CHILLINGLY UNCERTAIN: NAVIGATING HEALTH CARE AGENCY DECISION-MAKING POST-*WEST VIRGINIA V. EPA*

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INTRODUCTION

The word *necessary* may be defined as "absolutely needed."[1] The definition of the word standing alone invites no ambiguity. When the word is placed within the context of a sentence, however, the clarity of what is *necessary*, what is absolutely needed, becomes dependent on who is asked. For example, what measures are *necessary* to prevent the introduction, transmission, or spread of communicable diseases?[2] Vaccines? Quarantines? Mask mandates? This question is undoubtedly ambiguous and is thus open to various reasonable answers. And if that is true, then which interpretation should be given priority?

These questions—while considerably simplified—are the exact questions courts around the country have spent decades asking when reviewing a federal agency's interpretation of a Congressional

1. *Necessary*, MERRIAM WEBSTER'S DICTIONARY, https://www.merriam-webster.com/dictionary/necessary#:~:text=%3A%20absolutely%20needed%20%3A%20required (last visited Feb. 29, 2024).

2. *See* 42 U.S.C. § 264(a).

statute. The source of law which guides this inquiry is familiar to anyone that has taken an administrative law class: *Chevron, U.S.A, Inc. v. Natural Resource Defense Council*.[3] Arguably the most significant administrative law case of all time, the *Chevron* holding and colloquial "*Chevron* deference" have long provided agency interpretations of ambiguous statutes with a presumptive level of authority.[4] This authority has enabled agencies like the Center for Disease Control ("CDC") to implement forward-looking, robust policies that best protect the American public in the face of a health crisis.[5] Importantly, agency authority under *Chevron* is not unlimited; there are necessary checks and balances in place to prevent overreach. However, the *Chevron* balancing act can sometimes cross the line into undue judicial and executive-level interference with agency authority.[6]

When a global health crisis strikes, healthcare agencies have routinely relied upon their broad delegation of authority to implement forward-looking, combative policies.[7] While agencies like the CDC are best positioned to handle the United States' response to such a crisis, they are often hindered by executive-level interference.[8] For example, in the infancy of the COVID-19 pandemic, then-President Donald Trump consistently contradicted the messaging of the CDC regarding the effectiveness of masks, the readiness of a vaccine, and the effects of the virus on children.[9] President Trump and his advisors determined that his path to re-election would likely be more successful if the seriousness of the pandemic was downplayed.[10] As a

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3. 467 U.S. 837 (1984).

4. *Id.* at 865–66.

5. Andrew J. Twinamatsiko & Katie Keith, *Unpacking* West Virginia v. EPA *And Its Impact on Health Policy*, O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. (Jul. 13, 2022), https://oneill.law.georgetown.edu/unpacking-west-virginia-v-epa-and-its-impact-on-health-policy/; *see also* Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2486 (2021); 86 Fed. Reg. 43244 (2021).

6. *See* Allison M. Whelan, *Executive Capture of Agency Decisionmaking*, 75 VAND. L. REV. 1787, 1789–91, 1868 (2022).

7. Twinamatsiko & Keith, *supra* note 5; *Ala. Ass'n of Realtors*, 141 S. Ct. at 2486; 86 Fed. Reg. 43244 (2021).

8. Whelan, *supra* note 6, at 1788–89.

9. Mara Liasson & Pien Huang, *President Trump Contradicts Head of CDC Regarding Vaccine, Masks*, NPR (Sept. 17, 2020, 7:19 AM), https://www.npr.org/2020/09/17/913897033/president-trump-contradicts-head-of-cdc-regarding-vaccine-masks.

10. *See* Press Release, House Select Subcomm. on the Coronavirus Crisis, At Hearing, GAO and Experts Detail Trump Administration's Unprecedented Political Interference in Coronavirus Response (Apr. 29, 2022), https://coronavirus.house.gov/news/press-releases/hearing-gao-and-experts-detail-trump-administration-s-unprecedented-political [https://perma.cc/65S3-KVJB] (discussing the Trump Administration's efforts to interfere with the COVID-19 response).

result, the administration effectively muzzled the voice of science by prohibiting the CDC from holding press briefings for the American public and questioning the credibility of career scientists at every turn.[11]

Dr. Deborah Brix, one of Trump's advisors, recognized that many deaths could have been prevented had President Trump not interfered so significantly with the work of scientific agencies.[12] Unfortunately, the damage had already been done. The effects of undermining the knowledge of these agencies on a national stage are stark, and the American people suffered the direct consequences of executive-level interference with scientific and healthcare agency decision-making.[13]

The U.S.'s handling of the COVID-19 pandemic was a categoric failure—largely in part due to this executive-level interference—which has created significant concerns among scientists and the public for the next major health crisis. However, with the Supreme Court's recent decision in *West Virginia v. Environmental Protection Agency*, and the apparent rise of the "Major Questions Doctrine," these agencies will potentially now have to contend with another significant interference: judicial.[14]

The Major Questions Doctrine is a perplexingly complicated area of law. Five years ago, it may have been considered a "minor excrescence on administrative law," but now there can be no doubts: major questions are here to stay.[15] The Supreme Court's invocation of this doctrine in *West Virginia v. EPA* has cemented its presence while providing little to no guidance of how it will be applied in the future.[16] With that in mind, this Note enters the fray to argue the

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11. *Id.*

12. Ryan Chatelain, *Pandemic Officials Say Trump Administration Could Have Prevented Many Deaths*, SPECTRUM NEWS NY1 (Mar. 30, 2021, 8:33 AM), https://ny1.com/nyc/all-boroughs/health/2021/03/29/pandemic-officials-say-trump-administration-marginalized-them--interfered--could-have-prevented-many-deaths.

13. INST. OF MED. OF THE NAT'L ACADS., THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 9, 90 (2007) (explaining the "FDA's credibility is its most crucial asset" and that "[t]he perception of political considerations overruling scientific judgment, even just in a single case, inevitably raises concerns about the legitimacy of decision making in every case").

14. West Virginia v. EPA, 142 S. Ct. 2587, 2610, 2615–16 (2022).

15. Note, *Major Question Objections*, 129 HARV. L. REV. 2191, 2192 (2016).

16. Jonathan H. Adler, West Virginia v. EPA*: Some Answers about Major Questions*, 2021 CATO SUP. CT. REV. 37, 38, 38–39 ("By skimping on statutory analysis and front-loading consideration of whether a case presents a major question, Chief Justice Roberts's opinion failed to provide much guidance for lower courts."). *But see* West Virginia v. EPA, 142 S. Ct. at 2620, 2620–22 (Gorsuch, J., joined by Alito, J., concurring) ("Turning from the doctrine's function to its application, it seems to me that our cases supply a good deal of

dangers of an unguided application of the Major Questions Doctrine in the lower courts—specifically concerning the review of the CDC's statutory authority.

This Note casts a feverish eye towards a not-yet existent, but undoubtedly inevitable future health crisis.[17] The COVID-19 pandemic saw excessive executive-level interference with federal agencies' ability to perform their roles in protecting the American public, largely based on political posturing.[18] As a result, scientists are politicized, standpoints on vaccines are polarizing, and views on masks are divisive. It has arguably become second nature for the American public to second guess the wisdom of scientific policy choices made by those with more expertise than themselves. This new attitude, coupled with the recent application of the Major Questions Doctrine, has created an environment for anti-regulation litigants to feel emboldened and unelected judges to question the authority of agencies more freely in the face of a national health crisis.[19] Consequently, the Major Questions Doctrine needs serious clarification and restraint.

This Note proceeds in three Parts. Part I will briefly review the roots of agency authority—specifically noting the CDC's statutory authority to regulate—and discuss the longstanding application of *Chevron* as the standard for judicial review. Part II will then dissect the evolution of the Major Questions Doctrine and explain how it has interacted with *Chevron* over time. Part II will also analyze the Supreme Court's first explicit invocation of the Major Questions Doctrine in *West Virginia v. EPA* and discuss how this will affect the application of the doctrine going forward. Part III will: (i) outline the lower courts attempts to identify what constitutes a major question in the healthcare context under the Supreme Court's holding in *West Virginia v. EPA*; (ii) analyze how this new application of the Major Questions Doctrine could affect the CDC's statutory authority to regulate under Section 361 of the Public Health Services Act ("PHSA"); and (iii) suggest both legislative and judicial solutions to clarify the doctrine before the next major health crisis strikes.

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guidance about when an agency action involves a major question for which clear congressional authority is required.").

17. Eric S. Lander & Jacob J. Sullivan, *American Pandemic Preparedness: Transforming Our Capabilities*, WHITE HOUSE GOV. (Sept. 2021), https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf?page=29 ("there is a reasonable likelihood that another serious pandemic that may be worse than COVID-19 will soon occur–possibly within the next decade").

18. Chatelain, *supra* note 12.

19. Twinamatsiko & Keith, *supra* note 5.

I. CDC AUTHORITY AND JUDICIAL REVIEW

While the executive branch yields a significant amount of power over federal agencies, it does not control the power granted to such agencies to promulgate rules and policies.[20] Rather, agencies derive their authority to issue regulations, rules, and policies from statutes enacted by Congress.[21] For example, the CDC derives its authority from Section 361 of the PHSA.[22] The section is comprised of five subsections (a) through (e).[23] In part, subsection (a) provides:

> The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are *necessary* to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.[24]

Although this subsection delegates authority to the Surgeon General, the Health Education and Welfare Secretary—following departmental reorganizations ratified by Congress—delegated Section 361 authority to the CDC.[25] Since then, the CDC has primarily invoked its authority under Section 361 via subsections (b) through (d) to support regulations and rules concerning isolation and quarantine.[26] Subsections (b) through (d) provide specific delegations of authority that enable the CDC to apprehend individuals for the purpose of preventing the transmission, introduction, or spread of communicable diseases.[27] This authority applies to both the regulation of individuals residing in the United States and those entering from foreign countries.[28] Subsection (a), however, provides a much broader delegation of authority to issue and enforce regulations that the agency believes *necessary* to prevent the

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20. TODD GARVEY & DANIEL J. SHEFFNER, CONG. RSCH. SERV., R45442, CONGRESS'S AUTHORITY TO INFLUENCE AND CONTROL EXECUTIVE BRANCH AGENCIES 1–15 (2021).

21. *Id.* at 2, 9–10.

22. WEN W. SHEN, CONG. RSCH. SERV., R46758, SCOPE OF CDC AUTHORITY UNDER SECTION 361 OF THE PUBLIC HEALTH SERVICE ACT (PHSA) 3 (2021). The headings and subheadings of Section 361 in the PHSA differ slightly from the versions codified in Title 42 of the U.S. Code. This Note will refer to the headings as stated in the PHSA but will cite to the U.S. Code.

23. 42 U.S.C. § 264(a)–(e).

24. *Id.* §264(a) (emphasis added).

25. *See* C. STEPHEN REDHEAD ET AL., CONG. RSCH. SERV, R44916, PUBLIC HEALTH SERVICE AGENCIES: OVERVIEW AND FUNDING (FY2016-FY2018) 1 (2017); SHEN, *supra* note 22 at 3, 12.

26. SHEN, *supra* note 22, at 5.

27. 42 U.S.C. § 264(b)–(d).

28. *Id.*

introduction or spread of communicable diseases from foreign countries into the United States.[29]

In general, an agency has only the authority delegated to it by Congress—meaning Congress has significant power to control a federal agency by specifying its jurisdiction and authority.[30] Yet, when Congress constructs a statute that delegates authority to an agency to regulate an area of law as they deem *necessary*, questions inevitably arise to the extent of such authority. Hence why the CDC's ability to invoke such power under Section 361 is ultimately a question of statutory interpretation.[31] Notably, issues of statutory interpretation have primarily been governed by the Supreme Court's holding in *Chevron, U.S.A, Inc. v. Natural Resource Defense Council* for the last three decades.[32]

A. Chevron: *A Brief Overview*

When the Supreme Court published its opinion in *Chevron*, the Justices were likely unaware they had decided what would later be described as the "the most important administrative law decision in the history of the United States."[33] Whether that statement is true or not, the *Chevron* holding has undoubtedly proved divisive among scholars, with some referring to it as an "accidental landmark," and others as a "complete and total failure," or "Frankenstein's monster of administrative law: a hideous 'behemoth.'"[34] Perhaps the most infamous colloquial phrase to come out of the case is the one that best represents the holding: *Chevron Deference*.[35] This phrase is derived from the deferential standard employed by courts reviewing an agency's interpretation of an ambiguous statute.

The holding in *Chevron* outlined a two-part test for courts to employ when reviewing an agency's interpretation of a statute.[36] At Step One, a court must determine whether Congress has spoken to the precise question at issue—in other words, is the statute ambiguous?[37] If the statute clearly speaks to how Congress intended

29. 42 U.S.C. § 264(a) (emphasis added).

30. SHEN, *supra* note 22, at 15.

31. *Id.* at 15–16.

32. 467 U.S. 837 (1984).

33. Lawrence B. Solum, Essay, *Disaggregating* Chevron, 82 OHIO ST. L.J. 249, 251 (2021).

34. *See* Thomas W. Merrill, *The Story of* Chevron*: The Making of an Accidental Landmark*, 66 ADMIN. L. REV. 253, 253 (2014); Jack M. Beermann, *End the Failed* Chevron *Experiment Now: How* Chevron *Has Failed and Why It Can and Should Be Overruled*, 42 CONN. L. REV. 779, 782 (2010); Kristin E. Hickman & R. David Hahn, *Categorizing* Chevron, 81 OHIO ST. L.J. 611, 614 (2020).

35. *Social Security Act – Administrative Law* Chevron *Deference* – American Hospital Ass'n v. Becerra, 136 HARV. L. REV. 480, 480 (2022).

36. *Chevron*, 467 U.S. at 842–43.

37. *Id.*

the agency to resolve the question at issue, the court and the agency must abide by that unambiguous intent and the *Chevron* analysis is complete.[38]

If, however, the court determines that Congress did not speak directly to the question at issue, Step Two is applied.[39] Step Two requires a court to defer to an agency's interpretation of an ambiguous statute if its interpretation is *reasonable*.[40] The reasonableness of an agency's interpretation will depend on the court's satisfaction with the agency's reasoning and whether the interpretation aligns with the general purpose of the statute.[41] Generally, agency interpretations will be accorded deference at Step Two because an ambiguous statute naturally permits a range of plausible interpretations.[42]

The policy underlying the holding of *Chevron* rests upon the notion that ambiguity in congressional statutes inherently invites agencies to apply their apparent expertise in the subject matter to "fill any gap[s]."[43] "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."[44] Delegation is the necessary condition for deference; Step One must come before Step Two. The Court agrees on that much. The long-standing issue among the Justices, however, is determining when Congress has delegated such authority to an agency.[45]

Section 361(a) of the PHSA, for example, provides the CDC with the authority to create and enforce regulations that are "*necessary* to prevent the introduction, transmission, or spread of communicable diseases."[46] This statute provides rulemaking and adjudicative authority without specifically defining the extent of such authority. The term "necessary" within this context is not self-defining; the answer to what may be necessary to prevent the introduction or spread of diseases will change depending on who is asked. As such, it would appear Congress has purposely delegated the authority to make such decisions to the executive branch—whose comparative expertise best positions it to do so.

However, courts need not solely rely on the plain meaning of the statute when undertaking a *Chevron* analysis. Some courts may choose to analyze the legislative history, including the drafters'

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38. *Id.*
39. *Id.* at 843.
40. *Id.* at 844.
41. *Id.*
42. BENJAMIN M. BARCZEWSKI, CONG. RSCH. SERV., R44954, CHEVRON DEFERENCE: A PRIMER 12 (2023).
43. *Chevron*, 467 U.S. at 843–44.
44. *Id.*
45. Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 516–17; *see also* Note, *supra* note 15, at 2193.
46. 42 U.S.C. § 264(a) (emphasis added).

comments of Section 361, which depending on their interpretation, could yield two possible answers concerning the ambiguity of the term "necessary."[47] Regardless of the interpretation a court lands upon, the *Chevron* doctrine provides agencies with the opportunity to argue the ambiguity of a statute more freely than the Major Questions Doctrine does. And in the face of a national health crisis, that wide breadth is necessary to ensure agencies like the CDC can operate without substantial interference. However, with the Supreme Court's revival of the Major Questions Doctrine, it is unclear whether a *Chevron* analysis will apply to the CDC's invocation of authority under Section 361(a) for much longer.

II. THE MAJOR QUESTIONS DOCTRINE

Attempting to understand how the Major Questions Doctrine interacts with *Chevron* is a decidedly complex undertaking. Many legal scholars devote entire articles to that exact question. That undertaking is necessary here—admittedly with brevity—to better understand how legal challenges to the CDC's exercise of authority under Section 361(a) will proceed in the future.

The following section of this Note will proceed in two Subparts. Subpart (a) will provide a brief overview of the Major Questions Doctrine from its generally accepted conception in *FDA v. Brown & Williamson Tobacco Corp*,[48] tracing its evolution to present day. Subpart (b) will then outline the Supreme Court's decision in *West Virginia v. EPA*[49]—which cemented the use of the Major Questions Doctrine in challenging the policies of federal agencies—specifically highlighting the lack of clarity provided by the majority's holding as to what exactly constitutes a "Major Question."

A. An Evolution: Tracing The Major Questions Doctrine

The Major Questions Doctrine first rose its amorphous head in *FDA v. Brown & Williamson Tobacco Corp*, which involved the Food and Drug Administration's ("FDA") *unauthorized* regulation of the tobacco industry.[50] Under the Food, Drug, and Cosmetic Act ("FDCA"), the FDA was granted authority to regulate "drugs" and "devices."[51] The FDA interpreted this statutory language to include nicotine—as a "drug"—and cigarettes and other forms of smokeless

47. SHEN, *supra* note 22, at 30–31 (explaining the drafters' comments accompanying Section 361 could be interpreted to support a broad reading that authorize the use of Section 361(a) to issue regulations that implement *any* evidence–based on public health measures to prevent transmission of diseases, or more narrowly limiting regulatory authority to "quarantine and inspection").

48. 529 U.S. 120 (2000).

49. 142 S. Ct. 2587 (2022).

50. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 125.

51. *Id.* at 126; 21 U.S.C. §§ 321(g)–(h).

tobacco—as "devices."[52] Although this interpretation appears reasonable, the Court found the FDA's interpretation to be impermissible, in part due to inconsistencies with other aspects of the statute.[53] Because the case involved an agency's construction of a statute it administers, the Court acknowledged that *Chevron* governed its analysis.[54] Under *Chevron*, the majority concluded that when reading the FDCA in its entirety, as well as looking to Congress's specific tobacco legislation, Congress had "directly spoken to the question at issue and precluded the FDA from regulating tobacco products."[55]

This holding appears to be entirely at odds with the basic premise of *Chevron*. As dissenting Justice Breyer noted, courts will usually "reverse an agency interpretation of this kind . . . if Congress has clearly answered the interpretive question or if the agency's interpretation is unreasonable."[56] Here, Congress did not specify the parameters of what constitutes a "drug" or "device," and considering the FDA's rationale, it does not defy reason to conclude nicotine and cigarettes fall within this gambit.

Escaping this reality, the majority further supported their position by citing the "economic and political magnitude" of a regulation concerning the tobacco industry, explaining that in "extraordinary cases . . . there may be reason to hesitate before concluding that Congress has intended such an implicit delegation."[57] According to the majority, this was such a case. Given the "economic and political magnitude" of the issue, the Court opined that Congress could surely not have intended to leave such an important issue to a federal agency—regardless of the ambiguity in the statutory language.[58]

In the final pages of the majority opinion, Justice O'Connor noted that the inquiry into Step One of *Chevron* "is shaped, at least in some measure, by the nature of the question presented."[59] This suggests that the Major Questions Doctrine would not act as a separate entity or exception to a *Chevron* analysis, rather it would be a consideration that shapes the answer to Step One. Thus, when asking whether Congress has spoken directly to the question at issue, a court must

52. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 125–26.

53. *Id.* at 126, 130 (explaining the FDA was required by the Act "to determine that any regulated product is 'safe' before it can be sold or allowed to remain on the market, yet the FDA found in its rulemaking proceeding that tobacco products are 'dangerous' and 'unsafe'"); *see also* Note, *supra* note 15, at 2197.

54. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 125–26.

55. *Id.* at 160–61.

56. *Id.* at 170–71 (Breyer, J., dissenting) (citing Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984)).

57. *Id.* at 133, 159.

58. *Id.* at 133, 159–60.

59. *Id.* at 159.

not find ambiguity as a dispositive answer to Congress's intent to delegate; instead, a court must look past ambiguity to consider whether Congress could have truly intended to delegate an issue of such importance. As the Major Questions Doctrine evolved, however, the Supreme Court did not hold themselves to this guidance.

In *Utility Air Regulatory Group v. EPA*,[60] the Supreme Court invoked the issue of "major questions" to supplement its decision that the Environmental Protection Agency's ("EPA") interpretation of the Clean Air Act ("CAA") was unreasonable at Step Two of the *Chevron* analysis.[61] Based on the holding in *Massachusetts v. EPA*,[62] the EPA determined that under the CAA it was required to regulate greenhouse gas emissions from stationary sources in addition to moving sources—meaning automobiles.[63] Applying *Chevron*, the Court acknowledged that the EPA was not without some basis of authority to regulate greenhouse gas emission under the CAA.[64] The issue, however, arose based on the EPA's interpretation of the term "air pollutant" under the CAA.[65]

The majority opinion stated that the "EPA's interpretation [wa]s . . . unreasonable because it would bring about an enormous and transformative expansion in EPA's regulatory authority without clear congressional authorization."[66] If it wasn't clear enough that the Court was invoking the Major Questions Doctrine, it went on to cite *Brown & Williamson* and insisted that "the power to require permits for the construction and modification of tens of thousands, and the operation of millions, of small sources nationwide falls comfortably within the class of authorizations that we have been reluctant to read into ambiguous statutory text."[67]

This holding, viewed alongside *Brown & Williamson*, highlights the Court's plasticity in applying the Major Questions Doctrine at either stage of the *Chevron* analysis. Here, the EPA had the authority to regulate greenhouse gases; however, it still could not clear the major question hurdle, suggesting the timing of the Court's application of the Major Questions Doctrine appears to have little effect on the outcome of the case.[68] If the Court invokes the Major Questions Doctrine—no matter where it is embedded within a *Chevron* analysis—the likely conclusion will be that the agency exceeded its statutory authority.[69] This seems to be a great departure

60. 573 U.S. 302 (2014).
61. *Id.* at 308, 324–28.
62. 549 U.S. 497 (2007).
63. *Util. Air Regul. Grp.*, 573 U.S. at 308, 310.
64. *Id.* at 308, 310, 319.
65. *Id.* at 319–20, 320 n.6.
66. *Id.* at 324.
67. *Id.*
68. *Id.* at 310, 332–34.
69. SHEN, *supra* note 22, at 18.

from Justice O'Connor's suggestion that Step One of a *Chevron* analysis will be shaped by an inquiry into the nature of the question presented.

In *King v. Burnell*,[70] the Supreme Court further emboldened its departure from Justice O'Connor's roadmap for the *Chevron* analysis.[71] In *King*, the Court held that Section 1311 of the Affordable Care Act was ambiguous because the phrase "an Exchange established by the State" could be interpreted either broadly or narrowly.[72] The Court explained that on one hand it could be limited to State Exchanges or, alternatively, the phrase could refer to both State and Federal Exchanges for tax credit purposes.[73] Consequently, the case appeared to turn on a singular question under the traditional *Chevron* analysis: was the IRS's interpretation of Section 1311 reasonable?

The Court, noting that this was an "extraordinary case" involving "a question of deep economic and political significance," avoided the application of *Chevron* entirely.[74] Nevertheless, the Court still upheld the IRS regulation, explaining that the intent of Congress when passing the Affordable Care Act aligned with the IRS regulation.[75] The significance of this holding is two-fold: (1) it shows that agency action can survive the historically dooming application of the Major Questions Doctrine; and (2) it suggests that the Major Questions Doctrine will act as more of a threshold matter to a *Chevron* analysis, rather than existing within *Chevron*.

In 2005—ten years before the holding of *King*—Cass Sunstein wrote an article titled "Chevron Step Zero," warning of the dangers of creating a major question precursor to a *Chevron* analysis.[76] While Sunstein did not suggest that *Brown & Williamson*—or any other major question case at the time—should be read to establish an independent Step Zero constraint on the application of *Chevron*, she appeared concerned by the progression of the Supreme Court towards a point where the *Chevron* analysis could be entirely precluded by the Major Questions Doctrine.[77] In the wake of *King*, it would be difficult

70. 576 U.S. 473 (2015).

71. SHEN, *supra* note 22, at 18 (citing *King*, 576 U.S. at 485) ("In *King v. Burwell*, the Court invoked the doctrine to deem the *Chevron* framework entirely inapplicable, providing the basis for the Court to conduct the interpretive task anew.").

72. *See King*, 576 U.S. at 490.

73. *Id.*

74. *Id.* at 485–86.

75. *Id*. at 498 ("Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter. Section 36B can fairly be read consistent with what we see as Congress's plan, and that is the reading we adopt.").

76. Cass R. Sunstein, Chevron *Step Zero*, 92 VA. L. REV. 187, 236–42 (2006).

77. *Id.*

to ignore the glaring presence of a "Step Zero" analysis the Court had created.

The evolution of the Major Questions Doctrine is not limited to the three cases discussed in this Part—of course, the entire evolution would demand more than a mere five pages. But these cases sufficiently highlight the fluidity and unpredictability with which the doctrine has traditionally been applied, ultimately leading to the pinnacle major question case: *West Virginia v. EPA*.

B. West Virginia v. EPA*: "The Arrival of the Major Questions Doctrine"*

The Supreme Court's most recent and arguably most significant major question decision came in the past term in *West Virginia v. EPA*.[78] In contrast to the progeny of cases that came before it, *West Virginia v. EPA* characterizes the Major Questions Doctrine as a "clear statement rule," rather than a consideration within the *Chevron* framework or a precursor hurdle to a *Chevron* analysis.[79]

In 2015, the EPA promulgated the Clean Power Plan ("CPP"), "which addressed carbon dioxide emissions from existing coal and natural gas fired power plants."[80] The agency claimed its authority to promulgate such a rule could be found in Section 111 of the CAA, which authorized regulation of certain pollutants from *existing* sources.[81] Republican attorneys general and other members of the energy industry challenged the EPA's CPP, arguing it violated the Major Questions Doctrine because Congress had not explicitly authorized the agency to promulgate such a plan.[82]

At the time of oral arguments, the Supreme Court had not deferred to an agency's interpretation under *Chevron* in over six years, and in the 2021–22 term, the Supreme Court had "signaled a heightened interest in applying the [Major Questions Doctrine] to the review of agency actions."[83] Consequently, in the lead up to the Court's decision, many commentators believed a majority of Justices

78. 142 S. Ct. 2587 (2022).

79. Brandon J. Johnson, *The Accountability-Accessibility Disconnect*, 58 WAKE FOREST L. REV. 65, 84 (2022) (quoting West Virginia v. EPA, 142 S. Ct. at 2616 (Gorsuch, J., concurring)).

80. West Virginia v. EPA, 142 S. Ct. at 2602.

81. *Id.* at 2600–02.

82. *Id.* at 2587 (Petitioners Westmoreland Mining Holdings LLC and the North America Coal Corporation); *id.* at 2596 (listing the attorneys general that filed suit on behalf of their state); *id.* at 2593–94, 2609.

83. SHEN, *supra* note 22, at 2; Isaiah McKinney, *The* Chevron *Ball Ended at Midnight, but the Circuits Are Still Two–Stepping by Themselves*, YALE J. ON REGUL. (Dec. 18, 2022), https://www.yalejreg.com/nc/chevron-ended/.

would side with the challengers and finally clarify the parameters of the complex doctrine.[84] The Court somewhat did this.

Chief Justice John Roberts, writing for the majority, agreed with the petitioners stating, "this is a *major questions case*."[85] This acknowledgment alone carries great significance because, up until this point, the Supreme Court had not explicitly referred to the doctrine by name in a majority opinion. As noted by the dissent, this explicit reference somewhat "announces the arrival of the major questions doctrine."[86] The majority opinion went on to note that "[p]recedent teaches that there are 'extraordinary cases' . . . in which the 'history and the breadth of the authority that [the agency] has asserted,' and the 'economic and political significance' of that assertion, provide a 'reason to hesitate before concluding that Congress' meant to confer such authority."[87]

The majority goes further than merely invoking "precedent." Rather, the majority invoked the doctrine by name—a name which had never been explicitly used by the Court—and outlined a new, two-factor Major Questions Doctrine framework.[88] First, a court must decide, by weighing a variety of factors, whether agency action presents an "extraordinary case."[89] These (non-exhaustive) factors could include whether the agency has adopted a program that "Congress has conspicuously and repeatedly declined to enact itself" or "whether the agency's claimed authority derives from an 'ancillary,'

84. LINDA TSANG & KATE R. BOWERS, CONG. RSCH. SERV., LSB10666, CONGRESS'S DELEGATION OF "MAJOR QUESTIONS": THE SUPREME COURT'S REVIEW OF EPA'S AUTHORITY TO REGULATE GREENHOUSE GAS EMISSIONS MAY HAVE BROAD IMPACTS 4 (2021); Matt Ford, *The Supreme Court Decided to Leave the Administrative State Alone—for Now*, THE NEW REPUBLIC (June 20, 2022), https://newrepublic.com/article/166847/supreme-court-decided-leave-administrative-state-alonefor-now ("In the next fortnight or so, the [C]ourt will also hand down its decision in *West Virginia v. Environmental Protection Agency*. That case is yet another instance where the conservative justices could write or rewrite an existing precedent—in this case, the so-called 'major questions doctrine'—to make it harder for federal agencies to carry out their missions or for Congress to legislate in broad terms."); Ian Millhiser, *A New Supreme Court Case Could Gut the Government's Power to Fight Climate Change*, VOX (Nov. 3, 2021, 10:30 AM), https://www.vox.com/2021/11/3/22758188/climate-change-epa-clean-power-plan-supreme-court ("Indeed, a majority of the Court has already expressed sympathy toward Gorsuch's plans to shrink the power of federal agencies, which is a strong sign that the West Virginia petitioners are likely to prevail on at least some of their claims.").

85. West Virginia v. EPA, 142 S. Ct. at 2610 (emphasis added).

86. *Id.* at 2633–34.

87. *Id.* at 2608 (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 159–60 (2000)).

88. *Id.* at 2634 (Kagan, J., dissenting).

89. *Compare id.* at 2609 (majority opinion), *with id.* at 2634 (Kagan, J., dissenting).

'gap filler,' or otherwise 'rarely used' provision of the statute."[90] Second, if it does present an "extraordinary case," the agency "must point to clear congressional authorization for the power it claims."[91] The Court provided little guidance to how clear this authorization must be for an agency to meet the standard; Justice Kagan noted, however, that the majority appears to be asking for something above the normal statutory basis that has previously been required.[92]

This two-factor test hardly seems to be "following precedent." Admittedly, in the major question cases that have come before it, the Court has conducted an inquiry into the level of delegation Congress could have intended to provide, but that inquiry has not been conducted with "multiple steps, triggers, or special presumptions."[93] This structure is new and putting a name and two-step test to a once ambiguous, almost mystical doctrine, will inevitably empower lower-level courts to apply the doctrine with greater confidence. As such, agencies face the danger of being subject to major question challenges with much more consistency and subjectivity. The noose on agency deference is officially tightening.

Arguably the most concerning aspect of *West Virginia v. EPA* is the lack of clarity the Supreme Court has given as to what will constitute a major question. Despite the two-step analysis outlined by the Court, an "I will know it when I see it" approach appears to be looming. The effects of this new precedent are yet to be seen in their entirety; however, the major battleground for what is a "major question" will likely be fought in the lower courts.[94] And if further clarification of the parameters of the Major Questions Doctrine are not provided soon by Congress or the Supreme Court, this battleground will remain clouded in smoke indefinitely, leaving healthcare agencies wounded and anti-regulators victorious.

III. THE BATTLEGROUND: HOW DO HEALTHCARE AGENCIES FAIR?

The holding in *West Virginia v. EPA* will extend well beyond the environmental realm. Going forward, any agency that seeks to regulate on issues that could be considered to present an "extraordinary case" will likely be subject to a major question challenge. This Part of the Note seeks to predict how the major question battlefield will play out and analyzes how the authority of healthcare agencies will be impacted. As such, Subpart (a) will

90. *'Major Questions'? Supreme Court Decision in Climate Change Case Sends Ripples Across the Regulatory Landscape*, AKIN GUMP 2 (Jul. 6, 2022), https://www.akingump.com/a/web/2gi1BEr3hN4EMFVD3CXA8L/46C8jy/major-questions-of-supreme-court-decision.pdf.

91. West Virginia v. EPA, 142 S. Ct. at 2634 (Kagan, J., dissenting) (quoting West Virginia v. EPA, 142 S. Ct. at 2609).

92. *Id.*

93. *Id.*

94. *See infra* pp. 115–18.

discuss how lower courts are interpreting the holding in *West Virginia v. EPA* with a targeted emphasis on healthcare cases. Subpart (b) will then narrow in scope to focus on the CDC's authority under Section 361(a) of the PHSA and analyze how that authority could be affected going forward. Subpart (c) will proffer practical solutions at the judicial and legislative level to rectify the dangers of judicial interference before the next major health crisis.

A. A Murky Battleground: The Lower Courts

While *Chevron* may not technically be dead, lower courts will likely now approach "big" agency regulations—those which are not explicitly authorized in statutes—with a greater deal of skepticism than they once previously applied.[95] Given the infancy of *West Virginia v. EPA*, there have only been a handful of lower courts that have invoked this somewhat repolished Major Questions Doctrine—a cautious beginning. Nevertheless, this Subpart will outline the holdings of two of those cases—*Georgia v. President of the U.S.*[96] and *Louisiana v. Becerra*[97]—to better understand how the majority's guidance in *West Virginia v. EPA* is being applied.

The case of *Georgia v. President of the U.S.* involved the judicial review of an executive order relating to COVID-19 protections.[98] President Biden signed Executive Order 14042 which required "COVID-19 vaccination of covered contractor employees, except in limited circumstances where an employee is legally entitled to an accommodation."[99] The executive branch contended that the Procurement Act authorizes the president to issue these contractor vaccine mandates.[100] Similar to Section 361(a) of the PHSA, the grant of power to the president in the Procurement Act is broadly worded, stating that the "[p]resident may prescribe policies and directives that the [p]resident *considers necessary.*"[101] While this action

95. *See* Jaclyn Lopez, *The Major Questions Doctrine Post*-West Virginia v. EPA, A.B.A. (Jan. 3, 2023), https://www.americanbar.org/groups/environment_energy_resources/publications/trends/2022-2023/january-february-2023/the-major-questions-doctrine/.

96. 46 F.4th 1283 (11th Cir. 2022).

97. 629 F. Supp 3d. 477 (W.D. La. 2022).

98. 46 F.4th at 1289.

99. *Id.* at 1291 (quoting Safer Federal Workforce Task Force, COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors 1, 6–7 (Sept. 24, 2021)).

100. *Id.* at 1291, 1292 ("We first consider the plaintiffs' likelihood of success on the merits. The central question is whether the Procurement Act authorizes the [p]resident to require the employees of federal contractors to be vaccinated as a condition of all procurement contracts and solicitations.").

101. 40 U.S.C. § 121(a) (emphasis added).

involved an issue of presidential authority, the court still relied on the Major Questions Doctrine under *West Virginia v. EPA*.[102]

The court ultimately found that the executive order exceeded the president's authority.[103] "As the Supreme Court has emphasized, requiring widespread Covid-19 vaccination is 'no everyday exercise of federal power.'"[104] And using the well-established principle of statutory interpretation, the court expected Congress to "speak clearly when authorizing an agency to exercise powers of vast economic and political significance."[105] In this case, according to the majority, the term "necessary" does not indicate "clear congressional authorization" delegated to the president to include a COVID-19 vaccination requirement in every contract and solicitation.[106]

The dissent acknowledged that while this was an issue of "major economic and political significance," the statute provided evidence of clear congressional authorization for the president's actions.[107] The dissent focused on the broad language of the statute—specifically the term "necessary"—as an indication of Congress's intent to provide broad discretion to the president to achieve "broad goals."[108] The dissent argued that the Major Questions Doctrine has not been used to find unlawful delegations of power that are granted broadly through a statute, rather it has been used to invalidate actions that do not fit within the statutory scheme.[109] Whereas, the majority reasoned that the broadness of the statute prevented Congress from intending to delegate such specific authoritative power to the president.[110]

In the healthcare sphere, this presents a monumental issue. Because as Justice Kagan noted in her dissenting opinion in *West Virginia v. EPA*,

> A key reason Congress makes broad delegations like Section 111 is so an agency can respond, appropriately and commensurately, to new and big problems. Congress knows what it [does not] and [cannot] know when it drafts a statute; and Congress therefore gives an expert agency the power to

102. *Georgia v. President of the U.S.*, 46 F.4th at 1313 (Anderson, J., concurring in part and dissenting in part).

103. *Id.* at 1297 (majority opinion).

104. *Id.* at 1296 (quoting Nat'l Fed'n of Indep. Bus. v. Occupational Safety & Health Admin., 142 S. Ct. 661, 665 (2022)).

105. *Id.* at 1295 (quoting Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2489 (2021)).

106. *Id.* at 1296 (quoting West Virginia v. EPA, 142 S. Ct. at 2609); 40 U.S.C. § 121(a).

107. *Id.* at 1313, 1313–15.

108. *Id.* at 1314–15; 40 U.S.C. § 121(a).

109. Georgia v. President of the U.S., 46 F.4th at 1315.

110. *Id.* at 1298.

> address issues—even significant ones—as and when they arise.[111]

Consequently, while Congress may draft a statute like Section 361(a) broadly because it does not know what will be *necessary* to prevent the transmission of diseases and believes that healthcare agencies are in the best position to make that determination, judges applying the Major Questions Doctrine could use that broad language against agencies like the CDC.

The second case involving the Major Questions Doctrine in the wake of *West Virginia v. EPA*'s holding was *Louisiana v. Becerra.* In that case, the department of Human Health Services ("HHS") enacted the Head Start Mandate, which required all Head Start staff, volunteers working in classrooms or directly with children, and contractors working closely with children and families to be fully vaccinated for COVID-19 by January 31, 2022.[112]

Similar to *Georgia v. President of the U.S.*, because the court determined that a nationwide vaccine mandate invoked an issue of "vast economic and political significance," the analysis hinged on the second step of the Major Questions Doctrine: did HHS have clear congressional authorization to issue such a mandate?[113] Interestingly, instead of primarily focusing on the statutory language, the court utilized a four-clue framework outlined by Justice Gorsuch in his concurring opinion in *West Virginia v. EPA* to determine what qualifies as clear congressional authorization.[114] Those factors include:

> (1) Where the legislative provisions on which the agency seeks to rely are with regard to their place in the overall statutory scheme;
> (2) The age and focus of the statute the agency invokes in relations to the problem the agency seeks to address;
> (3) The agency's past interpretations of the relevant statute; and
> (4) When there is a mismatch between an agency's challenged actions and its assigned mission and expertise.[115]

After applying these factors, the court concluded that the statutory language the agency relied on was not adequate to highlight clear congressional authorization.[116] In particular, the court focused

111. West Virginia v. EPA, 142 S. Ct. at 2628.

112. Louisiana v. Becerra, 629 F. Supp. 3d 477, 484 (W.D. La. 2022).

113. *Id.* at 489–95, 491 (quoting Util. Air Regul. Grp. v. EPA 573 U.S. 302, 324 (2014)).

114. *Id.* at 492 (citing West Virginia v. EPA, 142 S. Ct. at 2609 (Gorsuch, J., concurring)).

115. *Id.*

116. *Id.* at 492–95.

on factor four, stating there was a "disconnect between the [a]gency's challenged actions and its assigned mission and expertise [because the] [a]gency [d]efendant's expertise is not making medical decisions for its students, volunteers, or employees."[117]

This approach to major question issues, while still relatively subjective, at the very least provides agencies with more of a guideline as to what would constitute "clear congressional authorization" to act. By using Justice Gorsuch's factors, the court went beyond an analysis of the statutory terms and their ambiguity (or lack thereof) to dissect the overall scheme and context that the agency sought to rely on. Consequently, utilizing this framework could prevent judges from concluding broad delegations of authority, such as the term "necessary," preclude congressional authorization of a specific act.

B. CDC Authority: A New Era

Considering these decisions, it is still not entirely clear how the Major Questions Doctrine will apply to the CDC moving forward. However, it would be naïve to believe the CDC's authority will not be challenged more consistently going forward under *West Virginia v. EPA*'s major question holding. As such, this Subpart will analyze the reach of the CDC's authority under Section 361 of the PHSA concerning future major question challenges, focusing on what CDC actions could constitute a major question, and then analyzing how courts might determine if the CDC has clear congressional authority for such actions.

Section 361(a) of the PHSA provides a broad delegation of authority to the CDC to "make and enforce . . . regulations [that] in [its] judgement are *necessary* to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States. . . ."[118] As mentioned earlier in this Note, the construction of this statute is inherently broad. Admittedly, there are conflicting interpretations of Section 361's scope.[119] On one hand, the plain reading of Section 361(a) indicates a broad authority to regulate as *necessary* to prevent transmission of diseases, which could include numerous reasonable interpretations. On the other hand, Section 361 falls within several provisions under a statutory scheme titled "Quarantine and Inspection," which suggests the limits of such interpretations must fall within quarantines and inspections.[120]

The multiple interpretations of Section 361(a) indicate its inherent ambiguity, which under *Chevron* would enable the CDC to enforce regulations with a comparative amount of deference. However, with the Major Questions Doctrine being applied with

117. *Id.* at 493.
118. *See* 42 U.S.C. § 264(a) (emphasis added).
119. SHEN, *supra* note 22, at 26–27.
120. *Id.*

greater frequency, courts may inconsistently compress the outer limit of the CDC's authority under this section. As *West Virginia v. EPA* has shown, a court will not get to a deferential analysis if an agency action presents an issue of major significance. So, the first question that needs to be asked is what CDC actions could invoke the Major Questions Doctrine?

1. Step One – Is It Major?

Three regulatory provisions come to mind concerning the CDC's response to a national health crisis: vaccines, mask mandates, and quarantines. Each of these regulatory provisions could reasonably be construed as *necessary* to prevent the transmission of communicable diseases in the U.S. However, whether regulations like these will trigger a major question will likely depend upon the context of the regulation and its scope.

First, it is likely safe to assume that most vaccine mandates will raise an issue of major questions because the Supreme Court has already held as much.[121] Federal vaccine mandates are implemented nationwide and they have become a topic of great political significance.[122] Consequently, nationwide vaccine mandates would appear to fit into the murky definition of major questions, requiring the CDC to point to clear congressional authority to implement any such mandate.

It is not quite so clear, however, whether mask mandates would trigger the Major Questions Doctrine. To be sure, the topic of masks has become highly contentious in the political sphere both on an individual and legislative scale, with some individuals seeing masks as pieces of cloth to protect against disease and others as a direct attack on freedom.[123] However, it is currently an open question as to

121. NFIB v. OSHA, 142 S. Ct. 661, 668 (2022) (Gorsuch, J., concurring) (noting "far less consequential agency actions have run afoul of the major questions doctrine" than vaccine mandates (citing MCI Telecomm. Corp. v. Am. Tel. & Tel. Co., 512 U.S. 218, 231 (1994))).

122. Jennifer Alsever, *The Political Divide Between the Vaxxed and Unvaxxed Is Widening, According to New Report*, FORTUNE (Sept. 28, 2021, 5:00 AM), https://fortune.com/2021/09/28/the-political-divide-between-the-vaxxed-and-unvaxxed-is-widening-according-to-new-report/.

123. Lauren Aratani, *How Did Face Masks Become a Political Issue in America?*, GUARDIAN (June 29, 2020, 5:00), https://www.theguardian.com/world/2020/jun/29/face-masks-us-politics-coronavirus; Amy B. Wang, *Fla. Gov. Ron DeSantis Upbraids Students for Wearing Masks, Calling it 'Covid Theater'*, WASH. POST (Mar. 3, 2022, 10:05 AM), washingtonpost.com/politics/2022/03/02/florida-gov-ron-desantis-chastises-students-masks-middleton-usf/; Tina Reed, *DeSantis Signs "Medical Freedom" Laws*, AXIOS (May 12, 2023), https://www.axios.com/2023/05/12/desantis-medical-freedom-laws ("Florida Gov. Ron DeSantis on Thursday sought to draw a contrast with the expiring COVID-19 public health emergency, signing a set of 'medical

whether masks mandates impose any significant impact on the economy. Some commentators have argued that mask mandates actually benefit the economy, but the benefit is likely too insignificant to constitute a substantial impact.[124] Thus, this dilemma leaves another question left unanswered by the Supreme Court: could a regulation's great political significance trigger the Major Questions Doctrine despite the seemingly minimal economic impact? To date, the Court has seldom invoked the Major Questions Doctrine where the issue lacked significant economic impact.[125] However, with the lack of guidance supplied by the Court as to what constitutes a major question, it is not outlandish to imagine lower courts invoking the doctrine on the political nature of mask mandates alone.

Finally, courts will have to determine whether quarantine regulations implore a major questions analysis. Section 361 of the PHSA directly concerns the CDC's capacity to impose quarantine measures in addition to other *necessary* regulations to prevent the transmission of diseases.[126] Thus, the CDC will likely find more success in pointing to congressional authorization for regulations relating to quarantines. However, this does not prevent the court from using a major question analysis in such a review, which could significantly limit the outer limits of the CDC's authority under Section 361. Quarantines undoubtedly put a strain on the success of the economy, with production shutting down when workers stay home.[127] And the political significance of nationwide quarantines is visibly evident from the public and heated debates between lawmakers throughout the COVID-19 pandemic.[128] Consequently, courts could rationally adduce that a quarantine mandate requires a major question analysis.

Hopefully the trend outlined in this Subpart is clear. Federal regulations—especially those related to the prevention of a transmissible disease—will almost always affect the economy on a national scale and involve issues of significant political importance.

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freedom' measures into law, including bans on mask and vaccine mandates, and new conscience protections for health providers.").

124. Sara Savat, *Masks Don't Just Save Lives, They Also Boost the Economy*, THE SOURCE (Nov. 9, 2020), https://source.wustl.edu/2020/11/masks-dont-just-save-lives-they-also-boost-economy/.

125. SHEN, *supra* note 22, at 31 (explaining the Supreme Court has only invoked the Major Questions Doctrine when there was little economic impact in a case concerning physician-assisted suicide).

126. *See* 42 U.S.C. § 264(a) (emphasis added).

127. Lauren Bauer et. Al., *Ten Facts About COVID-19 and the U.S. Economy*, BROOKINGS (Sept. 17, 2020), https://www.brookings.edu/research/ten-facts-about-covid-19-and-the-u-s-economy/.

128. Kimberly Wehle, *Yes, a National Quarantine Is Constitutional . . . and Necessary*, POLITICO (May 15, 2020, 6:45 PM), https://www.politico.com/news/magazine/2020/05/15/national-quarantine-constitutional-261165.

It is important to remember, however, that the mere invocation of the Major Questions Doctrine is not necessarily a death sentence. If the agency can point to *clear congressional authorization* for their actions, the regulation may still just survive. But does the CDC have such clear congressional authorization to implement regulations concerning vaccines, masks, and quarantines?

2. Step Two – Where Is The Authority?

As already mentioned, the majority holding of *West Virginia v. EPA* did little to educate agencies as to what would satisfy the second element of a major question analysis: clear congressional authorization.[129] While Justice Gorsuch did supply a four-factor framework in his concurrence outlining how agencies could prove their authorization, lower courts are under no obligation to utilize such a framework.[130] This is evident from the holding in *Georgia v. President of the U.S.*, where the court focused solely on the statutory language without reference to Justice Gorsuch's concurrence.[131]

If courts disregard Justice Gorsuch's concurrence and follow an analysis like that in *Georgia v. President of the U.S.*, the CDC will likely struggle to prove that it has clear congressional authorization to implement mask and vaccine mandates. The court in *Georgia v. President of the U.S.* took issue with broad statutory language, arguing that ambiguous language does not indicate *clear congressional authority* to regulate.[132] This holding is bad news for agencies like the CDC that rely on statutorily broad language to implement regulations that Congress could not have necessarily foreseen.

Alternatively, if courts utilize the four-factor framework laid out by Justice Gorsuch, the CDC may have a better chance of proving congressional authority to regulate major issues like mask mandates and vaccines. As a reminder, the factors outlined by Justice Gorsuch are as follows:

(1) Where the legislative provisions on which the agency seeks to rely are with regard to their place in the overall statutory scheme;

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129. West Virginia v. EPA, 142 S. Ct. 2587, 2634 (Kagan, J., dissenting).

130. Thomas B. Bennett et al., *Divide & Concur: Separate Opinions & Legal Change*, 103 CORNELL L. REV. 817, 820 (2018); Ryan M. Moore, Comment, *I Concur! Do I Matter? Developing a Framework For Determining The Precedential Influence of Concurring Opinions*, 84 TEMP. L. REV. 743, 744 (2012) (explaining concurring opinions have almost "no dispositive impact upon the law on which they speak" (citing Bronson v. Bd. of Educ. of Cincinnati, 510 F. Supp. 1251, 1265 (S.D. Ohio 1980))).

131. Georgia v. President of the U.S., 46 F.4th 1283, 1296 (11th Cir. 2022).

132. *Id.* at 1296, 1300.

(2) The age and focus of the statute the agency invokes in relations to the problem the agency seeks to address;
(3) The agency's past interpretations of the relevant statute; and
(4) When there is a mismatch between an agency's challenged actions and its assigned mission and expertise.[133]

First, the legislative provision the CDC would seek to rely on to implement mask and vaccine mandates would likely be subsection (a) of Section 361 of the PHSA, enabling the agency to implement measures *necessary* to prevent the transmission of the disease.[134] How a court would view this subsection within the overall statutory scheme will not necessarily be consistent. For example, Section 361 is one of several provisions under a statutory part titled "Quarantine and Inspection," which could lead a court to view Section 361 as a narrow authorization from Congress whereby "quarantine and isolation authority is the principal, if not the maximum, authority granted under the provision."[135] Alternatively, Section 361 is titled "Regulations to control communicable diseases," which could suggest a broader delegation of authority within the statutory scheme.[136] However, when this seemingly broad title is placed within the context of the statutory scheme, a judge could reasonably determine that Congress intended "regulation to control communicable diseases" to mean regulations related to quarantines, not vaccine or mask mandates. Either reading could be plausible, hence why the first factor will not necessarily be applied consistently.

The second factor likely favors the CDC in any attempts to implement mask or vaccine mandates. The focus of the statute—stated broadly—is to prevent the transmission of communicable diseases within the United States.[137] If the agency invoked its authority under this section during a national health crisis, it would be seeking to address that purpose, whether by mask mandates, vaccine requirements, or quarantines. Consequently, factor two would weigh in favor of the CDC.

The favor of factor three would depend on the type of regulation the CDC is attempting to implement. Prior to COVID-19, the CDC primarily invoked its authority under Section 361 to "issue and refine regulations relating to quarantine and isolation."[138] This could indicate that it did not interpret the language of Section 361 to authorize regulations outside of quarantine and isolation. However, in response to the COVID-19 pandemic, the CDC invoked its

133. West Virginia v. EPA, 142 S. Ct. at 2622–24 (Gorsuch, J., concurring) (cleaned up).
134. *See* 42 U.S.C. § 264(a) (emphasis added).
135. SHEN, *supra* note 22, at 27; 42 U.S.C § 264(a).
136. 42 U.S.C § 264.
137. 42 U.S.C § 264(a)–(e).
138. SHEN, *supra* note 22, at 12.

authority more broadly by introducing a national eviction moratorium to curb the transmission of the virus in congregate settings.[139] Thus, the CDC has interpreted Section 361 to provide broad authority outside the realm of isolation and quarantine regulations. This could support any future decision to invoke Section 361 to implement mask or vaccine related regulations; however, if a court interprets factor three to require an agency to point to a past example of the same interpretation, the CDC will likely falter.

Considering the CDC's mission is "to protect America from health, safety and security threats, both foreign and in the U.S.," factor four's comparison between the agency's missions and expertise versus the challenged action would likely favor the CDC.[140] The CDC is on the scientific forefront of disease prevention and has accumulated years of knowledge and experience in combative measures against national health crises. Consequently, the implementation of a vaccine, mask, or other related regulation in an effort to prevent the transmission of diseases would appear to be within the wheelhouse of the agency.

Ultimately, the short analysis in this Note of Justice Gorsuch's four-factor framework cannot accurately predict the conclusion courts will arrive at if they undertake the same analysis. The factors are subjective, and Justice Gorsuch did not specify whether certain factors carry more weight than others.[141] But this analysis hopefully highlights a contrast between the choice courts will have to make when determining if an agency has clear congressional authorization to act. Courts can utilize a similar analysis to that in *Georgia v. President of the U.S.* by focusing primarily on the statutory language and penalizing agencies for ambiguity in the statutes they seek to rely on, or courts can undertake a more detailed analysis that looks beyond the plain meaning of the written statute. These two options will undoubtedly lead to inconsistent applications of the second step in a major question analysis, leaving agencies at the mercy of the reviewing judge's prerogative.

C. Adapting To The Extraordinary: How to Move Forward

This Note outlined the perplexing evolution of judicial review of agency action by traveling from the days of *Chevron* deference and quiet grumblings of a major question analysis to the current Major Questions Doctrine takeover following *West Virginia v. EPA*. If the Major Questions Doctrine is here to stay—which appears likely—it cannot merely float through the judicial system as an arbitrary

139. Temporary Halt in Residential Evictions to Prevent the Further Spread of COVID-19, 85 Fed. Reg. 55292, 55292–93 (Sept. 4, 2020).

140. *Mission, Role and Pledge*, CDC, https://www.cdc.gov/about/organization/mission.htm (last visited Feb. 29, 2024).

141. West Virginia v. EPA, 142 S. Ct. 2587, 2622–24 (2022) (Gorsuch, J., concurring).

stopping mechanism to agency action. It must be clarified. This Subpart turns an eye to the future and lays out two possibilities for the judicial and legislative branches to ensure agencies like the CDC are not dangerously second-guessed by unelected and unaccountable judges.

1. Judicial Solutions

This Subpart will not argue the merits of the Major Questions Doctrine in its whole or suggest an entirely alternative type of review. Instead, it will suggest ways the doctrine can be applied more consistently at the judicial level with a greater level of clarity moving forward. The primary suggestion is that courts should use Justice Gorsuch's four-factor framework across all levels of the judiciary—at least for the time being.

Justice Gorsuch's four-factor approach—while not perfect—clarifies what agencies should expect when facing a major question analysis. Should the factors be adopted, agencies would be aware of the standard they are being held against to prove congressional authorization. This is drastically preferable to an unarticulated, unguided standard that appears to be asking for something "over and above the normal statutory basis" the Court has previously required without indicating what that may be.[142] As seen in *Georgia v. President of the U.S.*, if courts do not use this reference point, there is a danger of hyper-focusing on the absence of explicit authorization to regulate a certain issue instead of dissecting the language within the overall scheme (among other factors) to ascertain if Congress may have authorized the agency to act implicitly.[143] Indeed, Congress knows what it does not and cannot know when it drafts a statute, and it is impossible for it to explicitly authorize every agency action it intends to delegate to agencies. Thus, any tool of judicial review that takes this into account should be considered in a major question analysis.[144]

At this point, Justice Gorsuch's framework is the only option available that acknowledges this issue. Ideally, the Supreme Court would use an upcoming case like *Sakket v. EPA*[145]—an administrative law case that will likely invoke the Major Questions Doctrine—to adopt the factor framework, or some variation of it.[146] Until that holding, lower courts should follow the lead of *Becerra* by utilizing the framework themselves.

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142. *Id.* at 2634 (Kagan, J., dissenting).

143. *Id.*

144. *Id.* at 2642.

145. 143 S. Ct. 1322 (2023).

146. Anna Todd, Sackett v. EPA *and the Definition of Waters of the United States*, ENV'T & ENERGY L. PROGRAM (Jun. 24, 2022), https://eelp.law.harvard.edu/2022/06/sackett-v-epa-and-the-definition-of-waters-of-the-united-states/.

2. Legislative Solutions

Failing a judicial resolution, the next alternative would be legislative. If the current major question framework remains in place, the best safeguard against the penalization of agencies for ambiguous language would obviously be to clarify that language.[147] For example, if Congress determined that more coordinated CDC action is necessary to address any future health crisis, it should update Section 361's broad language to encompass the specific authority the CDC should have by stating it explicitly.

As already noted, mask mandates and vaccine-related regulations are at risk of triggering a major question analysis. Therefore, if the current Congress believes the CDC should have the authority to regulate such areas—considering its expertise and positioning—then it should act legislatively to supply the authority needed before the next major health crisis. In theory, this seems a logical solution; however, considering the current make-up of the legislative chambers—a slim majority for the Republicans in the House and an even slimmer majority for the Democrats in the Senate—it is unlikely such legislation would be successful considering the partisan nature of the issue.[148]

CONCLUSION

When the complexity of the issues surrounding the Major Questions Doctrine and judicial review of agency action are stripped away, there remains an almost naively simple question: who decides? Who decides what is *necessary* to prevent the transmission of communicable diseases throughout the United States? The answer to that question, however, is unsurprisingly not quite as simple. It is shrouded in longstanding legal debate that stretches the gambit of judicial precedent, constitutional limits, and policy.

While this Note did not address every aspect of that debate, it provided context to the danger of giving unelected judicial figures a free pass to utilize an unclarified Major Questions Doctrine, specifically in the context of CDC action relating to future health crises. The CDC should not be given an unchecked amount of authority to regulate. It is vital that its authority is reviewed across the nation consistently against the backdrop of an established framework that balances the inquiry into the "who decides" question evenly among the executive, legislative, and judicial branch. Without such a backdrop, there is a danger that the "extraordinary will become ordinary" in the eyes of the judiciary,[149] which will only

147. *See* SHEN, *supra* note 22, at 32.

148. James M. Lindsay, *The 118th Congress by the Numbers*, COUNCIL ON FOREIGN RELS. (Jan. 9, 2023, 5:07 PM), https://www.cfr.org/blog/118th-congress-numbers.

149. Lopez, *supra* note 95.

further increase the chances of judicial-level interference for the CDC in the next health crisis. And considering the effects of interference with CDC authority in the COVID-19 pandemic, this is a reality that should be avoided at all costs.

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