such as gathering information online).") (last visited Jan. 24, 2022).

95. *See, e.g.*, U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. HEALTH SERV., AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, TOXICOLOGICAL PROFILE FOR ARSENIC §§ 1.3-1.4, at 4–6 (Aug. 2007), https://www.atsdr.cdc.gov/ToxProfiles/tp2.pdf (explaining how arsenic enters, damages, and leaves the body without mentioning replication).

96. *Compare* 29 U.S.C. § 655(b)(5) *with* 29 U.S.C. § 655(c)(1).

97. *See* 29 U.S.C § 655(b)(5); 29 U.S.C. § 655(c)(1).

That discrepancy is odd. It makes little sense to impose more lenient requirements to enable an agency to make a standard effective immediately than to adopt the standard itself. Yet that is what the text of Section 6 might seem to imply if read literally. In addition, Congress did not draft the ETS provision in Section 6 with precision. Subsection 6(c)(1) requires the Labor Secretary to find that "employees are *exposed* to grave danger from *exposure*," which is obviously redundant.[98] Subsection 6(c)(1) is such an example, and courts should be mindful of that principle when construing the OSH Act.[99]

B. The Entire OSH Act

Next, step back and consider the OSH Act as a whole. The purpose of the act was to reduce "personal injuries and illnesses arising out of work situations"[100] caused by "occupational safety and health standards at their [viz., employers and employees] places of employment"[101] by "providing safe and healthful working conditions"[102]—not to resolve a health-care matter, like the COVID-19 pandemic, that can arise at work, at home, and at any point in between. Congress sought to "provid[e] for research in the field of occupational safety and health, including the psychological factors involved," as well as "developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems"[103]—not for research into virology or vaccines. Moreover, the term "toxic" appears elsewhere in the OSH Act, where the government must prepare a report "listing all toxic substances in industrial usage."[104] That provision reveals that the term "toxic" in the ETS subsection refers to chemical ingredients or wastes, not viruses like SARS-CoV-2, since the latter are hardly "in industrial usage."

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98. 29 U.S.C. § 655(c)(1) (emphases added).

99. *See, e.g.*, Env't Def. v. Duke Energy Corp., 549 U.S. 561, 574 (2007) ("[T]he natural presumption that identical words used in different parts of the same act are intended to have the same meaning is . . . not rigid and readily yields whenever there is such variation in the connection in which the words are used as reasonably to warrant the conclusion that they were employed in different parts of the act with different intent.") (internal quotations omitted) (quoting Atl. Cleaners & Dyers, Inc. v. United States, 286 U.S. 427, 433 (1932)); Price Waterhouse v. Hopkins, 490 U.S. 228, 241 (1989) (plurality opinion) ("We need not leave our common sense at the doorstep when we interpret a statute."); Bell v. United States, 349 U.S. 81, 83 (1955) (noting that courts should read statutes with the "saving grace of common sense").

100. 29 U.S.C. § 651(a).

101. 29 U.S.C. § 651(b)(1).

102. 29 U.S.C. § 651(b)(1), (b)(4).

103. 29 U.S.C. § 651(b)(5).

104. 29 U.S.C. § 675.

The OSH Act also requires studies about "the contamination of workers' homes" by "hazardous chemicals and substances, including infectious agents, transported from the workplaces" of such workers.[105] Congress was concerned with the health of employees' family members because of the onsite exposure of employees to a hazard at work.[106] A pandemic, however, exposes everyone everywhere to a pathogen, not merely industrial workers at a petroleum refinery or similar lines of business. It is unlikely that Congress sought to use that provision to obtain reports from the Labor Secretary about viruses found across the land. Accordingly, the entirety of the OSH Act shows that Congress did not grant OSHA authority to impose a vaccination requirement by virtue of the terms in the ETS provision that make no mention of viruses.

In its Federal Register notice, as a legal justification for the vaccination mandate OSHA pointed to two statutory provisions that, it said, contemplate that OSHA may adopt such a requirement.[107] That argument is unconvincing.

One section is a provision of the OSH Act, entitled "Research and related activities."[108] It states that no one may be subject to a "medical examination, immunization, or treatment" over a religious objection except where it is "necessary for the protection of the health of safety of others."[109] But that sentence follows two others that supply the context for the sentence OSHA cites. They provide that the HHS Secretary may adopt regulations requiring employers to report on "the exposure of employees to substances or physical agents" that the HHS Secretary "reasonably believes may endanger the health or safety of employees," as well as establish "such programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the susceptibility of employees to such illness."[110]

Aside from the fact that all three sentences speak to what the *HHS Secretary*, *not* the *Labor Secretary* may do, the text of neither antecedent sentence imposes a vaccination requirement against a virus like SARS-CoV-2. If Congress had intended to empower grant OSHA that authority, Congress could easily have done so. The simplest way would have been to copy or paraphrase the text of the Massachusetts statute and ordinance that the Supreme Court upheld in

105. 29 U.S.C. § 671a(c)(1)(A).

106. *See generally* U.S. DEP'T HEALTH & HUM. SERVS., PUB. HEALTH SERV., CTRS. FOR DISEASE CONTROL & PREVENTION, NAT'L INST. FOR OCCUPATIONAL SAFETY & HEALTH, REPORT TO CONGRESS ON WORKERS' HOME CONTAMINATION STUDY CONDUCTED UNDER THE WORKERS' FAMILY PROTECTION ACT (29 U.S.C. 671a) (1995).

107. OSHA Vaccination Mandate, 86 Fed. Reg. at 61,406-07; *see supra* note 21.

108. 29 U.S.C. § 669.

109. 29 U.S.C. § 669(a)(5).

110. *Id.*

Jacobson v. Massachusetts.[111] Both of those provisions expressly empowered the government to adopt a vaccination requirement—there, for smallpox. The OSH Act provision cited by the government is not remotely similar to the requirement that the Supreme Court upheld.[112] The presence of the term "immunization" in a religious exemption to the authorization of "examinations" and "tests" is a far cry from the power to impose a vaccination mandate.

The other provision that OSHA invokes is a component of an appropriations bill for the Departments of Labor, Health and Human Services, Education, and related agencies.[113] In 1989, OSHA proposed

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111. 197 U.S. 11 (1905).

112. *Id.* at 2–13:

> The Revised Laws of that commonwealth, chap. 75, § 137, provide that 'the board of health of a city or town, if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit $5.'
>
> An exception is made in favor of 'children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination.' § 139.
>
> Proceeding under the above statutes, the board of health of the city of Cambridge, Massachusetts, on the 27th day of February, 1902, adopted the following regulation: 'Whereas, smallpox has been prevalent to some extent in the city of Cambridge, and still continues to increase; and whereas, it is necessary for the speedy extermination of the disease that all persons not protected by vaccination should be vaccinated; and whereas, in the opinion of the board, the public health and safety require the vaccination or revaccination of all the inhabitants of Cambridge; be it ordered, that all the inhabitants habitants of the city who have not been successfully vaccinated since March 1st, 1897, be vaccinated or revaccinated.'
>
> Subsequently, the board adopted an additional regulation empowering a named physician to enforce the vaccination of persons as directed by the board at its special meeting of February 27th.

113. Pub. L. No. 102–170, Tit. I, § 100, 105 Stat. 1107 (1991):

> GENERAL PROVISIONS
>
> SEC. 100. (a) Notwithstanding any other provision of law, on or before December 1, 1991, the Secretary of Labor, acting under the Occupational Safety and Health Act of 1970, shall promulgate a final occupational health standard concerning occupational exposure to bloodborne pathogens. The final standard shall be based on the proposed standard as published in the Federal Register on May 30, 1989 (54 FR 23042), concerning occupational exposures to the hepatitis B virus, the human immunodeficiency virus and other bloodborne pathogens.
>
> (b) In the event that the final standard referred to in subsection (a) is not promulgated by the date required under such subsection, the proposed standard on occupational exposure to bloodborne pathogens as published in the Federal Register

issuing a rule dealing with bloodborne pathogens to prevent workers from becoming infected with Hepatitis B or the Human Immunodeficiency Virus (HIV).[114] To prevent parties from becoming infected by those pathogens, the rule sought to require the adoption of protective measures such as "universal precautions" (viz., treating all human blood as infectious), "engineering and work practice controls" (viz., mechanisms that reduce the likelihood of exposure to a bloodborne pathogen, such as physical separation of a "high-containment work area from access corridors or other areas"), and the mandatory use of "personal protection equipment" (such as gloves, gowns, face shields, and safety goggles).[115] The proposed rule would have directed employers to *offer* Hepatitis B vaccinations to employees, but would not have *required* employees to receive them.[116] In fact, the proposed rule would have provided that employers would not have been required to provide Hepatitis B vaccinations to employees if blood tests showed that they had a natural immunity against that disease.[117] That is significant. All that the 1991 appropriations act did was provide that, if OSHA had not promulgated a final bloodborne pathogen rule by December 1, 1991, the proposed rule contained in the 1989 Federal Register notice would go into effect. Because the proposed rule did not require Hepatitis B vaccinations, the 1991 appropriations act also did not do so. In sum, the 1991 appropriations act cited by OSHA does not empower the agency to require employees to be vaccinated.

To be sure, OSHA adopted a rule dealing with bloodborne pathogens (albeit five days late, on December 6).[118] That rule forces employers not only to prevent such contamination through the use of PPE designed to protect against "needle sticks" and skin punctures by other sharp objects,[119] but also to

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on May 30, 1989 (54 FR 23042) shall become effective as if such proposed standard had been promulgated as a final standard by the Secretary of Labor, and remain in effect until the date on which such Secretary promulgates the final standard referred to in subsection (a).

(c) Nothing in this Act shall be construed to require the Secretary of Labor (acting through the Occupational Safety and Health Administration) to revise the employment accident reporting regulations published at 29 C.F.R. 1904.8.

114. *See* OSHA, Occupational Exposure to Bloodborne Pathogens, 54 Fed. Reg. 23,042-139 (May 30, 1989).

115. *Id.* at 23,135–39.

116. *Id.* at 23,137.

117. *Id.* ("HBV antibody testing shall be made available to an employee who desires such testing prior to decide whether or not to receive HBV vaccination. If the employee is found to be immune to HBV by virtue of adequate antibody titer, then the employer is not required to offer the HBV vaccine to that employee.").

118. *See* 29 C.F.R. § 1910.1030.

119. *See id.* § 1910.1030(c) ("Exposure control"); *id.* § 1910.1030(d) ("methods of compliance").

offer a vaccine against the bloodborne pathogen Hepatitis B.[120] But that rule does *not require* medical workers to get vaccinated. An employee, after being notified of a vaccine's availability without cost, can decline it.[121] Accordingly, OSHA has never previously construed the OSH Act as granting the agency authority to impose a vaccine mandate as a workplace safety condition.

Moreover, Congress knows how to demand that OSHA enhance its regulatory protections against viruses. In 2000, Congress passed the Needlestick Safety and Prevention Act to force OSHA to adopt stricter regulations to prevent the workplace transmission of bloodborne pathogens.[122] Notably, Congress did *not* demand that anyone be vaccinated against Hepatitis B in addition to or in lieu of the newly imposed additional safety precautions.[123] Congress's failure to impose a vaccination requirement, while not dispositive, is powerful evidence that Congress did not empower OSHA to make vaccination decisions for Americans.

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120. *See id.* § 1910.1030(f) ("Hepatitis B vaccination and post-exposure evaluation and follow-up"); *id.* § 1910.1030(f)(2)(i) ("Hepatitis B Vaccination") ("Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.").

121. *Id.* § 1910.1030(f)(2)(iii) ("If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time."); *id.* § 1910.1030(f)(2)(iv) ("The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A."); *id.* § 1910.1030, App. A ("Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory): "I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me."

122. *See* Needlestick Safety and Prevention Act, Pub. L. No. 106-430, 114 Stat. 1901 (2000); U.S. DEP'T OF LABOR, OSHA, Bloodborne Pathogens and Needlestick Prevention, https://www.osha.gov/bloodborne-pathogens/standards (last visited Jan. 24, 2022); U.S. DEP'T OF LABOR, OSHA, Standard Interpretations, Letter from Richard E. Fairfax, Director, Directorate of Enforcement Ops. Re: Bloodborne pathogens Standard (Feb. 20, 2003; corrected Oct. 2, 2004), https://www.osha.gov/laws-regs/standardinterpretations/2003-02-20.

123. *See* Needlestick Safety and Prevention Act, Pub. L. No. 106-430 § 3, 114 Stat. 1901, 1901–02 (2000) (listing the modifications to the bloodborne pathogens standard which do not mention mandatory vaccination or immunization against Hepatitis B).

C. The Congressional Allocation of Regulatory Authority Over Vaccines

Now, consider the other, related, health-care statutes found elsewhere in the U.S. Code. They reinforce the points already made.

In 1971, when the OSH Act became law, no act of Congress entered the world the same way that Adam populated the Garden of Eden: as the first and only resident.[124] There were a host of other laws that touched on the subject of federal public health regulatory power, sometimes only glancingly, but other times embracingly. The latter is true here. So, we should take a step back from the OSH Act and consider how it fit into the framework of laws that predated it, particularly ones that addressed public health, especially ones that specifically focused on viruses, like SARS-CoV-2. Indeed, § 4(b)(1) of the OSH Act, entitled (in part) "applicability to existing standards," instructs us to do just that. It provides that the statute does not supersede the authority of other federal agencies, particularly the Department of Health and Human Services, with respect to "working conditions of employees" and the "statutory authority" those agencies possess "to prescribe or enforce standards or regulations affecting occupational safety or health."[125] The OSH Act was not designed to replace other congressional health and safety regimens or oust agencies other than OSHA from their health-care responsibilities.

History proves that point. Congress treated the subject of "viruses" separately from that of "occupational safety and health standard[s]" for 69 years before the OSH Act became law. The Biologics Control Act of 1902, Congress's first effort to regulate viruses under federal law, regulated the use of biological products, such as vaccines.[126] That statute prohibited the distribution of viruses without a license from the Secretary of the Treasury, who was placed in charge of that field.[127] The Act designated the Surgeons General of the Army, Navy, and Marine Service as a board to issue rules governing the issuance and revocation of licenses.[128] Violations of the Act could be criminally prosecuted.[129] When Congress enacted the Federal Food

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124. *Genesis* 2:7 (King James).

125. 29 U.S.C. § 653(b)(1): "Nothing in this chapter shall apply to working conditions of employees with respect to which other Federal agencies, and State agencies acting under section 2021 of title 42, exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

126. Act of July 1, 1902, Pub. L. No. 57-244, 32 Stat. 728. *See generally* U.S. FOOD & DRUG ADMIN., SCIENCE AND THE REGULATION OF BIOLOGICAL PRODUCTS (Mar. 28, 2018), https://www.fda.gov/about-fda/histories-product-regulation/science-and-regulation-biological-products#FromaRichHistorytoaChallengingFuture (last visited Jan. 24, 2022).

127. § 1, 32 Stat. at 728.

128. § 4, 32 Stat. at 729.

129. § 7, 32 Stat. at 729.

Drug and Cosmetic Act of 1938 (FDCA),[130] Congress defined viruses as "biologics" and "drugs" and placed the authority to regulate them within the jurisdiction of the Commissioner of Food and Drugs (Commissioner).[131] The FDCA carried forward the mission of the Biologics Control Act; the FDCA just gave those responsibilities to a different, newly created agency.[132]

Today, federal law generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until the FDA has determined that it is safe and effective for its intended uses.[133] Under the FDCA, a vaccine is legally deemed a "drug" and a "biological product,"[134] which means that the FDA

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130. *See generally* Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301399i (2019)).

131. *See* 21 U.S.C § 321(g)(1); 42 U.S.C. § 262(i)(1).

132. *See supra* note 29; Linda Bren, *The Road to the Biotech Revolution—Highlights of 100 Years of Biologics Regulation*, FDA Consumer Mag., Centennial Edition (Jan.-Feb. 2006) https://www.fda.gov/files/about%20fda/published/The-Road-to-the-Biotech-Revolution--Highlights-of-100-Years-of-Biologics-Regulation.pdf (last visited Jan. 24, 2022)

133. *See, e.g.*, 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C § 262(a).

134. *See* 21 U.S.C. § 321(g)(1) ("The term 'drug' means . . . articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."), § 321(p)(1)(2) (defining "new drug"); §§ 33137a; 42 U.S.C. § 262(i)(1) (a "biological product" is a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings."); 21 C.F.R. § 600.3(h)(5)(iii) (2021); United States v. Loran Med. Sys., Inc., 25 F. Supp. 2d 1082, 1084 (C.D. Cal. 1997); U.S. Food & Drug Admin, Drugs, Therapeutic Biologics Applications, Frequently Asked Questions About Therapeutic Biological Products, July 7, 2015, https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/frequently-asked-questions-about-therapeutic-biological-products (last visited Jan. 24, 2022); 21 U.S.C. § 360bbb-3 (Congress also has given the FDA authority to issue "emergency use authorization" for vaccines and other products during public health emergencies.); U.S. Food & Drug Admin., *FDA Approves First Covid-19 Vaccine* (Aug. 23, 2021), https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Jan. 24, 2022) (the FDA used this authority to allow Pfizer-BioNTech, Moderna, and Johnson & Johnson to introduce COVID-19 vaccines into interstate commerce. In August 2021, the agency formally approved two doses of the Pfizer BioNTech vaccine for people aged 16 and older.) U.S. Food & Drug Admin., *FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations* (Sept. 22, 2021), https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations (last visited Jan. 24, 2022) (in September 2021, the FDA granted "emergency use authorization" for a third shot of the Pfizer-BioNTech vaccine for certain populations that had already received two doses of that vaccine).

must approve the distribution of a vaccine in interstate commerce.[135] The responsibility for making that judgment rests with the FDA Center for Biologics Evaluation and Research (CBER), which has the federal responsibility to regulate vaccines, particularly its Office of Vaccines Research and Review.[136] Biologics differ from chemically manufactured drugs because they "are derived from living sources (such as humans, animals, and microorganisms), [they] are not easily identified or characterized, and many are manufactured using biotechnology."[137] An intra-agency agreement lodges jurisdiction over vaccines in CBER as "biologics," rather than in the FDA Center for Drug Evaluation and Research (CDER) as "drugs."[138] The critical point, though, is that CBER, CDER, and FDA are components of *HHS*, *not* the Department of Labor.

It makes sense to place the federal responsibility over viruses within the FDA's (and CDC's) jurisdiction, not OSHA's.[139] SARS-CoV-2 is a virus;

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135. *See* 21 U.S.C. § 321(b) (defining interstate commerce); 42 U.S.C § 262(a)(1)(B)(iiii) (describing the markings required in a biological product package); § 262(a)(2)(A)(C)(iiii) (explaining when the Secretary shall approve a approve a biologics license application); § 262(j) (describing the Application of Federal Food, Drug, and Cosmetic Act); § 262(k)(1) (explaining who can apply for an application for licensure of a biological product and what is required).

136. *CBER Product Jurisdiction*, U.S. FOOD & DRUG ADMIN., (Mar. 26, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/cber-product-jurisdiction ("CBER regulates a variety of different product types including biologics such as allergenics, blood and blood products, cellular & gene therapies, tissue and tissue-based products, vaccines and xenotransplantation products. We also regulate some devices including selected in vitro diagnostics and devices that manufacture a biologic at the point of care, as well as a small number of drug products related to blood banking or cellular therapies. These products are distributed among three product review offices within CBER**: Office of Vaccines Research and Review (OVRR), Office of Tissues and Advanced Therapies (OTAT) and the Office of Blood Research and Review (OBRR).** CBER's allergenic products, infectious disease vaccines and live biotherapeutic (probiotic) therapies are regulated by OVRR. OTAT regulates cell, tissue and gene therapies as well as therapeutic vaccines for various disease indications. OBRR regulates blood and blood products, including plasma derivatives and their recombinant analogues. OBRR is also responsible for the regulation of blood donor screening assays and retroviral diagnostic tests.").

137. About CBER, *supra* note 131.

138. *Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research*, U.S. FOOD & DRUG ADMIN. (Feb. 16, 2018), https://www.fda.gov/combination-products/jurisdictional-information/intercenter-agreement-between-center-drug-evaluation-and-research-and-center-biologics-evaluation.

139. The FDA and CDC are both involved with regard to vaccines. The FDA (via CBER) determines whether vaccines are safe and effective, while the CDC makes recommendations as to their use. *See SAFETY OF COVID-19 VACCINES*, CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html (last visited Jan. 24, 2022).

COVID-19 is a disease; the FDA has approved or granted emergency authorization to the vaccines that fend off that disease; and those vaccines are produced in FDA-regulated laboratories to stimulate antibody production to the presence of the SARS-CoV-2 virus.[140] Those are traditional functions of the nation's lead agency in the regulation of drugs and biologics.[141] If any federal agency had the authority to impose a vaccination requirement, it would be the FDA, or its parent HHS. After all, given the role that the FDA plays in the regulation of drugs and biologics, how likely is it that Congress intended to empower the Labor Secretary to regulate the transmission of disease-causing viruses, or to compel individuals to be vaccinated over their objection, rather than grant that responsibility to the HHS Secretary, or a director of one of HHS's constituent agencies such as the FDA Commissioner or the Director of the CDC? Common sense teaches us that the answer is, not very likely, certainly not without a very clear indication in the OSH Act of that unusual assignment. As Justice Antonin Scalia once wrote, Congress "does not, one might say, hide elephants in mouseholes."[142] Put differently, the OSH Act does not allow OSHA's Director to play magician.

That assignment of responsibilities is important. Federal agencies have only the authority that Congress vests in them by law.[143] Congress granted the FDA the power to *approve and regulate* vaccines for distribution in interstate commerce (and their subsequent use), but not the power to *compel* the public (or any class of that population) to be vaccinated (or be subject to periodic testing) by force of law.[144] If Congress had granted the FDA Commissioner that power, the

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140. *See Developing COVID-19 Vaccines*, U.S. CNTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 8, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/distributing/steps-ensure-safety.html (explaining the process for how the FDA approves and authorizes vaccines); How Do the Vaccines Work, MAYO CLINIC, https://www.mayoclinic.org/coronavirus-covid-19/how-the-vaccines-work (last visited Jan. 24, 2022) (noting how the FDA has approved an emergency authorization for the COVID-19 vaccines which helps the immune system create antibodies); FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations, *supra* note 134 (detailing FDA's statement authorizing the Pfizer-BioNTech COVID-19 vaccine booster shot).

141. *See supra* note 134 (explaining that the vaccine is a drug under 21 U.S.C. § 321(g)(1) and a biological product under 42 U.S.C. § 262(i)(1)).

142. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 468 (2001).

143. *See, e.g.*, Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."); Louisiana Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon it."). The Constitution does not grant the President authority to impose a vaccination requirement, *see* U.S. CONST. art. II, so Biden cannot delegate a power he lacks to OSHA.

144. *See* COVID-19 Vaccines, U.S. FOOD & DRUG ADMIN. (Sept. 10, 2021),

President would have simply directed HHS Secretary Xavier Becerra, not Labor Secretary Marty Walsh, to require every adult to be vaccinated.[145] Easy-peasy. Yet, that is precisely what Biden did *not* do. The President also would not need to have issued separate orders governing federal employees, federal contractors, and businesses with 100 or more employees. He could have simply told Becerra to, "Make it so."[146] Yet, the President did not because Becerra lacks the authority to compel people to be vaccinated. Acting through the FDA, the HHS Secretary may permit or forbid a vaccine from being distributed in interstate commerce and, acting through the CDC, the Secretary may issue advice as to a vaccine's use. Yet, Title 42 does not authorize the FDA, the CDC, or the HHS Secretary to compel individuals to be vaccinated. That omission is quite important. When the occupational safety provisions of Title 29 are read in conjunction with the health care provisions of Titles 21 and 42, it becomes clear that the federal government has overreached.

There is another relevant consideration. I n several cases the Supreme Court has cautioned federal agencies and courts against construing acts of Congress as having delegated massive amounts of legislative authority to unelected federal officials.[147] In effect, the Court has created a canon of

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https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines (discussing the FDA's responsibility over COVID-19 vaccines).

145. The President also would not have needed to rely on a Medicare funding nexus to impose vaccine mandates in healthcare facilities. *See* Biden's COVID-19 Action Plan, *supra* note 11 ("Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers at Medicare and Medicaid Participating Hospitals and Other Health Care Settings"); Biden's COVID-19 Remarks, *supra* note 9 ("My plan will extend the vaccination requirements that I previously issued in the healthcare field. Already, I've announced, we'll be requiring vaccinations that all nursing home workers who treat patients on Medicare and Medicaid, because I have that federal authority.").

146. Jibb's Compilations, *Star Trek TNG Compilation - Every "Make it So,"* YOUTUBE (June 30, 2017), https://www.youtube.com/watch?v=FaLyasJPyUU&t=11s.

147. *See*, *e.g.*, Ala. Ass'n of Realtors v. HHS, 141 S. Ct. 2485, 2489 (2021) ("Even if the text were ambiguous, the sheer scope of the CDC's claimed authority under § 361(a) would counsel against the Government's interpretation. We expect Congress to speak clearly when authorizing an agency to exercise powers of "vast 'economic and political significance.") (citations and punctuation omitted); King v. Burwell, 576 U.S. 473, 485 (2015) (noting that Congress "surely" would have "expressly" given an agency power itself to answer "a question of deep economic and political significance that is central to [a] statutory scheme" if Congress had so wished) (punctuation omitted); Utility Air Reg'y Grp. v. EPA, 573 U.S. 302, 324 (2014) ("When an agency claims to discover in a long-extant statute an unheralded power to regulate "a significant portion of the American economy, . . . we typically greet its announcement with a measure of skepticism. We expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.") (citation and punctuation omitted); FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 133 (2000); MCI Telecommunications Corp. v. American Telephone & Telegraph Co., 512 U.S. 218, 231

statutory construction known as the "Major Question" or "Clear Statement" Doctrine that is designed to keep agencies from unilaterally expanding their regulatory empires by adopting surprisingly broad interpretations of anodyne statutory terms.[148] As the Court explained in *Utility Air Regulatory Group v. EPA*, federal courts should treat "with a measure of skepticism" an "agency['s] claim to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy.'"[149] The courts should "expect Congress to speak clearly if it wishes to assign" to unelected agency officials "decisions of vast 'economic and political significance.'"[150]

That doctrine has considerable purchase here. The size of the effect that OSHA's rule would have on the economy alone might make the Clear Statement Doctrine applicable, because the rule is estimated to apply to at least 80 million employees.[151] But there is more, far more. Despite suffering through smallpox, polio, and a raft of other diseases—including the influenza viruses that attack us every year—there has never been a general federal vaccination mandate.[152] The FDA has approved a host of vaccines to protect Americans against a variety of fatal pathogens: Smallpox, Cholera, Hepatitis A and B, Rabies, Yellow Fever, Ebola, and various influenza viruses.[153] Yet,

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(1994); Industrial Union Dept., AFL–CIO v. American Petroleum Inst., 448 U.S. 607, 645–46 (1980) (plurality opinion) (expressing skepticism that Congress gave unprecedented power over industries to OSHA).

148. *See*, *e.g.*, Cass R. Sunstein, *The American Nondelegation Doctrine*, 86 GEO. WASH. L. REV. 1181, 1182 (2018) ("In the United States, there is a nondelegation doctrine. Far from being a dead letter, it is flourishing. In terms of administrative law and regulatory practice, it greatly matters. It affects administrative behavior; it produces multiple losses for agencies in court. Contrary to the more familiar version, it does not forbid Congress from granting open-ended discretion to executive agencies. Instead the American nondelegation doctrine is far narrower and more targeted. It says, very simply, this: [¶] *Executive agencies cannot make certain kinds of decisions unless Congress has explicitly authorized them to do so*. [¶] Thus understood, the American nondelegation doctrine, as it is actually implemented, fulfills some of the central goals of the more familiar version. It prevents Congress from shirking (though in a restricted way), and it requires Congress, rather than the executive branch, to make central decisions of policy. It also safeguards liberty.") (emphasis in original; footnotes omitted).

149. 573 U.S. 302, 324 (2014).

150. *Id*. (quoting *Brown & Williamson*, 529 U.S. at 159).

151. *See* The White House, Path Out of the Pandemic: President Biden's Covid-19 Action Plan (Sept. 2021), https://www.whitehouse.gov/covidplan/.

152. Tara Subramaniam, Fact Check: Can the President enact a nationwide mask mandate? (Nov. 1, 2020, 9:57 AM) https://www.cnn.com/2020/11/01/politics/mask-mandate-fact-check/index.html.

153. *See* U.S. Food & Drug Admin., Vaccines Licensed for Use in the United States, (Aug. 23, 2021), https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states (last visited Jan. 24, 2022).

Congress has never imposed a general vaccination requirement by statute, and neither the FDA nor HHS (nor HHS's, predecessor the Department of Health, Education and Welfare) has even claimed to possess the statutory authority to adopt one. If any agency had that authority, it would be HHS—which deals with public health—or one of its components, not OSHA—which deals with workplace safety. That is noteworthy. Sometimes the dog that does not bark is actually quite vocal.[154]

In fact, until recently OSHA had never claimed to possess authority to require a vaccination. OSHA had promulgated rules governing personal protective equipment (PPE), such as gloves, masks, gowns, and surgical caps,[155] which must be designed to insulate an employee against an infectious hazard,[156] as well as respiratory protection,[157] which must "prevent atmospheric contamination."[158] A vaccination, however, does not simply provide an external shield against a dangerous substance. A vaccine inserts a biological agent into a person's body to stimulate the immune system, and it can trigger adverse reactions in recipients.[159] The Covid-19

154. *See* Arthur Conan Doyle, *Silver Blaze*, *in* THE COMPLETE SHERLOCK HOLMES 335 (1927); *see also* Chisom v. Roemer, 501 U.S. 380, 396 n.23 (1991).

155. 29 C.F.R. § 1910.132 (2020).

156. *See id.* § 1910.132(a) ("*Application*. Protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.").

157. 29 C.F.R. § 1910.134 (2020).

158. *See id.* § 1910.134(a) ("a) *Permissible practice*. [¶] (1) In the control of those occupational diseases caused by breathing air contaminated with harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors, the primary objective shall be to prevent atmospheric contamination. This shall be accomplished as far as feasible by accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and substitution of less toxic materials). When effective engineering controls are not feasible, or while they are being instituted, appropriate respirators shall be used pursuant to this section. [¶] (2) A respirator shall be provided to each employee when such equipment is necessary to protect the health of such employee. The employer shall provide the respirators which are applicable and suitable for the purpose intended. The employer shall be responsible for the establishment and maintenance of a respiratory protection program, which shall include the requirements outlined in paragraph (c) of this section. The program shall cover each employee required by this section to use respirator.").

159. *See*, *e.g.*, CNTRS. FOR DISEASE CONTROL & PREVENTION, Understanding How COVID-19 Vaccines Work, (Dec. 14, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/how-they-work.html (last visited Jan. 24, 2022) ("When

vaccines can generate such responses.[160] That consequence is materially

germs, such as the virus that causes COVID-19, invade our bodies, they attack and multiply. This invasion, called an infection, is what causes illness. Our immune system uses several tools to fight infection. Blood contains red cells, which carry oxygen to tissues and organs, and white or immune cells, which fight infection. Different types of white blood cells fight infection in different ways: [¶] •**Macrophages** are white blood cells that swallow up and digest germs and dead or dying cells. The macrophages leave behind parts of the invading germs, called "antigens". The body identifies antigens as dangerous and stimulates antibodies to attack them. [¶] •**B-lymphocytes** are defensive white blood cells. They produce antibodies that attack the pieces of the virus left behind by the macrophages. [¶] •**T-lymphocytes** are another type of defensive white blood cell. They attack cells in the body that have already been infected. [¶] The first time a person is infected with the virus that causes COVID-19, it can take several days or weeks for their body to make and use all the germ-fighting tools needed to get over the infection. After the infection, the person's immune system remembers what it learned about how to protect the body against that disease. [¶] The body keeps a few T-lymphocytes, called "memory cells," that go into action quickly if the body encounters the same virus again. When the familiar antigens are detected, B-lymphocytes produce antibodies to attack them. Experts are still learning how long these memory cells protect a person against the virus that causes COVID-19. . . . . Different types of vaccines work in different ways to offer protection. But with all types of vaccines, the body is left with a supply of "memory" T-lymphocytes as well as B-lymphocytes that will remember how to fight that virus in the future."); *id.* ("Currently, there are three main types of COVID-19 vaccines that are authorized and recommended or undergoing large-scale (Phase 3) clinical trials in the United States. . . . [¶] • **mRNA vaccines** contain material from the virus that causes COVID-19 that gives our cells instructions for how to make a harmless protein that is unique to the virus. After our cells make copies of the protein, they destroy the genetic material from the vaccine. Our bodies recognize that the protein should not be there and build T-lymphocytes and B-lymphocytes that will remember how to fight the virus that causes COVID-19 if we are infected in the future. [¶] •**Protein subunit vaccines** include harmless pieces (proteins) of the virus that causes COVID-19 instead of the entire germ. Once vaccinated, our bodies recognize that the protein should not be there and build T-lymphocytes and antibodies that will remember how to fight the virus that causes COVID-19 if we are infected in the future. [¶] • **Vector variants** contain a modified version of a different virus than the one that causes COVID-19. Inside the shell of the modified virus, there is material from the virus that causes COVID-19. This is called a 'viral vector.' Once the viral vector is inside our cells, the genetic material gives cells instructions to make a protein that is unique to the virus that causes COVID-19. Using these instructions, our cells make copies of the protein. This prompts our bodies to build T-lymphocytes and B-lymphocytes that will remember how to fight that virus if we are infected in the future.").

160. The Covid-19 vaccines can generate adverse reactions. *See*, *e.g.*, CNTRS. FOR DISEASE CONTROL & PREVENTION, Possible Side Effects After Getting a COVID-19 Vaccine (Dec. 16, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html (last visited Jan. 24, 2022); U.S. FOOD & DRUG ADM'N., Learn More About COVID-19 Vaccines From the FDA: What Safety Information Is Available about COVID-19 Vaccines?

different from what happens when someone simply wears a pair of protective glasses, gloves, or a gown.[161]

The bottom line is this: Congress did not grant OSHA authority to require the use of vaccines as a condition of providing a safe workplace. Here, as in the case of the CDC Home Eviction Moratorium, a federal agency has taken up a responsibility that, however noble its goal, exceeds the authority that Congress has vested in administrative officials. As the Supreme Court explained a few months ago in *Alabama Association of Realtors v. Department of Health and Human Services*, "our system does not permit agencies to act unlawfully even in pursuit of desirable ends," to include "combatting the spread of the COVID-19 Delta variant."[162] Here, as there, "it is up to Congress," not an agency, "to decide whether the public interest merits" the government's proposed action.[163]

CONCLUSION

The Biden Administration has tried to force a federal safety law designed to protect against hazards that arise only in the workplace to serve double

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(Dec. 9, 2021), https://www.fda.gov/consumers/consumer-updates/learn-more-about-covid-19-vaccines-fda (last visited Jan. 24, 2022) (listing allergic reactions, including anaphylaxis; myocarditis, pericarditis, Guillain Barre Syndrome, and blood clots as possible side effects from receiving one of the three FDA-approved vaccines).

161. *See*, e.g., Washington v. Harper, 494 U.S. 210, 229 (1990) ("The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty. . . . The purpose of the drugs is to alter the chemical balance in a patient's brain, leading to changes, intended to be beneficial, in his or her cognitive processes. . . . While the therapeutic benefits of antipsychotic drugs are well documented, it is also true that the drugs can have serious, even fatal, side effects.") (citations omitted).
Also instructive in this regard is the National Defense Authorization Act for Fiscal Year 2004, Pub. L. No. 108-136, Div. A, Title XVI, §§ 1601–1603, 117 Stat. 1392, 1684 (2003) (codified as amended at 21 U.S.C. §§ 360bbb–3 to 360bbb-3c). A few years after the 9/11 attacks, Congress amended the FDCA to ensure that, in the case of (inter alia) a biological attack on the nation's armed forces involving "a serious or life-threatening disease or condition," the federal government could authorize the use of drugs or biological products not yet approved by the FDA but intended for use in an actual or potential emergency as long as it is "it is reasonable to believe" that "the product may be effective in diagnosing, treating or preventing" the disease or condition. 21 U.S.C. § 360bbb–3. The statute was clear, however, that despite the potentially urgent need for an as-yet unapproved vaccine against a widespread and deadly pathogen, that "individuals to whom the product [viz., drug, device, or biological product," *id.* § 360bbb–3(a)(4)(C) is administered" is made aware of (inter alia) "the option to accept or refuse administration of the product." *Id.* § 360bbb–3(e)(1)(A)(ii)(III). The OSHA mandate contains no such opt-out provision.

162. 141 S. Ct. 2485, 2490 (2021).

163. *Id.* Constitutional issues will be addressed separately.

duty as a basis for compelling tens of millions of people to submit to a vaccine that they might not want. The legal problem the Administration faces is that the OSH Act does not grant the Labor Secretary that authority. The political problem that the President faces is that he does not want to ask Congress to adopt the first-ever general federal vaccination requirement. President Biden is facing many challenges in Congress and elsewhere and understandably is reluctant to take on another one. But if he wants to impose a vaccine mandate, he has no other option.