

# Biden's Vaccine Mandates Between Vertical and Horizontal Separation of Powers

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**Abstract:** *Gli obblighi vaccinali della Presidenza Biden tra separazione verticale ed orizzontale dei poteri* – The U.S. Supreme Court struck down the Biden administration's vaccine-or-test mandate, ruling that the Occupational Safety and Health Administration (OSHA) had exceeded its authority (*NFIB v. OSHA*). Simultaneously, the Court upheld a regulation issued by the Centers for Medicare and Medicaid Services (CMS) mandating vaccines for nearly all employees at hospitals and healthcare providers receiving federal funds (*Biden v. Missouri*). Beyond the ideological polarization among the justices, these cases are particularly significant as they underscore the tension between vertical and horizontal separation of powers in the U.S. constitutional system. A comparison of these two rulings offers valuable insights into the principles of federalism, the separation of powers doctrine, and the issue of democratic legitimacy within the administrative state.

**Keywords:** Vaccine mandate; Federalism; Delegated powers; Major question doctrine

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## 1. Introduction

As is often the case during times of emergency, the rise of the pandemic posed a formidable challenge for governments worldwide, including the Biden administration. Split between two different presidencies, the U.S. response to COVID-19 was notably poor from a public health perspective, largely due to the government's failure to establish a unified national strategy. However, from a constitutional perspective, the pandemic highlighted «a longstanding libertarian tradition distrustful of all government as a matter of principle»<sup>1</sup> which is deeply rooted in the U.S. Constitution. The Framers were skeptical about including an emergency clause, fearing that executives might exploit emergency powers to consolidate authority. As a result, they created a constitutional framework that granted the federal government only a few, clearly defined powers, while leaving most authority to the states.

From a comparative perspective, the U.S. response to the pandemic highlights the country's constitutional exceptionalism. While comparative law scholars have generally examined the pandemic as a stress test for democratic systems, focusing on the clash between emergency powers and

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<sup>1</sup> T. Ginsburg, *Covid-19 and the US Constitution*, in S. De La Garza (ed.), *Covid-19 and Constitutional Law*, México, 2020, 69.

fundamental rights,<sup>2</sup> the U.S. experience has instead underscored the tension between horizontal and vertical separation of powers. This offers a unique perspective on the structure of American constitutionalism, revealing how the distribution of powers between federal and state governments and among the branches of government shapes crisis responses.

Biden's vaccine mandate policies offer a clear example of this approach. After replacing Trump in the midst of the pandemic, the Biden administration enacted several vaccine policies, requiring vaccination or testing as a condition for workplace access. Notably, Biden approved two highly contested policies: the Medicare/Medicaid provider mandate and Occupational Safety and Health Administration (OSHA) large-employer vaccination and testing mandate. The former allowed the Centers for Medicare and Medicaid Services (CMS) to require approximately 10 million employees of hospitals and other healthcare facilities nationwide to be vaccinated against COVID-19. The latter involved the Secretary of Labor, through the Occupational Safety and Health Administration (OSHA), mandating that employers with 100 or more workers require nearly all employees either to get vaccinated against COVID-19 or wear masks on the job and undergo regular COVID testing.

Reactions to the two policies «have been largely polarized along left-right ideological lines»,<sup>3</sup> and both were challenged in state and federal courts, ultimately reaching the U.S. Supreme Court, which delivered opposite rulings. In *Biden v. Missouri*, the Court upheld the Medicare and Medicaid provider mandate,<sup>4</sup> while in *National Federation of Independent Business v. OSHA*, it struck down the Secretary of Labor's large-employer vaccination and testing mandate.<sup>5</sup> The conflicting outcomes concern scholars, because both decisions «authorized protection from threats to health». <sup>6</sup> Since the virus does not differentiate between victims based on their occupation, a federal vaccination requirement may legitimately raise concerns about restricting the privacy of some workers while not applying to others. This uneven application of mandates could lead to questions about fairness and consistency in public health measures, particularly when similar risks are faced by individuals across different sectors.<sup>7</sup>

The real interest of these cases lies in the way they highlight the tension between vertical and horizontal separation of powers that inform the US Constitution. As Justice Gorsuch argued, «the question before us is not how to respond to the pandemic, but who holds the power to do so». <sup>8</sup> This echoed

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<sup>2</sup> See (among others) G. D'ignazio, *L'impatto del Covid-19 sui federalizing process degli Stati composti. Riflessioni comparate* in *DPCE Online*, Special issue: *Diritto e pandemia tra rotture e continuità*, 1, 2023, 498.

<sup>3</sup> I. Somin, *A Major Question of Power: The Vaccine Mandate Cases and the Limits of Executive Authority*, in 84 *Cato Supreme Court Review* 69 (2022).

<sup>4</sup> *Biden v. Missouri*, n. 21A240, 595 U. S. \_\_\_\_ (2022).

<sup>5</sup> *National Federation of Independent Business v. OSHA*, n. 21A244, 595 U. S. \_\_\_\_ (2022).

<sup>6</sup> D.M. Drisen, *The Death of Law and Equity A Comment on Two COVID Cases*, in *Verfassungsblog*, 19 gennaio 2022, //verfassungsblog.de/the-death-of-law-and-equity/.

<sup>7</sup> S. Filippi, *Due pesi e due misure. La Corte Suprema USA si pronuncia sull'obbligo vaccinale rivolto ai dipendenti delle grandi aziende e ai sanitari*, in *Diritti Comparati*, 7 febbraio 2021.

<sup>8</sup> *National Federation of Independent Business v. OSHA*, n. 21A244, 595 U. S. \_\_\_\_ (2022), Gorsuch concurring.

a fundamental question that is rooted in American Constitutionalism: who decides?

In this paper, I will address this question. In the first part, I will examine the state and federal powers to impose vaccine mandates within the framework of American federalism. Second, I will explore the cases in relation to the complex issue of delegated legislation, focusing on the interplay between the nondelegation doctrine, Chevron deference, and the major questions doctrine. Lastly, I will analyze the Supreme Court's decisions in *Biden v. Missouri* and *National Federation of Independent Business v. OSHA* and their impact on American Constitutionalism.

## 2. Vaccine mandate and the American Federalism: state powers (...)

The legitimacy of regulatory provisions mandating vaccinations has been a longstanding issue in the United States. The U.S. Constitution does not grant to the federal government broad authority to regulate public health. According to the principle of enumerated powers, the federal government's powers are «few and defined», while those reserved to the states are «numerous and indefinite».<sup>9</sup> As a result, Congress can exercise its limited powers only in areas explicitly outlined in Article I, Section 8 of the Constitution.

In contrast, State legislatures have the power to regulate public health through their police powers, which allow them to impose «reasonable restraints on the personal freedom and property rights of persons' in order to protect 'the public safety, health, and morals or (...) general prosperity'».<sup>10</sup> Although this authority is not unlimited, it grants state and local governments broad powers which were largely exercised by governors and mayors during the early stages of the pandemic.

For over a century, the states' police power to promote public health and safety has encompassed the authority to mandate vaccinations. In the early 20th century, the Supreme Court specifically addressed constitutional challenges to state vaccination mandates, rejecting those challenges and affirming that such laws clearly fall within the scope of the states' police power. In the 1905 case *Jacobson v. Massachusetts*, the Supreme Court upheld the constitutionality of a state law that granted the municipal board of health the authority to require smallpox vaccination for individuals over the age of 21. Writing for the Court, Justice Harlan stated that «it is within the police power of a State to enact a compulsory vaccination law», as such laws bear «a real [and] substantial relation to the protection of ... public health and safety».<sup>11</sup> Less than two decades later, in *Zucht v. King*, parents of a child who was excluded from school due to her unvaccinated status challenged the local ordinance requiring vaccination for schoolchildren, arguing that the ordinance violated the Fourteenth Amendment's Equal Protection and Due Process Clauses. Relying on *Jacobson*, Justice Brandeis rejected the

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<sup>9</sup> *The Federalist* No. 45.

<sup>10</sup> Black's Law Dictionary (6th edn, West Publishing Co. 1990).

<sup>11</sup> *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) at. 12 and 31.

constitutional challenges, arguing that «[a] state may delegate to a municipality authority to determine under what conditions health regulations shall become operative», and therefore that the ordinance «confers not arbitrary power, but only that broad discretion required for the protection of the public health».<sup>12</sup>

Both *Jacobson* and *Zucht* thus affirmed the legitimate power of state and local governments to exercise broad authority in matters of compulsory vaccination. Although these cases were decided over a century ago during a time when the Court was more deferential to legislators,<sup>13</sup> and while «one can speculate that *Jacobson* might be decided differently today»,<sup>14</sup> no ruling has expressly overturned it. As a result, «the general principles set forth in *Jacobson* remain sound and well-established».<sup>15</sup>

Based on the Supreme Court's recognition of states' authority to make laws with respect to their police power for the protection of public health, states and local governments have enacted, over the years, various vaccination mandates for certain populations and circumstances. All 50 states and the District of Columbia, for instance, currently have laws requiring students and health care workers to receive specified vaccines as a condition of school and hospital entry.<sup>16</sup> Although rules and policies may vary from state to state, vaccination requirements generally allow for certain exemptions, including those for medical reasons, religious objections, and even personal, moral, or other beliefs.<sup>17</sup> These laws, though challenged in some cases, have generally been upheld by federal courts. In rejecting appeals based on alleged violations of the Equal Protection and Due Process Clauses, the courts have recognized «a considerable deference to the states' use of their police power to require immunization to protect public health».<sup>18</sup>

<sup>12</sup> *Zucht v. King*, 260 U.S. 177 (1922).

<sup>13</sup> Decided during the *Lochner* era, *Jacobson* and *Zucht* reflects the substantial deference judges afforded to the legislature, a stance that might overlook the transformations the American legal system underwent during the *New Deal* era and the increasingly active role judges have since played in protecting the rights and freedoms of American citizens. It is well known that, beginning with the Warren Court, the Supreme Court expanded the concept of privacy under the 14th Amendment. The Court ruled that any infringement on this deeply personal right by state laws would only be deemed legitimate if supported by a compelling state interest significant enough to pass the Court's strict scrutiny.

<sup>14</sup> D. Rubinstein Reiss, L.A. Weithorn, *Responding to the Childhood Vaccination Crisis: Legal Frameworks and Tools in the Context of Parental Vaccine Refusal*, in 63 *Buff. L. Rev.* 901 (2015).

<sup>15</sup> *Id.*

<sup>16</sup> See *States with Religious and Philosophical Exemptions from School Immunization Requirements*, last update August 13 2024, at <https://www.ncsl.org/research/health/school-immunization-exemption-state-laws.aspx>.

<sup>17</sup> See B.D. Abramson, *Vaccine Law in the Health Care Workplace*, 12 *J. Health & Life Sci. L.* 22, 24–27 (2019).

<sup>18</sup> W.W. Shen, *State and Federal Authority to Mandate COVID-19 Vaccination*, CRS Report R46745, 18 January 2022, 3 available at <https://crsreports.congress.gov/product/pdf/R/R46745> commenting *Phillips v. City of New York*, 775 F.3d 538, 542–44 (2d Cir. 2015); *Workman v. Mingo Cty. Bd. of Edu.* 419 F. App' 348 (4th Cir. 2011); *Whitlow v. California*, 203 F. Supp. 3d 1079, 1085–89 (S.D. Cal. 2016).

The COVID-19 pandemic has significantly expanded the range and extent of vaccination mandates. Beginning in 2021, the use of police powers enabled governors and local authorities to impose various vaccination requirements on specific categories of workers. In five states, health workers were subjected to «vaccination or termination» policies, while in another twenty-one, they were subjected to «vaccination or regular testing».<sup>19</sup> The vaccination requirement also extends to state employees in nineteen states, while few measures are enacted for private workers.<sup>20</sup> In the field of education, only five states have implemented a statewide COVID-19 vaccine mandate for students,<sup>21</sup> while seventeen governors have imposed strict limitations or strict bans on the introduction of broad vaccination requirements within their jurisdictions. These bans, however, did not prevent several public universities from exercising their autonomy to establish certain vaccination requirements for students and faculty as a condition for returning to in-person classes.<sup>22</sup>

Vaccination policies implemented by American public universities represent one test of the current applicability of the principles established in *Jacobson*. In *Klaassen v. Trustees of Indiana University*, the judges of the Seventh Circuit upheld Indiana University's vaccination policy. They found the case to be «easier than *Jacobson*», as the university's policy, unlike the 1905 law, applies only to students and employees and includes specific exemptions. In *Klaassen*, the Court stated that « [e]ach university may decide what is necessary to keep other students safe in a congregate setting» since vaccinations protect «not only the vaccinated persons but also those who come in contact with them, and at a university close contact is inevitable».<sup>23</sup>

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<sup>19</sup> D. Pekruhn, *Vaccine Mandates by State: Who is, Who isn't, and How?* 22 December 2021, at <https://leadingage.org/workforce-vaccine-mandates-state-who-who-isnt-and-how/>.

<sup>20</sup> In response to the decisions of some private companies to implement workplace policies imposing restrictive measures based on vaccination status, several states have introduced general regulations. Specifically, Texas, Iowa, Utah, North Dakota, Kansas, Arizona, Alabama, Florida, and West Virginia have enacted rules that allow employers to require vaccinations. However, these rules also mandate that such policies provide exemptions for medical reasons or sincerely held religious beliefs. In contrast, Montana and Tennessee explicitly prohibit employers from discriminating against employees based on their vaccination status. In the remaining states, no general rule exists, leaving the decision to private companies. (See NASHP, *State Efforts to Ban or Enforce COVID-19 Vaccine Mandates and Passports*, January 14, 2022, available at <https://www.nashp.org/state-lawmakers-submit-bills-to-ban-employer-vaccine-mandates/>).

<sup>21</sup> These are Louisiana, California, Illinois, New York as well as the territory of D.C.. For an analysis of the various provisions on vaccination requirements in schools, see data collected by NASHP, *States Address School Vaccine Mandates and Mask Mandates*, 14 January 2022, available at <https://www.nashp.org/states-enact-policies-to-support-students-transition-back-to-school>).

<sup>22</sup> See E. Nadworny, *Full FDA Approval Triggers More Universities to Require the COVID-19 Vaccine*, NPR (Sept. 1, 2021), <https://www.npr.org/2021/09/01/1031385629/fullfda-approval-triggers-more-universities-to-requirethe-covid-19-vaccine>.

<sup>23</sup> *Klaassen v. Trustees of Indiana University*, No. 21-2326 (7th Cir. 2021). Similarly, US federal courts have also upheld the policies of state universities or schools in New



### 3. (...) and federal powers

Outlining state powers regarding vaccination is relatively straightforward. More complex is determining whether, and under what authority, vaccination mandates can be implemented at the federal level. Article I, Section 8 of the Constitution does not list public health among the powers granted to Congress. However, during the 20th century, a broad interpretation of federal clauses significantly expanded the scope of federal intervention, even though such actions must still be grounded in specifically enumerated powers. Congress has primarily relied on two specific clauses to justify its intervention in public health: the Interstate Commerce Clause and the Taxing and Spending Power.<sup>24</sup>

The Interstate Commerce Clause grant the Congress the power to «to regulate commerce among foreign nations, and among the several States».<sup>25</sup> Primarily used after Roosevelt's New Deal, the Interstate Commerce Clause enables the federal government to intervene in areas traditionally reserved for state jurisdiction whenever policies «affect interstate commerce in order to bring them within the scope of the commerce power».<sup>26</sup> This interpretation has enabled Congress to regulate a wide range of issues, including air, water, and food quality, drug and pesticide safety, consumer protection, and worker health. It empowers Congress to establish general rules which are then implemented by specialized federal agencies. For instance, the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>27</sup> outlines various provisions for the regulation of food and drug marketing, while the Food and Drug Administration (FDA) is tasked with setting efficacy and safety standards for products, exercising authority delegated explicitly by the Act.

In addition to the Interstate Commerce Clause, the federal government has advanced its health policies through the Tax and Spending Clause, which grants Congress the power to «lay and collect Taxes, Duties, Imposts and Excises (...) and provide for the general Welfare of the United States».<sup>28</sup> Over the years, particularly following the New Deal, this clause has been interpreted broadly, granting Congress a general power that is not

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Jersey, Massachusetts and New York (see *Children's Health Defense, Inc. v. Rutgers, the State University of New Jersey*, 2021 WL4398743 D.N.J. 27 September 2021; *Maniscalco v. New York City Department of Education*, 2021 WL 4344267 E.D.N.Y. Sept. 23, 2021; *Harris v. University of Massachusetts*, 2021 WL 3848012, D. Mass. Aug. 27, 2021). See J.M. Beck, *This is not news: mandatory vaccination has been constitutional for over a century*, ABA Group, 28 October 2021, available at <https://www.americanbar.org/groups/litigation/committees/masstorts/articles/2021/winter2022-not-breaking-news-mandatory-vaccination-hasbeen-constitutional-for-over-a-century/>.

<sup>24</sup> Cfr. J.G. Hodge, *The Role of New Federalism and Public Health Law*, in 12 J.L. & HEALTH 309, 312 (1998): «Federal control over public health matters significantly increased as a result of the Court's broadened interpretations of Congress' Commerce powers and Tax and Spend powers during the New Deal era».

<sup>25</sup> Art. I sez. 8 Cl. 3 US Const.

<sup>26</sup> F.P. Grad, *The Public Health law Manual*, American Public Health Association, Washington, D.C., 2005, 13.

<sup>27</sup> 21 U.S.C. § 301 ss.

<sup>28</sup> Art. 8 Sez. 3 Cl. 1 US Const.

restricted by the subject-matter limitations defined by the enumerated powers.<sup>29</sup> It has been defined as «the Trojan horse»<sup>30</sup> of American cooperative federalism, as it allows the federal government to regulate, through its spending power, areas traditionally under state jurisdiction, such as local public works, welfare, public education, and environmental policy and so on. In these areas, the Tax and Spending Clause allows federal funds to be allocated as an incentive for local authorities to adopt specific public policies through the grant-in-aid mechanism. Typically, federal money «is offered for specific expenditures by the states, which, upon accepting it, plan to administer it».<sup>31</sup> However, grants-in-aid may «legitimately come with Congressional mandates specifying precise methods of use and administration».<sup>32</sup> Through grants in aid, Congress is able to coordinate specific public health programs such as the Medicare and Medicaid, assisting states in financing health care costs for the indigent.<sup>33</sup>

Relying on these two clauses, Congress has shaped federal public health policies over the years. However, establishing a clear federal authority over mandatory vaccination remains challenging.

First, Congress's power under the Interstate Commerce Clause is limited. As affirmed in *NFIB v. Sebelius*, «[t]he power to regulate commerce presupposes the existence of commercial activity to be regulated»<sup>34</sup> and does not extend to creating such activity. Congress cannot derive from the Commerce Clause the authority to impose a duty «to become active in commerce by purchasing a product» because «to permit Congress to regulate individuals precisely because they are doing nothing would open a new and potentially vast domain to congressional authority».<sup>35</sup> Therefore, a federal vaccine mandate could be deemed unconstitutional, as it could be interpreted as «compelling individuals who are “doing nothing” to participate in the commercial activity of receiving a specific healthcare service».<sup>36</sup>

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<sup>29</sup> This interpretation has been upheld by the Supreme Court since *United States v. Butler*, 297 U.S. 1 (1936), where the Court, favoring Hamilton's view over Madison's, affirmed the federal government's power to use public funds to finance or promote any operation or activity that serves the general welfare of the nation.

<sup>30</sup> T.R. McCoy, B. Friedman, *Conditional Federal Spending: Federalism's Trojan Horse*, in 1988 *Sup. Ct. Rev.* 85 (1989).

<sup>31</sup> G. Boggetti, *Lo Spirito del Costituzionalismo americano. La Costituzione democratica*, Torino, 2000, 215.

<sup>32</sup> *Id.*, 216.

<sup>33</sup> See F.P. Grad, *The Public Health Law Manual*, cit., 14: «Grant programmes involve the provision of funds by the federal government to the state or municipal government for a particular purpose defined at the legislative level. The state and local government may obtain the grant funds and spend them for the designated purpose if they agree to the terms of the grant. (...). Through these categorical grant programs, the federal government influences the manner in which public health is administered and the methods of service delivery».

<sup>34</sup> *National Federation of Independent Business v. Sebelius*, 567 U.S. 540 (2012).

<sup>35</sup> *Id.* 551.

<sup>36</sup> W.W. Shen, *State and Federal Authority to Mandate COVID-19 Vaccination*, cit., 31. See also J. Woo, R.J. Delahunty, *Why Biden's vaccine mandate fails the constitutional test*, in *National Review*, 23 September 2021, available at

Second, it may appear simpler to derive federal authority to impose vaccination mandates through the Spending Power, as Congress could indirectly encourage vaccination by tying it to eligibility for federal funding. However, even the Spending Power has its limits. As ruled in *South Dakota v. Dole*, the amount of federal funds offered cannot be «so coercive as to pass the point at which pressure turns into compulsion».<sup>37</sup> Moreover, as stated by the Supreme Court in *New York v. United States* and *Printz v. United States*, the X Amendment prohibits the federal government from «commandeering or conscripting state governments to implement federal policies by directly compelling them to enact and enforce a federal regulatory program».<sup>38</sup> This interpretation of the X Amendment was recently reaffirmed in *Murphy v. NCAA*<sup>39</sup> and could pose a significant obstacle to a federal vaccine mandate. In summary, as noted by the Congressional Research Service, the Spending Clause allows Congress to incentivize states to enforce vaccine policies «as long as the amount offered is not so significant as to effectively coerce, or functionally commandeer, states into enacting the mandate».<sup>40</sup>

#### 4. Vaccine mandate and horizontal separation of powers

The difficulty of defining a general federal competence in public health explains why, before the pandemic, the government's role in vaccination mandates was limited to areas like immigration and the armed forces.<sup>41</sup> However, with the spread of COVID-19, the urgency for consistent health and vaccination policies nationwide has increased. In response, the Biden administration has invoked emergency powers,<sup>42</sup> seeking to ground its authority in existing regulatory provisions that delegate certain functions to the executive branch. Among others, two are the government's most hotly contested mandates: the CMS's Medicare/Medicaid provider mandate<sup>43</sup> and OSHA's large-employer vaccination and testing mandate.<sup>44</sup>

The CMS Medicare/Medicaid provider mandate is statutorily grounded in the Social Security Act (SSA) of 1935, which empowers the Secretary of Health to approve rules «necessary to the efficient administration of the functions with which he is charged»<sup>45</sup> and to establish certain requirements «in the interest of the health and safety of individuals who are furnished services in the institution».<sup>46</sup> In a long-established framework under the Spending Clause, the federal government has progressively outlined the

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<https://www.nationalreview.com/2021/09/why-bidens-vaccine-mandate-fails-the-constitutional-test/>.

<sup>37</sup> *South Dakota v. Dole*, 483 U.S. 203, 211 (1987).

<sup>38</sup> Cfr. A. Nolan, M. Lewis, *Federalism-Based Limitations on Congressional Power: An Overview*, cit., 16.

<sup>39</sup> *Murphy v. National Collegiate Athletic Association*, n. 16-646, 584 U.S. 453 (2018).

<sup>40</sup> W.W. Shen, *State and Federal Authority to Mandate COVID-19 Vaccination*, cit., 31.

<sup>41</sup> For example, under 8 U.S.C. § 1182(a)(1)(A), immigrants seeking permanent entry must provide documentation of vaccination against vaccine-preventable diseases.

<sup>42</sup> *Exec. Order No. 14,042* of Sept. 9, 2021, 86 Fed. Reg. 50,985 (Sept. 14, 2021).

<sup>43</sup> 86 Fed. Reg. 61,555 (Nov. 5, 2021).

<sup>44</sup> 86 Fed. Reg. 61,402 (Nov. 5, 2021).

<sup>45</sup> 42 U.S.C. § 1302(a).

<sup>46</sup> 42 U.S.C. §§ 1395x(e)(9).



standards that hospitals, outpatient clinics, and specialized facilities must meet to receive federal funding. Following this approach, CMS enacted an Interim Final Rule (IFR) mandating that facilities participating in federal programs must require their employees to be vaccinated.<sup>47</sup>

OSHA's vaccination and testing mandate for large employers is grounded in the Occupational Safety and Health Act (OSHAct), enacted by Congress in 1970 to «ensure, as far as practicable, safe and healthy working conditions for all working men and women in the nation».<sup>48</sup> Relying on the Interstate Commerce Clause,<sup>49</sup> the Act grants the Secretary of Labor broad authority to issue regulations related to workplace safety and establishes OSHA to enforce its provisions. Over the years, OSHA has developed a range of measures and standards (such as requiring personal protective equipment and defining permissible exposure limits for hazardous chemicals) that obligate employers to take all necessary steps «to provide workplaces free of recognized serious hazards».<sup>50</sup>

Section 6(c) of the OSHAct also grants federal government the authority to enact Emergency Temporary Standards (ETS) whenever it determines «(A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards» and «(B) that such emergency standard are necessary to protect employees from such danger».<sup>51</sup> Through these emergency procedures, the federal administration introduced six-month emergency rules and standards in the Federal Register. These regulations require that employers with more than 100 employees implement company policies that either confirm their workers have completed the vaccination cycle or, alternatively, mandate weekly testing alongside the use of personal protective equipment, under penalty of removal from the workplace.<sup>52</sup> With limited exceptions,<sup>53</sup> this policy applies to all workers regardless of job role and imposes financial penalties on employers who fail to comply.<sup>54</sup>

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<sup>47</sup> 86 Fed. Reg. 61,555, 61,563, 61,573.

<sup>48</sup> 29 U.S.C. § 651 (2) (b).

<sup>49</sup> See 86 Fed. Reg. 61402, 61505 (5 nov. 2021) «The Occupational Safety and Health Act is an exercise of Congress's Commerce Clause authority, and under Section 18 of the Act, 29 U.S.C. 667, Congress expressly provided that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards».

<sup>50</sup> 29 U.S.C. § 654(a)(1).

<sup>51</sup> 29 U.S.C. § 655(c)(1).

<sup>52</sup> See 86 Fed. Reg. 61402, 61552 (Nov. 5, 2021): «(1) requires all employees to receive a COVID-19 vaccination, subject to legally required exceptions; or (2) requires employees to receive either a COVID-19 vaccination or provide proof of regular COVID-19 testing and wear a face covering when indoors or occupying a vehicle with another person».

<sup>53</sup> The exemptions specified by the Federal Register concern «the employees of covered employers: (1) who do not report to a workplace where other individuals, such as coworkers or customers, are present; or (2) while working from home; or (3) who work exclusively outdoors. Based on this scope, employers in nearly every sector are expected to be covered by this ETS». See 86 Fed. Reg. 61402, 6140 (2021).

<sup>54</sup> Violations are sanctioned from a minimum of \$13,653 to a maximum of \$136,532. See 29 C.F.R. 1903.15(d).

Both emergency measures impose federal health mandates on citizens within individual states. The extension of OSHA's vaccination or regular testing rule, in particular, has the potential to affect over eighty million workers, placing costly monitoring and enforcement responsibilities on employers. More importantly, both measures appear to shift the constitutional debate on health mandates from the vertical dimension of separation of powers to the horizontal one, intensifying the conflict between legislative and executive authority. From this perspective, the issue of vaccination mandates could offer an opportunity for valuable insight into the expansion of the American administrative state and the shift in the horizontal separation of powers that has taken place in the U.S. legal system since the New Deal.

## 5. The rise of Administrative State: nondelegation, Chevron and major questions doctrines

The U.S. Constitution does not establish a clear mechanism for delegating legislative powers because, adhering to the strict separation of powers principle, it states that «All legislative powers herein granted shall be vested in a Congress». However, after the constitutional turn of the New Deal era, the Supreme Court opened the door to delegated legislation, ruling that Congress could grant federal agencies regulatory authority, but only if it defined «an intelligible principle to guide executive action».<sup>55</sup> This principle, known as the *nondelegation doctrine*, has allowed Congress to share its legislative power with federal agencies, but only if Congress clearly defines the limits and boundaries of the agencies' authority and actions.<sup>56</sup>

Over time, the use of delegated legislation has expanded significantly, and the *nondelegation doctrine* has rarely been used by judges to strike down legislation. Congress has frequently granted federal agencies a wide range of powers, requiring that their administrative actions comply with «vague and indeterminate standards such as “the public interest,” “public coexistence,” “reasonableness”, or similar broad formulas».<sup>57</sup> A clear example of this trend is the OSHAct, which contains provisions that were used by the Biden administration to impose vaccination requirements on American workers. Passed in 1970, the OSHAct is one of the most significant laws in the United States and grants the federal government authority to regulate workplace safety. The OSHAct outlines the principles of delegation in broad terms, assigning the Secretary of Labor the responsibility of establishing safety standards and criteria whenever they are

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<sup>55</sup> *J. W. Hampton, Jr. & Co. v. United States*, 276 U.S. 394 (1928).

<sup>56</sup> See *Mistretta v. United States*, 276 U.S. 394, 406, (1989): «In determining what [Congress] may do in seeking assistance from another branch, the extent and character of that assistance must be fixed according to common sense and the inherent necessities of government coordination. (*J. W. Hampton, Jr., & Co. v. United States*) So long as Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power».

<sup>57</sup> G. Boggetti, *Lo spirito del Costituzionalismo americano. La costituzione democratica*, cit., 260.

deemed «reasonably necessary or appropriate»<sup>58</sup> to protect workers' health. In sum, here and in general, the legislature appears to have refrained from clearly defining the boundaries of delegated powers. As a result, «a reader might be tempted to conclude that Congress has said, “make things better,” without giving the Secretary guidance about how, exactly, he is to go about accomplishing that task».<sup>59</sup>

The expansion of delegated legislation has raised two constitutional issues. First, it has blurred the constitutional boundaries between executive and legislative powers, transforming «the traditional model of administrative law» which originally conceived agencies «as a mere transmission belt for implementing legislative directives».<sup>60</sup> The size and scope of the administrative state have expanded significantly over the last century<sup>61</sup> because today «Congress simply cannot do its job absent an ability to delegate power under broad general directives».<sup>62</sup> Nonetheless, the lack of clear intelligible principles in delegated legislation risks «depriving citizens of effective protections against the abusive exercise of administrative power».<sup>63</sup> In the modern administrative state, Congress delegates «vast swathes of policy-making power to the regulatory agencies» and the courts «no longer even attempt to ensure that the key policy choices are made by the legislative branch».<sup>64</sup>

Second, the ambiguity of the criteria contained in legislative delegations raises the issue of their interpretation. Since Congress started delegating legislative power to the executive, agencies started relying on broad interpretations of these criteria to expand their authority. According to the Administrative Procedure Act (APA), federal judges are called to «hold unlawful and set aside agency actions» when those actions are enacted «not in accordance with law» or «in excess of statutory jurisdiction, authority, or limitations».<sup>65</sup> However, especially in the last few decades, «the courts have generally been deferential to Congress and agencies when it comes to

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<sup>58</sup> 29 USC § 652(8).

<sup>59</sup> C.R. Sunstein, *Is Osha Unconstitutional?*, cit., 1409: «The broadest difficulty is that with the “reasonably necessary or appropriate” language, Congress appears, at least at first glance, to have made no decision at all about the substantive standard under which the Secretary of Labor is supposed to proceed».

<sup>60</sup> R.B. Stewart, *The Reformation of American Administrative Law*, in 88 *Harv. L. Rev.* 1675 (1975).

<sup>61</sup> See S. Dudley, *Milestones in the Evolution of the Administrative State*, in 150(3) *Daedalus* 33 (2021): «There is no question that the size and scope of the administrative state have grown over the last century. Today, scores of federal agencies issue thousands of regulations every year. The Code of Federal Regulations contains 242 volumes and more than 185,000 pages. That is four times as big as the U.S. Code of Laws passed by Congress, which contains fewer than 44,000 pages».

<sup>62</sup> *Mistretta v. United States*, 488 U.S. 361, 409 (1989).

<sup>63</sup> R.B. Stewart, *The Reformation of American Administrative Law*, cit., 1675.

<sup>64</sup> M.W. McConnell, *Kavanaugh and the “Chevron Doctrine”*, in *SLS Blog*, 2 agosto 2018, <https://law.stanford.edu/2018/08/02/kavanaugh-and-the-chevron-doctrine/>.

<sup>65</sup> U.S.C. § 706(2)(A), (C): «court[s] shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action».

regulation, leading many to conclude that the nondelegation standard is dead».<sup>66</sup>

The Supreme Court addressed these issues in the landmark case *Chevron, U.S.A., Inc. v. National Resources Defense Council, Inc.*, establishing a two-step review approach useful for analyzing an agency's legal interpretations of its delegated powers. Under this review process, courts have to investigate (1) «if the Congress has directly spoken to the precise question at issue» and, (when the law is ambiguous) (2) «whether the agency's answer is based (or not) on a permissible construction of the statute».<sup>67</sup> This two-step approach relies on the Court's deference to administrative authority, implicitly acknowledging that Congress may have tacitly delegated to agencies the power to «fill any gap left in a particular statute» as «a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency».<sup>68</sup> *Chevron deference* naturally conflicts with the *nondelegation doctrine*. While the latter upholds administrative actions only if they align with Congress' clear and intelligible principles, the former «green-lights agency assertions of power, even when it is fairly obvious from the context that Congress had no such intention, so long as the words of the statute can be reasonably stretched to accommodate them».<sup>69</sup>

Before being recently overturned by *Loper Bright Enterprises v. Raimondo*,<sup>70</sup> the *Chevron doctrine* had operated as a cornerstone of U.S. administrative law for nearly 40 years. It strengthened the power of the executive branch to turn the administrative state into «a mere extension of the President's political agenda»<sup>71</sup> and significantly reshaped the balance of powers «among courts, Congress and administrative agencies in an

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<sup>66</sup> S. Dudley, *Milestones in the Evolution of the Administrative State*, cit., 42.

<sup>67</sup> *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-843 (1984): «When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute».

<sup>68</sup> *Id.*, 843-844: «If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation (...). Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency».

<sup>69</sup> M.W. McConnell, *Kavanaugh and the "Chevron Doctrine"*, cit.

<sup>70</sup> *Loper Bright Enterprises v. Raimondo*, n. 22-451, 603 U.S. \_\_\_\_ (2024).

<sup>71</sup> See E. Kagan, *Presidential Administration*, in 114 *Harv. L. Rev.* 2246 (2001): «we live today in an era of presidential administration», where federal agency operates «as an extension of his own political agenda».

extraordinarily wide range of areas».<sup>72</sup> Potentially, *Chevron* limited the interpretative power of judges, because «even if the Supreme Court would find that the best interpretation of a statute contradicts an agency's interpretation, so long as the agency's interpretation is a "reasonable" one, the agency is free to ignore the judgement of the Court, which would have found the agency's interpretation unlawful».<sup>73</sup>

To minimize these effects, the Supreme Court has sometimes applied stricter oversight to delegated acts under what is known as the *major questions doctrine*, which limits *Chevron deference* by preventing agencies from acting without clear congressional authorization in extraordinary cases that have significant political and economic consequences.

The *major questions doctrine* emerged in *FDA v. Brown & Williamson Tobacco Corp.* (2000), where the Supreme Court was tasked with deciding whether the FDCA<sup>74</sup> granted the FDA the authority to regulate tobacco products. The FDA had claimed this authority through a broad interpretation of the term "drugs", arguing that nicotine in tobacco, due to its addictive nature, could be classified as a drug under the FDCA.<sup>75</sup> Writing for the Court, Justice O'Connor mitigated the effect of *Chevron deference*, arguing that even if in ordinary cases a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps, «in extraordinary cases, there may be reason to hesitate before concluding that Congress has intended such an implicit delegation».<sup>76</sup> Since the tobacco industry constitutes a significant portion of the American economy and Congress had passed six statutes regulating its commerce, this qualifies as an extraordinary case. Therefore, for the Court, it was reasonable to conclude that «Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion»,<sup>77</sup> and that therefore the FDA lacked the jurisdiction to regulate tobacco products.

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<sup>72</sup> See C.R. Sunstein, *Law and Administration after "Chevron"* in 90 *Col. Law Rev.* 8, 1990, 2075 «in an extraordinarily wide range of areas – of areas-including the environment, welfare benefits, labour relations, civil rights, energy, food and drugs, banking and many others – *Chevron* has altered the distribution of national powers among courts, Congress and administrative agencies».

<sup>73</sup> A. Howayeck, *The Major Questions Doctrine: How the Supreme Court's Efforts to Rein in the Effects of Chevron Have Failed to Meet Expectations*, in 25(1) *Roger Williams Univ. Law Rev.* 175 (2020): «A statute that Congress has authorized an agency to administer may have countless "reasonable" interpretations, and these interpretations may vary drastically depending on the presidential administration. Who is to decide which of the many reasonable interpretations is the "correct" one? Under *Chevron*, it is up to the agency. Even if the Supreme Court would find that the best interpretation of a statute contradicts an agency's interpretation, so long as the agency's interpretation is a "reasonable" one, the agency is free to ignore the judgement of the Court, which would have found the agency's interpretation unlawful».

<sup>74</sup> 21 U. S. C. § 301.

<sup>75</sup> *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 126 (2000): «under the FDCA, nicotine is a "drug" (...) and cigarettes and smokeless tobacco are "devices" that deliver nicotine to the body»

<sup>76</sup> *Id.*, 123.

<sup>77</sup> *Id.*, 160.



During the last two decades, the Supreme Court has relied on the *major questions doctrine* in a number of cases, and even if its justices never used that term prior to 2022,<sup>78</sup> its use has recently become more frequent. In *Utility Air Regulatory Group v. EPA* in *King v. Burwell* the Court has used this interpretative methodology to reject agency claims when those claims resulted in «an enormous and transformative expansion in agency regulatory authority without clear congressional authorization»<sup>79</sup> or involved «a question of deep “economic and political significance”».<sup>80</sup> More recently, the Supreme Court explicitly endorsed the *major questions doctrine*, rejecting the expansive view of the EPA’s regulatory authority favored by the Obama and Biden administrations and upheld by the U.S. Court of Appeals for the D.C. Circuit<sup>81</sup>.

The *major questions doctrine* has been described as «a primary manifestation of ... [judicial] skepticism»<sup>82</sup> toward the expansion of the administrative state. It is been understood in both strong and weak forms<sup>83</sup>, as it sometimes operates alongside *Chevron*’s two-step analysis while other times serves as a reason to reject the *Chevron* test altogether. Scholars have characterized it as «a toothless judicial tool»<sup>84</sup> but also as an interpretative test capable of «restricting the application of Chevron deference».<sup>85</sup> Nonetheless, the Court has not clearly explained when an agency’s regulatory action will raise a question so significant that the doctrine applies, nor has it specified what legislative acts could constitute clear congressional authorization.

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<sup>78</sup> *West Virginia v. EPA*, 142 S. Ct. 2587, 2607 (2022).

<sup>79</sup> *Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014).

<sup>80</sup> *King v. Burwell*, 135 S. Ct. 2480 (2015).

<sup>81</sup> *West Virginia v. EPA*, 142 S. Ct. 2587 (2022): «our precedent counsels skepticism toward EPA’s claim that Section 111 empowers it to devise carbon emissions caps based on a generation shifting approach. To overcome that skepticism, the Government must—under the major questions doctrine—point to “clear congressional authorization” to regulate in that manner».

<sup>82</sup> C.R. Sunstein, *There are Two “Major Questions” Doctrine*, in 73 *Admin. L. Rev.* 475 (2021).

<sup>83</sup> *Id.* 2-3: «(...) the major question doctrine has been understood in two radically different way. The first suggests a kind of “carve out” from *Chevron* deference when a major question is involved. (...). The strong version, by contrast, operates as a clear statement principle, in the form of firm barrier to certain agency interpretations (...) The two versions have different justifications. The weak version is rooted in the prevailing theory behind *Chevron*, which is that Congress has implicitly delegated law-interpreting power to the agency. (...).

<sup>84</sup> A. Howayeck, *The Major Questions Doctrine: How the Supreme Court’s Efforts to Rein in the Effects of Chevron Have Failed to Meet Expectations*, cit., 184: «The sparse and inconsistent invocation of the major questions doctrine illustrates that it is a toothless judicial tool when it comes to limiting the scope of Chevron».

<sup>85</sup> See J.J. Monast, *Major Questions about the Major Questions Doctrine*, in 68(3) *Adm. L. Rev.* 445, 452 (2016): «[A] reading of *Burwell* suggests that the Court may intend to expand its authority and, therefore, restrict the power of the Executive Branch, at least in “extraordinary cases”, by limiting the application of Chevron deference».

## 6. Vaccine mandate and the U.S. Supreme Court: *NFIB v. OSHA* and *Biden v. Missouri*

Biden's vaccine mandate policies operate within this complex and intertwined constitutional framework. On one hand, the absence of explicit federal authority prevented, from a vertical separation of powers perspective, the establishment of a unified, nationwide vaccination policy. On the other hand, the use of delegated powers, even if implicitly derived from previously enacted laws, enabled the President, through federal agencies, to impose specific vaccination mandates in certain sectors. This strategy capitalized on the historical expansion of the administrative state, allowing—within the framework of the horizontal separation of powers—emergency regulations that grant OSHA and CMS the authority to enact, respectively, the OSHA's large-employer vaccination and testing mandate and the CMS Medicare/Medicaid provider mandate.

A few days after their publication in the Federal Register, both vaccination mandates were challenged in state and federal courts. In both cases, judges reached different conclusions. The CMS mandate was dismissed in Florida but upheld in Louisiana and Missouri.<sup>86</sup> The OSHA rule was invalidated by the Fifth Circuit, which ruled that it «grossly exceeds OSHA's statutory authority»,<sup>87</sup> while the Sixth Circuit concluded that the OSHAct grants the federal agency the authority «to form and implement the best possible solution to ensure the health and safety of all workers».<sup>88</sup>

The US Supreme Court decided the two cases in January 2022, reaching opposite conclusions. In *National Federation of Independent Business v. Occupational Safety and Health Administration*, a 6-3 ruling invalidated the OSHA's large-employer vaccination and testing mandate. In *Biden v. Missouri*, decided the same day, a 5-4 Court upheld the Centers for Medicare and Medicaid Services (CMS) mandate vaccination policy.

In *NFIB v. OSHA*, the Supreme Court justices presented two interconnected arguments. The first focused on interpreting the regulatory provisions that define the limits of OSHA's authority. The second, in line with the evolution of American administrative law, addressed the relationship between the legislative and executive branches within the framework of the separation of powers principle.

The *per curiam* opinion first examines the Emergency Temporary Standard (ETS) provision of the OSHAct, which allows the agency to impose rules without following the usual notice-and-comment procedures only in cases where «employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards».<sup>89</sup> According to the federal government, the pandemic falls within this category because most unvaccinated workers across the U.S. face

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<sup>86</sup> *Florida v. Department of Health & Human Services*, 2021 WL 5416122; *Missouri v. Biden*, 2021 WL 5564501; *Louisiana v. Becerra*, 2021 WL 5609846.

<sup>87</sup> *BST Holdings, LLC v. Occupational Safety & Health Admin.*, 17 F. 4th 604 (5th Cir. 2021), 612.

<sup>88</sup> *In re: MCP No. 165, Occupational Safety and Health Admin., Interim Final Rule: COVID19 Vaccination and Testing*, 86 Fed. Reg. 61402, No. 21-7000 (6th Cir. 2021) 15.

<sup>89</sup> ETS - OSHA act (86 Fed. Reg. 61403).

a grave danger posed by the COVID-19 hazard. However, the Supreme Court majority rejected this argument, asserting that the COVID-19 vaccination mandate does not fall within this category because «the Act empowers the Secretary to set workplace safety standards, not broad public health measures».<sup>90</sup>

The Court emphasized this argument, stating that, although the pandemic posed a risk that occurs in many workplaces, it is more a «universal» than an «*occupational hazard*» because the virus «does spread at home, in schools, during sporting events, and everywhere else that people gather». Permitting OSHA to regulate such a hazard of daily life «simply because most Americans have jobs and face those same risks while on the clock (...) would significantly expand OSHA’s regulatory authority without clear congressional authorization». Therefore, «OSHA’s indiscriminate approach fails to account for this crucial distinction between occupational risk and risk more generally» and «the mandate takes on the character of a general public health measure, rather than an “*occupational safety or health standard*”».<sup>91</sup>

This argument is closely tied to a broader reflection on the principle of separation of powers. Early in the opinion, the majority reminds us that «administrative agencies are creatures of statute», because they «possess only the authority that Congress has provided».<sup>92</sup> From this perspective, the case presents an opportunity to explore the limits of the *Chevron doctrine* and the conditions for applying the *major questions doctrine*.

While the majority opinion did not directly address these issues, it stated that «when authorizing an agency to exercise powers of vast economic and political significance» judges «expect Congress to speak clearly».<sup>93</sup> The Supreme Court noted that OSHA, «in its half-century of existence, has never before adopted a broad public health regulation of this kind» and that Congress «has disapproved the vaccine mandate regulation with a majority vote». This underscores the Court’s concern about the unprecedented nature of the mandate and serves as «a telling indication» that the mandate extends beyond the agency’s legitimate reach».<sup>94</sup>

Even though the majority opinion did not explicitly mention the *major questions doctrine*, it appears to have applied its criteria indirectly, tightening its review when the exercise of administrative powers involves economically and politically significant issues without explicit congressional authorization. This impression is reinforced by Justice Gorsuch’s concurring opinion, which explicitly states that the Court resolved the case by applying a test «we sometimes call the *major questions doctrine*».<sup>95</sup>

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<sup>90</sup> *NFIB v. OSHA*, 595 U. S. \_\_\_\_ (2022), p. 6

<sup>91</sup> *NFIB v. OSHA*, 595 U. S. \_\_\_\_ (2022), p. 7.

<sup>92</sup> *Id.*, p. 5.

<sup>93</sup> *Id.*, p. 6.

<sup>94</sup> *Id.*, p. 5.

<sup>95</sup> *NFIB v. OSHA*, n. 21A244, 595 U. S. \_\_\_\_ (2022), (Gorsuch J concurring) p. 2: «this Court has established at least one firm rule: «We expect Congress to speak clearly» if it wishes to assign to an executive agency «decision of vast economic and political significance». We sometimes call this the major questions doctrine [and] OSHA’s mandate fails that doctrine’s test».

Justice Gorsuch's opinion frames the case within the principles of horizontal and vertical separation of powers. He first emphasizes that while «state and local authorities possess the general power to regulate public health», the federal government's powers «are not general but limited and divided». Second, Justice Gorsuch asserts that federal power «must also act consistently with the Constitution's separation of powers», meaning that «Congress must "speak clearly" if it wishes to delegate to an executive agency decision of vast economic and political significance». Both these arguments highlight the importance of the *major questions doctrine*, as it «ensures that the national government's power to make the laws that govern us remains where Article I of the Constitution says it belongs—with the people's elected representatives»,<sup>96</sup> and constitutes «a vital check on expansive and aggressive assertions of executive authority».<sup>97</sup> In sum, Justice Gorsuch argued that «the question before us is not how to respond to the pandemic, but who holds the power to do so». The answer is clear: «under the law as it stands today, that power rests with the States and Congress, not OSHA».<sup>98</sup>

In *Biden v. Missouri* the majority reached the opposite conclusion. Medicare and Medicaid programs are administered by the Secretary of Health and Human Services, who has general statutory authority to promulgate rules and regulations, as well as all requirements he finds necessary in the interest of the health and safety of individuals.<sup>99</sup> Relying on these authorities, the Secretary established long lists of detailed conditions with which facilities must comply to be eligible to receive Medicare and Medicaid funds. During the pandemic, the Secretary issued the rule requiring the vaccination of healthcare workers against COVID-19 because, in his view, it was necessary for the health and safety of individuals to whom care and services are administered.

There are many differences between this case and *NFIB v. OSHA*. First, unlike the ETS provision of the OSHA Act, «this authorization is not a special emergency power, nor is it limited to countering grave dangers», since «it covers any regulations that might counter threats to the "health and safety" of patients».<sup>100</sup> Second, the Medicare and Medicaid vaccination rule is grounded on the longstanding interpretation of the Tax and Spending Power Clause. Consequently, in this case, the Government did not need to adopt a broad interpretation of its powers because it operated within the authority granted to it by Congress.

As stated in the majority opinion, the vaccine mandate falls within the authority conferred by Congress. First, «ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession», and it would be bizarre to rule that an administration in charge of establishing efficient and effective

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<sup>96</sup> Id., p. 4.

<sup>97</sup> Id. p. 5.

<sup>98</sup> Id., pp. 6-7.

<sup>99</sup> 42 U. S. C. §1395x(e)(9): «requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution»

<sup>100</sup> I. Somin, *A Major Question of Power: The Vaccine Mandate Cases and the Limits of Executive Authority*, cit., 84.

working conditions is not permitted to establish measures to prevent infection of patients. Second, healthcare facilities that wish to participate in Medicare and Medicaid have always been obligated to satisfy some conditions in order to do so, and «vaccination requirements are a common feature of the provision of healthcare in America».<sup>101</sup> Therefore, «the rule fits neatly within the language of the statute». As concluded by the majority, «the challenges posed by a global pandemic do not allow a federal agency to exercise power that Congress has not conferred upon it. At the same time, such unprecedented circumstances provide no grounds for limiting the exercise of authorities the agency has long been recognized to have».<sup>102</sup>

## 7. Conclusions

The Biden Presidency marked a significant shift in the political strategy for combating the pandemic compared to the Trump administration. The White House enhanced engagement with governors through the Council of Governors and sought to streamline federal actions, particularly in the economic sphere, by enacting the American Rescue Plan and the Bipartisan Infrastructure Law, which complemented the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) previously passed by Congress during the prior administration.

These efforts undoubtedly fostered a more unified approach to managing the pandemic, characterized by more consistent dialogue between the President and the states. However, tensions inherent to the structure of American federalism have persisted to some degree. To address these challenges, the Biden administration invoked emergency powers, anchoring its authority in existing regulatory provisions that delegate specific functions to the executive branch. Notably, the administration's vaccine mandate policies shifted the constitutional debate over health mandates from a vertical focus on the separation of powers to a horizontal conflict, intensifying the tension between legislative and executive authority.

The Supreme Court's January 2022 vaccine mandate rulings resolved legal disputes over these policies. Both appeals addressed the sensitive issue of vaccination mandates, which garnered significant media attention in jurisdictions worldwide affected by the pandemic. However, the justices' arguments in these cases did not primarily focus on the legitimacy of the mandates in terms of potential infringements of individual rights. Instead, the central issue in both cases was the proper exercise of federal powers by the agencies involved, specifically whether the agencies had the authority to impose such mandates under the legal framework governing their powers.

In particular, the rulings could have provided valuable insight into addressing the issue of delegated legislation amid the rise of the administrative state in the U.S. The extended use of *Chevron deference* over recent decades has raised significant concerns among scholars and judges, as it has expanded the power of agencies through broad interpretations of delegated legislation. This expansion has sparked debate over whether

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<sup>101</sup> *Biden v. Missouri*, n. 21A240, 595 U. S. \_\_\_\_ (2022), p. 7.

<sup>102</sup> *Id.*, p. 9.



agencies are exercising too much authority without sufficient congressional oversight, highlighting the need for clearer limits on administrative power.

The *major questions doctrine* can be seen as a useful tool for restoring a more appropriate balance between *Chevron deference* and the *nondelegation doctrine*. This balance was addressed by Justice Kavanaugh when he served as a judge on the D.C. Circuit, stating that «while the Chevron doctrine allows an agency to rely on statutory ambiguity to issue *ordinary* rules, the major rules doctrine prevents an agency from relying on statutory ambiguity to issue *major* rules». <sup>103</sup> Even though it can be difficult to distinguish between major and minor cases, the vaccine mandate rulings demonstrated that, by examining cases from the perspective of vertical division of powers, judges could differentiate between a long-standing relationship between state and federal authority, as seen in *Biden v. Missouri*, and an improper exercise of health care authority by a labor law agency, as in *NFIB v. OSHA*. In other words, as Ilya Somin argues, «the broad large-employer mandate effectively gives presidential administrations a blank check to control nearly every aspect of every workplace in the country» while «the health care worker requirement is much narrower, well within the scope of existing law and does not threaten to set a problematic precedent». <sup>104</sup> From this perspective, the difference between *major* or *minor* cases could be used to minimize the excess of *Chevron deference* without overruling it and (impractically) returning to the *nondelegation doctrine*. <sup>105</sup>

The Supreme Court appeared to follow the path of the *major questions doctrine* in *West Virginia v. EPA*, where it limited the scope of agency authority in cases of major economic and political significance. However, just a year later, the Court took a more decisive step by overruling *Chevron deference* in *Loper Bright Enterprises v. Raimondo*, effectively abandoning the *major questions doctrine* as the primary tool for restraining agency overreach. <sup>106</sup> This marked a new shift in administrative law, moving away from deference to agency interpretations and emphasizing the need for clear congressional authorization in all agency actions.

The effects of *Loper Bright* are currently unclear, <sup>107</sup> as the ruling is likely to shake the very foundations of the Administrative State. By reinstating the

<sup>103</sup> *U.S. Telecom Ass'n v. FCC*, 855 F.3d 381, 418 (D.C. Cir. 2017)

<sup>104</sup> I. Somin, *Supreme Court blocks vaccine mandate for businesses, exposing Biden's overreach*, in NBCnews, 13 gennaio 2019, <https://www.nbcnews.com/think/opinion/supreme-court-covid-vaccine-mandate-hearing-exposes-biden-administration-overreach-ncna1287202>.

<sup>105</sup> As noted by G.F. Ferrari, *Loper Bright: cronaca di una morte annunciata?*, in *DPCE Online*, 65, 3, 2024, 2119: «starting from the early 1980s (...) the nondelegation doctrine was considered unworkable due to its generality, unpredictability, and practical unmanageability». These concerns arose because the doctrine offered little clarity on how to determine when Congress had delegated too much power to administrative agencies, making it difficult to apply consistently and effectively in practice. As a result, courts and scholars largely moved away from strict adherence to the *nondelegation doctrine* in favor of more flexible approaches, like *Chevron deference*, to address the complexities of modern governance.

<sup>106</sup> *Loper Bright Enterprises et al. v. Raimondo*, 603 U.S. \_\_\_\_ (2024).

<sup>107</sup> It is also unclear the ruling is using an originalist methodology. See G. Romeo, *Statutory stare decisis e tenuta del precedente wrongly decided: una lettura di Loper Bright Enterprises v. Raimondo*, in *DPCE Online*, 65, 3, 2024, pp. 2131-2143.

pre-*Chevron* approach to delegated powers, the Court will likely need to reorganize a legal framework which moves away from reliance on ambiguity and deference to agency rules. This shift may require a more defined structure for how agencies exercise their authority, emphasizing clearer congressional mandates and stricter judicial oversight. But what is clear is that «the real winner of *Loper Bright* is the judiciary».<sup>108</sup> By holding that courts «must exercise their independent judgment in deciding whether an agency has acted within its statutory authority»,<sup>109</sup> *Loper Bright* strengthened the role of the judiciary, potentially allowing judges to limit or direct the actions of the other two branches of government beyond the traditional constitutional framework. This shift could grant the judiciary an expanded role in shaping policy, further blurring the lines between judicial interpretation and legislative intent. From a separation of powers perspective, it therefore raises concerns about a fundamental constitutional question rooted in American exceptionalism: “Who decides?”.

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<sup>108</sup> G.F. Ferrari, *Loper Bright: cronaca di una morte annunciata?*, cit., 2129.

<sup>109</sup> *Loper Bright Enterprises et al. v. Raimondo*, 603 U.S. \_\_\_\_ (2024), p. 16.