

The OSHA Vaccine Mandate: Legal, Practical, and Economic Considerations

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KEY TAKEAWAYS

The Occupational Health and Safety Administration lacks any authority to issue a general vaccine mandate on Americans.

Moreover, OSHA pushed this mandate without gathering data on how such a mandate would impact the economy. It has likely overlooked costs to push its agenda.

At a time when U.S. labor force participation is declining, OSHA's general vaccine mandate will only worsen the labor shortage and enlarge its effects.

On November 5, 2021, the Occupational Health and Safety Administration (OSHA) promulgated a rule directing companies with 100 or more workers to require either that their employees be vaccinated or that unvaccinated employees wear masks and undergo weekly COVID-19 tests.¹ The action took the form of an emergency temporary standard (ETS), which allows the agency to implement the standard immediately and without first satisfying the notice-and-comment process of the Administrative Procedure Act.² This *Legal Memorandum* will summarize the ETS, analyze whether OSHA has the legal warrant to implement it, examine the agency's analysis of its cost and benefits, and assess its potential effects on the broader economy.

The paper finds that the ETS is without legal basis. As we have explained in greater detail elsewhere,³ Congress has not invested OSHA with the statutory authority to enforce a general vaccine mandate. Further, OSHA has

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not adequately assessed the direct costs and benefits of the ETS. Nor does the agency have the expertise to weigh the ETS's broader economic implications. The Constitution empowers Congress alone with the power to legislate, which entails consideration by elected representatives of the mandate's constitutional, public health, economic, and other implications. Congress has not legislated a general vaccine mandate. OSHA cannot speak where Congress has remained silent.

This *Legal Memorandum* will discuss those points by asking and answering four questions:

1. What does the OSHA ETS require?
2. Does OSHA have the authority to adopt a vaccination mandate?
3. What are the small-scale benefits and costs of the OSHA Vaccination Mandate—viz., the effects on employers and employees?
4. What are the large-scale benefits and costs of the OSHA Vaccination Mandate—viz., the effects on national economic welfare?

What Does the OSHA ETS Require?

The OSHA ETS establishes “minimum vaccination, verification, face-covering, and testing requirements” that, according to the agency, would preempt state requirements “that ban or limit employers’ authority” to impose such requirements.⁴

By December 5, each company with 100 or more employees⁵ must establish, implement, and enforce a vaccination policy that either requires its workers to be fully vaccinated or requires unvaccinated workers to wear face coverings in the workplace and provide negative test results for COVID-19 every seven days.⁶ A worker is “fully vaccinated” if at least two weeks have passed since completing a vaccination course (e.g., two shots for Moderna, one for J&J).⁷

Whichever policy the employer chooses must allow for exemptions where vaccines are medically contraindicated, required to be delayed due to medical necessity or where federal civil rights laws require employers to make reasonable accommodations for workers based on their disability or “sincerely held religious beliefs.”⁸ The ETS does *not* exempt people who have already suffered COVID-19 and therefore have developed a so-called natural immunity to it. Specific categories of workers also are exempt from the mandate. These include employees “who work exclusively outdoors”

and those “who do not report to a workplace where other individuals, such as coworkers or customers, are present.”⁹ Such workers count when determining whether a firm has 100 employees but they need not be vaccinated, masked, or tested. Unvaccinated remote workers, however, must comply with testing and masking requirements whenever they enter the workplace. The employer must “inform each employee, in a language and at a literacy level the employee understands,” about the new requirements, the value of vaccines, and the potential federal criminal penalties for “knowingly supplying false statements and documentation.”¹⁰

Employers must determine, document, and retain records of each employee’s vaccination status.¹¹ That includes requiring each worker to provide “acceptable proof of vaccination status.”¹² A copy of a vaccine record card, an immunization record from a doctor or a pharmacy, or other medical record showing the employee to be fully vaccinated is acceptable proof.¹³ An employee who cannot produce such documentation can issue a signed and dated attestation that he or she has been vaccinated, has lost the relevant documents, and understands that knowingly providing false attestation subjects one to criminal penalties.¹⁴

Companies must keep records of the vaccination status of each employee. In addition to individual records, they must compile a roster listing every employee’s vaccination status.¹⁵ Within one business day of a request from an employee or labor union, the company must make available the aggregate number of fully vaccinated employees and the total number of employees in that workplace.¹⁶ The employer has four business hours to comply with an OSHA request for this information and the employer’s written vaccination policy.¹⁷ If OSHA requests the vaccination records of all employees, the company must comply by the end of the next business day.¹⁸

Firms must provide workers with up to four hours of paid leave to get immunized and provide “reasonable time and paid sick time” to recover from the vaccine’s side effects.¹⁹ Employees must “promptly” notify their company if they test positive for COVID-19, and employers must remove such employees from the workplace.²⁰ Employers need not provide paid time to any employee for removal due to a positive test or diagnosis with COVID-19.²¹ Employers must promptly report any COVID-19 hospitalization or fatality to OSHA, but not adverse reactions that workers suffer from a vaccine.²²

All of those these requirements were scheduled to take effect on December 5, 2021. Nonetheless, the courts have stayed their effectiveness.²³ OSHA has also “suspended activities related to the implementation and enforcement of the ETS pending future developments in the litigation.”²⁴

Under the now-stayed ETS, unvaccinated workers must wear face coverings in the workplace beginning December 5.²⁵ The employer must ensure

that these devices fully cover each worker’s nose and mouth and that the worker replaces wet, soiled, or damaged masks.²⁶ Employees can remove their masks when eating or drinking or for identification purposes.²⁷ Companies can excuse workers from the face-covering requirement in cases where the employer shows that their use is “infeasible or creates a greater hazard” than would be created by not wearing a mask.²⁸

Beginning January 4, workers who are not fully vaccinated must provide documentation of a negative test result for COVID-19 taken within the past seven days when they enter the workplace.²⁹ Workers who are regularly in the workplace must provide negative test results every seven days; those who are in the workplace only periodically must produce such documentation when they enter it.³⁰ The employer must remove from the workplace any unvaccinated worker who is without a negative test result.³¹ The company must maintain records of each employee’s results.³²

The ETS does not require employers to pay for the tests.³³ Employees may use the most affordable COVID-19 tests—self-administered and self-read versions—but only if they perform the test in their employer’s presence or before an “authorized telehealth proctor.”³⁴ Employers are subject to civil monetary penalties of up to \$7,000 per violation and up to \$70,000 for willful or repeated violations.³⁵

Does OSHA Have the Authority to Adopt a Vaccination Mandate?

The short answer is “No.”³⁶ OSHA devotes the bulk of the preamble to the ETS to documenting that COVID-19 is “bad” and vaccines are “good.” Those two propositions, though inarguable, do not provide a sufficient legal basis for mandating vaccines.

Start with the proposition that nothing in the Occupational Safety and Health Act of 1970 (OSH Act) expressly empowers OSHA to impose any “vaccination” or “immunization” requirement of any type.³⁷ That is significant. Those terms are well known in public health law.³⁸ In fact, the most famous case in public health law—the United States Supreme Court’s 1905 decision in *Jacobson v. Massachusetts*,³⁹ which upheld a state-law smallpox vaccination requirement over a Due Process Clause challenge—involved a statute that expressly used the term “vaccination.”⁴⁰ Today, states impose such requirements on schoolchildren, for example, and state law uses those terms to leave no doubt about what the state may require.⁴¹ There has never been a general federal vaccination requirement, and nothing in the OSH Act suggests that Congress intended to create one.

Atop that, since passing the Biologics Act of 1902,⁴² Congress has always empowered health care officials to determine whether vaccines are safe and effective and also whether they can be used in an emergency.⁴³ The Federal Food Drug and Cosmetic Act of 1938 (FDCA)⁴⁴ defined vaccines as “biologics” and “drugs” and placed the authority to regulate them within the jurisdiction of the Commissioner of the Food and Drug Administration (FDA).⁴⁵ The responsibility for making those judgments rests with the FDA Center for Biologics Evaluation and Research (CBER), particularly its Office of Vaccines Research and Review,⁴⁶ which has the federal authority to regulate vaccines.⁴⁷ If any federal agency had the authority to impose a vaccination requirement, Congress would have vested that power in the FDA or its parent, the Department of Health and Human Services (HHS), rather than OSHA. Yet Congress has not empowered HHS or *any* of its components to require vaccinations for anyone.

The OSH Act’s terms do not grant OSHA any power to impose a vaccination requirement. OSHA may require employers to provide safety gear, such as goggles, gloves, masks, and the like. Vaccines, however, are materially different from such equipment. Such protective gear supplies workers with a shield against external hazards, and workers can shed them at the end of the workday. By contrast, vaccines work only by activating the human immunological system; to have that effect, they must reach that system via injection, ingestion, inhalation, or otherwise; and workers cannot leave T cells behind when they go home.

Whether someone should receive a vaccination is a medical decision, not a workplace safety issue. There is, consequently, no reason to expand the reach of OSH Act terms like “toxic materials or harmful physical agents”⁴⁸ to empower the Department of Labor to make decisions that even the Department of Health and Human Services cannot make. 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,” even “combatting the spread of the COVID-19 Delta variant.”⁴⁹ Here, as there, “it is up to Congress,” not an agency, “to decide whether the public interest merits” the government’s proposed action.⁵⁰

What Are the Small-Scale Benefits and Costs of the OSHA Vaccination Mandate—viz., the Effects on Employers and Employees?

Legal infirmities aside, the question of whether the federal government should enforce a general vaccine mandate raises numerous considerations. Some involve the policy’s direct costs and benefits. Others relate to the ETS’s

broader economic and social implications. OSHA has done an inadequate assessment of the immediate benefits and costs of the ETS, as explained below. Nor did it assess the policy's far-reaching effects.

OSHA argues that the ETS imposes only minimal burdens on covered companies—those with 100 or more employees. The agency believes that those burdens are more than offset by the benefits of increasing the number of vaccinated people. The benefits derive from an increase in the number of workers who become vaccinated because of the ETS. In calculating the benefits, OSHA begins by estimating that 84.2 million workers work in firms that are required to impose mandates.⁵¹ The agency next estimates that 31.7 million workers in those firms are unvaccinated.⁵² It then asserts that 22.8 million workers will be “vaccinated under the ETS” and that another 6.3 million will remain unvaccinated.⁵³ In essence, the agency suggests that the ETS *itself* will result in the immunization of those 22.8 million workers.

That inference is mistaken. The reason is that *association* and *causation* are quite different concepts. Indeed, the difference is elementary. OSHA's failure to respect that difference casts doubt on its entire rationale for the ETS.

OSHA suggests that those “vaccinated *under* the ETS” will be vaccinated *because* of the ETS. “OSHA assumes that all unvaccinated employees subject to an employer mandate will be vaccinated under that employer mandate, except for those seeking a medical or religious exemption.”⁵⁴ Why make that assumption? In firms that independently require unvaccinated workers to be masked and tested, all employees “will also be vaccinated at their employer's request, except for employees who are vaccine-hesitant.”⁵⁵

As a result, OSHA has quite likely overstated the effect of the ETS. While the *rate* of new vaccinations is lower now than when vaccines first became available, it remains high, and the number of vaccinated individuals continues to increase. Between September 9, when President Joe Biden directed OSHA to issue the ETS, and November 5, when the rule was published in the *Federal Register*, 27.2 million adults received either a first or second dose of a COVID-19 vaccine according to the CDC.⁵⁶ Of these, 13.2 million adults received an initial dose, and more than 14 million completed the series.

Thus, in the time it took OSHA to write the ETS, adults were becoming fully vaccinated at a rate of seven million per month and were getting their first shots at the rate of 6.6 million per month. If immunizations were to continue at the same rate, then by the time the ETS takes full effect on January 4, another 14 million adults would be fully immunized without the ETS.

Even if one accepts OSHA's premise that, except for 6.3 million workers who are vaccine-hesitant, 100 percent of covered employees will get the

vaccine, the benefits of the ETS would appear to be marginal because so many of them would likely get the vaccine under any circumstances.

OSHA asserts—mistakenly in our view—that the mandate would save 6,830 lives over a six-month period.⁵⁷ “These are the lives that are saved,” the agency asserts, “because of the ETS, or to put another [sic] another way, the lives that would be lost but for the ETS.”⁵⁸ The agency has not substantiated that claim. It merely assumes that every worker in every company with at least 100 employees who is vaccinated beginning November 5, 2021, was vaccinated *only because of the ETS*.⁵⁹ That assumption is false. Vaccination rates have been rising steadily without a federal vaccine mandate. OSHA has not offered persuasive evidence that the mandate would materially improve those rates.

What is more, the relevant issue is not the number of people who are *vaccinated* against COVID-19. As Johns Hopkins University School of Medicine Professor Martin Makary has explained, the relevant issue is the number of people who are *immunized* against that disease.⁶⁰ The goal is to prevent people from becoming ill or dying from the disease. Vaccinations are one way to achieve that result, but not the only way. People who already have had the disease are now immune to it for some as yet unknown period.⁶¹ That factor should be considered in any calculus of the benefits and costs of OSHA’s mandate. To be sure, it is not as easy to measure as is the number of vaccinations that have been administered. Health care professionals authorized to administer vaccines keep that number and report it to state and federal authorities. But that number is an inadequate measure of how the nation is faring against COVID-19. That is a measure of the number of people vaccinated and who have had and survived infection by SARS-CoV-2. OSHA has ignored the difference between *outputs* and *outcomes*, and the difficulty involved in measuring the latter is not a good reason for ignoring it.

OSHA also has done an inadequate job of estimating the costs the mandate will impose on firms and workers. The estimates are based in every case on best case scenarios—viz., employees using less than an hour of paid leave to receive the vaccine (the ETS requires them to grant up to four hours); employees using available paid sick leave to recover from adverse reactions to the vaccines; and a seamless process for collecting and maintaining vaccine records. All of that might turn out to be true, but those are speculative assumptions and are thus inherently unreliable. OSHA has not explained why the courts should accept the agency’s rosy predictions about the mandate’s costs of businesses and employees.

Those shortcomings result directly from OSHA’s decision to promulgate and enforce the standards without following a notice-and-comment

rulemaking process. Allowing affected parties to present data before OSHA finalizes a rule would enable the agency to make informed judgments about the rule's costs. This is especially true of a rule that affects a broad swath of industries across firms of various sizes. The only distinguishing factor between firms covered by the ETS and those exempt from it is the employee headcount. A landscaping firm with a workforce of over 100 people scattered across several counties is covered. A firm with 99 employees working indoors in close proximity to one another is exempt.

The agency bases that somewhat arbitrary distinction on its assertion that firms with 100 workers can easily afford to comply with the requirements, while those with fewer employers may not be able to do so. In all, OSHA estimates that compliance would cost covered companies around \$3 billion, or an average of around \$11,300 per company.⁶² In formulating that estimate, OSHA assumes that employers and employees can comply with the ETS with little disruption or cost. The agency reckons that employers will have to provide compensation for less than one hour for employees to get vaccinated (30 minutes roundtrip travel, five minutes to check in and get the shot, and 20 minutes for post-vaccine observation).⁶³ And although employers are required to give employees paid time off for post-vaccine reactions, OSHA estimates the cost at zero for most companies because it assumes that employees will use existing paid sick leave.⁶⁴ It does price in a small cost to account for the estimated 12 percent of firms that do not offer paid sick leave. Despite these relatively small costs, employer support for employee vaccinations accounts for roughly \$2 billion of the \$3 billion in the OSHA-estimated cost of compliance with the ETS.

The balance of the estimated cost to covered employers comes from the new recordkeeping requirements. It will take just five minutes, according to OSHA, to collect a worker's vaccination status or test results and another five minutes of clerical time to record the information.⁶⁵ OSHA thus assumes that more than 84 million employees at roughly 264,000 firms will meet this entirely novel and unprecedented federal requirement smoothly and efficiently.⁶⁶

OSHA also appears to assume that every worker who lacks a religious, medical, or other exemption will agree to wear a face covering at the workplace and take a weekly COVID-19 test. That is the clear implication of the preamble's Table IV.B.8, which contains OSHA's assessment of how 84.2 million workers will respond to the mandate: 75.3 million are either already immunized or will get shots, 6.3 million unvaccinated workers will comply with masking and weekly testing requirements, and 2.6 million vaccine-hesitant people will return to telework.⁶⁷ None of the 84.2 million covered employees will quit or get fired according to the data in the table.

That may, of course, turn out to be true, but it is improbable. As OSHA points out elsewhere in the preamble, at least some small percentage of workers subject to mandates have quit their jobs or have been terminated. OSHA cites data suggesting that 1 percent to 3 percent of workers would leave their jobs due to the ETS but does not include the cost of replacing 2.5 million workers (3 percent of 84.2 million).⁶⁸ The costs of lost productivity and training would fall on affected firms. Given an economy-wide labor shortage discussed below, some of these workers may not be replaced, and this also would inflict adverse consequences on affected companies.

OSHA neglects to estimate the costs of other duties the ETS imposes on employers. Employers must make legal judgments as to which employees are exempt from the mandates. For example, those who work “exclusively outdoors” need not be immunized, masked, or tested. But the preamble to the ETS draws a sharp distinction between those who work “*exclusively* outdoors”—who are exempt from the mandates—and those who work “*constantly* outdoors,” who are not.

The preamble notes that construction workers inside a partially completed structure “are not truly outdoors.”⁶⁹ It also states that construction workers may “spend significant amounts of time in construction trailers, where other individuals are present.”⁷⁰

“If there are several brief periods in a day when an employee goes inside, OSHA will total those periods of time when determining whether the exception for exclusively outdoor work applies.”⁷¹ (The agency seems willing to exclude the use of an indoor “multi-stall bathroom” from this calculation.⁷²)

As a result, most employees who work outdoors do not meet the rule’s standard of working “outdoors exclusively.” OSHA estimates that only 9 percent of landscapers, 8 percent of construction workers, 5 percent of lifeguards and ski patrols, and 1 percent of coaches and scouts will be exempt from the mandates.⁷³

Employers must sort out which of their employees who work outdoors qualify for the exemptions. They face substantial penalties if OSHA disagrees with their conclusions.

Employers also must decide which employees qualify for exemptions from the vaccination, masking, and testing mandates based on their disability or sincerely held religious beliefs. OSHA offers little guidance here, advising employers to “consult the Equal Employment Opportunity Commission’s regulations, guidance and technical assistance” and providing a link to the EEOC website.⁷⁴ Here, employers face a dueling set of penalties—from the EEOC if they deny an exemption in violation of civil rights laws, from OSHA if they grant an exemption in violation of the ETS.

Employers also must confront a series of medical issues. Despite its lack of medical expertise, OSHA has addressed several medical issues that could affect how employers decide when to grant medical exemptions to their workers. The agency has declared that “workers who have been infected with COVID-19 but have not been fully vaccinated still face a grave danger from workplace exposure to SARS-CoV-2.”⁷⁵ Thus, employers cannot grant medical exemptions for natural immunity despite a substantial body of scientific literature attesting to its efficacy.⁷⁶

OSHA also has decided that workers are fully immunized two weeks after receiving doses of two different vaccines (e.g., a dose of the Moderna vaccine followed by a dose of the Pfizer-BioNTech vaccine).⁷⁷ The second dose, OSHA has declared, “must not be received earlier than 17 days (21 days with a four-day grace period) after the first dose.”⁷⁸ Some studies have shown that heterologous vaccine doses are associated with a higher incidence of adverse reactions.⁷⁹

The ETS does not, however, require employers to report adverse vaccine reactions to OSHA. This seems a curious omission. Employers must promptly notify OSHA of any COVID-related hospitalization or death. They also must provide paid leave to workers who suffer adverse reactions to the vaccine. Since OSHA mandates that employers require workers to get vaccinated, the agency has an obvious interest in compiling instances of adverse events associated with the vaccine. A surge of serious adverse effects related to the ETS vaccine mandate should interest the agency and could expose employers to legal liability.

OSHA has not accounted for any of the potential costs associated with the legal and medical judgments that employers will confront when complying with the ETS, particularly if those judgments do not align with those of federal regulators.

Nor does it estimate the potential costs the ETS may impose on workers. In addition to medical expenses associated with vaccine-related adverse reactions, workers who remain unvaccinated have to pay for weekly COVID-19 tests. Consumers can purchase self-administered antigen tests for as little as \$24 on Amazon.⁸⁰ The ETS, however, requires a worker to perform such a test either in the employer’s presence—something many workers may find uncomfortable—or before an “authorized telehealth proctor,” which would result in an additional cost.⁸¹ Rapid tests also are offered at pharmacies and clinics, though at a higher price than at-home self-tests. Workers can also take tests that require laboratory analysis. An April 2021 study by the Kaiser Family Foundation and the Peterson Institute found that hospital prices for these tests can vary from \$32–\$478, excluding the cost of specimen collection and the visit itself.⁸²

While private insurance will cover COVID-19 tests for individuals who are symptomatic or who may have been exposed to an infected individual, insurers are unlikely to pay for weekly tests. Many workers will find these costs challenging. Despite its estimate that more than 6.3 million workers will adhere to the weekly testing requirement, OSHA does not estimate how much they will pay for these tests.⁸³

OSHA has offered a flawed and incomplete estimate of the costs and benefits to people the ETS directly affects. It has not presented a realistic assessment of the number of people that will be vaccinated solely because of the agency mandate. Its estimate of the cost to employers, prepared without the benefit of stakeholder input during a notice-and-comment rulemaking process, assumes that companies can implement this policy at unrealistically low costs. It ignores the costs to employers of determining which workers are exempt, whether because they work outdoors or apply for exemptions for religious or medical reasons, as well as the potential costs of making a determination with which a federal regulator subsequently disagrees. It also ignores the costs that covered employees will incur by meeting the ETS's weekly testing requirement.

What Are the Large-Scale Benefits and Costs of the OSHA Vaccination Mandate—viz., the Effects on National Economic Welfare?

OSHA could have lessened some of the deficiencies in its estimate of the ETS's direct costs and benefits by soliciting public comment. Even a public comment period, however, would not have enabled the agency to do what it is unequipped to do by itself: assess the broader social and economic effects of the mandate.

The potential effect of the ETS on the labor force is especially urgent. Like OSHA, the Bureau of Labor Statistics (BLS) is housed at the Department of Labor. BLS issues monthly updates on the employment situation. BLS data document a labor shortage that is contributing to a supply shortage and inflation.

The Labor Department estimates that a record 11 million jobs remained unfilled at the end of October, the most recent month for which figures are available.⁸⁴ That same month, 4.2 million people quit their jobs.⁸⁵ The government reported that nearly three million fewer people were working or seeking work in October 2021 than in February 2020 before lockdowns began in response to the COVID-19 pandemic.⁸⁶

This decline in labor force participation is harming industries that are most directly affected by the pandemic. For example, hospital employment declined by 165,000 between February and May 2020. As of November 2021, with hospitals still facing pandemic-related strains, the sector had recovered fewer than half of those lost workers.⁸⁷ Nursing homes have not begun to reverse their staff losses, having shed 398,000 employees, or nearly 12 percent of the industry workforce, between February 2020 and November 2021.⁸⁸ The labor shortage also extends to the education sector. There were 156,000 fewer school employees in November 2021 than in February 2020.⁸⁹

Industries that are critical to the supply chain also are short of workers, producing reverberating effects throughout the economy. The U.S. faces a shortage of warehouse space and truckers, and undermanned ports continue to roil the supply chain.⁹⁰ That, in turn, is contributing to inflation. The consumer price index rose by 6.8 percent from November 2020 to November 2021—the most significant increase in nearly four decades.⁹¹

The reasons behind this economic disruption are many and complex. Yet it is clear that OSHA's general vaccine mandate can only worsen the labor shortage and enlarge its effects. The U.S. Postal Service has warned in a financial filing that the mandate “will be extremely challenging to implement and administer during the height of our peak season, particularly given its expedited schedule.”⁹² Complying with the ETS “could result in labor challenges and high levels of absenteeism.” The Postal Service fears that the mandate will prompt some workers to leave, which “could cause significant business disruptions, and could adversely impact service performance and result in lower mail volume and revenue.”

Nearly a dozen employer groups, including associations representing retailers, truckers, convenience stores, grocers, and small businesses, have asked the U.S. Court of Appeals for the Fifth Circuit to enjoin the OSHA ETS.⁹³ The lawsuit alleges that the ETS would inflict “immediate irreparable harm of losing employees, incurring substantial and unrecoverable compliance costs, and worsening already fragile supply chains and labor markets.”⁹⁴

OSHA has not included an assessment of the systemic economic effects of the ETS. Nor is it equipped to do so. Congress created OSHA to regulate job-related working conditions and workplace hazards—improperly stored chemicals, inadequately lighted and ventilated workplaces, and exposure to carcinogenic substances. It authorized OSHA to inspect establishments to ensure compliance with workplace-focused safety procedures, not to make medical decisions for employees or to penalize companies for not threatening the jobs of workers who refuse vaccinations.

The question of whether the federal government should promulgate a general vaccine mandate, such as the one OSHA is seeking to impose, is a novel one that is fraught with complexity. It lies beyond OSHA's competence and portfolio. Indeed, it lies outside the reach of any executive branch agency. The Constitution has vested the authority to engage issues of this scope and magnitude exclusively in the legislative branch. Congress alone can deal with the thorny constitutional, economic, and practical considerations that a proposed mandate engenders. Congress has not addressed this matter. OSHA cannot legislate where Congress has remained silent.

Conclusion

Congress has not conferred on OSHA the authority to issue a general vaccine mandate. OSHA is a workplace safety agency, not a public health agency. Congress has tasked the FDA with determining whether vaccines are safe and effective and the CDC with recommending who should be immunized. It has vested no federal agency with the authority to issue the general vaccine mandate that OSHA seeks to enforce.

Moreover, OSHA is proceeding without gathering data from affected industries that would enable it to conduct an informed cost-benefit analysis. Its analysis therefore could overstate the benefits of the mandate and understate its costs. What seems likely is that OSHA has overlooked the broader economic implications of the ETS, including its potential to worsen the acute labor shortage, the supply chain crisis, and the emergence of inflation.

Those deficiencies show that Congress acted appropriately in not granting OSHA authority to enforce a general vaccine mandate. OSHA lacks the capacity to consider all of the factors relevant to a policy decision on vaccine mandates. These considerations range from the constitutional to the medical, from the economic to the epidemiological, from the theoretical to the practical. There is only one entity established to weigh those considerations and formulate policy. That entity is not OSHA; it is Congress.

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Endnotes

1. Dep't of Labor, OSHA, COVID-19 Vaccination and Testing: Emergency Temporary Standard, 86 Fed. Reg. 61,402–555 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917-18, 1926, and 1928) [hereinafter OSHA Vaccination Mandate].
2. 29 U.S.C. § 655(c) (2018).
3. See Paul J. Larkin & Doug Badger, *The First General Federal Vaccination Requirement: The OSHA Emergency Temporary Standard for COVID-19 Vaccinations*, 73 ADMIN. L. REV. ACCORD (forthcoming 2022), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3935420.
4. 29 C.F.R. § 1910.501(a).
5. In determining whether it meets the 100-employee threshold, a company must count part-time as well as full-time workers. It also must count employees who may be exempt from the mandate, including those who never enter the workplace, such as employees who work only remotely and those who work exclusively outdoors.
6. 29 C.F.R. § 1910.501(d).
7. 29 C.F.R. § 1910.501(c), definition of “fully vaccinated.” As discussed below, workers who are not fully vaccinated and are not otherwise exempt must be tested weekly for COVID-19. A worker must take two weekly tests after receiving the J&J vaccine; five weekly tests after receiving the first dose of the Pfizer–BioNTech vaccine (three weeks between shots and two weeks after the second shot); six weekly tests after receiving the Moderna vaccine (four weeks between shots and two weeks after the second shot); and five weekly tests in the case of heterologous doses (three weeks between doses and two weeks after the second dose). 86 Fed. Reg. at 61,484.
8. 29 C.F.R. § 1910.501(c) (definition of “mandatory vaccine policy”).
9. 29 C.F.R. § 1910.501(b)(3)(iii).
10. 29 C.F.R. § 1910.501(j).
11. 29 C.F.R. § 1910.501(e).
12. *Id.*
13. *Id.*
14. *Id.*
15. 29 C.F.R. § 1910.501(e)(4).
16. 29 C.F.R. § 1910.501(l)(2).
17. 29 C.F.R. § 1910.501(l)(3).
18. *Id.*
19. 29 C.F.R. § 1910.501(f).
20. 29 C.F.R. § 1910.501(h).
21. *Id.*, note to (h)(2). It is not clear why OSHA would collect data on COVID-related hospitalizations and deaths. CDC has primary responsibility for those data, which it gathers from hospitals, public health agencies, and other entities.
22. 29 C.F.R. § 1910.501(k).
23. 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. 1 (5th Cir. Nov. 6, 2021). Six days later, that court stayed the effect of the OSHA mandate pending a final ruling on its validity. *BST Holdings, L.L.C. v. OSHA*, No. 21-60845, 2021 WL 5279381 (5th Cir. Nov. 12, 2021). Subsequently, OSHA announced that it “has suspended activities related to the implementation and enforcement of the ETS pending future developments in the litigation.” OSHA, U.S. Dep’t of Labor, COVID-19 Vaccination and Testing ETS, <https://www.osha.gov/coronavirus/ets2> (last accessed Nov. 17, 2021). On November 16, the Judicial Panel consolidated and transferred petitions that were pending in the Fifth Circuit to the Sixth Circuit. See *In re: OSHA, Interim Final Rule*...Issued on Nov. 4, 2021, No. MCP No. 165 (U.S. Jud’l Panel on Multidist. Lit. Nov. 16, 2021). On November 23, the Administration filed an emergency motion to dissolve the stay in the Sixth Circuit. *In re: OSHA Rule on COVID-19 Vaccination and Testing*, 86 FR 61402, Respondents’ Emergency Motion to Dissolve Stay, Nov. 23, 2021.
24. Occupational Safety & Health Admin., U.S. Dep’t of Labor, COVID-19 Vaccination and Testing ETS, <https://www.osha.gov/coronavirus/ets2> (last accessed Nov. 24, 2021).
25. 29 C.F.R. § 1910.501(i).
26. *Id.*
27. *Id.*
28. *Id.*

29. 29 C.F.R. § 1910.501(g)(1).
30. *Id.*
31. 29 C.F.R. § 1910.501(g)(2).
32. 29 C.F.R. § 1910.501(g)(4).
33. Note to paragraph (g)(1). Payment for such tests may be required by other laws, regulations, or collective bargaining agreements.
34. 29 C.F.R. § 1910.501(c) (definition of COVID-19 test). Neither the ETS nor its preamble defines “authorized telehealth proctor.”
35. 29 U.S.C. § 666.
36. The long answer can be found at Larkin & Badger, *supra* note 3.
37. 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), 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.”
38. See, e.g., LAWRENCE O. GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 348–64 (3d ed. 1916).
39. 197 U.S. 11 (1905).
40. *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 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.”).
41. See, e.g., 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 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. 61-8.1.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.”).
42. Act of July 1, 1902, Pub. L. No. 57-244, 32 Stat. 728.
43. 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 accessed Nov. 28, 2021).
44. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i (2019)).
45. See 21 U.S.C. § 321(g)(1); 42 U.S.C. § 262(i)(1).
46. U.S. Food & Drug Admin., CBER Product Jurisdiction, Mar. 26, 2018, <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/cber-product-jurisdiction> (last accessed Sept. 28, 2021) (“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 (OVR), 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 OVR. 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.”) (emphasis omitted).

47. As the agency's website explains, "CBER's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies." U.S. Food & Drug Admin., About CBER (Feb. 6, 2018), <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/about-cber> (last accessed Sept. 15, 2021).
48. *Id.*
49. 141 S. Ct. 2485, 2490 (2021).
50. *Id.* Constitutional issues will be addressed separately.
51. 86 Fed. Reg. at 61472, Tbl. IV.B-7.
52. *Id.*
53. 86 Fed. Reg. at 61473, Tbl. IV.B.8. [See note 34.]
54. 86 Fed. Reg. at 61472.
55. *Id.*
56. Cntrs. for Disease Control & Prevention, COVID-19 Vaccinations in the United States, Jurisdiction, <https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdiction> (last accessed Nov. 9, 2021).
57. OSHA, Health Impacts of the COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS), OSHA-2021-0007-0491, at 13 (undated) [hereafter Health Impacts], <https://www.regulations.gov/document/OSHA-2021-0007-0491> (last accessed Nov. 30, 2021).
58. *Id.*
59. The agency's "Health Impacts" study, on which the estimate of 6,830 saved lives is based, includes a series of flawed assumptions too numerous to chronicle. For example, the agency based its estimate of the number of infections that would occur over a six-month period on the rates that prevailed between April 1 and August 31, 2021, a time during which infection rates were significantly above the 19-month average. Health Impacts, *supra* note 57, at 4. It based its estimates of infections on a select group of states and localities whose COVID-19 fatality rates over that period were 46 percent higher than the national average (40.39 in the selected localities vs. 27.75 for the U.S.) *Id.* at 9. It assumed that 80 percent of cases among covered workers would be acquired in the workplace rather than in the community. *Id.* Moreover, its data did not differentiate between vaccinated and unvaccinated persons. *Id.* at 10.
60. Hon. Ron Johnson, Doug Badger, Paul J. Larkin, Martin Makary & Robert Moffit, *What Is Wrong with President Biden's COVID-19 Vaccine Mandate?*, The Heritage Found., Lecture No. 1327, at 8–9 (delivered Nov. 4, 2021; published Nov. 19, 2021), <https://www.heritage.org/public-health/event/whats-wrong-president-bidens-covid-19-vaccine-mandate> (last accessed Nov. 28, 2021):

[Dr. Makary] The 27-fold increased level of protection of natural immunity in the same Israeli population was ignored. I believe it's for two reasons: One, politically, politicians entrenched themselves in a position that every human being with two feet needs to get vaccinated, period. They would ignore the evolving science. Two, people have told me privately, "Don't talk about natural immunity. People will go out there and just get the infection and not get vaccinated."

I say, "We can both be honest with the science and still encourage vaccination at the same time."

So the data is solid on natural immunity. All the studies show that it's highly effective, except for two, both put out by the CDC, jerry-rigged and forced. They used what we call statistical fishing, where even though they have data on all 50 states over 19 months, they cherry-picked a two-month interval in the state of Kentucky and said, "Ah, in this little sliver of data, natural immunity was worse." In fact, the rate of infection of both groups, natural and vaccinated, in that study were less than 0.1 percent. So it was extremely rare. And the other was the study they just put out, and I tweeted a long critique of it.

Id. at 12 (Dr. Makary: "The whole lexicon is wrong. We should be talking about the immune and non-immune. Not the vaccinated and unvaccinated. That was an imprecise framework that was imposed upon us despite many of us trying to use a different vocabulary.").
61. For example, based on a study involving people in the U.K. who had recovered from COVID-19, researchers estimated that "antibody levels associated with protection against reinfection likely last 1.5–2 years on average, with levels associated with protection from severe infection present for several years." Ja Wei et al., *Anti-Spike Antibody Response to Natural SARS-CoV-2 Infection in the General Population*, NATURE COMM'NS, Oct. 29, 2021, <https://www.nature.com/articles/s41467-021-26479-2> (accessed Nov. 24, 2021).
62. 86 Fed. Reg. at 61493, Tbl. IV.B.13.
63. 86 Fed. Reg. at 61,479.
64. 86 Fed. Reg. at 61,480.
65. 86 Fed. Reg. at 61,488.

66. The estimate of 264,000 firms is based on author calculation using data found in Table IV.B.13 (86 Fed. Reg. at 61493). That document estimates total compliance cost to firms of \$2,981,347,368 and an average cost of \$11,298 per covered entity. Dividing total costs by cost per entity yields 263,883 covered entities. If compliance costs are this low, one wonders why OSHA didn't apply the rule to all firms rather than limiting it to companies with 100 or more workers. The ETS preamble states that it is because the agency is certain that implementation is feasible for firms of that size. But most of the costs, like giving workers time off to get their shots and to recover from adverse events, collecting documentation of vaccination status, and maintaining those records, would seem to be about the same for small firms as they would be for larger ones. Indeed, a very small company might encounter fewer logistical difficulties in collecting vaccination records from four or five workers than would be the case for a company with thousands of employees working at multiple locations.
67. 86 Fed. Reg. at 61,473, Tbl. IV.B.8, and author calculations.
68. 86 Fed. Reg. at 61,475.
69. 86 Fed. Reg. at 61,516.
70. *Id.*
71. *Id.*
72. *Id.*
73. 86 Fed. Reg. at 61,461, Tbl. IV.B-1.
74. 29 C.F.R. § 1910.501(d).
75. 86 Fed. Reg. at 61,403. The agency has, however, acknowledged "scientific uncertainty" in this matter and requested public comment.
76. *See, e.g.,* Wei et al., *supra* note 58.
77. 86 Fed. Reg. at 61,479.
78. *Id.* OSHA's methodology is opaque. The FDA has determined that the two doses of the Pfizer-BioNTech vaccine are to be administered at least three weeks apart. For Moderna, the interval is at least four weeks. For heterologous doses, OSHA appears to have chosen the shorter of the two intervals and then subtracted four days as a "grace period." Their medical basis for this declaration, like their medical qualifications to establish it, is unclear.
79. Annabel Powell et al., "Real World Data Demonstrating Increased Reactogenicity in Adults Receiving Heterologous Compared to Homologous Prime-Boost COVID-19 Vaccinations: March-May 2021, England," SSRN, July 13, 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3880967 (accessed Nov. 24, 2021).
80. Quidel-Quick Vue-at-Home COVID-19 Self-Collected Test, https://www.amazon.com/Quidel-QuickVue-at-Home-COVID-19-Self-Collected/dp/B093ND7LX4/ref=sr_1_1?crid=3ICC9W3IT2P9Q&keywords=rapid+at+home+covid+test&qid=1636586030&qsid=136-6249979-7881307&sprefix=rapid+a%2Caps%2C197&sr=8-1&sres=B093ND7LX4%2CB09FP6HWCV%2CB099HXCBSW%2CB08ZR5XNBM%2CB08X67137P%2CB08Q1TMY7X%2CB092KGQT2Y%2CB09K7K8JXF%2CB0879CWJYW%2CB0792QJ3F8%2CB0888ST8ZS%2CB01G7PYQTM%2CB07PMT5H78%2CB092VHFZFL%2CB00TRLVKWO%2CB0828WFD5J (accessed Nov. 24, 2021).
81. 29 C.F.R. 1910.501(c).
82. Nisha Kurani et al., COVID-19 Test Prices and Payment Policy, Peterson-KFF Health System Tracker, Apr. 2021, <https://www.healthsystemtracker.org/brief/covid-19-test-prices-and-payment-policy/> (last accessed Nov. 24, 2021).
83. 86 Fed. Reg. at 61473, Tbl. IV.B.8.
84. U.S. Bureau of Labor Statistics, Job Openings and Labor Turnover Summary," Dec. 8, 2021, <https://www.bls.gov/news.release/jolts.nr0.htm> (last accessed Dec. 14, 2021).
85. *Id.*
86. U.S. Bureau of Labor Statistics, Data Tools (Dec. 14, 2021) <https://data.bls.gov/cgi-bin/surveymost> (link stopped functioning as of Nov. 28, 2021).
87. St. Louis Fed'I Reserve, All Employees, Hospitals, <https://fred.stlouisfed.org/series/CES6562200001> (last accessed Dec. 14, 2021).
88. *Id.*, All Employees, Nursing and Residential Care Facilities, <https://fred.stlouisfed.org/series/CEU6562300001> (last accessed Dec. 14, 2021).
89. *Id.*, All Employees, Educational Services, <https://fred.stlouisfed.org/series/CES6561000001> (last accessed Dec. 14, 2021).
90. Christopher Grimes & Andrew Edgecliffe-Johnson, *The Supply Chain Crisis and U.S. Ports: Disruption on Top of Disruption*, FIN. TIMES, Oct. 14, 2021, <https://www.ft.com/content/aa24d82e-16c7-4e3e-868e-42bd32f593be>; Ruth Simon, *With Vaccine Mandates Looming, Business Owners Face Wary Workers*, WALL ST. J., Nov. 20, 2021, https://www.wsj.com/articles/with-vaccine-mandate-looming-business-owners-face-wary-workers-11637404200?mod=Searchresults_pos4&page=1; Ted Rall, *The Left Betrays the Working Class on COVID Mandates*, WALL ST. J., Nov. 21, 2021, https://www.wsj.com/articles/left-betrays-working-class-covid-mandates-vaccine-religious-approval-exemption-nyc-osh-11637505203?mod=Searchresults_pos3&page=1.
91. U.S. Bureau of Labor Statistics, Consumer Price Index Summary, Dec. 10, 2021, <https://www.bls.gov/news.release/cpi.nr0.htm> (last accessed Dec. 16, 2021).

92. David Shepardson, *U.S. Postal Service Warns Vaccine Rules Could Affect Deliveries*, REUTERS, Nov. 10, 2021, https://www.reuters.com/world/us/us-postal-service-warns-vaccine-rules-could-affect-deliveries-2021-11-10/?utm_campaign=KHN%3A%20First%20Edition&utm_medium=email&_hsmi=181563649&_hsenc=p2ANqtz--cys9KzOeQpBm-xeEs7VzBlhE65jQqsr34L_OrQWqJy_QsYRdD0sajBqrsWDY60ptKy_24imUzktvltTy-6xsepJbkaQ&utm_content=181563649&utm_source=hs_email.
93. Motion for Stay Pending Disposition of Petitioners' Petition for Review, Texas Trucking Ass'n v. OSHA, <http://d22f3d5c92fe72fd8ca1-d54e62f2f7fc3e2ff1881e7f0cef284e.r22.cf1.rackcdn.com/Coronavirus%20attachments%20docs%20etc/OSHA%20ETS%20Stay%20Motion%5B3%5D.pdf> (last accessed Nov. 28, 2021).
94. *Id.* at 3.