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SLOUCHING TOWARDS DEREGULATION: THE THREAT TO HEALTH POLICY

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As anyone who has ever been sick or had a sick family member knows, health care in the United States can be exceedingly complex. Our fragmented, decentralized health system relies on a wide array of insurers, providers, and government programs to provide coverage and care to more than 330 million people—often with overlapping federal and state regulatory requirements. Among these federal requirements, Congress has enacted significant health care laws that include the Medicare and Medicaid Act, the Affordable Care Act, and the No Surprises Act.

Given the specialized nature of health care, Congress seldom has the expertise to foresee all circumstances and address every policy complexity or nuance needed for an effective health care system. Instead, Congress has long directed federal agencies to implement its agenda. Congress writes the laws, sets the standards, and instructs federal agencies to implement those laws. Federal agencies can also clarify policies in response to new circumstances, such as emergencies or technological advances. There are many benefits to this system: it promotes efficiency, draws upon agency expertise, and preserves flexibility to effectuate federal health care legislation.

While Congress and federal agencies have operated this way for centuries, this approach is increasingly threatened by the recent uptick in litigation over the so-called “nondelegation doctrine” and related concepts such as the “major questions doctrine” and “*Chevron* deference.” Coupled with increased judicial skepticism of the administrative state, this shift could severely limit the executive branch’s ability to implement federal law. These doctrines are increasingly cited by courts and interest groups to derail health policies that range from vaccination requirements to Medicare reimbursement to the coverage of preventive services to environmental protections.

If embraced, these theories could devastate the health care system. Federal officials have been tasked by Congress with administering trillions of dollars in annual health care spending, managing large government programs like Medicare and Medicaid, providing health care for veterans and members of the

military, regulating private insurers, and overseeing the operation of health care clinics, among other roles. This role, in turn, requires agencies to clarify issues like eligibility, covered benefits, safety and approval standards, reimbursement—or adopt measures needed to prevent fraud and abuse, protect patient privacy, or clarify overlapping legal obligations.

If federal agencies are constrained in their ability to issue regulations or interpret federal law, the health care system could be severely disrupted. Given how much Congress defers health care implementation to the executive branch, a wide range of health laws and regulations could be vulnerable to legal challenge if courts embrace these theories.

Despite the potentially devastating impact, these developments are little understood outside of legal circles. This resource is meant to help fill that gap by 1) explaining the nondelegation doctrine and related doctrines; 2) highlighting the importance of congressional delegation to administrative agencies in health care; and 3) looking ahead to what major pending court cases might mean for the future of health policy.

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THE NONDELEGATION DOCTRINE AND BEYOND

THE “NONDELEGATION DOCTRINE” IS A JUDICIALLY CREATED PRINCIPLE that Congress cannot delegate its legislative authority to administrative agencies or other entities.² This doctrine is rooted in the Constitution, which defines the roles and powers of each of three branches of the government. The legislative role is vested in Congress,³ meaning that the power to make laws is the exclusive province of Congress. As the lawmaking body, Congress cannot simply abdicate its legislative functions⁴ or “pass the buck to the other branches on hard policy choices.”⁵ The nondelegation doctrine was created by courts to limit Congress from passing the buck.

Even so, the nondelegation doctrine has historically not been used to prevent Congress from seeking the help of the executive branch in implementing the laws it passes.⁶ Congress has delegated authority to administrative agencies since the nation’s founding,⁷ and the Supreme Court has long upheld delegation as constitutional. In fact, the Supreme Court has invalidated congressional delegation only twice ever, and that was almost 90 years ago.

In 1935, the Supreme Court issued two opinions invalidating Congress’s delegation of power under the National Industrial Recovery Act (NIRA), a law enacted during the New Deal era that gave significant authority to the executive branch to respond to the Great Depression. These decisions—*Panama Refining Company v. Ryan* and *A. L. A. Schechter Poultry Corporation v. United States*—are clear outliers that involved challenges to open-ended provisions that authorized the president to promulgate a petroleum code with no limits or conditions⁸ and set “codes of fair competition” for different trades and industries.⁹ Delegation, the Supreme Court held, was impermissible because it lacked a so-called “intelligible principle”—Congress failed to provide sufficient standards to guide the president’s discretion.¹⁰ The Supreme Court invalidated the NIRA provisions in those cases because Congress passed the buck to the executive branch while truly failing to limit the executive branch’s discretion.

Since 1935, however, the Supreme Court has not invalidated congressional delegations of power. Instead, it has deferred to Congress in deciding whether and how to delegate the implementation of federal laws to administrative agencies.¹¹ Delegation is permissible so long as Congress identifies a policy goal and provides an “intelligible principle” to guide an agency in achieving that goal.¹² What constitutes an intelligible principle? Congress must clearly delineate the general policy, the relevant agency, and the boundaries of the delegated authority.¹³ Under this deferential standard, the Supreme Court has upheld broad delegations that direct federal agencies to implement laws that are: (1) based on “public interest;” (2) “just and reasonable;” and (3) “requisite to protect public health.”¹⁴

What’s more, when Congress broadly delegates authority under this deferential standard, it implicitly grants agencies the authority to resolve statutory ambiguities or “fill in” statutory gaps.¹⁵ And courts have deferred to agencies’ reasonable interpretation of the laws that the agencies are charged with implementing under a framework known as “**Chevron deference.**” Even when Congress legislates detailed policies, federal agencies often still need to fill in details to help regulated entities operationalize new requirements and to reconcile overlapping or conflicting standards. The *Chevron* framework is deferential to both Congress and the agencies and precludes courts from substituting their own interpretations for those of the agencies.¹⁶

Despite these settled norms, courts are increasingly adopting an antiregulatory approach that seeks to limit deference to the executive branch. At least five current Supreme Court justices have said they would be interested in revisiting the nondelegation doctrine.¹⁷ While the Supreme Court has not (yet) invoked the nondelegation doctrine as it did in *Panama* and *Schechter*, it has increasingly invoked related doctrines to strike down federal regulations.

In particular, courts have applied the so-called **“major questions doctrine”** to invalidate federal regulations. What is the major questions doctrine?¹⁸ The Supreme Court has not clearly defined it. But recent decisions suggest the Supreme Court will not defer to agency interpretations (as it would under *Chevron*) in “extraordinary cases” or on issues of “vast economic and political significance” when Congress has not directly spoken to that issue.¹⁹ What qualifies as an “extraordinary case” or issue of “vast economic and political significance”? Those are open questions, and the Supreme Court has not articulated a limiting principle.²⁰ Thus, what constitutes a “major question” appears to be in the eye of the beholder, meaning courts could strike down a range of regulations that seemingly fail to meet this new and evolving standard.

The willingness of a majority of Supreme Court justices to entertain claims that erode administrative authority has emboldened advocates and lower courts to view agency action skeptically and aggressively invalidate federal regulations on nondelegation and related grounds.²¹ As just one example, the number of federal filings that mention the major questions doctrine “surge[d]” to 69 filings in 2021, up from fewer than 10 filings in 2020.²²

Recent court decisions suggest that the nondelegation doctrine is not a singular principle, but a collection of ever-evolving interpretive canons or rules that courts use to police delegation.²³ The links between the nondelegation doctrine, *Chevron* deference, and the major questions doctrine—and how courts are applying these concepts to agency action—are discussed in more detail below.

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WHY DO THESE DOCTRINES MATTER FOR HEALTH POLICY?

DELEGATING POWER TO ADMINISTRATIVE AGENCIES plays a vital role in achieving Congress's health care objectives. A long list of major federal health laws delegate authority to federal agencies. Examples include the Food, Drug, and Cosmetic Act (FDCA); the Public Health Service Act; the laws establishing Medicare and Medicaid; the Medicare Modernization Act; the Affordable Care Act (ACA); the 21st Century Cures Act; and, most recently, the No Surprises Act. Even in a law as detailed as the ACA, for instance, Congress explicitly directed or permitted federal officials to act in more than 1,000 instances.²⁴

This degree of delegation should not be a surprise. Health care involves complex substantive issues and technical minutiae—such as eligibility rules, scientific analysis, and program integrity—that require specialized knowledge that Congress seldom has.²⁵ Congress therefore delegates implementation to the Department of Health and Human Services (HHS) and its subagencies, such as the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) who have “everyday experience” and technical expertise in implementing and administering specific laws and programs.²⁶

Further, Congress cannot foresee all circumstances and address every detail of a broad legislative agenda.²⁷ Federal agencies like HHS must often clarify new and revisit older health care standards. This flexibility, enabled by Congress's delegation, is critical to implementing federal health care laws and for the ongoing management and oversight of the health care system.

Given this backdrop, health care has unsurprisingly featured prominently in litigation involving agency delegation. In *FDA v. Brown & Williamson Tobacco Corporation*, for example, the Supreme Court rejected the FDA's attempt to regulate tobacco products under the FDCA.²⁸ Despite the FDA's broad authority to regulate drugs and devices under the FDCA, the statute did not explicitly mention tobacco products at the time. The FDA interpreted FDCA's broad definition of drugs and devices as permitting regulation of nicotine as a drug and cigarettes and smokeless tobacco as devices. The Supreme Court disagreed, concluding that the FDA could not regulate tobacco products without explicit congressional authorization. The answer to this major question—one with deep economic and political significance—could not be based on a broad, ambiguous statute. The Supreme Court could have deferred to the FDA's reasonable interpretation of the FDCA but instead concluded that *Chevron* did not apply in this type of major questions case.

Delegating power to administrative agencies plays a vital role in achieving Congress's health care objectives

In *King v. Burwell*, the Supreme Court relied on *Brown & Williamson* to hold that federal premium tax credits were available through all ACA marketplaces, whether established by the state or the federal government.²⁹ The issue in *King* was whether the Internal Revenue Service (IRS) was correct in interpreting the ACA to conclude that the tax credits were available in all marketplaces. There, too, the Supreme Court could have answered this question under the *Chevron* doctrine. But it sidestepped *Chevron* altogether. Rather than deferring to the IRS interpretation, the Supreme Court looked to the statute and invoked the major questions doctrine to conclude that Congress (not the IRS) had decided that tax credits would be available in all marketplaces.

These cases are now regularly cited in lawsuits challenging the scope of agency delegation. After the Supreme Court concluded that the FDA could not regulate tobacco, Congress stepped in to grant the FDA with explicit authority to do so. And while *King* preserved financial help for health insurance for millions of people, the Supreme Court reached this conclusion by limiting agency authority to interpret the law.

RECENT CASES UNDERMINING HEALTH REGULATION

Despite the long history of congressional delegation on health care issues, a shift is underway in the courts. This section summarizes two recent Supreme Court decisions that invoked the nondelegation and major questions doctrines to invalidate regulations by federal agencies.

COVID-19 Vaccine-or-Test Standard. In *National Federation of Independent Business v. Department of Labor*, the Supreme Court held that an emergency temporary standard issued by the Occupational Safety and Health Administration (OSHA) was likely invalid.³⁰ This emergency temporary standard—a type of emergency regulation—required certain employees to be vaccinated or take weekly COVID-19 tests and mask at work. OSHA cited its broad emergency authority under the Occupational Safety and Health Act, which authorizes emergency rules when employees are “exposed to grave danger from exposure” and a rule is “necessary to protect employees from such danger.”³¹

The challengers—who included businesses and Republican attorneys general—argued that OSHA did not have the authority to adopt the standard. Applying what Justice Gorsuch characterized as the major questions doctrine,³² the Supreme Court agreed and concluded that OSHA improperly adopted a standard that had vast economic and political significance without clear authorization from Congress. The Supreme Court did so without explaining how it made this determination, stating simply that the standard was “no everyday exercise of federal power” because it affected 84 million workers.³³ For the standard to be valid, the Supreme Court ruled, Congress would have needed to specifically authorize OSHA to require employee vaccination. Congress’s broad delegation to OSHA to set emergency workplace safety standards was insufficient to justify the vaccination-or-test requirement.

Eviction Moratorium. In *Alabama Association of Realtors v. HHS*, the Supreme Court sided with realtor associations and rental property managers to strike down a moratorium on evictions of any tenants who lived in counties experiencing high levels of COVID-19 transmission.³⁴ The

CDC issued the eviction moratorium under a provision of the Public Health Service Act that authorizes federal officials to “make and enforce such regulations . . . necessary to prevent the introduction, transmission, or spread of communicable diseases.”³⁵ Similar to the OSHA case, the Supreme Court found that the eviction moratorium—which affected between 6 to 17 million tenants—had a significant economic and political impact. Because Congress had not specifically authorized CDC to make housing policy, CDC could not impose an eviction moratorium.

What do these cases tell us about the Supreme Court’s newfound view of delegation to federal agencies? In a significant deviation from the deferential intelligible principle approach that has guided the courts for almost a century, the Supreme Court appears to be saying that Congress must clearly authorize an agency to address major policy questions. This narrow reading of delegation imposes a heightened standard on both Congress and the agencies. It also puts in doubt the ability of federal agencies to rely on general statutory authorizations to adopt new health policies and address needs as they arise.

WHAT COMES NEXT: CASES TO WATCH IN 2022

THE RECENT OSHA AND CDC CASES MAY BE JUST THE BEGINNING in the Supreme Court’s shifting view of the nondelegation and major questions doctrines. Indeed, there are several challenges to regulatory action that the Supreme Court will decide this term and other cases pending before lower courts that portend serious limitations to agency rulemaking.

1. PENDING SUPREME COURT CASES

The Supreme Court will soon decide at least two major cases on the scope of agency authority before its term ends in summer 2022. The potential implications of both cases go beyond their focus on environmental law and Medicare reimbursement and could significantly reshape agencies’ ability to adopt new regulations and policies.

There are several challenges to regulatory action that the Supreme Court will decide this term and other cases pending before lower courts that portend serious limitations to agency rulemaking.

Clean Energy. In *West Virginia v. Environmental Protection Agency*, the justices will consider a challenge to the Environmental Protection Agency's (EPA's) regulation of greenhouse emissions under the Clean Air Act (CAA). Under the CAA, the EPA can identify sources that significantly contribute to air pollution and set guidelines for achieving "the best system of emission reduction" based on various criteria.³⁶ Citing that authority, the Obama administration issued the Clean Power Plan (CPP), which set guidelines for states to develop power plant emission standards that prioritized cleaner energy.³⁷

The energy industry and Republican attorneys general challenged the scope of EPA's authority to issue the CPP as early as 2014, and the litigation—after many twists and turns—continued even after the Trump administration repealed the CPP and issued a more industry-friendly policy in 2019. Challengers argue that in enacting the CAA, Congress violated the nondelegation doctrine by giving the EPA "a blank check . . . to mandate any nationwide 'system' it can devise."³⁸ They claim that the statute fails to include an intelligible principle to guide the EPA's actions and that devising the appropriate method to reduce greenhouse emissions is a major policy choice that only Congress, not the EPA, can address.³⁹ Defenders of the CPP argue that the CAA more than satisfies the intelligible principle requirement: the law clearly states the general policy (emission reductions to reduce pollution) and sets boundaries for the EPA (by directing it to consider several factors) to achieve this policy goal.⁴⁰

Depending on how it rules, the Supreme Court could transform its view of congressional delegation by moving away from almost a century of settled law that allows Congress to delegate to federal agencies so long as it includes an intelligible principle. By constraining Congress's delegation of authority, the Supreme Court could upend Congress's ability to seek the help of agencies to implement new policy goals and jeopardize existing regulations, triggering what could be an unprecedented number of lawsuits.

Medicare Reimbursement. In *American Hospital Association v. Becerra*, the Supreme Court could limit agency authority by revisiting the *Chevron* doctrine.⁴¹ At issue is HHS's decision in 2018 to cut reimbursement rates for certain prescription drugs under the Section 340B program. HHS argued that cutting the reimbursement rates was permissible because the Medicare Act provides discretion to calculate and adjust prescription drug payments. Hospitals disagreed, arguing that HHS exceeded its authority by adjusting the reimbursement rates without complying with statutory requirements and that HHS's interpretation was incorrect and therefore not entitled to *Chevron* deference.⁴²

In its briefs and at oral argument, the hospitals suggested that the Supreme Court reconsider the *Chevron* framework itself. Overruling or limiting *Chevron* deference could curtail agencies' ability to interpret and implement the laws they are charged with administering.

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2. LOWER COURT CASES TO WATCH

The nondelegation and major questions doctrines are increasingly invoked by challengers and courts alike, especially in the context of the COVID-19 pandemic. Recent examples include court decisions striking the CDC's authority to limit cruise ship operations,⁴³ vaccine-or-test requirements for federal contractors and subcontractors,⁴⁴ mask mandates for Head Start staff and volunteers,⁴⁵ and mask mandates for air travel.⁴⁶ There are several other lower court cases worth watching.

Preventive Services. In *Kelley v. Becerra*, several individuals and two employers—many of whom are repeat players in ACA litigation—rely on the nondelegation doctrine in challenging the ACA's preventive service mandate. Under the ACA, most private health plans are required to cover specified, evidence-based preventive services without cost-sharing.⁴⁷ Covered preventive services include those identified by the U.S. Preventive Services Task Force (USPSTF), the CDC's Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA). This requirement, which extends to services such as vaccines and cancer screenings, minimizes financial barriers to preventive care, thereby encouraging their use. About 150 million Americans have benefitted from the preventive services mandate under the ACA.⁴⁸

The challengers claim that the ACA empowers the USPSTF, ACIP, and HRSA to determine preventive services unilaterally without providing an intelligible principle to guide their discretion.⁴⁹ To support their challenge, they cite *Little Sisters of the Poor v. Pennsylvania*,⁵⁰ a 2020 decision where the Supreme Court upheld HRSA's regulations on the contraceptive mandate. Justice Thomas, writing for the majority, noted that the statute grants HRSA "virtually unbridled discretion to decide what counts as preventive care."⁵¹ Justice Thomas made this statement even though none of the parties raised a nondelegation argument. Briefing in *Kelley* is ongoing, and a decision is expected later this year.

Social Costs of Greenhouse Gas Emissions. In *Louisiana v. Biden*, Republican attorneys general challenged President Biden's executive order on public health and climate change.⁵² To inform cost-benefit analyses for future regulations, the executive order directed an interagency working group to determine the full cost of greenhouse gas emissions, including their social costs. The executive order gave preliminary guidance to federal agencies on how to evaluate actions related to greenhouse gas emissions. In February 2021, the working group adopted the greenhouse gas emissions social costs calculations that had been established under the Obama administration.

The challengers argued that the order violates the nondelegation doctrine because it imposes significant costs on the economy. Deploying the major questions doctrine,⁵³ a district court agreed and prohibited federal agencies from using the social cost estimates. The executive order, the court said, was an attempt by President Biden to adopt "fundamentally transformative legislative rules in areas of vast political, social, and economic importance."⁵⁴ The government appealed, and the Fifth Circuit Court of Appeals stayed the district court's decision after concluding that the challengers' claims were speculative since no agency had promulgated a rule using the cost-benefit analysis.⁵⁵

The decision has been widely criticized, including by conservative legal scholars,⁵⁶ and is already having an impact. Citing the court's decision, the Department of the Interior indefinitely froze decisions about new federal and oil gas drilling.⁵⁷

These are only some of the lower court cases to watch that have the potential to reshape constitutional and administrative law as well as deference to executive agencies.

CONCLUSION

The Supreme Court appears to be on a path to constrain the authority of federal administrative agencies by reinvigorating and expanding the nondelegation doctrine, regularly invoking the major questions doctrine, and sidestepping or undermining *Chevron* deference. A new approach on any of these issues will limit the executive branch's ability to adopt evidence-based, equitable health care and public health policies. In the meantime, the lower courts are not waiting, and the willingness of the Supreme Court to entertain nondelegation and related claims has emboldened lower courts to stymie federal regulations. The development of nondelegation and related doctrines will be a key issue to watch for those who care about the regulation of health care and health policy.

ENDNOTES

- 1 We are grateful for the excellent research support of Erin Coughlin and Suhasini Ravi and the substantive feedback and insightful comments we received from Will Dobbs-Allsopp, Timothy Jost, Rachael Klarman, Mark Regan, Sara Rosenbaum, and Joseph Wardski.
- 2 *Mistretta v. United States*, 488 U.S. 361, 372 (1989); see also *Wayman v. Southard*, 23 U.S. 1, 42 (1825) (“It will not be contended that Congress can delegate . . . powers which are strictly and exclusively legislative.”).
- 3 U.S. CONST. art. 1, § 1 (“All legislative Powers herein granted shall be vested in a Congress of the United States[.]”).
- 4 *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935).
- 5 See LAURENCE TRIBE, *AMERICAN CONSTITUTIONAL LAW*, 3d Ed, Vol 1, p 986.
- 6 *Mistretta*, 488 U.S. at 372; *Touby v. United States*, 500 U.S. 160, 165 (1991).
- 7 See *United States v. Grimaud*, 220 U.S. 506, 517 (1911) (“From the beginning of the government, various acts have been passed conferring upon executive officers power to make rules and regulations.”); see also Julian Davis Mortenson & Nicholas Bagley, *Delegation at the Founding*, 121 COLUM. L. REV. 277 (2021).
- 8 293 U.S. 388 (1935).
- 9 295 U.S. at 539.
- 10 293 U.S. at 430.
- 11 *Loving v. United States*, 517 U.S. 748, 771 (1996); *Whitman v. Am. Trucking Associations*, 531 U.S. 457, 474–75 (2001) (“[W]e have ‘almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law.’”).
- 12 *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019); see also *J.W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394, 409 (1928).
- 13 *Am. Power & Light Co. v. Sec. & Exch. Comm’n*, 329 U.S. 90, 105 (1946)
- 14 *Am. Trucking Associations*, 531 U.S. at 474; *Gundy*, 139 S. Ct. at 2129; *I.N.S. v. Chadha*, 462 U.S. 919, 985 (1983) (White, J., dissenting).
- 15 *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000).
- 16 Cass R. Sunstein, *The American Nondelegation Doctrine*, 86 GEO. WASH. L. REV. 1181, 1198 (2018).
- 17 *Gundy*, 139 S. Ct. at 2141 (Gorsuch, J., dissenting). The dissent was joined by Chief Justice Roberts and Justice Thomas. Justice Alito did not join the dissent but said he would be willing to reconsider the Court’s nondelegation approach. Justice Kavanaugh expressed his openness to revisiting this issue in a separate case. See *Paul v. United States*, 140 S. Ct. 342 (2019) (statement by Kavanaugh, J., respecting the denial of certiorari).
- 18 See Cass R. Sunstein, *There Are Two “Major Questions” Doctrines*, 73 Admin. L. Rev. 475 (2021) (concluding that there is a weak major questions doctrine where agencies will not receive deference if they are dealing with a question of fundamental importance and a strong major questions doctrine where agencies cannot claim broad new authority to regulate a sector of the economy unless Congress has clearly granted that power).
- 19 See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159 (2000) (“A court may also ask whether the legal question is an important one. Congress is more likely to have focused upon, and answered, major questions, while leaving interstitial matters to answer themselves in the course of the statute’s daily administration.”); *King v. Burwell*, 576 U.S. 473, 485 (2015); *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 324 (2014).
- 20 The Supreme Court seems to care *how many* people are affected but has not given guidance as to what threshold of impact is needed to trigger this doctrine. *Compare Gundy*, 139 S. Ct. 2116 (Gorsuch, J., dissenting) (suggesting that the Sex Offender Registration and Act gave vast authority to the attorney general by granting the power to apply the law to at least 500,000 sex offenders) and *NFIB v. DOL*, 142 S. Ct. 661 (2022) (holding that requiring 84 million people to vaccinate or test for COVID-19 had vast economic and political significance), with *Biden v. Missouri*, 142 S. Ct. 647, 658 (2022) (Thomas, J., dissenting) (arguing that requiring 10 million health care workers to be vaccinated had vast economic and political significance); and *Alabama Ass’n of Realtors v. HHS*, 141 S. Ct. 2485 (2021) (stating that the CDC eviction moratorium had vast economic and political significance because it affected 6 and 17 million tenants).
- 21 See e.g., *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021) (finding that a CDC rule on pandemic-related restrictions for the cruise ship industry likely violates the nondelegation doctrine); *Kentucky v. Biden*, No. 3:21-CV-00055-GFVT, 2021 WL 5587446 (E.D. Ky. Nov. 30, 2021) (finding that COVID-19 vaccine requirements for federal contractors and subcontractors likely violate the nondelegation doctrine). *But see Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 447 (5th Cir. 2020), cert. denied, 141 S. Ct. 2746 (2021) (“The Court might well decide—perhaps soon—to reexamine or revive the nondelegation doctrine. But ‘we are not supposed to read tea leaves to predict where it might end up.’”).
- 22 Erin Webb, “Major Questions Doctrine Filings Are Up in a Major Way,” *Bloomberg Law* (Feb. 1, 2022) (noting that the phrase “major questions doctrine” appeared at least 69 times in federal docket filings in 2021).
- 23 See generally Sunstein, *supra* note 16 at 1184 (“The nondelegation doctrine . . . consists of a set of clear statement principles or . . . nondelegation canons, and they change over time. [T]he [nondelegation] doctrine is an umbrella concept[.]”); Lisa Heinzerling, *The Power Canons*, 58 WM. & MARY L. REV. 1933, 1937 (2017); *Gundy*, 139 S. Ct. at 2141 (Gorsuch, J., dissenting) (“We still regularly rein in Congress’s efforts to delegate legislative power; we just call what we’re doing by different names.”).
- 24 Simon F. Haeder and Susan W. Yackee, *A Look Under the Hood: Regulatory Policy Making and the Affordable Care Act*, 45 J. HEALTH POLIT POLICY LAW 771 (Oct. 2020).

- 25 See *e.g.*, *Am. Elec. Power Co. v. Connecticut*, 564 U.S. 410, 428 (2011) (noting that an expert agency like the EPA was “best suited to serve as primary regulator of greenhouse gas emissions”).
- 26 Stephen Breyer, *Judicial Review of Questions of Law and Policy*, 38 ADMIN. L. REV. 363, 366 (1986); see also *Brown & Williamson Tobacco Corp.*, 529 U.S. at 132 (noting that *Chevron* deference is based on agencies’ “greater familiarity with the ever-changing facts and circumstances surrounding the subjects regulated”).
- 27 *Mistretta*, 488 U.S. at 372 (“[O]ur jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives.”); *Panama Ref. Co.*, 293 U.S. at 440 (Cardozo, J., dissenting) (“There must be sensible approximation, there must be elasticity of adjustment, in response to the practical necessities of government, which cannot foresee to-day the developments of tomorrow in their nearly infinite variety.”).
- 28 *Brown & Williamson Tobacco Corp.*, 529 U.S. at 159.
- 29 *King v. Burwell*, 576 U.S. 473.
- 30 *NFIB v. DOL*, 142 S. Ct. 661 (2022).
- 31 *Id.* at 663.
- 32 *Id.* at 667 (Gorsuch, J., concurring) (“We sometimes call this the major questions doctrine.”). The majority characterized the OSHA vaccination-or-test requirement as an exercise of “powers of vast economic and political significance,” a test that the Supreme Court has used to decide major questions cases.
- 33 *Id.* at 665.
- 34 141 S. Ct. 2485 (2021).
- 35 42 U.S.C. § 264(a).
- 36 42 U.S.C. § 7411. In determining the “best system,” Congress directed the EPA to consider various criteria: (1) cost of reducing emissions; (2) nonair quality health and environmental impact; and (3) energy requirements.
- 37 See *Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units*, 80 Fed. Reg. 64661, 64662-964 (Oct. 23, 2015).
- 38 See *Petition for Cert*, at 25-26, *West Virginia v. EPA*, No. 20-1530.
- 39 See *id.*; *Brief for Petitioner the North American Coal Corporation*, at 20, *West Virginia v. EPA*, No. 20-1530.
- 40 See *Brief for the Federal Respondents* at 50, *West Virginia v. EPA*, No. 20-1530; *Brief for the Power Company Respondents* at 19, *West Virginia v. EPA*, No. 20-1530.
- 41 See Katie Keith & Joseph Wardenski, *Supreme Court Hears Two Medicare Disputes*, *O’Neill Institute for National and Global Health Law Blog* (Dec. 9, 2021).
- 42 In a split decision, the D.C. Circuit agreed with HHS and concluded that its interpretation was reasonable and therefore entitled to *Chevron* deference. See *Am. Hosp. Ass’n v. Azar*, 967 F.3d 818 (D.C. Cir. 2020).
- 43 544 F. Supp. 3d 1241.
- 44 *Kentucky v. Biden*, No. 3:21-CV-00055-GFVT; *Brnovich v. Biden*, No. CV-21-01568-PHX-MTL, 2022 WL 252396 (D. Ariz. Jan. 27, 2022).
- 45 *Louisiana v. Becerra*, No. 3:21-CV-04370, 2022 WL 16571 (W.D. La. 2022).
- 46 *Health Freedom Defense Fund, Inc. v. Biden*, No. 8:21-cv-1693 (M.D. Fla. Apr. 18, 2022).
- 47 42 U.S.C. § 300gg-13.
- 48 Assistant Secretary for Planning and Evaluation, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, HP-2022-01 (2022).
- 49 See *Complaint* at 17-18, *Kelley v. Azar*, No. 4:20-cv-00283-O, 2021 U.S. Dist. LEXIS 193489 (N.D. Tex. Feb. 25, 2021).
- 50 140 S. Ct. 2367, 2380 (2020).
- 51 *Id.* Other courts have rejected subsequent nondelegation challenges to the contraceptive mandate. See *Leal v. Becerra*, No. 2:20-CV-185, 2020 WL 7672177, at *16 (N.D. Tex. Dec. 23, 2020) (“It is plain from the text of the statute that Congress has limited the authority it delegated. Congress’s purpose in this section was to mandate coverage of certain health insurance items.”).
- 52 *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*, Exec. Order No. 13990, 86 Fed. Reg. 7037 (Jan. 20, 2021).
- 53 Citing Justice Gorsuch’s dissent in *Gundy*, the court characterizes the major questions doctrine as an enforcement mechanism of the nondelegation doctrine. *Louisiana v. Biden*, No. 2:21-CV-01074, 2022 WL 438313, at *16 (W.D. La. Feb. 11, 2022).
- 54 *Id.*
- 55 *Louisiana v. Biden*, No. 22-30087, 2022 WL 866282 (5th Cir. Mar. 16, 2022).
- 56 See, *e.g.*, Elena Chachko, “[International Factors in Domestic Regulation: What the District Court Got Wrong in Louisiana v. Biden](#),” *Notice & Comment Blog* (Mar. 3, 2022); Jonathan H. Adler, “[Federal Court Bars Federal Agencies from Considering the Costs of Climate Change in Rulemakings](#),” *Volokh Conspiracy* (Feb. 21, 2022) (noting serious errors in the court’s rationale and arguing that the opinion “embodies a bizarre notion of executive power”).
- 57 Lisa Friedman, “[Biden Administration Halts New Drilling in Legal Fight Over Climate Costs](#),” *New York Times* (Feb. 20, 2022) (“In an ironic twist, the fallout from the judge’s ruling — at least initially — is that the federal government has stopped work on new oil and gas leases, as well as permits to drill on federal lands and waters.”).