VIEWPOINT

The US Supreme Court's Rulings on Large Business and Health Care Worker Vaccine Mandates

Ramifications for the COVID-19 Response and the Future of Federal Public Health Protection

Lawrence O. Gostin,

O'Neill Institute for National and Global Health Law, Georgetown University, Washington, DC.

Wendy E. Parmet, JD Northeastern

Northeastern University School of Law, Boston, Massachusetts.

Sara Rosenbaum, JDMilken Institute School of Public Health, George Washington

of Public Health, George Washington University, Washington, DC.

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On January 13, 2022, the Supreme Court issued 2 landmark rulings on the federal government's power to mandate COVID-19 vaccinations. The Court curtailed the government's ability to respond to the pandemic and may have also severely limited the authority of federal agencies to issue health and safety regulations.

In National Federation of Independent Business v Department of Labor, 1 the Court blocked an Occupational Safety and Health Administration (OSHA) emergency temporary standard (ETS) requiring vaccination, subject to religious or disability accommodations, or weekly testing and masking in businesses with 100 or more employees. In Biden v Missouri, 2 the Court upheld a Centers for Medicare & Medicaid Services (CMS) regulation mandating health worker vaccinations, subject to the same accommodations. What do these decisions reveal about the future of federal protection of public health and safety?

Beyond COVID-19, the Court's decisions have...consequential implications for the federal government's ability to protect the public's health and safety against a wide array of risks.

OSHA's Large Business Vaccine-or-Test Mandate

On November 5, 2021, OSHA issued an ETS to protect workers from COVID-19, finding that SARS-CoV-2 transmission in the workplace posed a grave danger and vaccination was the most effective risk reduction measure.3 OSHA had estimated the ETS would save 6500 lives and prevent 250 000 hospitalizations over 6 months, although those estimates predated the major surge in cases and hospitalizations due to the Omicron variant. Several states and businesses challenged OSHA's standard. The Supreme Court, in a 6-3 unsigned per curiam opinion (a judicial opinion presented as that of the entire court rather than that of any one justice), ruled that OSHA lacked statutory authority to issue its vaccine-or-test mandate, stating it is "no everyday exercise of federal power," but "a significant encroachment into the lives-and health-of a vast number of employees."1

The Occupational Safety and Health Act (OSH Act) requires OSHA to issue an ETS when it determines it is "necessary" to protect employees from a "grave danger" of exposure to "physically harmful" "new hazards"

or "agents." ⁴ The Court did not view COVID-19 as an occupational danger in most workplace settings because the SARS-CoV-2 virus can be transmitted throughout society and vaccination "cannot be undone at the end of the workday." Notably, the OSH Act does not specify that hazards must be primarily or exclusively occupational. Workers, moreover, are at heightened risk because they spend long periods in crowded indoor settings, often unable to protect themselves.

The Court also expressed concern with the breadth of the ETS, noting it affects an estimated 84 million workers. Applying the controversial "major questions" doctrine, the Court demanded Congress "speak clearly when authorizing an agency to exercise powers of vast economic and political significance" but did not specify what makes a question "major." Concurring, the most conservative justices—Gorsuch, Thomas, and Alito—emphasized that federalism and separation of

powers protect the "liberties of millions of Americans."

CMS' Health Worker Vaccine Mandate

On November 5, 2021, CMS issued an interim final rule requiring staff working in Medicare- or Medicaid-certified facilities to be fully vaccinated against COVID-19 unless they qualify for a medical or religious exemption. In a narrow 5-4 per curiam rul-

ing, the Supreme Court permitted CMS to enforce the rule nationwide affecting an estimated more than 10 million health care workers. The Court noted CMS has wide powers to condition facilities' participation in Medicare and Medicaid on requirements it deems necessary for patient health and safety. CMS has a long history of setting health and safety standards for participating facilities, including health care professionals' qualifications and duties, infection control protocols, and the extent to which physicians may delegate tasks to advanced-practice clinicians.

The Court recognized that unvaccinated health care workers pose a unique and independent risk to hospital staff and patients. The COVID-19 vaccine mandate was necessary because "COVID-19 is a highly contagious, dangerous—and especially for Medicare and Medicaid patients—deadly disease." Evidence in the CMS record demonstrated that Medicare and Medicaid patients have heightened vulnerability given their age and chronic conditions. Approximately 30% of health care workers are currently unvaccinated, posing "a serious threat" to patient health and safety. SARS-CoV-2 "canspread rapidly among healthcare workers and from them to patients," which is

Gostin, JD, O'Neill Institute for National and Global Health Law, Georgetown University

Corresponding

Author: Lawrence O

Global Health Law, Georgetown University Law Center, 500 First St NW, Office 810, Washington, DC 20001 (gostin@ georgetown.edu).

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more likely when health care workers are unvaccinated. The vaccine mandate, therefore, "fits neatly" within powers granted by Congress.²

Preventing health care–acquired infections is consistent with a fundamental principle of medical ethics: first, do no harm. The Court indicated that it would be the "very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19." Although CMS has never mandated a vaccine before, it was justified by an unprecedented health emergency.

How the Court's Rulings Affect the Ongoing COVID-19 Response

The Court's decisions carry enormous significance for the federal response to COVID-19. As of January 16, the US had a full vaccination rate of 62.9%—among the lowest in high-income countries. OSHA's mandate would have reached 84 million workers. Tens of millions of employees are unable to work remotely, with little control over occupational exposures to SARS-CoV-2, which also places members of their households at risk.

The judiciary has been largely supportive of states, localities, universities, and private businesses that have required their employees to be vaccinated. Restrictions on vaccine mandates, however, currently exist in at least 11 states and can now be enforced. The OSHA ETS would have set national uniform COVID-19 safety standards and preempted state restrictions. The Court's ruling will mean that nationwide workplace protection now can be implemented only in health care facilities, where the justification is patient safety, not worker protection.

The Biden administration could propose more limited COVID-19 workplace standards—for example, applying only to workplaces with especially high risks of SARS-CoV-2 transmission (eg, assembly lines or cruise ships), but the Court's ruling gives OSHA very limited scope for future action.

The Future of Federal Public Health and Safety Protection

Beyond COVID-19, the Court's decisions have even more consequential implications for the federal government's ability to pro-

tect the public's health and safety against a wide array of risks. Under the Constitution's federalist system, states hold primary public health powers, and all states require childhood vaccinations as a condition of school entry. Yet, dating back at least to President Roosevelt's New Deal, Congress has delegated wide and flexible authority to federal agencies to set health and safety standards to address issues ranging from infectious diseases and food, drugs, and tobacco, to consumer products, motor vehicle safety, and chemical, nuclear, and environmental hazards. The conservative justices now appear skeptical of that understanding and want to rein in federal laws that relate to public health.

The Court's reasoning in *National Federation of Independent Business*¹ could considerably curtail existing and future federal agency action to address major national and global hazards, at least for regulations that have significant effects on society and the economy. Many agency regulations do have such effects beyond those issued by the departments of Labor and Health and Human Services. The logic of requiring explicit congressional authority for "major" questions could significantly constrain agencies in effectively responding to new or significant health and safety threats.

Congress has historically granted agencies wide and flexible authority for good reason. Public health agencies, not Congress, possess the expertise to respond to complex and changing scientific evidence. As the COVID-19 pandemic has shown, Congress also cannot know what future risks the population will face, so it affords agency officials flexibility. Because most health hazards affect whole regions and even the entire nation, states acting alone are unable to take effective measures without federal regulation.

As Justices Breyer, Sotomayor, and Kagan wrote in their dissent in the OSHA case, the majority's decision "stymies the Federal Government's ability to counter unparalleled" threats.¹

By limiting the federal government's ability to flexibly protect public health, the justices gave themselves an outsize role in formulating federal health policy, with significant ramifications that will remain long after the pandemic ends.

ARTICLE INFORMATION

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REFERENCES

- 1. National Federation of Independent Business v Department of Labor, Occupational Safety and Health Administration, 1595 US __, No. 21A244 (January 13, 2022).
- **2**. *Biden v Missouri*, 595 US _, No. 21A240 (January 13, 2022).
- **3**. COVID-19 Vaccination and Testing: Emergency Temporary Standard, Occupational Safety and Health Administration. *Fed Reg.* 2021;86:61402.

- **4**. Occupational Safety and Health, Standards, 29 USC §655.
- 5. CMS. Interim Final Rule with comment period, "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination." Fed Reg. 2021:86:61555.
- **6.** Reses HE, Jones ES, Richardson DB, Cate KM, Walker DW, Shapiro CN. COVID-19 vaccination coverage among hospital-based healthcare personnel reported through the Department of Health and Human Services Unified Hospital Data Surveillance System, United States, January 20, 2021-September 15, 2021. *Am J Infect Control*. 2021; 49(12):1554-1557. doi:10.1016/j.ajic.2021.10.008
- 7. Our World in Data. Coronavirus (COVID-19) vaccinations. Accessed January 19, 2022. https://ourworldindata.org/covid-vaccinations? country=USA

- 8. Ryan Klaassen et al v Trustees of Indiana University; US Supreme Court. Accessed January 19, 2022. https://www.supremecourt.gov/DocketPDF/ 21/21A15/186877/20210806095541542_IU% 20VAX%20SCOTUS%20writ%20of%20inj% 20app%20FINAL.pdf
- 9. Association of State and Territorial Health Officers. The shifting legal landscape of COVID-19 vaccine requirements. November 3, 2021. Accessed January 19, 2022. https://www.astho.org/ StatePublicHealth/Shifting-Legal-Landscape-of-COVID-19-Vaccine-Requirements/11-03-21/
- **10.** Gostin LO, Salmon DA, Larson HJ. Mandating COVID-19 vaccines. *JAMA*. 2021;325(6):532-533. doi:10.1001/jama.2020.26553