No. 22-11287

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

HEALTH FREEDOM DEFENSE FUND, INC., *et al*.,

Plaintiffs-Appellees,

v.

JOSEPH R. BIDEN, JR., President of the United States, *et al*.,

Defendants-Appellants.

On Appeal from the United States District Court
for the Middle District of Florida

ANSWER BRIEF OF APPELLEES

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1(a)(3), counsel for Plaintiffs-Appellees certify that the following persons have an interest in the outcome of this appeal:

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STATEMENT REGARDING ORAL ARGUMENT

Appellees rely on the Court's discretion as to whether to hold oral argument.

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INTRODUCTION

Up until the time of the COVID-19 pandemic, the Centers for Disease Control ("CDC") was mainly known for providing advice, guidance, and assistance to state and local governments on matters of public health. Aside from the occasional, discrete enforcement of quarantine at ports of entry to the United States, it had never claimed any authority to directly govern the life or conduct of any person, let alone the entire population.

That ended in 2020 when CDC began to take extraordinary measures that were completely unprecedented in scope. First, CDC imposed its nationwide Temporary Halt in Rental Evictions (the "eviction moratorium"), 85 Fed. Reg. 55,292 (Sept. 4, 2020), then later a Conditional Sailing Order that indefinitely shut down the entire cruise industry. 85 Fed. Reg. 70,153 (Nov. 4, 2020). Both were stunning usurpations of legislative authority and state police power. But, at least arguably, both governed property interests. For the first full year of the pandemic, CDC still took no steps to cross the Rubicon of directly ruling over the lives of untold millions of healthy individuals.

Meanwhile, presidential candidate Joseph R. Biden acknowledged that, as President, he would lack authority to institute a nationwide mask requirement, but promised that, if elected, he would "use the bully pulpit of the presidency to urge"

the states and local governments to impose mask mandates.[1] Nevertheless, on his first full day in office President Biden ordered CDC and other agencies to require masks on conveyances and in transportation hubs. 86 Fed. Reg. 7205. In response, and without publishing a notice of proposed rulemaking or allowing for comments, CDC dutifully crossed the Rubicon—claiming the power to directly rule over our lives—by enacting the Mask Order. 86 Fed. Reg. 8025 (Feb. 3, 2021).

As authority for the Mask Order, CDC relied (as it had for the eviction moratorium and sailing order) on the broadly-worded first sentence of § 361(a) of the Public Health Service Act of 1944 ("PHSA"), which provides that 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." PHSA § 361(a), encoded at 42 U.S.C. § 264(a). That might have seemed plausible to some, but then courts began to push back against CDC's claim of authority under § 361(a).

The judicial pushback culminated in the Supreme Court's decision striking down the eviction moratorium as unlawful in *Alabama Ass'n of Realtors v. Dep't of*

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[1] *See* https://abcnews.go.com/Politics/wireStory/latest-biden-game-person-debate-safe-73432288 (last viewed on July 7, 2022).

Health and Human Svc's, 141 S. Ct. 2485 (2021) (per curiam) ("*AAR*").[2] In *AAR*, the Court held that the second sentence of § 361(a) "informs the grant of authority [in the first sentence] by illustrating the kinds of measures that could be necessary: inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles"—measures that "directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself." 141 S. Ct. at 2488.

This turnabout left CDC with the unenviable task of trying to shoe-horn the broad authority it had claimed for the Mask Order into one of the measures enumerated in the second sentence of § 361(a). Seizing on the word "sanitation," CDC argued in its Motion for Summary Judgment below, as it argues here, that the Mask Order is a "sanitation" measure within the meaning of § 361(a)'s second sentence. The district court properly rejected this post-hoc rationale. Dkt. 53 at 11-31.

First, unlike the measures enumerated in the second sentence of § 361(a) the Mask Order does nothing to directly target COVID-19 by "identifying, isolating, and

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[2] CDC's Conditional Sailing Order was struck down by the Middle District of Florida in *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021), *motion for stay denied*, Case No. 21-12243-D (11th Cir. July 23, 2021), *appeal dismissed* (January 19, 2022).

destroying the disease itself." *AAR*, 141 S. Ct. at 2488. It applies universally to every healthy individual who enters a transportation hub or sets foot on an airplane, bus, subway, or taxi. CDC's post-hoc reliance on "sanitation" is also unavailing because it is clear from the words that surround it, as well as § 361(a)'s neighboring subsections (b)—(d), that "sanitation" refers to active measures towards property. CDC would have the Court divorce "sanitation" from its statutory context, giving the word a meaning so broad that it would effectively nullify the entire second sentence of § 361(a). This would, in turn, render the decision in *AAR* superfluous, as almost any "public health" measure could be justified by the word "sanitation."

CDC's interpretation of "sanitation" could be used, for example, to authorize measures such as requirements for diet, exercise, and good hygiene, vaccination mandates, or even the mandatory use of prophylactics to prevent the spread of venereal disease. The district court thus properly scrutinized CDC's argument regarding the power conferred by § 361(a) under the major questions doctrine.

The Mask Order is also procedurally invalid. CDC failed to allow notice-and-comment based on the conclusory invocation of a "public health emergency," one full year after the state of emergency had been declared. This was a patently insufficient showing of good cause, and lacked anything approaching the detailed

findings and reasoning that the Supreme Court approved in *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam).

The Mask Order is also arbitrary and capricious. CDC utterly failed to explain its line-drawing choices, ignored its own data on the known harms of long-term mask-wearing, and failed to heed its own rule for promulgating interstate regulations, 42 CFR § 70.2. The Order is substantively arbitrary and capricious because CDC never had any evidence that requiring tens of millions of laymen to don a medical device, without doing anything to actually identify sick individuals, was ever going to prevent the interstate spread of COVID-19. Indeed, the Mask Order *was not even designed* to achieve § 361(a)'s purpose of preventing the spread of COVID into the United States or from state to state. And CDC's own data shows that it in fact *did not do so*.

The district court's remedy of vacatur was also proper, as the Administrative Procedure Act specifically provides for that remedy, and CDC never objected to Plaintiff Health Freedom Defense Fund, Inc. ("Health Freedom") seeking such relief on behalf of its members.

Finally, in the alternative, in the unlikely event that the Court should conclude that § 361(a) is as broad as CDC *claims* it is, then § 361(a) is invalid as an unconstitutional delegation of legislative authority.

STATEMENT OF THE ISSUES

1. Whether the district court correctly found that the Mask Order exceeded CDC's statutory authority under § 361(a) of the PHSA when it issued a completely unprecedented rule governing the conduct of every person who enters a transportation hub or boards a non-private conveyance, anywhere in the country.

2. Whether the district court correctly found that the Mask Order was procedurally invalid because CDC declined to provide for notice-and-comment by invoking a "public health emergency" that had already been pending for a full year.

3. Whether the district court correctly found that the Mask Order was arbitrary and capricious, where CDC failed to explain its line-drawing choices, failed to adhere to its own regulation, and where the Mask Order would do nothing to prevent the interstate spread of COVID-19.

4. Whether the district court correctly granted the relief of vacatur under the Administrative Procedure Act.

5. Whether, in the alternative, § 361(a) as interpreted by CDC violates the non-delegation doctrine.

STATEMENT OF THE CASE

I. The Mask Order.

On January 31, 2020, then-Secretary of Health and Human Services Alex Azar declared a public health state of emergency, retroactive to January 27, 2020, in relation to the COVID-19 pandemic.[3]

On January 26, 2021, President Biden issued Executive Order 13998 (the "EO") (86 Fed. Reg. 7205), in which he directed, *inter alia*, the Secretary of 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*.

Approximately one week later, CDC published the Mask Order under review, making it effective February 1, 2021. 86 Fed. Reg. 8025 (Feb. 3, 2021). The Mask Order extends not just to aircraft but to "any conveyance (e.g., airplanes, trains, subways, buses, taxis, ride-shares, ferries, ships, trolleys, and cable cars) into or within the United States," as well as "any transportation hub within the United States." *Id*. at 8026.

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[3] *See* https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx (last viewed on July 1, 2022).

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*. 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).[4]

Even though the public health emergency had been declared a year before, CDC claimed that there was good cause to forgo notice-and-comment because, "[c]onsidering 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" the Mask Order. *Id*. at 8030.[5]

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[4] CDC admitted below that not a single passenger was penalized for the mere failure to wear a mask on an aircraft. *See* Dkt. 41 at ¶51. Rather, the Federal Aviation Administration enforced pre-existing law and regulations against disruptive passengers for interfering with or assaulting a flight crew. *Id*. *See* 49 U.S.C. § 46318 and 14 CFR §§ 91.11, 121.580, 125.328, 135.210. Despite having been directed to do so in the President's EO, 86 Fed. Reg. 7205, the FAA never promulgated its own rule requiring masks.

[5] CDC initially claimed that the Mask Order was exempt from notice-and-comment because it was not actually a "rule" under the APA but an emergency

II. Proceedings Below

Plaintiffs/Appellees (hereinafter, "Plaintiffs") filed suit on July 12, 2021. Dkt. 1. After Defendants/Appellants (hereinafter, "CDC") appeared in the case, the parties agreed for Plaintiffs to file an Amended Complaint and for the case to proceed to summary judgment based on the administrative record. Dkt. 27, 28, 30-34, 36, 38. Plaintiffs filed their Amended Complaint on December 13, 2021, Dkt. 39, which CDC answered on January 6, 2022. Dkt. 41. The Amended Complaint included declarations by members of Plaintiff Health Freedom. Dkt. 39-4. CDC never objected to Health Freedom's associational standing to seek relief on behalf of its members under the APA.

Per their agreed schedule, the parties filed cross-motions for summary judgment and cross-reply briefs. Dkt. 45, 48, 50, and 51. In support of their cross-motion for summary judgment, Plaintiffs incorporated the previously-filed Health Freedom member declarations (Dkt. 39-4) and added declarations by the individual Plaintiffs, Ana Carolina Daza and Sarah Pope. Dkt. 48-2, 48-3.

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action taken under existing authority. 86 Fed. Reg. at 8030. CDC made no effort to defend that claim, below.

After receiving the parties' cross-motions and reply briefs, the district court granted summary judgment to Plaintiffs, and denied CDC's motion for summary judgment, on April 18, 2022. Dkt. 53.

SUMMARY OF ARGUMENT

I.A. The district court correctly held that CDC lacked statutory authority for the mask order under § 361(a). Heeding the Supreme Court's opinion in *AAR*, the district court correctly found that CDC's post-hoc reliance on the word "sanitation" in the second sentence of § 361(a) was unjustified because the Mask Order did not directly target COVID-19 by identifying, isolating, and destroying it. CDC would have the Court lift "sanitation" from its statutory context and define it in a manner so broad that it would subsume and nullify the other words of the statute; indeed, it would nullify the entire second sentence of § 361(a) and render the Court's decision in *AAR* superfluous. Also, when read in context with its neighboring subsections, § 361(a) clearly governs property, not individuals.

B. CDC's sudden finding of a previously unheralded power of such vast economic and political consequence, buried in a 77-year old statute, also justified the district court's application of the major questions doctrine. Section 361(a) has historically been seen as ancillary to CDC's quarantine authority under subsections (b)—(d). It has never been used to govern individuals, let alone untold millions of

individuals, regardless of whether they are infected with a particular pathogen. CDC's interpretation of "sanitation" in § 361(a) would bestow the agency with a breathtaking power, one that could be used to justify a limitless authority to regulate any matter that arguably relates to public health. Section 361(a) is a wafer-thin reed on which to rest such a sweeping claim.

II. CDC enacted the Mask Order without providing for notice-and-comment, and its claim of good cause was limited to a single, conclusory sentence that, already a year into the pandemic, invoked "the public health emergency caused by COVID-19[.]" The district court correctly held that this conclusory statement was insufficient. The emergency had long-since passed, and CDC could not invoke good cause merely because it had delayed taking action for a whole year.

III.A. The district court also correctly found that the Mask Order is arbitrary and capricious because CDC failed to offer an explanation for its line-drawing decisions and choices.

B. Regardless of what one believes about the efficacy of masks to block a virus, community-wide mask mandates have not worked, and even on its own terms the Mask Order can do nothing to prevent the interstate spread of COVID-19. Thus, the Mask Order is substantively unreasonable.

C. Alternatively, the district court's holding can be affirmed on grounds that CDC failed to heed its own regulation when promulgating the Order.

IV. The district court's remedy of vacatur was proper. CDC never objected to Plaintiff Health Freedom Defense Fund, Inc. ("Health Freedom") seeking relief on behalf of its members to have the Mask Order set aside under the Administrative Procedure Act ("APA"). Unlike injunctive relief, vacatur is statutorily authorized, and under this Court's precedent it is regarded as the ordinary APA remedy.

V. Finally, although the district court did not reach the issue, this Court may alternatively affirm on grounds that § 361(a), as construed by CDC, violates the nondelegation doctrine.

ARGUMENT

I. THE DISTRICT COURT CORRECTLY FOUND THAT CDC LACKED STATUTORY AUTHORITY FOR THE MASK ORDER

CDC premises its statutory authority for the Mask Order on § 361(a) of the PHSA, which provides that 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 [its] judgment may be necessary.

42 U.S.C. § 264(a).[6]

The parties agree that construing the scope of § 361(a) is largely governed by the decision in *AAR*, wherein the Court held that CDC's nationwide rental eviction moratorium exceeded CDC's authority under the statute. 141 S. Ct. at 2488-89. The Court found two reasons for rejecting CDC's broad interpretation of its authority under that statute. First, unlike the measures specified in § 361(a)—inspection, fumigation, disinfection, sanitation, etc.—the moratorium did not "direct[ly] target[]" COVID by "identifying, isolating, and destroying" it. *AAR*, 141 S. Ct. at 2488. Second, "[e]ven if the text were ambiguous," under the major questions doctrine "the sheer scope of CDC's claimed authority under § 361(a) would counsel against the Government's interpretation." *Id*. at 2489. CDC's "claim of expansive authority under § 361(a) [wa]s unprecedented" because no prior rule issued under § 361(a) "ha[d] even begun to approach the size or scope" of the moratorium. *Id*. The Court concluded that Congress had not enacted the "exceedingly clear language" required for significantly altering "the balance between federal and state

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[6] Except when referring to its encoded version (42 U.S.C. § 264), Plaintiffs will refer to the statute herein as § 361.

power and the power of the Government over private property," and that § 361(a) was too "wafer-thin" a "reed on which to rest such sweeping power." *Id*.

The district court correctly applied the Court's reasoning in *AAR* to find that the Mask Order exceeds CDC's authority under § 361(a). First, the Mask Order is unlike the measures enumerated in the second sentence of § 361(a) in that it does not directly target disease by identifying, isolating, and destroying it. As a consequence, and because § 361(a) applies to property, the district court correctly rejected CDC's post-hoc invocation of the word, "sanitation". Dkt. 53 at 11-31.

Second, even if the statute was ambiguous, the major questions doctrine counsels against deferring to CDC's interpretation. Dkt. 53 at 26-30. Like the eviction moratorium in *AAR*, the Mask Order is completely unprecedented and far exceeds the scope of any prior claim of authority under § 361(a) (indeed, the Mask Order itself admits to being a "major rule"). *Id*. The district court thus correctly found the government's interpretation of § 361(a) to be untenable because courts "expect Congress to speak clearly" when assigning decisions "of vast economic and political significance" to an administrative agency." Dkt. 53 at 26 (citing *AAR*, 141 S. Ct. at 2489).

A. The District Court Correctly Held That The Mask Order Is Not Authorized By § 361(a).

1. The Mask Order Does Not Identify, Isolate, or Destroy COVID-19.

In *AAR*, CDC argued that the first sentence of § 361(a) gave it "broad authority to take whatever measures it deems necessary to control the spread of COVID-19, including issuing the moratorium." *AAR*, 141 S. Ct. at 2488. But the Court held that the second sentence of § 361(a) "informs the grant of authority [in the first sentence] by illustrating the kinds of measures that could be necessary: inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles." *Id.* The Court observed that "[t]hese measures directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself." *Id.* In contrast, the connection between the eviction moratorium and the spread of COVID was "markedly different from the *direct targeting* of disease that characterizes the measures identified in the statute." *Id.* (emphasis added).

Like the eviction moratorium, the Mask Order does not operate like the measures specified in the second sentence of § 361(a). As the district court put it, "What these [specified measures] have in common [] is that they involve identifying and eliminating known sources of disease." Dkt. 53 at 16; *see also id.* at 19 ("[T]he

federal government's use of the quarantine power has been traditionally limited to localized disease elimination measures applied to individuals and objects suspected of carrying disease."). In short, the measures in § 361(a) contemplate targeted, localized *processes* to (1) *identify* a communicable disease in order to (2) *isolate* it, with the ultimate goal of (3) *destroying* it.

The Mask Order does nothing to *identify* who has COVID as a step toward isolating and treating them. It is instead an entirely generic measure that, if allowed to stand, could become an enduring feature of domestic and international travel—and perhaps other commercial activities—by U.S. residents.[7]

Like the eviction moratorium, the Mask Order is not targeted, much less directly targeted, at the disease that supposedly justifies it. It applies to virtually all travelers, whether or not they have, or are even likely to have, COVID. 86 Fed. Reg. at 8029. It applies on virtually all non-private conveyances, like school buses, metros, and taxis, whether or not their passengers are infected. *Id.* at 8026. It applies at all transportation hubs—including open-air marinas, seaports, and bus terminals—whether or not they pose particular risks of infection. *Id*. As the district

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[7] *See* Paulina Villegas, *Fauci Says Wearing Masks Could Become Seasonal Following the Pandemic*, Wash. Post, May 9, 2021, https://www.washingtonpost.com/health/2021/05/09/fauci-covid-masks-seasonal-pandemic/.

court determined, the Mask Order is the opposite of targeted—it is universal. Dkt. 53 at 19, 30.

CDC argues, however, that masks "*isolate* the disease itself by trapping viral particles exhaled by infected travelers and preventing non-infected travelers from inhaling viral particles." Init. Br. 1, 5, 10, 13, and 18 (quoting *AAR*, 141 S. Ct. at 2488) (emphasis added). Among other flaws, this argument ignores that requiring all travelers to wear masks does nothing to identify who has COVID and nothing to prevent infected persons from moving from one state or territory into another. Thus, the Mask Order is no more directly targeted at COVID than was the moratorium struck down in *AAR*. On that ground alone, *AAR* requires the Mask Order to be found outside CDC's authority under § 361(a).

2. The District Court Properly Rejected CDC's Post-Hoc Claim That Masking Passengers Is the Type of "Sanitation" Measure Contemplated by § 361(a).

The decision in *AAR* presented CDC with a dilemma: Because CDC apparently relied solely on § 361(a)'s broadly-worded first sentence as authority for the Mask Order, nothing in the Mask Order itself, or in the administrative record (Dkt. 30-34), referred to masking as being equivalent to "sanitation" or any other measure enumerated in the second sentence of § 361(a). Indeed, where "sanitation"

was mentioned at all in the studies relied upon by CDC, it was clearly distinguished as a separate measure from masks.[8]

The holding in *AAR*—that the second sentence of § 361(a) "informs the grant of authority [in the first sentence] by illustrating the kinds of measures that could be necessary: inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles," 141 S. Ct. 2488—led CDC to argue that the Mask Order is a "sanitation" measure within the meaning of § 361(a)'s second sentence. Dkt. 45 at 13-16; Init. Br. 13. After engaging in a thorough statutory analysis, the district court rejected CDC's post-hoc rationale.[9] Dkt. 53 at 11-31.

a. CDC has waived *Chevron* deference.

As a threshold matter, CDC has abandoned its contention, raised below, that its interpretation of "sanitation" in § 361(a) is entitled to *Chevron*[10] deference, and

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[8] *See, e.g.*, 86 Fed. Reg. at 8028 fn. 19 (citing Gallaway, et al., *Trends in COVID-19 Incidence After Implementation of Mitigation Measures*, MMWR Morb Mortal Wkly Rep., 2020 Oct 9; 69(40): 1460-1463), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7561223/.

[9] Contrary to CDC's assertions (Init. Br. 10, 13), the district never acknowledged that masking is a "conventional" or "paradigmatic" sanitation measure. The district court simply said that "sanitation" as used in the PHSA could have referred to measures that "preserve the cleanliness of something," and that this meaning "would appear to cover" the Mask Order. Dkt No. 53 at 13. But the district court ultimately rejected that interpretation.

[10] *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Dkt. 45 at 16-18; Dkt. 50 at 8-12.

for good reason: A post-hoc rationale cannot support an agency's interpretation of a statute under the second prong of *Chevron*. *See America's Cmty. Bankers v. F.D.I.C.*, 200 F.3d 822, 835 (D.C. Cir. 2000). CDC's abandonment of its argument for *Chevron* deference means that the argument is waived. *See HollyFrontier Cheyenne Ref., LLC v. Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2180 (2021). Thus, this Court should apply regular canons of statutory construction rather than defer to CDC's post-hoc reliance on "sanitation." *See Villareal v. R.J. Reynolds Tobacco Co.*, 839 F.3d 958, 970 (11th Cir. 2016).[11]

b. The district correctly rejected CDC's definition of the word "sanitation" in § 361(a).

Because the PHSA provides no definition of the word "sanitation," the district court correctly noted that the word should be given its ordinary meaning at the time that the statute was enacted. Dkt. 53 at 12 (citing *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 566 (2012)). However, because the district court concluded that "sanitation" was susceptible to interpretation as either an active measure or a preventative measure, its meaning in § 361(a) required reading the word in context

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[11] In fact, this Court need not even consider CDC's belated invocation of "sanitation" at all, as "judicial review of agency action is limited to the grounds that the agency invoked when it took the action." *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (citation and internal quotation marks omitted).

with the rest of the statute. Dkt. 53 at 12-14 (citing, *inter alia*, *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299, 1307-08 (11th Cir. 2021)). In doing so, the district court properly looked to a number of decisions, in addition to *AAR*, in which the Supreme Court applied the doctrine of *noscitur a sociis* to clarify the meaning of words that were otherwise susceptible of more than one meaning. Dkt. 53 at 15-16. *See United States v. Williams*, 553 U.S. 285, 294 (2008) (noting that a word that is "susceptible of multiple and wide-ranging meanings [] is given more precise content by the neighboring words with which it is associated.") (citations omitted); *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 466 (2001) (same); *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36 (1990) ("[W]ords grouped in a list should be given related meaning.") (citation omitted); *Deal v. United States*, 508 U.S. 129, 132 (1993) (noting "that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used.").

Thus, the precise meaning of "sanitation" in § 361(a) must be informed by the words that surround it—"inspection, fumigation, disinfection, [] pest extermination, [and] destruction." Dkt. 53 at 16 (citing *Williams*, 553 U.S. at 294). "What these words have in common," the district correctly concluded, "is that they involve identifying and eliminating known sources of disease" by "chang[ing] an object's status." *Id*. "More specifically, they involve the '*direct targeting* of disease,' *AAR*,

141 S. Ct. at 2488 (emphasis added), through 'a discrete action.'" *Id*. (citing *Becerra*, 544 F. Supp. 3d at 1264). With this conclusion, the district court placed the meaning of "sanitation" squarely within the holding of *AAR*.

By contrast, CDC would divorce the word "sanitation" from its statutory context and define it broadly as "[t]he devising and applying of measures for preserving and promoting public health." Init. Br. 14 (internal quotation marks omitted). *Accord* Public Health Law Experts' ("PHLE") Amicus Brief 24 (defining "sanitation" to mean "[p]ertaining to the public health"). The district court correctly rejected such a broad definition because it renders superfluous the other measures specified in § 361(a)—i.e., "inspection, fumigation, disinfection, sanitation, pest extermination, [and] destruction of animals or articles found to be so infected"—as surplusage. Dkt. 53 18-19 (citing *United States v. Butler*, 297 U.S. 1, 65 (1936)).

Contrary to CDC's contention (Init. Br. 18), adopting its broad definition does not merely create "overlap" between "sanitation" and the other measures specified in § 361(a); it would cause the term "sanitation" to swallow up the other specified measures, rendering it "impossible to give effect 'to every clause and word of [the] statute.'" Dkt. 53 at 18 (quoting *Moskal v. United States*, 498 U.S. 103, 109-10 (1990)). That would be patently contrary to the directive that "[c]ourts 'avoid ascribing to one word a meaning so broad that it is inconsistent with its

accompanying words.'" *Id*. (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)).

Indeed, the glaring problem with CDC's reliance on widely-varying dictionary definitions of "sanitation" (as well as that of Amicus PHLE), without any reference to statutory context, is that *it offers no limiting principle*. For example, the proposed definitions of "sanitation" offered by Amicus PHLE include: "Devising and applying of measures for preserving and promoting public health; removal or neutralization of elements injurious to health; practical application of sanitary science;" "Pertaining to the public health;" and "Regulations intended to prevent the spread of communicable disease." PHLE Br. 23-24. Worse than usurping the other measures enumerated in the second sentence of § 361(a) ("inspection, fumigation, disinfection," etc.), any one of these broad definitions of "sanitation" would render that entire second sentence a nullity. This, in turn, would render the Supreme Court's labor in *AAR* superfluous.

By CDC's definition, "[e]very act necessary to prevent disease spread would be possible under sanitation." Dkt. 53 at 18. The district thus properly rejected CDC's post-hoc justification for the Mask Order.

c. The district court correctly found that the measures in § 361(a) govern property.

Beyond the commonality between the words in the second sentence of § 361(a), the district court also considered the relationship between subsection (a) and its neighboring subsections, (b)—(d), as further evidence of the statute's intended scope. Dkt. 53 at 20 (citing *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132-33 (2000) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.") (internal quotation marks and citation omitted)). A review of those neighboring subsections correctly led the district court to conclude that "subsection (a)[] gives CDC power to directly impose on an individual's *property* interests," whereas subsections (b) through (d) authorize CDC "to directly impose on an individual's *liberty* interests" through its limited quarantine powers. Dkt. 53 at 20.

As the district court observed, the words in subsection (a) "are not commonly used to described what one does to a person," but are instead "tied to 'specific, tangible things on which the agency may act.'" Dkt. 53 at 21 (citing *Skyworks, Ltd. v. CDC*, 524 F. Supp. 3d 745, 758 (N.D. Ohio 2021)). Indeed, that fact that those tangible things must be "found to be [] sources of dangerous infection *to* human

beings," 42 U.S.C. § 264(a) (emphasis added), strongly indicates that such "sources of dangerous infection" do not include *other* human beings.

The distinction between subsections (a) and (b)—(d) is reflected in CDC's pre-COVID regulatory scheme under § 361. Regulations governing Sanitary Inspection under 42 CFR Part 71, Subpart E, are directed at articles and animals, such as rats, insects, the disposal of human waste, and potable water, whereas regulations governing quarantine of individuals from foreign ports are found in Subpart D. And § 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 § 361(d), 42 CFR § 70.6, is also separate from the agency's domestic rule construing § 361(a), which is found at 42 CFR § 70.2.

The district court thus correctly found that the measures enumerated in the second sentence of § 361(a) apply to property—*animals, articles, or things*—not people. Dkt. 53 at 20-25. Other courts, including the dissent in *AAR*, have reached this same conclusion. *See AAR*, 141 S. Ct. at 2491 (Breyer, J., dissenting) (interpreting the measures in § 361(a)'s second sentence as authorizing CDC "to *act* on *personal property* when necessary.") (emphasis added); *Tiger Lily, LLC v. U.S. Dep't of Hous. & Urb. Dev. (Tiger Lily I)*, 992 F.3d 518, 522-23 (6th Cir. 2021)

(distinguishing between "property interests," under § 361(a), and "liberty interests," under subsection (d), and concluding that subsection (a) only authorizes "government intrusions on property to sanitize and dispose of infected matter.")[12] (cited Dkt. 53 at 20). *See also Ala Ass'n of Realtors v. U.S. Dep't of Health and Hum. Servs.*, 539 F. Supp. 3d 29, 38-39, 42 (D.D.C. 2021) (Friedrich, J.) (same); *Becerra*, 544 F. Supp. 3d at 1270 (concluding that § 361(a) "allows the regulation only of an infected or infecting item.").

d. CDC's citations to various FDA and other regulations fail to rebut the district court's analysis.

CDC points to *Louisiana v. Matthews*, 427 F. Supp. 174 (E.D. La. 1977) as support for its claim that "sanitation" can include preventative measures,[13] but that decision stands for no broader a proposition than that § 361(a) has been cited by the

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[12] CDC argues that the Sixth Circuit did not embrace this property-liberty distinction in its merits decision in *Tiger Lily, LLC v. U.S. Dep't of Hous. & Urb. Dev. (Tiger Lily II)*, 5 F.4th 666 (6th Cir. 2021). Init. Br. 18. But the *Tiger Lily II* court clearly pointed out that if the first sentence of § 361(a) "really did grant the Secretary plenary authority to impose any regulation he thought necessary[,] there would be no need to specifically authorize the apprehension and detention of infected individuals in [42 U.S.C.] § 264(d), or the inspection and fumigation of contaminated properties in § 264(a)." 5 F.4th at 671. This was simply another way of saying the same thing it had said in *Tiger Lily I*.

[13] Contrary to CDC's bald assertion, the district court in the present case did not cite *Matthews* "with approval," Init. Br. 16, but simply acknowledged it as a historical fact. Dkt. 53 at 29.

FDA to justify interstate quarantine of animals—i.e., *property*—that are suspected of harboring disease-causing pathogens.[14] More fundamentally, it is doubtful that *Matthews* remains good law. The *Matthews* court described the FDA's authority under § 361(a) as "broad," without any discussion of the limiting language in the statute's second sentence. *See* 427 F. Supp. at 176. This broad interpretation of the statute was tacitly overruled by the Court in *AAR*.

CDC also claims that "many CDC and FDA measures issued pursuant to § 361(a) are preventative in nature." Inti. Br. at 16. But its cited regulations concern property interests, not individuals. The FDA regulations cited by CDC under Title 21 CFR Parts 1240, 1250 and 1271, for example, govern food safety on conveyances, which concerns property.[15] Other FDA regulations cited by CDC, as justifying "preventative" measures, likewise govern animals, articles, things, or other property. Init. Br. 16 (citing 21 CFR parts 118 (eggs), 606 (blood), and 630 (blood components)).

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[14] The same can be said of CDC's reliance on an FDA regulation intended to control the spread of monkeypox by restricting the sale and transport of certain animals. Init. Br. 17 (citing 68 Fed. Reg. 62,353 (Nov. 4, 2003)).

[15] And, of course, food safety falls squarely within the FDA's statutory remit. *See* 21 U.S.C. § 393(b)(2)(A) (directing the FDA to, *inter alia*, "protect the public health by ensuring that [] *foods* are *safe*, wholesome, [and] *sanitary*[.]") (emphasis added).

The Mask Order also differs from the "prevention measures" enumerated in 42 CFR § 70.10 which, far from imposing a blanket measure on every individual traveler, are designed to identify sick people who may require isolation under § 361(d). *AAR, supra*. CDC's reliance on this regulation (Init. Br. 16) is therefore misplaced, and in fact underscores one of the district court's criticisms of the Mask Order, itself. *See* Dkt. 53 at 48 (noting CDC's failure to address alternatives to masking "such as testing [and] temperature checks").

But even assuming *arguendo* that "sanitation" or "other" measures under § 361(a) could include measures to *keep* a particular place or a particular thing clean (as well as to *make* it clean)—that would not justify CDC's position that § 361(a) authorizes it to keep all "shared airspaces" clean. Init. Br. 15. And even assuming *arguendo* that measures such as "inspection" and "sanitation" could be applied to people as well as property, that would not justify population-wide measures, like the Mask Order, that do nothing to identify, isolate, or eliminate communicable diseases. *AAR, supra*.

B. The "Breathtaking" And "Unprecedented" Scope Of The Mask Order Mandates Scrutiny Under The Major Questions Doctrine.

Despite having waived *Chevron* deference,[16] CDC objects to the district court's conclusion that the Mask Order raises concerns under what it disparages as the "*so-called* 'major questions doctrine.'" Init. Br. 19-20 (emphasis added). But the major questions doctrine is no mythological creature. It is real and it has teeth. *See West Virginia v. EPA*, 597 U.S. __, Case No. 20-1530 (June 30, 2022), Slip Op. revised (July 13, 2022).

The Court in *AAR* made reference to the major questions doctrine when it set aside the eviction moratorium, partly because the moratorium's "sheer scope" was "unprecedented" under § 361. *AAR*, 141 S. Ct. at 2489. "Since [§ 361's] enactment in 1944," the Court observed, "no regulation premised on it has even begun to approach the size or scope of the eviction moratorium." *Id.* CDC's interpretation of the reach of § 361(a) would give it "a breathtaking amount of authority," making it hard to see what measures would be placed outside the agency's reach. *Id*. "Section 361(a)," the Court concluded, "is a wafer-thin reed on which to rest such sweeping power." *Id*.

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[16] *See supra*, Part I.A.2.a.

CDC's claim of authority in this case is no less sweeping and unprecedented. Like the eviction moratorium in *AAR*, and the EPA's Clean Power Plan Rule addressed in *West Virginia*, 597 U.S. __, the mask mandate is orders of magnitude removed from prior regulations under § 361(a), which has historically been invoked "to implement measures that support or facilitate the exercise of the agency's quarantine or isolation authority" under subsections (b)—(d). Wen W. Shen, R46758, Scope of CDC Authority Under § 361 of the Public Health Services Act (PHSA) 12-13 (Apr. 13, 2021). Regulations under § 361 were "generally limited to quarantining infected individuals and prohibiting the import or sale of animals known to transmit disease." *AAR*, 141 S. Ct. at 2487; *see also* Dkt. 53 at 19 ("[T]he federal government's use of the quarantine power has been traditionally limited to localized disease elimination measures applied to individuals and objects suspected of carrying disease."); 58 Stat. 703 (locating § 361 in Title III, part G of the Public Health Services Act, entitled "Quarantine and Inspection"); 11 Fed. Reg. 9389 (1946) (Notice issued by Public Health Service of Federal Security Agency of intent to issue "Interstate Quarantine Regulations" under § 361); 12 Fed. Reg. 3189 (1947) (publishing final rules implementing § 361 as Part 12 of 42 CFR, entitled "Interstate Quarantine"); 42 CFR at 5977 (1947 Supp.) (initial regulations implementing § 361 codified in Part 72, entitled "Interstate Quarantine").

The Mask Order simply bears no resemblance to these quarantine and isolation regulations; it is an entirely different beast.[17] *See Becerra*, 544 F. Supp. 3d at 1269 (noting that "the federal government's role in quarantine regulation throughout American history [] confirms CDC's historically limited application of inspection, sanitation, and isolation."). Thus, as in *AAR*, CDC's "claim of authority" in this case "is unprecedented." *AAR*, 141 S. Ct. at 2489. And here, as in *AAR*, its unprecedented nature "counsels against" accepting CDC's claim of a newly-unearthed power under a long-extant statute. *Id.*

The district court thus properly cited the major questions doctrine as a reason not to defer to CDC's post-hoc interpretation of "sanitation" in § 361(a). Dkt. 53 at 26-30. Like the eviction moratorium in *AAR*, the district court found CDC's interpretation of § 361(a) *vis a vis* the Mask Order "untenable because courts 'expect Congress to speak clearly' if it assigns decisions 'of vast economic and political

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[17] *Cf.* CDC Newsroom, CDC Issues Federal Quarantine Order to Repatriated U.S. Citizens at March Air Reserve Base (Jan. 31, 2020) (announcing individual quarantine orders against 195 U.S. citizens who repatriated to U.S. from Wuhan, People's Republic of China, on Jan. 29, 2020), https://www.cdc.gov/media/releases/2020/s0131-federal-quarantine-march-air-reserve-base.html#:~:text=The%20Centers%20for%20Disease%20Control,U.S.%20on%20January%2029%2C%202020.

significance' to an administrative agency." Dkt. 53 at 26 (citing *AAR*, 141 S. Ct. at 2489).

CDC can hardly disclaim the Mask Order's "vast economic and political significance." *AAR*, 141 S. Ct. at 2489. As noted by the district court, CDC itself classified the Mask Order as a "major rule" under the Congressional Review Act. *See* 86 Fed. Reg. at 8030; 5 U.S.C. § 804(2) (defining "major rule" in relevant part as one likely to have either an annual effect of $100 million or more on the economy, a major increase in consumer prices, or significant adverse effects on the economy). CDC also designated the Order a "significant regulatory action under Executive Order 12,866." 86 Fed. Reg. at 8030; *see also* Exec. Order 12,866, § 3(f) (defining "significant regulatory action"). On this point, the district court simply took CDC at its word. Dkt. 53 at 28.

The Mask Order's economic significance becomes clear when one considers the explosion of worldwide demand for masks, including in the United States, since the COVID pandemic started,[18] and the Mask Order's applicability to virtually all

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[18] Organisation for Economic Co-operation and Development (OECD), *The face mask global value chain in the COVID-19 outbreak: Evidence and policy lessons*, May 4, 2020 (estimating global demand for face masks in January 2020 at 240 million masks per day just "to equip health, manufacturing, and transport workers"), https://www.oecd.org/coronavirus/policy-responses/the-face-mask-global-value-

U.S. travelers, even those travelling solely intrastate, or even intracity via bus, taxi, or metro. 86 Fed. Reg. at 8029. Yes, travelers can be given "free" or inexpensive masks—a circumstance that leads CDC to describe the mandate as imposing "negligible (if any)" burdens on the traveler. Init. Br. 19 (internal quotation marks omitted). But *somebody* pays for the tens of millions of masks required by the Mask Order while other countries make billions of dollars producing them.[19]

Politically, mask mandates have been the focus of intense, often emotional national debate from the start of the COVID pandemic.[20] Indeed, the question of whether the federal government could or should impose some sort of nationwide mask mandate was a topic of political debate during the 2020 election campaign.[21] After the election, the transition team for the incoming administration disclaimed

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chain-in-the-COVID-19-outbreak-evidence-and-policy-lessons-a4df866d/#back-boxnote-d1e71

[19] *See generally* Karen M. Sutter et al., Cong. Res. Serv. R46304, *COVID-19: China Medical Supply Chains and Broader Trade Issues* (updated Dec. 23, 2020).

[20] *See, e.g.*, Valerie Castro, *School mask mandates spark debate across country*, CNBC, July 8, 2021, https://www.youtube.com/watch?v=AmaFffsfk-Q.

[21] *See, e.g.*, Cheryl Stolberg, *Biden's Call for 'National Mask Mandate' Gains Traction in Public Health Circles*, Oct. 29, 2020, https://www.nytimes.com/2020/10/29/us/politics/trump-biden-mask-mandate.html.

any authority to issue a nationwide mandate, saying instead that the President-elect would try to persuade state and local officials to mandate masks.[22]

The President thus issued the EO, and CDC promulgated the Mask Order, without any mandate to do so from the electorate, much less any authorization from Congress. And while Plaintiffs abhor disruptive behavior onboard any conveyance, the lack of a broad consensus for the Mask Order might have been a factor in some of the "air rage" incidents related to its enforcement.[23] It was certainly unsurprising that the district court's lifting of the Mask Order led to a flood of celebratory videos on social media.[24]

Thus, CDC cannot conceal the Mask Order's political significance by calling it "conventional" and "modest." Init. Br. 1, 10, 12, 14. An agency action of such

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[22] *See* Grace Hauck, *Biden Wants Mask Mandates Nationwide, But He Can't Actually Enforce Them. Here's What He Should Do Instead*, USA Today, Nov. 11, 2020, https://www.usatoday.com/story/news/nation/2020/11/11/joe-biden-national-face-mask-mandate-covid/6233249002/

[23] *See, e.g.*, Lindsey Roeschke, *How 'Air Rage' Is Impacting the Travel Industry*, Morning Consult, Dec. 9, 2021, https://morningconsult.com/2021/12/09/how-air-rage-is-impacting-the-travel-industry/.

[24] *E.g.*, Gerrard Kaonga, *Passengers Rejoice in Viral Videos as Airlines Ditch Mask Mandate*, Newsweek, Apr. 19, 2022, https://www.newsweek.com/airlines-ditch-mask-mandate-passengers-airplane-coronavirus-1698851.

sweeping impact on the lives of millions must require more than a single word, lifted from its statutory context.

The definition of "sanitation" offered by CDC—the "applying of measures for preserving and promoting the public health"—would bestow a "breathtaking" power on the agency. Dkt. 53 at 27. Such a power could be used to justify all kinds of measures geared towards the public health, of which the district court aptly named a few, such as mandatory vaccinations, requirements for businesses to install filtration systems, "mandatory social distancing, coughing into elbows, and daily multivitamins." *Id*. But why stop there? Perhaps CDC could, as a "sanitation" measure, mandate the use of condoms—or maybe it *should* simply declare a moratorium on all intimate human contact—until it gets the monkeypox outbreak under control.[25]

Worse still would be the power to choose from the veritable menu of broad definitions offered by Amicus PHLE. PHLE Br. 23-24. Such a power would allow future administrations to capriciously bend the meaning and scope of § 361(a) to their will, opening the floodgates to "pen-and-phone regulations as substitutes for

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[25] *See* Ariel Cohen, *Doctors warn U.S. monkeypox response is lagging*, Roll Call, July 14, 2022, https://rollcall.com/2022/07/14/doctors-warn-us-monkeypox-response-is-lagging/. *See also Becerra*, 544 F. Supp. 3d at 1280-81.

laws passed by the people's representatives." *West Virginia*, 597 U.S. at __ (Gorsuch, J., concurring). The resulting regulatory instability would turn *Chevron* on its ear.[26]

Thus, with the Mask Order "[t]he government purports 'to discover' [an] 'unheralded power to regulate' how individuals appear and behave in public 'in a long-extant statute'—one over seventy years old," a kind of discovery that courts greet with "a measure of skepticism." Dkt. 53 at 29 (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). CDC has not just vastly exceeded its traditional role of discretely enforcing quarantine at major ports of entry to the United States; it has assumed "a power over public health that 'was traditionally understood—and still is understood—as a function of state police power." Dkt. 53 at 29 (citing *Becerra*, 544 F. Supp. 3d at 1263-64).[27] The word "sanitation" in §361(a) "is a wafer-thin reed on which to rest such sweeping power." *AAR*, 141 S. Ct. at 2489.

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[26] An unfortunate legacy of *Chevron's* deferential standard towards agency rulemaking is its tacit encouragement for successive administrations to adopt hyper-partisan, and even polar-opposite, interpretations of statutes, leading to even greater regulatory instability than that which the *Chevron* Court had sought to avoid. *See* Richard J. Pierce, *The Combination of Chevron and Political Polarity Has Awful Effects*, 70 DUKE L.J. __, (2021), https://dlj.law.duke.edu/2021/01/chevron-and-polarity/.

[27] Consistent with this view, Amicus for Appellants Lawrence Gostin (PHLE Br. at C-5) was quoted as saying, "A national mandate is not possible because public health powers belong to the states, not the federal government," and, "The federal

When implementing a major rule such as the Mask Order, "something more than a merely plausible textual basis for agency action" is necessary to uphold the agency's statutory authority for the action. *West Virginia*, 597 U.S. at __, Slip Op. at 19. "The agency instead must point to clear congressional authorization for the power it claims." *Id*. CDC has failed to point to any such clear authorization in § 361(a). The district court's well-reasoned opinion must therefore be affirmed.

II. THE MASK ORDER IS PROCEDURALLY INVALID

The APA's "good cause" exception to notice-and-comment[28] "is to be 'narrowly construed and only reluctantly countenanced.'" Dkt. 53 at 33 (citing, *inter alia*, *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012)). It applies only "in emergency situations" or "where delay could result in serious harm." Dkt. 53 at 33-34 (citing *United States v. Dean*, 604 F.3d 1275, 1281 (11th Cir. 2010)).

CDC's statement of good cause in the Mask Order consisted of a single sentence: "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 [the] Order." 86 Fed. Reg. at 8030

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government couldn't implement its own mask orders, nor could it force the states to do it." Hauck, *supra* fn. 22.

[28] *See* 5 U.S.C. § 553(b)(B).

(emphasis added). The district court correctly found that this "single conclusory sentence" failed to carry CDC's burden. Dkt. 53 at 35-43.

As CDC admitted below, HHS had declared a public health emergency almost exactly one year prior to the date of the Mask Order. Dkt. 41 at ¶74. The district court also noted that, according to CDC data, "COVID-19 case numbers were decreasing" at the time that the Mask Order was promulgated. Dkt. 53 at 38 (citing Dkt. 48-1 at 2). Thus, whatever "emergency" existed in early 2020 had long passed by early 2021. *See Becerra*, 544 F. Supp. 3d at 1296 (finding that by October 2020 the public health threat from COVID-19 was no longer sufficient grounds for "good cause" to avoid notice-and-comment for CDC's highly consequential sailing order); *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 611-12 (5th Cir. 2021) (finding the OSHA ETS mandate's "stated impetus—a purported 'emergency' that the entire globe has now endured for nearly two years"—to be unavailing).

CDC understandably made no effort below to defend its conclusory recitation of a "public health emergency,"[29] and makes no such effort here. Instead, CDC raises a completely new argument in this case—that the Mask Order's substantive findings

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[29] CDC argued below that there was no need for an emergency to invoke "good cause," but never adequately explained how its conclusory "finding" of good cause otherwise satisfied the requirement of the APA. *See* Dkt. 45 at 30.

sufficed to show good cause. Init. Br. at 24-25 (citing *Wall v. CDC*, No. 6:21-cv-975, 2022 U.S. Dist. LEXIS 93556 (M.D. Fla. Apr. 29, 2022), *appeal pending*, No. 22-11532 (11th Cir.)).

CDC's reliance on the lifeline thrown to it in *Wall* at least tacitly concedes the inadequacy of its conclusory "good cause" sentence. However, as previously noted, "judicial review of agency action is limited to the grounds that the agency invoked when it took the action." *Regents of the Univ. of Cal.*, 140 S. Ct. at 1907 (internal quotation marks and citation omitted). Thus, neither CDC nor this Court may rely on grounds that were not included in the agency's statement of good cause.

This latter point bares the flaw in CDC's reliance on *Biden v. Missouri*, 142 S. Ct. 647. Init. Br. 25-27. As the district court correctly found, CDC's "terse conclusion contrast[ed] markedly with" the nearly four pages of findings of good cause (supported by forty footnotes) in the CMS mandate addressed by the Court in *Missouri*. Dkt. 53 at 36-37 (discussing 86 Fed. Reg. 61555, 61583-86 (Nov. 5, 2021)). These findings, which were clearly signaled by a discrete heading,[30] included, for example, observations such as a perceived shortfall in voluntary vaccine uptake, staffing shortages, the coming influenza season, and an estimated

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[30] *See* 86 Fed. Reg. at 61583 ("**III. Waiver of Proposed Rulemaking**").

human cost in lives from any delay. 86 Fed. Reg. at 61583-86; Dkt. 53 at 37 (citing *Florida v. HHS*, 19 F.4th 1271, 1289-90 (11th Cir. 2021)).

Furthermore, the CMS rule was published as an interim final rule and thus allowed for comments. 86 Fed. Reg. at 61555-56. This helped persuade the majority in *Missouri* that the CMS rule was procedurally valid. 142 S. Ct. at 654. Here, by contrast, CDC allowed no public input at all.

But even if CDC could rely on its substantive findings in the body of the Mask Order itself as justification for waiving notice-and-comment, "[g]ood cause cannot arise as a result of the agency's own delay[.]" *Nat. Res. Def. Council v. Nat'l Hwy. Traf. Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018). The district court thoroughly explained why CDC's one-year delay in issuing the Mask Order undermined its claim that allowing for notice-and-comment was not in the public interest. Dkt. 53 at 38-40.

CDC contends that the district court's reasoning "echoes" an argument rejected by the Supreme Court in *Missouri*. Init. Br. at 39. However, CMS explained its delay in issuing the vaccination mandate by pointing out that it had initially chosen "to encourage rather than mandate vaccination," but that "vaccine uptake among health care staff [had] not been as robust as hoped for[.]" 86 Fed. Reg. at 61583. CMS also acknowledged that voluntary uptake might have been inhibited by

the fact that no COVID vaccine was licensed prior to August 23, 2021. 86 Fed. Reg. at 61584.[31] CDC offered no similar justification for having bided its time.

CDC's "terse conclusion" of good cause fares no better when compared to this Court's decision in *Dean*, 604 F.3d 1275. In that case, the U.S. Attorney General was charged with enforcing a newly-enacted statute governing registration of sex offenders, for which non-compliance carried increased criminal penalties over existing law. *Id*. at 1282. Unlike CDC, the Attorney General published the rule as an interim rule, allowing thirty days for public comments. 72 Fed. Reg. 8894, 8896. Among its detailed reasons for good cause, the Attorney General found that the new rule "provid[ed] guidance to eliminate uncertainty" regarding the obligations of sex offenders under the statute, and "prevent[ed] delay in registration of sex offenders[.]" *Id*. at 1279; *see also* 72 Fed. Reg. at 8896-97. While acknowledging

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[31] Under federal law, a person being offered an unlicensed product under an emergency use authorization must be advised of, *inter alia*, his or her option to refuse administration of the product. *See* 21 U.S.C. § 360bbb-3(e)(1)(A). CMS took the position that this was no barrier to mandating vaccination. *See* 86 Fed. Reg. at 61583. But a government mandate requiring administration of an EUA product would have faced difficult legal challenges. *See Doe v. Rumsfeld I*, 297 F. Supp. 2d 119 (D.D.C. 2003); *Doe v. Rumsfeld II*, 341 F. Supp. 2d 1 (D.D.C. 2004).

that the good cause exception "should be read narrowly," the majority found the Attorney General's detailed reasoning persuasive. 604 F.3d at 1280-81.[32]

Because CDC failed to show good cause for avoiding notice-and-comment under the APA, the judgment of the district court should be affirmed.[33]

III. THE MASK ORDER IS ARBITRARY AND CAPRICIOUS

A. The District Court Correctly Held That The Mask Order Is Not Reasonably Explained.

Although 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). As well, "judicial review of agency action is limited to the grounds that the agency invoked when it took the action." *Regents of the Univ. of Cal.*, 140 S. Ct. at 1907. The district court correctly found that, because CDC made hardly any effort, and in many respects no effort at all, to explain its

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[32] While concurring in the result, Judge Wilson disagreed that the Attorney General had shown good cause. *See* 604 F.3d at 1282-83. *See also United States v. Reynolds*, 710 F.3d 498, 509 (3d Cir. 2013) (noting circuit split).

[33] CDC does not address the district court's rejection of its argument that the failure to allow notice-and-comment was harmless error. Dkt. 53 at 43-46. That argument is therefore waived. *See Mlakovich v. Uscic - Orlando*, 500 Fed. Appx. 873, 875 and n. 1 (11th Cir. 2012) (citation omitted).

choices or its line-drawing decisions, the Mask Order fails the reasonably explained standard for agency action. Dkt. 53 at 46-53.

For example, the Mask 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. Dkt. 53 at 48.

CDC argues that the district court "disregarded the agency's explanation that '[s]ocial distancing may be difficult if not impossible'" onboard conveyances. Init. Br. 23. But a conveyance is only crowded if you fail to limit occupancy. If the Mask Order really is about the "preservation of human life" (86 Fed. Reg. at 8027) (*which, one would assume, means that the choices being made are truly matters of life or death*), and not about reassuring the public that it is safe to board a crowded conveyance or about reassuring airlines that they may sell enough tickets for flights to be commercially viable, CDC should have explained its reasoning.

CDC also failed to consider the harms inflicted by extended mask-wearing. Many healthcare workers—who are trained in the use of masks—have experienced

adverse effects from prolonged mask use during the COVID-19 pandemic.[34] In its own Niosh Science Blog, CDC acknowledges that healthcare workers experience significant increases in blood CO2 after one hour of using an N95 respirator mask, and that this CO2 toxicity results in adverse physical symptoms that can only be relieved by removing the mask (and some facilities even administer oxygen).[35] Despite this knowledge, CDC endorses the use of N95s by untold millions of laymen as fulfilling the requirements of the Mask Order (86 Fed. Reg. 8027, fn. 6) without so much as a mention of their known adverse effects (much less a warning to consumers), or why CDC discounted those effects.

The district court also correctly found that the Mask Order does not actually require "universal masking," which it claims to endorse, but has a number of unexplained exemptions. Dkt. 53 at 49. Consider CDC's citation to *Why Doctors*

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[34] *See* Priya, et al, *Adverse Effects of Prolonged Mask Use among Healthcare Professionals during COVID-19,* Jnl. of Infectious Diseases and Epidemiology, Oct. 8, 2021, available at https://clinmedjournals.org/articles/jide/journal-of-infectious-diseases-and-epidemiology-jide-6-130.php?jid=jide. *See also* Robin-Jenya Wilcha, *Does Wearing a Face Mask During the COVID-19 Pandemic Increase the Incidence of Dermatological Conditions in Healthcare Workers?* Narrative Literature Review (National Library of Medicine) (finding considerable health consequences to the skin from long-term use of PPE), available at https://pubmed.ncbi.nlm.nih.gov/34028470/.

[35] *See* Williams, et al, *The Physiological Burden of Prolonged PPE Use on Healthcare Workers during Long Shifts*, CDC Niosh Science Blog, June 10, 2020, available at https://blogs.cdc.gov/niosh-science-blog/2020/06/10/ppe-burden/.

Wear Masks, Yale Medicine (Sept. 1, 2020). Init. Br. 14. Unlike most of us, doctors are trained in how to select and use masks, they do not hang them from one ear or stuff them in a pocket or purse between uses,[36] and do not take off their masks in the middle of a procedure to eat or drink. If CDC genuinely believes that mask use in a medical setting can be extrapolated to the traveling public, it should explain why the Mask Order allows conduct that would never be permitted in a medical facility.

Another example is CDC's arbitrary choice to exempt "a child under the age of 2 years[.]" 86 Fed. Reg. at 8027. Among other omissions, CDC failed to explain why it ignored WHO guidance on masking children—that "[c]hildren aged up to five years should not wear masks for source control," and that "[f]or children between six and 11 years of age, a risk-based approach should be applied to the decision to use a mask[.]"[37] CDC even acknowledged that mask exemptions for children in various U.S. jurisdictions "range in cutoff age from 2 to 12[.]" 86 Fed. Reg. at 8029, fn. 29. But CDC made no effort to explain why it chose a cutoff age

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36 *See* https://youtu.be/M_Ca2ay7cB0 (last viewed on July 26, 2022).

37 WHO, *Mask use in the context of COVID-19, Interim Guidance*, Dec. 1, 2020, available at https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak (last downloaded on July 18, 2022).

of 2 instead of some other age.[38] Moreover, the district court correctly noted that CDC offered no explanation as to why a 2-year-old did not present the same risk of transmission or infection as an adult. Dkt. 53 at 49.

CDC takes the district court to task for pointing out that the agency failed to consider things like temperature checks, claiming that masking is "less disruptive." Init. Br. 22. But touchless temperature screening kiosks,[39] which could have easily been erected at TSA checkpoints, have been widely used since the COVID outbreak. CDC should have at least explained why such a non-invasive screening would have been more disruptive than requiring everyone to wear a face-covering for hours[40] while it did nothing at all to identify ill passengers.

For these and other reasons (all aptly noted by the district court), CDC failed to "articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choices made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks and

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[38] It leaves one to wonder whether anyone at CDC has ever cared for a 2-year-old.

[39] *See, e.g.*, https://www.meridiankiosks.com/solutions/temperature-screening-kiosk/.

[40] CDC admitted below that the total duration of time in which passengers can be expected to wear masks includes the flight itself, which for a transcontinental flight is at least 5 hours, plus check-in time, security screening, and luggage retrieval. Dkt. 41 at ¶34. That is not accounting for layovers.

citation omitted). Dkt. 53 at 49-50. The district court's judgment should therefore be affirmed.

B. The Mask Order Is Substantively Unreasonable.

The district court declined to consider Plaintiffs' argument that the Mask Order was substantively unreasonable. Dkt. 53 at 47. However, this Court may affirm summary judgment "on any ground raised below and supported by the record." *Wilson v. Warden*, 834 F.3d 1227, 1237 (11th Cir. 2016). The Mask Order is substantively unreasonable, and therefore arbitrary and capricious, because it could not possibly prevent the spread of COVID, whether into the country or from state to state, nor was it designed to do so.

One need not delve into the debate over whether masks are capable of blocking a highly contagious virus to recognize the overwhelming evidence that mask *mandates* do not work. As Plaintiffs pointed out below, CDC failed to cite a single controlled trial demonstrating that mask mandates have had any impact in a community setting. The studies on which it did rely were of low quality.

For example, one study cited by CDC, entitled "Face Masks Considerably Reduce COVID-19 Cases in Germany: A Synthetic Control Approach" (Dkt. 30 at 55), claimed 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

failed to account for variables such as other non-pharmaceutical interventions and voluntary changes in behavior, it ignored the fact that cases had already started decreasing *across all of Germany* from April 2, 2020. *See* Dkt. 48-4. It was a classic example of *post hoc, ergo propter hoc*.

The Arizona schools study cited by CDC (Dkt. 31 at 14) came in for extensive criticism due to its failure to account for numerous variables.[41] As one public health economist remarked, "You can't learn anything about the effects of school mask mandates from this study."[42]

By contrast, in the closest thing to a non-randomized controlled trial study of mask mandates so far, researchers "took advantage of a unique natural experiment" by comparing data from neighboring school districts in North Dakota, one of which had a mask mandate while the other did not.[43] The districts had similar demographics, vaccination rates, and enrollment. *Id*. Yet, despite a compliance rate

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41 *See* David Zweig, *The CDC's Flawed Case for Wearing Masks in Schools*, The Atlantic, Dec. 16, 2021, https://www.theatlantic.com/science/archive/2021/12/mask-guidelines-cdc-walensky/621035/.

42 *Id*.

43 *See* Sood, et al, *Association between School Mask Mandates and SARS-CoV-2 Student Infections: Evidence from a Natural Experiment of Neighboring K-12 Districts in North Dakota*, Research Square, July 1, 2022, available at https://www.researchsquare.com/article/rs-1773983/v1.

of 95% in the masked schools, the "study found that K-12 school mask mandates were not associated with significantly lower COVID-19 student case rates." *Id*.

Another study, published in The Lancet, replicated a school masking study touted by CDC but then enlarged the sample size and increased the study's duration.[44] From this larger set of data, the researchers found "[c]ounties that required masks in schools saw slightly larger increases in cases in the weeks immediately before and after school opening, but by the second week [] there was no statistical difference."[45]

Even experts who believe that masks themselves work agree that mask mandates have not.[46] This should not be surprising. Much as CDC touts the fact that masks were (temporarily) required in some locations during the 1918 influenza pandemic (Init Br. 14), there was never any evidence that those mandates had any

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[44] *See* Chandra and Hoeg, *Revisiting Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1—October 20 2021*, The Lancet, 25 May, 2022, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4118566.

[45] *Id*.

[46] *See, e.g.*, Steven Salzberg, *Masks Work. Mask-Wearing Policies Don't*, Forbes, Feb. 2, 2022, https://www.forbes.com/sites/stevensalzberg/2022/02/01/masks-work-mask-wearing-policies-dont/?sh=21d41f581b5c; David Leonhardt, *Why Masks Work, but Mandates Haven't*, The New York Times, May 31, 2022, https://www.nytimes.com/2022/05/31/briefing/masks-mandates-us-covid.html.

effect.[47] In fact, community-wide mask mandates will never work because, whatever one thinks about the efficacy of masks, the real world outside of the laboratory is a chaotic place, full of flawed human beings who are prone to doing unpredictable things.[48]

Likewise, CDC's own data shows that, while the Mask Order was in effect, it made no difference in the pattern of infection waves among the ten HHS regions in the U.S. *See* Dkt. 48-1.[49] This is also unsurprising, as the Mask Order was simply not designed to "prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States [], or from one State [] into any other State[,]" 42 U.S.C. § 264(a).

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47 *See* Eliza McGraw, *Everyone wore masks during the 1918 flu pandemic. They were useless*, Washington Post, April 2, 2020, https://www.washingtonpost.com/history/2020/04/02/everyone-wore-masks-during-1918-flu-pandemic-they-were-useless/.

48 Indeed, requiring millions of untrained laymen to don a medical device might even be counterproductive: According to the WHO, "[u]sing a mask incorrectly [] may actually *increase* the risk of transmission[.]". WHO, *Advice on the use of masks in the community setting in Influenza A (H1N1) outbreaks*, May 3, 2009 (emphasis added), available at https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-setting-in-influenza-a-(h1n1)-outbreaks.

49 *See* CDC COVID Data Tracker website at https://covid.cdc.gov/covid-data-tracker/#compare-trends_comptrends-cases-daily-rate-lin.

Imagine a rule in which CDC presumes that a handful of passengers on any flight will be infected with an Ebola virus,[50] but mandates no steps to identify and isolate them. Instead, as long as each passenger wears latex gloves and a hospital gown during the flight (with some exemptions, of course), no one will be prevented from boarding, deplaning, and going out into the community.

That would be an irrational way of preventing the interstate spread of Ebola. But that is exactly how the Mask Order operates—it does nothing to directly target the disease, *AAR*, 141 S. Ct. at 2488. It instead just assumes that some number of passengers will be infected with COVID-19 (86 Fed. Reg. at 8030), but as long as everyone wears a mask, those infected passengers will be permitted to board, deplane, and go out into the community.

The Mask Order likewise exempts the millions of Americans who travel across state lines in their own vehicles,[51] including those who commute across state lines to work in our nation's capital.[52] 86 Fed. Reg. at 8028. The point here is not

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50 *See* https://www.cdc.gov/vhf/ebola/about.html.

51 *See* Spreadsheet at Bureau of Transportation Statistics, https://www.bts.gov/content/us-passenger-miles.

52 *See, e.g.*, Eliza Berkon, *D.C. Has Some Of The Longest Commutes In the Country. What Help Is Available?* NPR, Jan. 24, 2020, https://www.npr.org/local/305/2020/01/24/799292338/d-c-has-some-of-the-longest-commutes-in-the-country-what-help-is-available.

that CDC should require people to wear masks in their private vehicles. That would be ridiculous. The point is that requiring masks on non-private conveyances is nothing more than a performative gesture that, while inconveniencing tens of millions, wasting billions of dollars, and causing a great deal of social and political strife, was never seriously intended to "prevent the introduction, transmission, or spread of" COVID-19, whether into the United States or from state to state. 42 U.S.C. § 264(a). Indeed, it suggests that CDC does not even believe that passengers infected with the SARS-CoV-2 virus are actually "sources of dangerous infection to [other] human beings." *Id*.

The Mask Order is therefore substantively unreasonable.

C. CDC Failed To Adhere To Its Own Internal Regulation When Promulgating The Mask Order.

"The failure of an agency to comply with its own regulations constitutes arbitrary and capricious conduct." *Simmons v. Block*, 782 F.2d 1545, 1550 (11th Cir. 1986). Accordingly, "courts *must* overturn agency actions which do not scrupulously follow the regulations and procedures promulgated by the agency, itself." *Id*. (quoted in *Sierra Club v. Martin*, 168 F.3d 1, 4 (11th Cir. 1999)) (emphasis added). Plaintiffs pointed out below that CDC failed to adhere to its own regulation, 42 CFR § 70.2, when it issued the Mask Order. Dkt. 48 at 46-47; Dkt. 51 at 12-13. Although the district court declined to address the argument (Dkt. 53 at 47), this Court may

alternatively affirm summary judgment on grounds that CDC failed to adhere to § 70.2. *Wilson*, 834 F.3d at 1237.

As a prerequisite to issuing interstate regulations under § 361, CDC must determine "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 finding, but instead offers a circular conclusion:

> 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.

The district court in *Becerra* rejected a similarly-conclusory finding by CDC in relation to its conditional sailing order. 544 F. Supp. 3d at 1293. There, the court found that CDC's "global dismissal of state and local health measures fail[ed] 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*. Thus, it was "not at all a scrupulous attempt" to adhere to § 70.2, "and, apparently, no attempt at all[.]" *Id*.

Likewise, CDC's finding in the Mask Order said nothing evaluative about what constitutes "sufficient mask-wearing requirements for transportation systems," and what states or local governments failed to meet those requirements. Keeping in mind that the Mask Order extended to "any conveyance (e.g., airplanes, trains, subways, buses, taxis, ride-shares, ferries, ships, trolleys, and cable cars) into or within the United States," as well as "any transportation hub within the United States," 86 Fed. Reg. at 8026, the Order said nothing at all about what impact state and local mask rules were having on interstate spread of the virus. CDC's failure to "scrupulously follow" § 70.2 thus provides an alternative ground on which to affirm the district court's conclusion that the Mask Order is arbitrary and capricious.

IV. VACATUR WAS THE PROPER REMEDY

CDC argues that the district court should not have granted relief beyond the named plaintiffs and members of Health Freedom who identified themselves below. Init. Br. at 44-45. This argument comes a bit late. In its pleadings and cross-motion for summary judgment, Health Freedom put CDC on notice that it was seeking to have the Mask Order set aside under the APA on behalf of its members. Dkt. 39 at ¶¶47-48; 39-4; and 48 at 12. CDC never contested Health Freedom's right to do so. *See* Dkt. 53 at 55 ("The government, aside from a single sentence in its response

(Doc. 50 at 25), does not brief the propriety of vacatur."). In any event, CDC's challenge to the district court's vacatur of the Mask Order lacks merit.

First, CDC incorrectly equates vacatur with a nationwide injunction. Init. Br. 30. They are different remedies. As the district court recognized, vacatur is "a less drastic remedy" than injunctive relief. Dkt 53 at 56 (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010)).

But the analogy between vacatur and a nationwide injunction is at best highly imperfect because, unlike nationwide injunctions, vacatur is statutorily authorized. The APA empowers a reviewing court to "set aside" agency action that exceeds statutory authority or is arbitrary and capricious or procedurally flawed. 5 U.S.C. § 706(2)(A), (C) & (D) (emphasis added); *see* Dkt. 53 at 53-54 (explaining that courts have long understood the term "set aside" to mean vacatur, and "vacatur" to mean rendering an invalid agency rule unenforceable against anyone).

In addition to being statutorily authorized, the district court got it right in relying on this Court's decision in *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*¸781 F.3d 1271, 1290 (11th Cir. 2015), for the proposition that "vacatur [] is the ordinary APA remedy." As well, "[t]he decision whether to vacate agency action falls with [the Court's] broad equitable discretion." *Id*. Finally, the district court explained that under the specific circumstances of this case, the

ordinary remedy of vacatur was "necessary to grant complete relief to Plaintiffs." Dkt. 53 at 56-57 (citing, *inter alia*, *Florida v. HHS*, 19 F.4th at 1282). The judgment of the district court should therefore be affirmed.[53]

V. AS CONSTRUED BY CDC, § 361(a) VIOLATES THE NON-DELEGATION DOCTRINE

Again, this Court may affirm summary judgment on any grounds raised below and supported by the record. *Wilson*, 834 F.3d at 1237. Plaintiffs argued below that if § 361(a) grants the sort of broad, unfettered discretion that CDC claims it does, it violates the nondelegation doctrine because it fails to provide "an intelligible principle to guide the [CDC's] use of [that] discretion." Dkt. 48 at 41 (citing *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019)). The District Court found it unnecessary to reach this claim. Dkt 53 at 31. The claim is properly before this Court, and Plaintiffs ask this Court to resolve it in their favor.

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[53] Plaintiffs note, however, that should the district's court's ruling be likened to a nationwide injunction, a decision is pending in this Court on a similar question. *See State of Georgia, et al. v. President of the United States, et al*, Case No. 21-14269 (11th Cir.) (oral argument held on April 8, 2022). In that case, the Southern District of Georgia enjoined the Office of Management and Budget's vaccination mandate for federal contractors. The district court made the injunction nationwide based on the intervention of an unincorporated association that represented federal contractors from across the country. This Court's ruling on the unincorporated association's right to such relief might inform the decision in this case.

"The nondelegation doctrine is based on the principle of separation of powers . . . [and] holds that 'Congress manifestly is not permitted to abdicate or to transfer to others the essential legislative functions with which it is [constitutionally] vested.'" *United States v. Ambert*, 561 F.3d 1202, 1213 (11th Cir. 2009) (quoting *Panama Refining Co. v. Ryan*, 293 U.S. 388, 421 (1935)). In recent years, the federal courts' "application of the nondelegation doctrine principally has been limited to the interpretation of statutory texts, and, more particularly, to giving narrow constructions to statutory delegations that might otherwise be thought to be unconstitutional." *Mistretta v. United States*, 488 U.S. 361, 373 n.7 (1989). So applied, the nondelegation doctrine "is closely related to" the major questions doctrine. *National Fed'n of Indep. Bus. v. OSHA*, 142 S. Ct. 661, 668 (2022) (Gorsuch, J., concurring); *see also id*. ("[F]or decades courts have cited the nondelegation doctrine as a reason to apply the major questions doctrine.").

In a detailed analysis, the district court in *Becerra* found that if § 361(a) "conveys to the director of CDC the authority that CDC claims" (*vis a vis* CDC's conditional sailing order that effectively shut down the cruise industry), then the statute "fails the 'intelligible principle' test and unconstitutionally delegates legislative authority" to CDC. 544 F. Supp. 3d at 1278-88. In *Tiger Lily II*, the Sixth

Circuit likewise found that "the government's interpretation of [§ 361(a)] could raise a nondelegation problem." 5 F.4th at 672.

Both decisions preceded *AAR*, but as fully explained above CDC relies on a definition of "sanitation" that imposes no more of a limit on its authority than what it advocated in *AAR*, *Becerra*, and *Tiger Lily*. By fastening onto "sanitation," CDC is just peddling last year's model after modestly tweaking the tail lights. Thus, should this Court conclude that CDC is correct about the scope of § 361(a), the statute should be held invalid as an unconstitutional delegation of legislative authority.

CONCLUSION

Based on the foregoing points and authorities, Plaintiffs/Appellees ask that the well-reasoned decision of the district court be affirmed or, in the alternative, that § 361(a) of the Public Health Service Act be found invalid as an unconstitutional delegation of legislative authority.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,755 words. This brief also complies with the typeface and type-style requirement of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word in Times New Roman 14-point font, a proportionally spaced typeface.

s/ Brant C. Hadaway
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CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2022, I electronically filed the foregoing Answer Brief with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit via the Court's CM/ECF system, which will automatically serve all counsel of record via CM/ECF notice.

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