

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
Tampa Division

CASE NO. 8:21-cv-1693-KKM-AEP

Health Freedom Defense Fund,
Inc., et al,

Plaintiffs,

v.

Joseph R. Biden, Jr., et al,

Defendants.

_____/

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT AND PLAINTIFFS'
CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Prior to the COVID-19 pandemic, the Centers for Disease Control (“CDC”) was mainly known for providing advice and guidelines on matters of public health. It had never claimed any authority to directly govern the lives and conduct of millions of people across the country. That ended in 2020, when the CDC began to take a series of extraordinary measures, the statutory and Constitutional authority for which could never be satisfactorily explained. Two of those extraordinary measures – its national eviction moratorium and its conditional sailing order for the cruise industry – have been struck down. *See Ala. Ass’n of Realtors v. HHS*, 141 S. Ct. 2485 (2021) (hereinafter, “AAR”); *Florida v. Becerra*, Case No. 8:21-cv-839, __ F. Supp. 3d. __, 2021 U.S. Dist. LEXIS 114297, *32 (M.D. Fla. June 18, 2021) (Merryday, D.J.). The CDC’s Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs, 86 Fed. Reg. 8025 (hereinafter, the “Mask Order”), is the third such measure. Like the CDC’s actions in *AAR* and *Becerra*, the Mask Order must also be declared invalid.

First, the Mask Order exceeds the CDC’s statutory authority. The statute on which the CDC relies, 42 U.S.C. § 264(a), is to be narrowly construed as giving the CDC the authority to abate sources of disease, such as animals, articles, and things. It offers no basis for assuming authority over the conduct of individuals. Contrary to Defendants’ argument, masks are not a “sanitation” measure as contemplated

by the statute. The CDC's own regulations and common usage in the realm of public health confirm this. For that and other reasons, the CDC's novel interpretation of the statute is also not entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

Second, the CDC's refusal to provide notice and allow for comments violated Section 553(b) of the Administrative Procedure Act. The CDC failed to show good cause for avoiding that requirement, and the CDC's argument that the error was harmless lacks merit.

Third, the Mask Order is arbitrary and capricious. The CDC violated its own regulation, 42 CFR § 70.2, and the Order itself does not reflect a reasonable interpretation of Section 264(a). As well, the administrative record does not support the CDC's conclusions.

Fourth, if Section 264(a) does confer the authority claimed by the CDC, then it is an invalid delegation of legislative power.¹

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¹ Plaintiffs respectfully withdraw Counts V and VI of their Amended Complaint. *See Bldg. & Const. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 32-33 (D.C. Cir. 2002).

BACKGROUND

I. The Public Health Service Act.

For roughly the first century of the Republic, the federal government's role in public health was to provide support for the States in enforcing state quarantine laws. *See Becerra*, 2021 U.S. Dist. LEXIS 114297, *32-34 and authorities cited therein.

Even as the federal government's role in enforcing quarantine grew in the latter 19th century, its power was limited to inspection of vessels on arrival at a U.S. port and, if inspection warranted, detention of a vessel for the duration of a disease's incubation period. *Id.* at *34-37 (citations omitted). Quarantine officers were granted authority to issue a "pratique" or "provisional pratique" to vessels seeking entry to a U.S. port. *Id.* at *37 (citation omitted). A pratique permitted a vessel to enter and operate in a U.S. port, whereas "a provisional pratique permitted a vessel to enter the port only after completing some narrow and discrete task, typically fumigation of cargo or the like." *Id.* ²

In 1893, Congress adopted a "bill of health" system, which required a vessel to obtain a bill of health from a consular officer, which would be presented upon arrival at a U.S. quarantine station. Act of Feb. 15, 1893, Ch. 114, 27 Stat. 449, Sec.

² As Defendants tacitly acknowledge, MSJ at 20 fn. 8, the government's authority to prohibit or place conditions on a vessel's entry into a U.S. port has been limited to vessels arriving from foreign destinations.

2 (1893). The bill of health was to set forth “the sanitary history and condition” of the vessel, and to certify that it had “complied with the rules and regulations . . . prescribed for security the best sanitary condition of said vessel, its cargo, passengers, and crew[.]” *Id.* At the time, sanitary regulations for passenger ships included requirements such as separate facilities for preparing food and a minimum number of privies for passengers,³ and their locations. *See* Passenger Act of 1882, Ch. 374, 22 Stat. 186. Common measures for abating disease “included rapid inspection and sanitation.” *Becerra*, 2021 U.S. Dist. LEXIS 114297, *39. If an item was suspected of infection, it was “subjected to a process of disinfection, typically either steaming or fumigation.” *Id.* (citation and internal quotation marks omitted).

The Act directed the Supervising Surgeon-General of the Marine Hospital Service to “examine the quarantine regulations of all State and municipal boards of health,” and to “co-operate with and aid State and municipal boards of health in the execution and enforcement” of their rules and regulations, and the “execution and enforcement of the rules and regulations made by the Secretary of the Treasury. . . .” Ch. 114, 27 Stat. 449 at Sec. 3 . However, the Secretary’s role in promulgating regulations was limited to where state and municipal regulations

³ The regulation required, for example, separate privies for males and females – one privy for every 50 female passengers, and one for every 100 male passengers.

were deemed “not sufficient to prevent the introduction of such diseases into the United States,” or from one state or territory to another. *Id.*

The next significant development was the enactment of the Public Health Service Act in 1944 (the “PHSA”), which “largely organized, consolidated, and clarified the federal government’s existing authority[.]” *Becerra*, 2021 U.S. Dist. LEXIS 114297, *40. “The basic authority to make regulations to prevent the spread of disease into this country or between the States is contained in section 361(a).” H.R. Rep. No. 78-1364 at 24.

Section 361(a) provides that the CDC:

... is authorized to make and enforce such regulations as in [its] 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. For purposes of carrying out and enforcing such regulations, the [CDC] may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

PHSA § 361(a), codified at 42 U.S.C. § 264(a) (hereinafter, “Section 264(a)").

Defendants assert that § 264(a) “broadened the federal government’s basic authority to make regulations. . . .” MSJ at 3. “Yet the measures — inspection, fumigation, disinfection, sanitation, pest extermination, and similar measures —

introduced by the [PHSA] accorded comfortably with historical precedent.” *Becerra*, 2021 U.S. Dist. LEXIS 114297 at *41 and n. 25 (citation omitted). Section 311, encoded at 42 U.S.C. § 243, illustrates that Congress intended to preserve the leading role of the States in public health by giving the Surgeon General a “general direction . . . to assist and cooperate with State and local authorities in public health work, and an authorization to accept their assistance in the enforcement of Federal quarantine regulations.” H.R. Rep. No. 78-1364 at 17.

As the Supreme Court recently noted, Section 264(a) “has rarely been invoked[.]” *AAR*, 141 S. Ct. at 2487. “Regulations under this authority have generally been limited to quarantining infected individuals and prohibiting the sale of animals known to transmit disease.” *Id.* (citation omitted). The CDC has never previously invoked Section 264(a) to justify any sort of blanket requirement for individuals, whether on public conveyances or elsewhere, to comport themselves in any particular manner whatsoever, let alone wear masks.

II. The Mask Order.

On his first full day in office, a year into the COVID-19 pandemic,⁴ President Biden issued Executive Order 13998 (the “EO”). 86 Fed. Reg. 7205. The EO

⁴ On January 31, 2020, the prior administration issued a Declaration of a Public Health Emergency effective as of January 27, 2020. See <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (last visited on February 10, 2022).

directed, *inter alia*, the Secretaries of Health and Human Services (“HHS”) to “immediately take action . . . to require masks be worn in compliance with CDC guidelines in or on: (i) airports; (ii) commercial aircraft; (iii) public maritime vessels, including ferries; (iv) intercity bus services; and (v) all forms of public transportation as defined in section 5302 of title 49, United States Code.” *Id.*

Without publishing notice and allowing for comments, the CDC dutifully issued the Mask Order under review. 86 Fed. Reg. 8025. The Order requires that “[p]ersons must wear masks over the mouth and nose when traveling on conveyances into and within the United States,” and at “transportation hubs[.]” *Id.* at 8026. It further requires conveyance operators (and operators of transportation hubs) to use their best efforts to ensure that “any person on the conveyance wears a mask when board, disembarking, and for the duration of travel.” *Id.* Those best efforts include, *inter alia*, “instructing persons that *Federal law* requires wearing a mask on the conveyance and failure to comply constitutes a violation of *Federal law*.” *Id.* (emphasis added).

The Order recites that “[t]he virus that causes COVID-19 spreads very easily and sustainably between people who are in close contact with one another (within about 6 feet). . . .” *Id.* at 8028. Yet, despite claiming to be concerned with the “[p]reservation of human life,” *id.* at 8027, it mandates no limits on passenger density or requirements for distance between passengers onboard conveyances.

Despite instructing conveyance operators to inform passengers that “Federal law” requires wearing a mask, the Order states that it “is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather is an emergency action taken under the existing authority of” Section 264(a) and 42 CFR 70.2, 71.31(b), and 71.32(b). *Id.* at 8030. However, the Order further provides that, in the event that a court determines that it qualifies as a rule under the APA:

notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and comment and the opportunity to comment on this Order and the delay in effective date. Considering the public health emergency caused by COVID-19, it would be impracticable and contrary to the public’s health, and by extension the public’s interest, to delay the issuance and effective date of this Order.

Id. The CDC further concedes that, “if this Order were a rule, it would be a *major* rule under the Congressional Review Act. . . .”⁵ *Id.* (emphasis added). Likewise, the Order notes that it “is an economically significant regulatory action under Executive Order 12866. . . .” *Id.*

The necessity of the Order is premised on the rationale that:

[a]ny state or territory without sufficient mask-wearing requirements for transportation systems within its jurisdiction has not taken adequate measures to prevent the spread of COVID-19 from such state or territory to

⁵ A “major rule” is one that the Office of Management and Budget “finds has resulted in or is likely to result in,” *inter alia*, “an annual effect on the economy of \$100,000,000 or more[.]” 5 U.S.C. § 804(2)(A).

any other state or territory. That determination is based on, *inter alia*, the rapid and continuing transmission of the virus across all states and territories and across most of the world.

Id. The Order lacks any finding as to what would constitute “sufficient mask-wearing requirements for transportation systems,” and omits any mention of which states or territories failed to implement such requirements.

The phrase, “rapid and continuing transmission,” is also not quantified. When the Order came into force on February 1, 2021, the CDC’s own data showed that COVID-19 cases in the United States were actually declining. *See* Composite Exhibit “A”. Since then, every state and region in the U.S. has seen additional waves of transmission, including the now rapidly declining Omicron wave. *Id.* If the Mask Order had any impact on these waves, the CDC has not said so.

Notably, Defendants admit that, as of the date of their Answer to the Amended Complaint, there had been “no enforcement actions brought by the Federal Government against aircraft passengers solely as a result of violations of” the Mask Order. *Ans.*, ECF 41, at ¶51. Instead, Defendants admit, the FAA has enforced existing law and regulations against interfering with or assaulting a flight crew. *Id.* The FAA has not promulgated its own rule requiring masks.⁶

⁶ This might be regarded as “the dog that didn’t bark.”

III. The Mask Order's Impact On Plaintiffs.

Plaintiff Health Freedom Defense Fund, Inc. ("HFDF") is a not-for-profit member organization that seeks to advocate for and educate the public on the topics of medical choice, bodily autonomy, and self-determination, and that opposes laws and regulations that force individuals to submit to the administration of medical products, procedures, and devices against their will. As attested by the Declarations appended to the Amended Complaint, HFDF has members in this District who, for health reasons and/or due to their strongly-held objections to the Mask Order, have been unable to travel or have refrained from traveling. *See* Declarations, ECF 39-4.

Plaintiff Ana Carolina Daza took a trip to Colombia in September 2021, and wore a mask as required, despite her personal objections and despite the fact that she has been diagnosed as having anxiety. *See* Decl. of Ana Daza, attached as Exhibit "B". On her outbound flight, she experienced shortness of breath and a feeling of being unable to breathe. *Id.* On the return flight, her experience was worse, but she was afraid to remove her mask because she did not wish to be accused of violating federal law. *Id.* As a result of that experience, she does not believe that she can safely travel while the Mask Order is in place, and so has been forced to forego any trips for the foreseeable future. *Id.*

Plaintiff Sarah Pope has taken short-haul flights, during which she wore a mask as required, but she cannot tolerate wearing a mask for longer periods of time. *See* Decl. of Sarah Pope, attached as Exhibit “C”. She has suffered panic attacks in the past and is anxious about suffering one during a flight due to the constricted breathing from wearing a mask. *Id.* She does not want to be accused of violating federal law. *Id.* As a result, she had to forego a trip with her family to Hawaii in 2021, and is unable to plan other long-haul trips, including a trip she had hoped to take to Great Britain this summer (2022) to celebrate a friend’s birthday. *Id.*

ARGUMENT

I. Plaintiffs Have Standing To Seek Declaratory Relief.

As “Persons” under the Mask Order, Plaintiffs are directly compelled to wear masks while on conveyances and in transportation hubs. 86 Fed. Reg. 8025. Accordingly, Defendants “do not dispute that at least some Plaintiffs have Article III standing to challenge the [Mask Order] (which imposes a legal obligation on the individual Plaintiffs to wear masks when using public transportation)[.]” MSJ at 34. *See Planned Parenthood of the Atlanta Area, Inc. v. Miller*, 934 F.2d 1462, 1465-

66 (11th Cir. 1991) (noting that when one plaintiff has standing to bring all claims in an action, the court need not inquire into the standing of other plaintiffs).⁷

Plaintiffs also have statutory standing under the APA. *See* 5 U.S.C. § 702. Plaintiffs have suffered an injury in fact, and their injury is at least “arguably within the zone of interests to be protected or regulated” by the CDC’s violations of the APA. *See Sierra Club v. Morton*, 405 U.S. 727, 733 (1972).

Plaintiff HFDF has associational standing to represent its members. HFDF’s members would have standing to sue in their own right, the injuries asserted are germane to HFDF’s purpose, and the claims asserted do not require the personal involvement its members. *See Sierra Club, Inc. v. St. Johns River Water Mgmt. Dist.*, Case No. 6:14-cv-1877, 2015 U.S. Dist. LEXIS 151019, *25 (M.D. Fla. Nov. 6, 2015).

II. The Mask Order Exceeds The CDC’s Statutory Authority (Count I).

A court must “hold unlawful and set aside agency action” that is “in excess of statutory [] authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(C). Defendants argue that “Congress prudently gave the Executive Branch broad authority to take reasonable public-health measures to prevent the spread of communicable disease,” and that requiring individuals to wear masks, in travel hubs and onboard public conveyances, is a “conventional ‘sanitation’ measure”

⁷ Plaintiffs are prepared to provide supplemental briefing on Article III standing, should the Court request it.

that is plainly contemplated by 42 U.S.C. § 264(a). MSJ at 2. Both assertions overstate the scope of Defendants' authority.

A. Section 264(a) Must Be Narrowly Construed.

Section 264(a) is not a general authorization for the CDC to, as Defendants suggest, "take reasonable public-health measures to prevent the spread of communicable disease." MSJ at 2. Such a broad remit would effectively confer a general police power on the federal government. *See Skyworks, Ltd. v. CDC*, 524 F. Supp. 3d 745, 758 (N.D. Ohio 2021). It is of course well-established that the federal government has no such power. *See, e.g., Terkel v. CDC*, 521 F. Supp. 3d 662, 666 (E.D. Tex. 2021) (citing *Bond v. United States*, 572 U.S. 844, 854 (2014)).⁸

Considered in context and on its own terms, the statute's reach is much narrower than Defendants would have this Court conclude. While the scope of power conferred in the first sentence of Section 264(a) may be regarded as broad, a widely recognized canon of statutory interpretation holds that "an ambiguous term may be given more precise content by the neighboring words with which it is associated." *Bilski v. Kappos*, 561 U.S. 593, 604, 130 S. Ct. 3218, 3226 (2010). "In other words, '[a]ssociated words bear on one another's meaning.'" *Becerra*, 2021

⁸ In this context, Defendants' invocation of the Necessary and Proper Clause of U.S. Const. art. I, § 8 in its MSJ at 18-19, makes no sense. The question under APA Section 706(2)(C) is not whether a statute reflects a proper exercise of Congressional authority, but whether, assuming the statute is proper, the CDC has imbued it with a meaning that exceeds the bounds of what Congress intended.

U.S. Dist. LEXIS 114297 at *57 (*citing* Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 195 (2012)). *See also* *Tiger Lily, LLC v. United States HUD*, 992 F.3d 518, 522-24 (6th Cir. 2021).

Here, the second sentence of Section 264(a) proves critical to the analysis:

For purposes of carrying out and enforcing such regulations, the [CDC] may provide for such *inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings*, and other measures, as in his judgment may be necessary.

(emphasis added).

As elaborated by the Northern District of Ohio, the plain language of the second sentence:

. . . links the agency's power to specific, tangible things on which the agency may act. Even a reading of the statute that links "destruction" to "animals or articles" leaves the other actions in the statute (inspection, fumigation, disinfection, sanitation, and pest extermination), which by their common meanings and understandings are tied to specific, identifiable properties. And the next limitation in the statute reinforces the agency's targeted power: "found to be so infected or contaminated as to be sources of dangerous infection to human beings." With this language, Congress directs the agency to act on specific animals or articles which are themselves infected or a source of contagion that present a risk of transmission to other people.

Skyworks, Ltd. v. CDC, 524 F. Supp. 3d 745, 757-58 (N.D. Ohio 2021) (internal citation omitted).

The Supreme Court affirmed this narrow interpretation in *AAR*. Considering the CDC's national moratorium on rental evictions, the Court held that "the second sentence [of § 264(a)] informs the grant of authority by illustrating the kinds of measures that could be necessary: inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles." *AAR*, 141 S. Ct. at 2488. "These measures," the Court noted, "directly relate to preventing the interstate spread of disease *by identifying, isolating, and destroying the disease, itself.*" *Id.* (emphasis added). *See also Becerra*, 2021 U.S. Dist. LEXIS 114297 at *54-57 (reviewing authorities).⁹

Requiring every person who enters a transportation hub or who seeks to board a conveyance to wear a face covering goes far beyond "identifying, isolating, and destroying the disease. . . ." *AAR, supra*. It instead governs the daily conduct

⁹ Defendants argue that the CDC's governing domestic regulation under Section 264(a), 42 CFR § 70.2, "provides the CDC with broad discretion to address the uncontrolled spread of communicable disease." MSJ at 6. However, the sole authority that Section 70.2 adds to Section 264(a) is that the CDC may take the measures contemplated by Section 264(a) "*only after determining* that the measures taken by health authorities of any State or possession . . . are insufficient to prevent" the spread of disease. *Becerra*, 2021 U.S. Dist. LEXIS 114297 at *67-68 (emphasis added). "Consequently, Section 70.2 fails to suggest any broader authority" than that contained in Section 264(a), itself. *Id.* at *68. Indeed, the emphasis on local health authorities demonstrates that Section 70.2 "is intended to bridle the federal government and to encourage federalism." *Id.* at *118. In any event, the CDC failed to heed Section 70.2 when it issued the Mask Order. *See infra*, Part IV.A.

of millions of individuals – a power that neither the CDC nor its predecessor agencies previously claimed to have.

B. Masks Are Not “Sanitation”.

Recognizing the statutory construction dilemma presented by AAR, Defendants stake their argument on the contention that, because “masking is a conventional ‘sanitation’ measure,” the PHSA justifies its imposition. MSJ at 14 and fn. 4. First, this argument runs counter to the Supreme Court’s conclusion that the second sentence of § 264(a) limits the CDC’s authority to, *inter alia*, “. . . sanitation . . . of contaminated animals and articles.” AAR, 141 S. Ct. at 2488. And as noted in *Becerra*, the clause, “found to be so infected or contaminated,” imposes a further limitation, “suggesting that an animal or article must present more than a *possibility* or a *remote risk* of infection due to an instance of infection in another animal or article.” *Becerra*, 2021 U.S. Dist. LEXIS 114297 at *61 (emphasis added) (citation omitted). “In other words, Section 264(a) allows the regulation of only an infected or infecting item.” *Id.* (citation omitted). *See also See Skyworks, Ltd.*, 524 F. Supp. 3d at 757-58. Human beings are neither “animals” nor “articles.”

Second, Defendants’ reliance on common dictionary definitions of the word, “sanitation,” disregards a “fundamental principle of statutory construction,” which is “that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used.” *Deal v. United States*, 508 U.S. 129,

132 (1993). As observed the district court in *Skyworks*, the words in the second sentence of Section 264 authorize the CDC “to *act on* specific animals or articles which are themselves infected or a source of contagion that present a risk of transmission to other people.” *Skyworks*, 524 F. Supp. 3d at 757-58 (emphasis added). The Sixth Circuit likewise construed this authority in terms of a power “to sanitize and dispose of infected matter. . . .” *Tiger Lily*, 992 F.3d at 523.

In other words, Section 264(a) limits the CDC to acting upon tangible objects; i.e., *sanitizing* infected animals or articles, or *making them sanitary*. This interpretation is consistent with how those terms have been used in the context of both U.S. and international public health guidelines and regulations.

“Sanitation” has typically referred to the proper abatement of human waste. For example, the World Health Organization defines “sanitation” as “access to and use of facilities and services for the safe disposal of human urine and faeces.” WHO, Guidelines on Sanitation and Health, at Executive Summary.¹⁰ Other examples abound. A paper published via the U.S. National Library of Medicine, National Institutes of Health, defines “sanitation” as “the safe disposal of human excreta.” PLoS Med, “Sanitation and Health,” Nov. 7, 2010, published online Nov.

¹⁰ <https://apps.who.int/iris/bitstream/handle/10665/274939/9789241514705-eng.pdf> (last visited on February 3, 2022).

16, 2010 (citing WHO, UNICEF. *Progress on sanitation and drinking-water – 2010 update*. Geneva: World Health Organization; 2010).¹¹

Other federal statutes and regulations are consistent with this particular understanding of the word, “sanitation.” For example, federal law defines a “marine sanitation device” to be installed on covered marine vessels as including “any equipment for installation on board a vessel which is designed to *receive, retain, treat, or discharge sewage, and any process to treat such sewage.*” 33 U.S.C. § 1322(a)(5) (emphasis added). Similarly, federal regulations for railroads define “unsanitary” as “any condition in which any significant amount of filth, trash, or human waste is present in such a manner that a reasonable person would believe that the condition might constitute a health hazard.” 49 CFR § 229.5.¹²

That is not to say that “sanitation” is strictly limited to the abatement of human waste. At or about the time of the PHSA’s enactment, international regulations reflected the understanding that “sanitation” also referred to actions such as “disinfection, disinsecting, deratting and other sanitary operations.” *WHO Regulations No. 2 International Sanitary Regulations*, World Health Organization,

¹¹ (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2981586/>) (last viewed on February 4, 2022).

¹² Defendants’ own exhibit contains a diagram showing “arrangements providing sanitation for a modern house,” focused on plumbing fixtures—indeed, the same dictionary identifies that at the time the term “sanitary” was a term for a “public watercloset or urinal.” See ECF 45-3.

May 21, 1951,¹³ at Article 25; *see also* Article 32 (sanitary measures applied to a ship); Appendix 6 (refers to “disinsecting or sanitary treatment” performed during the flight of an aircraft). The CDC’s own regulations for “Sanitary Inspection,” found at 42 CFR Part 71, Subpart E, are largely identical in scope. Section 71.41 defines a “sanitary inspection” as being one “to determine whether there exists rodent, insect, or other vermin infestation, contaminated food or water, or other insanitary conditions requiring measures for the prevention of the introduction, transmission, or spread of communicable disease.” *See also* 42 CFR § 71.42 (Disinfection of imports); § 71.44 (Disinsection of aircraft); § 71.45 (Food, potable water, and waste....); and § 71.46 (Issuance of Deratting Certificates....).

Defendants urge that, “much like other ‘sanitation’ measures, such as wearing gloves or a gown, or disinfecting surfaces, wearing a mask is intended to reduce the transmission of viral particles.” MSJ at 14. However, only one of Defendants’ suggested measures – “disinfecting surfaces” – has been regarded by the CDC as falling within the realm of “sanitation”.

The CDC’s “Vessel Sanitation Program” for Cruise Ships (the “VSP”), by way of example,¹⁴ defines “*sanitization*”¹⁵ as “[t]he application of cumulative heat

¹³ https://apps.who.int/iris/bitstream/handle/10665/101391/WHA4_60_eng.pdf (last visited February 3, 2022).

¹⁴ *See* https://www.cdc.gov/nceh/vsp/docs/vsp_operations_manual_2018-508.pdf (last visited February 5, 2022).

¹⁵ The CDC might have spared some extra syllables by using the verb form, *sanitize*.

or chemicals on cleaned FOOD-CONTACT and NONFOOD-CONTACT SURFACES that, when evaluated for efficacy, provides a sufficient reduction of pathogens.” See VSP at Definitions 26. In other words, *at its broadest*, “sanitize” has essentially the same meaning as “disinfect” or “sterilize”. See also *WHO Regulations No. 2 International Sanitary Regulations*, *supra*. This fits well within the limitation found by recent interpretations of Section 264(a) – that the CDC has the authority “to act on specific animals or articles” *Skyworks*, 524 F. Supp. 3d at 757-58 (emphasis added). See also *Tiger Lily*, 992 F.3d at 523 (holding § 264(a) as authorizing the CDC “to sanitize and dispose of infected matter. . . .”).

Defendants’ argument that “sanitation” includes gloves, gowns, and masks also ignores important facts. Those items constitute personal protective equipment (“PPE”), which the FDA regulates as medical devices.¹⁶ While best practices hold that such garments should be maintained in a “sanitary and reliable condition,”¹⁷ Plaintiffs are unaware of any literature in which PPE items are *themselves* referred to as measures for “sanitation.”

Finally, the Mask Order *itself* lacks any finding that the wearing of masks constitutes a “sanitation” measure. The Order instead refers to masks as a method

¹⁶ <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control> (last visited February 5, 2022).

¹⁷ See OSHA Standard 1910.132(a), found at <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.132> (last visited February 7, 2022).

of “source control.” 86 Fed. Reg. at 8028. Likewise, nothing in the administrative record submitted by Defendants, ECF 30-34, refers to masking as a “sanitation” measure.¹⁸ Thus, Defendants’ reliance on the word “sanitation” in Section 264(a) appears to be little more than a *post hoc* justification for an *ultra vires* act.

C. The CDC’s Interpretation Is Not Entitled to *Chevron* Deference.

“Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.” *Nat’l Fed’n of Indep. Bus. v. OSHA, et al.*, 142 S. Ct. 661, 665 (2022). Defendants argue that, “[e]ven if the statute were ambiguous, the Court should defer to the [CDC’s] reasonable interpretation” of Section 264(a) pursuant to *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). MSJ at 16.¹⁹ Defendants’ argument in favor of *Chevron* deference fails. The statute is not ambiguous, and even if it was, the CDC’s interpretation of it is unreasonable. Alternatively, the Mask Order should be invalidated as a major rule that lacks clear Congressional authority.

¹⁸ Masks are, at times, referred to in the administrative record as one of several non-pharmaceutical interventions, or “NPIs,” which also include measures such as business and school closures. *See, e.g.*, ECF 31 at 40.

¹⁹ It appears that the CDC has abandoned the untenable assertion that the Mask Order “is not a rule within the meaning of” the APA but is rather “an emergency action. . . .” 86 Fed. Reg. 8030. Given that the Order, among other things, imposed new obligations on individuals, and moreover its contention that failure to wear a mask constitutes a violation of “federal law,” the bare assertion it is not a “rule” never had any merit. *See* 5 U.S.C. § 551(4); *Becerra*, 2021 Dist. LEXIS 114297 at *110-14 (discussing the same contention regarding the CDC’s conditional sailing order) (citations omitted).

1. The limits of Section 264(a) are clear and unambiguous.

As this Court has noted, *Chevron* deference “is not due unless a court, employing traditional tools of statutory construction, is left with an unresolved ambiguity.” *Turner v. Bristol at Tampa Rehab. & Nursing Ctr., LLC*, Case No. 8:21-cv-719, 2021 U.S. Dist. LEXIS 178062 at *21 (M.D. Fla. September 20, 2021) (citation and internal quotation marks omitted). As thoroughly discussed above, the scope of Section 264(a) is not ambiguous, but even if it was, any such ambiguity has been resolved by the Supreme Court in *AAR*: The statute authorizes the CDC to take such measures as to “prevent[] the interstate spread of disease *by identifying, isolating, and destroying the disease, itself.*” *AAR*, 141 S. Ct. at 2488. Section 264(a) confers no authority on the Government to regulate the conduct of individuals on travel conveyances, whether as a “sanitation” measure or otherwise.

Even if Section 264(a) could be regarded as facially ambiguous, “[a] statutory provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme[,] because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.” *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 321 (2014) (citation and internal quotation marks omitted). *See also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citation omitted). Reading Section 264(a) together with its neighboring subsections brings its limited scope into greater focus.

Whereas Section 264(a) relates to measures specifically directed to “animals or articles found to be . . . sources of dangerous infection to human beings” and the like, subsections (b) through (d) govern the CDC’s authority to burden individuals. As Defendants acknowledge, subsection (b) “imposes specific limits on the [CDC’s] ability to provide for the apprehension, detention, or conditional release of individuals – a power not specifically identified in subsection (a) – permitting such impositions . . . only for diseases specified by Executive Order.” MSJ at 4 (citing 42 U.S.C. § 264(b)) (internal quotation marks omitted). Subsections (c) and (d) set additional limits on the apprehension, detention, examination, or conditional release of individuals. Notably, subsection (d) limits the power to apprehend and examine persons moving from state to state to those who are “reasonably believed to be infected with a communicable disease in a qualifying stage. . . .” 42 U.S.C. § 264(d)(1). A “qualifying stage” is defined as “in a communicable stage,” or “in a precommunicable stage[] if the disease would be likely to cause a public health emergency if transmitted to other individuals.” *Id.* at § 264(d)(2)(A)-(B).

Thus, whereas Congress authorized the CDC to exercise discretion within the parameters of Section 264(a), to “prevent[] the interstate spread of disease by identifying, isolating, and destroying the disease, itself,” AAR, 141 S. Ct. at 2488, it is only through the quarantine authority of subsections (b) through (d) that

Congress has left the CDC a “gap” for imposing on the liberty of individuals. *See Chevron*, 467 U.S. at 843-44 (cited in *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001)). Said differently, the PHSA codified a limited regulatory power that is tightly focused and binary in nature: to either act on animals and articles, under Section 264(a), or to quarantine infected persons, under Section 264(b)-(d). It contains no *intermediate* authority to govern the behavior of the greater public.

The CDC’s own regulations support this conclusion. Regulations governing “Sanitary Inspection” of vessels are found under 42 CFR Part 71, Subpart E, whereas regulations governing quarantine of individuals from foreign ports are found in Subpart D. Regulations in Subpart E are clearly directed at articles and animals, such as rats, insects, the disposal of human waste, and potable water. And Section 71.32 draws clear distinctions between the agency’s foreign quarantine power over individuals, subsection (a), and the treatment of carriers, articles, or things, subsection (b). The section governing domestic quarantine under Section 264(d), 42 CFR § 70.6, is also separate from the agency’s domestic rule construing Section 264(a) which, as discussed above, is found in 42 CFR § 70.2.

Reading these provisions together shows that the CDC’s authority over persons is limited to specific circumstances. For example, had the CDC by some miracle been fortunate enough to have located and isolated COVID-19 “*Patient Zero*” in time to prevent him/her from passing the virus onto others, subsections

(b) and (c) or (d) might have been properly invoked as to that individual. But with the pandemic having already been upon the entire globe for at least a year as of the date of the Order, none of the provisions of Section 264, let alone subsection (a) (on which Defendants rely), conferred any authority upon the CDC to exercise a general police power over millions of individuals.

This answers the threshold question for *Chevron* deference, which is “whether Congress has directly spoken to the precise question at issue.” *Chevron*, 467 U.S. at 842. Congress clearly has spoken. Defendants are of course correct that Congress authorized the CDC to make binding regulations. But neither the text of Section 264, the CDC’s regulations interpreting it, nor the history of the PHSA and the federal government’s historical role in public health suggests that Congress conferred the CDC with the authority to burden every anonymous individual who boards a transportation conveyance or enters a transportation hub, whether traveling across the country or across town, and whether each such person *may or may not be* infectious. It is therefore unsurprising that the CDC has never previously claimed such sweeping authority.

2. **Even if Section 264(a) is ambiguous, the CDC's interpretation is not entitled to deference.**
 - i. **The Mask Order's interpretation of Section 264(a) is not reasonable.**

Defendants argue that “[t]he rationale underlying *Chevron* deference is that ‘ambiguities in statutes within an agency’s jurisdiction to administer are delegations of authority to the agency to fill the statutory gap in reasonable fashion. . . .’” MSJ at 17 (quoting *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005)). But deference only applies under this analysis “if the implementing agency’s construction is reasonable[.]” *Brand X*, 545 U.S. at 980 (emphasis added). The CDC’s construction of Section 264(a) is anything but reasonable.

With the stroke of a pen, the Mask Order suddenly elevated the CDC’s historical exercise of authority from discrete actions, “such as inspection and sanitation at a port of entry [and] detention for the duration of a disease’s incubation period,” *Becerra*, 2021 U.S. Dist. LEXIS 114297 at *43, to a never-before-claimed power to govern a vast part of the American economy and the public. The CDC acknowledges that, if the Order were a rule (which, Defendants now tacitly confess, it *is*), the Office of Information and Regulatory Affairs “has determined that [] it would be a major rule under the Congressional Review Act. . . .” 86 Fed. Reg. 8030. In other words, the Order would have a significant effect on the U.S.

economy. *See* 5 U.S.C. § 804(2). The Order was also found to be “an economically significant regulatory action under Executive Order 12866. . . .” 86 Fed. Reg. 8030.

“When an agency claims to discover in a long-extant statute an unheralded power to regulate a significant portion of the American economy, [the courts] typically greet its announcement with a measure of skepticism.” *EPA*, 573 U.S. at 324 (citations and internal quotation marks omitted). Thus, even if the scope of Section 264(a) was ambiguous, the CDC has given the Court ample reason to be skeptical of its claims.

On its own terms, the CDC’s interpretation places it squarely at odds with Section 264(a)’s express purpose, which is “to *prevent* the introduction, transmission, or spread of communicable diseases” into the United States or from state to state. (emphasis added). CDC cannot seriously claim that the Mask Order does anything to prevent the spread of COVID-19, whether into the United States or from state to state. The proof is in the CDC’s own data, *see* Comp. Ex. “A”, and in common sense.

The Mask Order treats every passenger as a potential vector for disease, and thus assumes that conveyances will invariably have some number of infectious passengers onboard, whether symptomatic, asymptomatic, or pre-symptomatic. *See* 86 Fed. Reg. 8028. But those passengers will eventually disembark, whether at the next bus top, subway stop, or airport. And there remains the fact that

Americans still often cross state lines in their private vehicles, on bicycles, or even on foot. A fair number of Americans even regularly commute across state lines, including many who work in our nation's capital.

All of this is aside from the fact that, by the time of the Order, COVID-19 had already spread throughout the country. Thus, no one could seriously claim that the Mask Order was going to prevent the spread of COVID-19, whether from abroad or among the states. That genie was long out of the bottle.

Tacitly recognizing this dilemma, the CDC attempts some sleight-of-hand by claiming that the Order is “to prevent the *further* introduction, transmission, or spread of COVID-19. . . .” *Id.* at 8029 (emphasis added). But it offers no metric for what “further” means.

Rather, taking its cue from the President's EO (“Promoting COVID-19 Safety in Domestic and International Travel,” 86 Fed. Reg. 7205), the CDC effectively claims authority to regulate the safety of individuals onboard any non-personal travel conveyance, anywhere in the country.²⁰ This overreach mirrors that of OSHA in *Nat'l Fed'n*, wherein the Court held that the Occupational Safety and Health Act empowered the Secretary of Labor “to set *workplace* safety standards,

²⁰ Defendants remark that Plaintiffs have not challenged the orders of the Transportation Security Administration. MSJ at 12, fn. 3. Plaintiffs are unsure of what to make of this. As Defendants surely know, this Court would lack subject matter jurisdiction over a challenge to the orders of the TSA. *See* 49 U.S.C. § 46110.

not broad public health measures.” 142 S. Ct. at 665. Similarly, Section 264(a) authorizes the CDC to carry out certain limited measures to protect the public health, not to regulate transportation safety. To conclude otherwise is to suggest that Congress hid an elephant in the mousehole of Section 264(a). *See Whitman v. Am Trucking Ass’ns*, 531 U.S. 457, 468 (2001).

The “lack of historical precedent” for the Mask Order, “coupled with the breadth of authority that the [CDC] now claims, is a telling indication that the [Mask Order] extends beyond the agency’s legitimate reach.” *Nat’l Fed’n*, 142 S. Ct. at 666. The CDC’s interpretation of Section 264(a) is unreasonable and not entitled to deference under *Chevron*.

ii. The CDC failed to provide notice-and-comment.

As addressed *infra*, Part III, the CDC improperly refused to provide notice and allow for comments as required by Section 553(b) of the APA. Regardless of whether this was justifiable under the APA, the lack of notice-and-comment bears on the *Chevron* analysis.

The notice-and-comment procedures of the APA are “designed to assure due deliberation” when an agency promulgates rules having the force of law. *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 741 (1996). And while the failure to provide notice-and-comment “does not automatically deprive [an agency’s] interpretation of” *Chevron* deference, *Barnhart v. Walton*, 535 U.S. 212, 222 (2002),

notice-and-comment are “significant . . . in pointing to *Chevron* authority[.]” *Mead*, 533 U.S. at 230-31. Defendants point to these cases in arguing that the Order must still be accorded *Chevron* deference. MSJ at 18 fn. 7.

But both *Barnhart* and *Mead* are distinguishable. In *Mead*, the Court found that *Chevron* did not apply to classification rulings by U.S. Customs, as those rulings were not intended to have the force of law over third parties. *Id.* at 231-33. It followed that “Customs [did] not generally engage in notice-and-comment practice when issuing” classification rulings. *Id.* at 233. In *Barnhart*, the agency interpretation at issue was found to be “one of long standing.” 535 U.S. at 221.

The contrast with this case could not be more stark: The Mask Order constitutes a radical departure from the CDC’s statutory and historical purview, binding every individual who steps onboard a bus, train, or airplane, or enters a travel hub. The only precedents for this sweeping power grab are also of *COVID-era* vintage – its overreaching eviction moratorium addressed in *AAR* and its conditional sailing order addressed in *Becerra*, both of which were found to be unlawful. Thus, the CDC’s failure to provide notice-and-comment strongly indicates that the Mask Order is not entitled to *Chevron* deference.

3. The Order should be invalidated under the “major rules” doctrine.

The courts of the United States “expect Congress to speak clearly if it wishes to assign to an agency decision of vast economic and political significance.” *Util. Air*, 573 U.S. at 374 (citations and internal quotation marks omitted). *See also Brown & Williamson*, 529 U.S. at 159 (noting that “[i]n extraordinary cases, . . . there may be reason to hesitate before concluding that Congress has intended [] an implicit delegation” of agency authority). Justice Kavanaugh, while on the D.C. Circuit, synthesized a series of Supreme Court decisions in which Court had invalidated extraordinary agency actions that lacked express Congressional authorization. *See United States Telecom Ass’n v. FCC*, 855 F.3d 381, 417-21 (D.C. Cir. 2017) (Kavanaugh, C.J., dissenting) (listing examples of decisions). These decisions point to an exception to *Chevron* that has come to be known as the major rules doctrine.²¹

As noted above, the CDC admits that the Mask Order is a “major rule,” having significant effects on the U.S. economy. *See* 86 Fed. Reg. 8030; 5 U.S.C. § 804(2). Moreover, the CDC’s interpretation of Section 264(a) is unreasonable. If,

²¹ As articulated by Justice Kavanaugh, “[t]he major rules doctrine helps preserve the separation of powers and operates as a vital check on expansive and aggressive assertions of executive authority.” *Id.* at 417.

as Defendants contend, Section 264(a) is ambiguous, then the Mask Order lacks Congressional authorization and, as it is a major rule, it must be deemed invalid.

Because the CDC has exceeded its statutory authority, because its interpretation of Section § 264(a) is not entitled to deference, and/or because the Mask Order constitutes a major rule that is not authorized by Congress, Plaintiffs ask that the Court enter an order holding the Mask Order as unlawful and setting it aside, pursuant to 5 U.S.C. § 706(2)(C).

III. The Mask Order Violates The APA's Requirement For Notice And Comment (Count II).

A. The CDC Failed to Show Good Cause for Not Providing Notice and Comment.

As noted above, Defendants make no effort to defend the CDC's original claim that the Mask Order "is not a rule within the meaning of the" APA. 86 Fed. Reg. 8030. And by the CDC's admission, if the Mask Order is a rule then it is "a major rule" as defined in the Congressional Review Act. *Id.* The APA thus obligated the CDC to treat the Order as a rule and provide for notice-and-comment under 5 U.S.C. § 553(b).

Defendants claim that the CDC properly invoked the "good cause" exception of Section 553(b)(B) when promulgating the Order. MSJ at 29-30. But Defendants' argument here is rather circular. They assert that the Mask Order properly concluded that good cause existed to dispense with prior public notice

and comment because, “*considering the public health emergency caused by COVID-19,*” any delay “would be impracticable and contrary to the public’s health. . . .” MSJ at 30 (quoting 86 Fed. Reg. 8030) (internal quotation marks omitted). However, rather than defend the CDC’s claim of a “public health emergency,” in response to Plaintiffs’ allegations that no emergency existed Defendants argue that there is no need for an emergency to invoke the “good cause” exception. MSJ at 30 (citing *United States v. Dean*, 604 F.3d 1275, 1281 (11th Cir. 2010)).

It thus appears that the CDC has abandoned the very reason for “good cause” cited in its Order – i.e., that a “public health emergency” existed. And if the CDC no longer relies on that assertion, then it is difficult to see how it complied with Section 553(b)(B) when it dispensed with notice-and-comment.

Defendants’ *post hoc* rationale undermines their reliance on *Dean*. In that case, the Attorney General of the United States never cited an “emergency” as the basis for dispensing with notice-and-comment. Rather, the A.G. published a detailed finding that the new rule “provid[ed] guidance to eliminate uncertainty” regarding the obligations of sex offenders under a newly-enacted statute, and “prevent[ed] delay in registration of sex offenders. . . .” 604 F.3d at 1279; *see also* 72 Fed. Reg. 8894, 8895-97. While acknowledging that the good cause exception “should be read narrowly,” the court found the A.G.’s detailed reasoning under the circumstances to be persuasive. *Dean*, 604 F.3d at 1280-81.

Even if the CDC could cure its failure to show good cause in the Order, itself, there is no basis to believe that such grounds existed at the time. Whether “good cause” exists depends on “the facts and context of each instance[.]” *Becerra*, 2021 U.S. Dist. LEXIS at *124. In *Becerra*, the court noted that the CDC lacked good cause to forego notice-and-comment regarding its conditional sailing order because, by October 2020, the COVID-19 pandemic was no longer new. *Id.* at *125. This was just as true in late January 2021, when according to the CDC’s own data cases were rapidly declining. *See* Comp. Ex. “A”.

Moreover, “[g]ood cause cannot arise as a result of the agency’s own delay[.]” *Nat. Res. Def. Council v. Nat’l Highway Traf. Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018); *Kollett v. Harris*, 619 F.2d 134, 145 (1st Cir. 1980). Here, the CDC waited almost a year before promulgating the Mask Order, and only then in response to an EO from the newly-sworn President. Thus, any “good cause” was the result of the CDC’s own delay.

B. The Failure to Allow Notice and Comment Was Not Harmless.

Defendants argue that, in the alternative, the failure to provide notice-and-comment was harmless error because Plaintiffs cannot show that remand would change the outcome. MSJ at 31. This overstates Plaintiffs’ burden.

In determining whether a procedural error under the APA was harmless, courts have distinguished between a mere “technical failure” to comply, or

“substantial compliance,” and a “complete failure” to comply. *Mid Continent Nail Corp. v. United States*, 846 F.3d 1364, 1383 (Fed. Cir. 2017) (internal quotation marks and citation omitted). The error here clearly falls into the latter category. In such cases, “the total absence of notice-and-comment rulemaking and the resulting thin or nonexistent record make it difficult for a reviewing court to conclude with certainty that no prejudice has ensued.” *Id.* (citation omitted). Thus, “even a minimal showing of prejudice may suffice to defeat a claim of harmless error.” *Id.* “Courts, then, should be hesitant to conclude that complete failure to comply with § 553’s requirements is harmless.” *United States v. Reynolds*, 710 F.3d 498, 518 (3d Cir. 2013).

Defendants’ argument that the CDC would likely reach the same conclusion cannot be supported. Leaving aside questions about the efficacy of masks, for example, the CDC’s consideration of the administrative record was entirely one-sided. Not one study in the record addressed the harms caused by wearing masks for hours on end. *See, e.g.*, Am. Cmpl’t. at ¶¶34-35, 37. Such harms must be considered in the balance.

Public attitudes are also rapidly changing. As of this writing, the Omicron wave is coming to a rapid end, hospitalizations are plummeting,²² and around the

²² See <https://covid.cdc.gov/covid-data-tracker/#hospitalizations> (last visited February 14, 2022).

country (and the world) we have witnessed a preference cascade in which state and local governments have announced an end to mask mandates²³ and other mandates, such as vaccine passports.²⁴ Governors are “leaving a cautious White House behind” on mask mandates, and are “hiking pressure on top government health officials to codify an Omicron endgame.”²⁵ Defendant Walensky has signaled that changes are coming.²⁶

Meanwhile, no less than three major airline executives have said that masks on airplanes do not add much, if anything, to the effect of HEPA filters.²⁷ And, according to reports, even “the CDC is considering a new benchmark for whether masks are needed[.]”²⁸ In other words, it appears that the time is ripe for a more deliberate consideration of the matter.

Accordingly, Plaintiffs ask that the Court hold the Mask Order as unlawful and set it aside as having been enacted “without observance of procedure required by law,” pursuant to 5 U.S.C. § 706(2)(D).

²³ See <https://abcnews.go.com/Health/dozen-states-move-end-masking-mandates-covid-19/story?id=82806903> (last visited February 17, 2022);

²⁴ See <https://theweek.com/coronavirus/1009986/new-york-to-lift-mask-or-vaccine-requirement-for-indoor-businesses> (last visited February 17, 2022).

²⁵ See <https://www.cnn.com/2022/02/08/politics/democratic-governors-school-masking-biden-white-house/index.html> (last visited February 17, 2022).

²⁶ See <https://www.nj.com/coronavirus/2022/02/crisis-over-more-covid-rules-fall-as-cdc-hints-at-better-times-ahead.html> (last visited February 17, 2022).

²⁷ See <https://www.foxbusiness.com/politics/southwest-ceo-masks-dont-add-much-if-anything-against-covid-19-on-planes> (last visited February 17, 2022).

²⁸ <https://www.nbcnews.com/health/health-news/cdc-masks-cdc-expected-update-mask-guidance-early-week-rcna16331> (last visited on February 16, 2022).

IV. The Mask Order Is Arbitrary And Capricious (Count III).

A. The CDC Violated Its Own Regulation.

While a court reviewing agency action under the arbitrary and capricious standard should normally give great deference to an agency's decision, "courts *must* overturn agency actions which do not scrupulously follow the regulations and procedures promulgated by the agency, itself." *Sierra Club v. Martin*, 168 F.3d 1, 4 (11th Cir. 1999) (emphasis added). That leaves no room for doubt.

Here, the CDC's regulation under Section 264(a) requires a determination from the CDC "that the measures taken by health authorities of any State or possession . . . are insufficient to prevent the spread of any of the communicable diseases" from state to state. 42 CFR § 70.2. The Mask Order contains no such determination, but instead recites a broad statement:

Any state or territory without sufficient mask-wearing requirements for transportation systems within its jurisdiction has not taken adequate measures to prevent the spread of COVID-19 from such state or territory to any other state or territory. That determination is based on, *inter alia*, the rapid and continuing transmission of the virus across all states and territories and across most of the world.

86 Fed. Reg. 8029.

Defendants assert that this is sufficient. MSJ at 19-20. On the contrary, it amounts to exactly the same broad, circular reasoning that the court found

wanting in *Becerra*. In that case, the CDC had premised its conditional sailing order under Section 70.2 on a determination “that state and local measures are ‘inadequate’ because ‘cruise ships by their very nature travel interstate and internationally. . . .’” *Becerra*, 2021 U.S. Dist. LEXIS 114297 at *119. The court found that this “global dismissal of state and local health measures fails to offer the type of reasoned finding required by Section 70.2,” and said “absolutely nothing evaluative about any ‘measure taken by health authorities of any state.’” *Id.* The court thus concluded that the conditional sailing order was arbitrary and capricious. *Id.* at *120-21.

The result here should be no different. The Order’s “determination” amounts to little more than a conclusory, “global dismissal” of state measures. The Order also lacks any express finding as to what would constitute “sufficient mask-wearing requirements for transportation systems,” or which states and localities lack such requirements. The Order also provides no metrics for: (1) what, in the CDC’s judgement, constitutes “rapid and continuing” spread of the virus;²⁹ and (2) how to determine when the CDC’s intervention would no longer, in the CDC’s view, be necessary.

²⁹ According to the CDC’s own COVID Data Tracker website, infections were already declining in the U.S. when the Order came into effect. See Comp. Ex. “A”.

B. The Mask Order Is Not Reasonable.

While the “reasonable and reasonably explained” standard under the APA is deferential, “the standard of review is not toothless: The court must ensure that the agency’s action – and the agency’s explanation for that action – falls within a zone of reasonableness.” *Multicultural Media Telecom & Internet Council v. FCC*, 873 F.3d 932, 937 (D.C. Cir. 2017). For the reasons set forth in Part III.C.2.i, *supra*, the Mask Order is not a reasonable interpretation of Section 264(a). *Multicultural Media*, 873 F.3d at 937. It is therefore arbitrary and capricious.

In addition, the CDC relied on an administrative record that: (1) is devoid of any controlled study showing that masks have any effect on the spread of the SARS-Cov-2 virus; (2) fails to separate cause from correlation; (3) fails to account for numerous variables; and (4) fails to consider any countervailing harms. Page limits do not allow for a full accounting, but for example: The study entitled “Face Masks Considerably Reduce COVID-19 Cases in Germany: A Synthetic Control Approach,” ECF 30 at 55, claims that after masks were introduced in the city of Jena, Germany, on April 6, 2020, “the number of new infections fell almost to zero.” *Id.* at 56. This not only fails to account for variables such as other non-pharmaceutical interventions and voluntary changes in behavior, it ignores the fact that cases had already started decreasing across Germany from April 2, 2020. *See* Exhibit “D”. It is a classic example of *post hoc, ergo propter hoc*. The Arizona

schools study, ECF 31 at 14, also failed to account for numerous variables.³⁰ As one public health economist remarked, “You can’t learn anything about the effects of school mask mandates from this study.”³¹

The CDC also failed to consider any countervailing harms resulting from extended mask-wearing, on adults and children. *See* Am. Cmplt. at ¶¶34-35, 37 & fn. 1, 3.³² It failed to consider whether requiring millions of untrained laymen to don a medical device might be counterproductive (according to the WHO, “[u]sing a mask incorrectly [] may actually increase the risk of transmission[.]”).³³ Finally, the CDC provides no metric by which to determine how and when this ends. Thus, the CDC “entirely failed to consider [] important aspect[s] of the problem[.]” *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Plaintiffs therefore ask that the Court hold the Mask Order as arbitrary and capricious and set it aside as unlawful, pursuant to 5 U.S.C. § 706(2)(A).

³⁰ See <https://www.theatlantic.com/science/archive/2021/12/mask-guidelines-cdc-walensky/621035/> (last viewed on February 15, 2022).

³¹ *Id.*

³² Defendants take Plaintiffs to task for addressing the Order’s age exemption of two years. MSJ at 23-24. Defendants miss the point of that allegation; Plaintiffs do not allege that they are children, but that the utter failure to consider harm to children, and the failure to articulate grounds for that arbitrary cut-off age (it leaves one to wonder whether anyone at the CDC has ever had children), point to the arbitrary and capricious nature of the rule. Am. Cmplt. ¶79.

³³ World Health Organization, “Advice on the use of masks in the community setting in Influenza A (H1N1) outbreaks,” May 3, 2009, available at [https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-setting-in-influenza-a-\(h1n1\)-outbreaks](https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-setting-in-influenza-a-(h1n1)-outbreaks).

V. If Section 264(a) Is As Broad As Defendants Claim, It Violates The Nondelegation Doctrine (Count IV).

The U.S. Constitution enumerates the limited powers of Congress while reserving a general police power to the States. *See United States v. Lopez*, 514 U.S. 549, 566-68 (1995). The question raised by Count IV of Plaintiffs' Amended Complaint is not, as Defendants frame it, whether Section 264(a) is facially overbroad or vague. MSJ at 32-33. Plaintiffs have not made that claim. Rather, the question is whether the statute gives the CDC the sort of broad, unfettered discretion that Defendants *claim* it does and, if so, whether Congress, consistent with its enumerated powers under Article I, provided an "intelligible principle to guide the [CDC's] use of [that] discretion." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019).³⁴

Defendants are correct that the Supreme Court has not invalidated a statute on nondelegation grounds since 1935. *See id.* at 2129. But there are reasons to believe that a majority of the current Justices would be likely to revive the doctrine, given an appropriate case.

Gundy rejected the petitioner's nondelegation argument, but it was only by a plurality opinion. Justice Alito concurred in the judgment, but noted that he

³⁴ The *Gundy* Court considered the same Sex Offender Registration and Notification Act ("SORNA") as the Eleventh Circuit in *Dean, supra*, but on nondelegation rather than APA grounds.

would support an effort to revisit the nondelegation doctrine. *Id.* at 2130-31. Justice Gorsuch wrote a lengthy dissenting opinion, in which the Chief Justice and Justice Thomas joined, explaining why, in his view, SORNA's delegation of authority to the Attorney General for creating policy on retroactive application was unconstitutional. *Id.* at 2131-48.

Justice Kavanaugh took no part in the decision. However, in a separate dissent in *Paul v. United States*, 140 S. Ct. 342 (2019), he signaled some sympathy for revisiting the nondelegation doctrine. Of course, Justice Ginsberg has been replaced by Justice Barrett, who also seems open to reconsidering nondelegation. *See* Barrett, Amy Coney, *Suspension and Delegation*, Cornell Law Rev., Vol. 99, No. 2 (Feb. 5, 2014). That adds up to six current Justices of the Supreme Court who at least appear open to revisiting the nondelegation doctrine.

Similar to its position in both *AAR* and *Becerra*, the CDC offers no limiting principle for its claim to authority under Section 264(a). *See AAR*, 141 S. Ct. at 2489 (noting that "the Government's read of § [264(a)] would give the CDC a breathtaking amount of authority."); *Becerra*, 2021 U.S. Dist. LEXIS 114297 at *82-88. By the CDC's reasoning, it could require, for example, that every passenger who boards a conveyance or enters a travel hub, anywhere in the country, be vaccinated. That would not only give the CDC broad authority to legislate; it would patently usurp a general police power of the States. *See Brnovich v. Biden*,

Case No. 21-cv-1568, __ F. Supp. 3d __, 2022 U.S. Dist. LEXIS 15137, *65-66 (D. Ariz. Jan. 7, 2022) (discussing authorities).

Thus, if the statute in fact does have the broad sweep that Defendants claim it does, then 42 U.S.C. § 264(a) is void as an unconstitutional delegation of legislative authority. See *Becerra*, 2021 U.S. Dist. LEXIS 114297, *89-109 (discussing history of the nondelegation doctrine and concluding that, if Section 264(a) means what the CDC claims, “the statute goes too far.”).

CONCLUSION

Based on the foregoing points and authorities, Plaintiffs respectfully ask that the Court deny Defendants’ Motion for Summary Judgment, ECF 45, and grant this, their Cross-Motion for Summary Judgment, holding the Mask Order as unlawful and setting it aside pursuant to 5 U.S.C. § 706(2)(A), (C), and/or (D), or, in the alternative, holding that 42 U.S.C. § 264(a) is an unconstitutional delegation of legislative authority, and that the Court grant such further relief as it deems just.

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