UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

HEALTH FREEDOM DEFENSE FUND, INC.; ANA CAROLINA DAZA; and SARAH POPE,

Plaintiffs,

v.

Case No. 8:21-cv-1693-KKM-AEP

JOSEPH R. BIDEN, JR., in his official capacity as President of the United States; XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; THE DEPARTMENT OF HEALTH AND HUMAN SERVICES; THE CENTERS FOR DISEASE CONTROL AND PREVENTION; ROCHELLE P. WALENSKY, MD, MPH, in her official capacity as Director of the CDC; MARTIN S. CETRON, MD, in his official capacity as Director of the CDC's Division of Global Migration and Quarantine; and THE UNITED STATES OF AMERICA,

Defendants.

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Congress has authorized the Secretary of Health and Human Services, through the Centers for Disease Control and Prevention (CDC), to adopt "such regulations as in [the agency's] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions [of the United States], or from one State or possession into any other State or possession." Public Health Service Act ("PHSA"), ch. 373, § 361(a), 58 Stat. 703 (1944) (codified at 42 U.S.C. § 264(a)). In particular, Congress explicitly authorized "sanitation" measures, as well as all "other measures" that are akin to "sanitation" measures. *Id.* Invoking that authority, the CDC has issued a temporary order that (with some exceptions) generally requires individuals to wear masks when traveling on public transportation conveyances like airplanes, trains, and buses. The order was issued to reduce the spread of COVID-19—"one of the greatest threats to the operational viability of the transportation system and the lives of those on it seen in decades." *Corbett v. TSA*, 19 F.4th 478, 480 (D.C. Cir. 2021).

Plaintiffs—a Wyoming corporation headquartered in Idaho, and two Florida residents—claim that the order exceeds the CDC's statutory authority, is arbitrary and capricious or procedurally infirm under the Administrative Procedure Act (APA), and (in the alternative) that the Public Health Service Act violates the non-delegation doctrine. Plaintiffs also challenge Executive Order 13998, even though (unlike the CDC's mask order) it does not actually impose any obligations on anyone outside of

the Executive Branch. Underlying all of these challenges is Plaintiffs' contrarian position that mask-wearing may cause "adverse health effects," and that "[i]n addition to safety concerns, there are substantial reasons to doubt the efficacy of masks for controlling virus spread." Am. Compl. ¶¶ 35, 41, ECF No. 39.

All of these claims are meritless—both on the science, and on the law. Congress prudently gave the Executive Branch broad authority to take reasonable public-health measures to prevent the spread of communicable disease. That authority has never been more important than during this pandemic, and, whatever its outer bounds, masking is a conventional "sanitation" measure, 42 U.S.C. § 264(a), squarely in its heartland. Plaintiffs' unsupported and unscientific skepticism about the efficacy and the safety of mask-wearing provides no basis to overturn the CDC's considered judgment. For those who seek to use our nation's public-transportation systems during an unprecedented global pandemic of an airborne respiratory virus, Congress has entrusted those judgments to the medical experts at the CDC—not to Plaintiffs.

The Court should enter summary judgment for Defendants on all claims.

BACKGROUND

I. Statutory and Regulatory Background

The federal government has a long history of acting to combat the spread of communicable diseases. Congress enacted the first federal quarantine law in 1796 in response to a yellow fever outbreak, delegating to President Washington the authority to direct federal officials to help states enforce quarantine laws. Act of May 27, 1796,

ch. 31, 1 Stat. 474 (1796) (repealed 1799); *see Smith v. Turner*, 48 U.S. 283, 300 (1849). Following a yellow fever outbreak, Congress replaced the 1796 Act with a federal inspection system for maritime quarantines. Act of Feb. 25, 1799, ch. 12, 1 Stat. 619 (1799). And in 1893, Congress authorized the Secretary of the Treasury to adopt additional regulations to prevent the introduction of communicable disease into the United States or across state lines where the Secretary considered state or local regulation inadequate. Act of Feb. 15, 1893, ch. 114, 27 Stat. 449 (1893).

Congress enacted the Public Health Service Act in 1944. *Consolidation & Revision of Laws Relating to the Public Health Service*, H.R. Rep. No. 78-1364, at 1 (1944). In section 361(a), Congress broadened the federal government's "basic authority to make regulations to prevent the spread of disease into this country or between the States." *Id.* at 24. For example, Congress removed references to specific diseases to provide federal health authorities flexibility to respond to new types of contagion and "expressly sanction[ed] the use of conventional public-health enforcement methods" by the government in disease-control efforts. *Id.* at 24-25.

The resulting statute, 42 U.S.C. § 264—part of a broader statutory scheme authorizing the Department of Health and Human Services (HHS) to take wide-ranging public-health actions, *see id.* §§ 264-272—authorizes the Secretary of Health and Human Services[1] "to make and enforce such regulations as in his judgment are

[1] Although the statute assigns authority to the Surgeon General, all statutory powers and functions of the Surgeon General were transferred to the Secretary of HHS in 1966, 31 Fed. Reg. 8855 (June 25, 1966), 80 Stat. 1610 (1966); *see also* Pub. L. No. 96-88, § 509(b), 93 Stat. 668, 695 (1979)

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." *Id.* § 264(a). The second sentence of subsection (a) further clarifies that "[f]or purposes of carrying out and enforcing such regulations," the Secretary "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." *Id.*

Subsection (b) imposes specific limits on the Secretary's ability to "provide for the apprehension, detention, or conditional release of individuals"—a power not specifically identified in subsection (a)—permitting such impositions on a person's physical movement only for diseases specified by Executive Order. *Id.* § 264(b). Subsections (c) and (d) set further limits on the detention of individuals. *See id.* § 264(c)-(d). The final subsection provides that the statute and any regulation adopted thereunder supersede state law "to the extent that such a provision conflicts with an exercise of Federal authority." *Id.* § 264(e).

The Secretary has promulgated several regulations implementing these provisions and delegating their enforcement to CDC. *See* 42 C.F.R. pt. 70; *Control of Communicable Diseases, Apprehension and Detention of Persons With Specific Diseases,*

(codified at 20 U.S.C. § 3508(b)). The Secretary has retained these authorities despite the reestablishment of the Office of the Surgeon General in 1987.

Transfer of Regulations, 65 Fed. Reg. 49,906, 49,907 (Aug. 16, 2000). The Secretary appears to have first promulgated the regulation titled "measures in the event of inadequate local control" in 1947, *see Interstate Quarantine*, 12 Fed. Reg. 3189 (May 16, 1947) (codified at 42 C.F.R. § 12.3 (1947)), following publication of a "general notice of proposed rule making" in the Federal Register, *see Interstate Quarantine Regulations*, 11 Fed. Reg. 9389 (Aug. 27, 1946).[2] The regulation has been relocated several times without substantive change. *See, e.g.*, *Interstate Quarantine*, 12 Fed. Reg. 6210 (Sept. 16, 1947) (*recodifying provision at* 42 C.F.R. § 73.2). In 2000, again without any alteration to its substance, the regulation was repromulgated to transfer, in part, authority from the Food & Drug Administration (FDA) to CDC, *see* Final Rule, *Control of Communicable Diseases; Apprehension and Detention of Persons With Specific Diseases; Transfer of Regulations*, 65 Fed. Reg. 49,906 (Aug. 16, 2000), and the agency provided a notice-and-comment period, *see Proposed Data Collections Submitted for Public Comment and Recommendations*, 65 Fed. Reg. 19,772 (Apr. 12, 2000). Although the notice specifically requested comments regarding proposed data collection projects, *see id.* at 19,772, it referenced the provision at issue here, stating that "[t]he regulations . . . being assumed by CDC were developed to facilitate Federal action in the event of

[2] This "general notice of proposed rule making" does not specifically seek comments on the "measures in the event of inadequate local control" provision, *see* 11 Fed. Reg. at 9389, but is referenced as the relevant notice for that regulation in subsequent Federal Register publications, *see* 12 Fed. Reg. at 3189.

large outbreaks of disease requiring a coordinated effort involving several States, or in the event of inadequate local control." *Id.*

That regulation, now codified at 42 C.F.R. § 70.2, provides the CDC with broad discretion to address the uncontrolled spread of communicable disease. Specifically, if the CDC Director "determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases" between or among states, he is empowered to "take such measures to prevent such spread of the diseases as he/she deems reasonably necessary." 42 C.F.R. § 70.2. These measures include, but are not limited to, "inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection." *Id.*

In addition, separate longstanding regulations provide that "[w]henever the Director has reason to believe that any arriving carrier . . . is or may be infected . . . with a communicable disease, he/she may require detention, disinfection, . . . or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases." 42 C.F.R. § 71.32(b); *see also id.* § 71.31(b) (allowing "detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease"). And other regulations authorize CDC to limit interstate travel of infected persons, *see id.* § 70.3, to apprehend and

detain persons, *id.* § 70.6, and to conduct medical examinations, *id.* § 70.12, to control the spread of disease.

II. The COVID-19 Pandemic

In December 2019, the novel coronavirus later named SARS-CoV-2 was first detected in Wuhan, Hubei Province, in the People's Republic of China. *See Declaring a Nat'l Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak*, 85 Fed. Reg. 15,337 (Mar. 13, 2020). The virus causes a respiratory disease known as COVID-19. *Id.* COVID-19 poses a risk of "severe" respiratory illness, meaning that infected persons may require hospitalization, intensive care, or the use of a ventilator. 85 Fed. Reg. at 55,292. Severe cases may be fatal. *Id.* The virus that causes COVID-19 transmits "very easily and sustainably," *id.* at 55,293, including when an individual "[b]reath[es] in air when close to an infected person," CDC, *How COVID-19 Spreads* (updated July 14, 2021), https://perma.cc/R38B-WAPL. Persons not displaying symptoms are capable of transmitting the virus. *Id.* at 55,292.

On January 31, 2020, the Secretary of HHS declared a public-health emergency. HHS, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), https://perma.cc/VZ5X-CT5R. On March 11, 2020, the World Health Organization (WHO) classified COVID-19 as a pandemic. 85 Fed. Reg. at 15,337. And on March 13, 2020, then-President Trump declared the outbreak a national emergency. *Id.* By late August 2020, the virus had spread to all 50 states. *Id.* at 55,292. As of the date of this filing, it has infected more than 65 million and killed more than 847,000 people in

the United States alone, and many more around the world. *See* CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data-tracker (last visited January 18, 2022).

To combat the spread of this highly contagious, deadly virus, governments at all levels have taken "unprecedented or exceedingly rare actions" to protect the public. 85 Fed. Reg. at 55,292. These include border closures, travel restrictions, stay-at-home orders, eviction moratoria, vaccine and testing mandates, and mask requirements. *See id.* "[M]ask wearing" in particular "is one of the most effective strategies available for reducing COVID-19 transmission." 86 Fed. Reg. at 8025.

By spring of 2021, significant progress had been made with vaccinations and falling case counts in the United States, which led the CDC to relax its mask-wearing guidance for fully vaccinated individuals, in some settings. But shortly thereafter, a more transmissible and more severe variant of the original virus (the Delta variant) began circulating, leading the CDC to recommend that, "[t]o maximize protection from the Delta variant and prevent possibly spreading it to others," even fully vaccinated individuals should "wear a mask indoors in public if you are in an area of substantial or high transmission." CDC, *When You've Been Fully Vaccinated* (updated July 27, 2021), https://perma.cc/C3LC-HMLF. Now, the new, even more transmissible Omicron variant is circulating at an alarming rate—breaking records for cases in many states, including Florida. *See CDC, Omicron Variant: What You Need to Know* (Dec. 20, 2021), https://perma.cc/UH3B-FESV; COVID Data Tracker,

https://covid.cdc.gov/covid-data-tracker/#trends_dailycases (last visited Jan. 18, 2022).

Meanwhile, for the first time in almost two years, passenger volume in commercial air travel has been approaching (and occasionally, even surpassing) pre-pandemic levels. *See* TSA, *Checkpoint Travel Numbers*, https://perma.cc/HCA7-FTAZ (last visited Jan. 18, 2022). And as of this filing, only about 62.9% of the country is fully vaccinated, and only 38.1% has received a booster dose. *See* https://covid.cdc.gov/covid-data-tracker/#vaccinations (last visited Jan. 18, 2022).

III. The Challenged Orders

On January 21, 2021, President Biden issued Executive Order 13998, explaining that public-health experts "have concluded that mask-wearing, physical distancing, appropriate ventilation, and timely testing can mitigate the risk of travelers spreading COVID-19." Ex. 1, Exec. Order 13998, *Promoting COVID-19 Safety in Domestic and Int'l Travel*, 86 Fed. Reg. 7205 (Jan. 21, 2021). "Accordingly, to save lives and allow all Americans, including the millions of people employed in the transportation industry, to travel and work safely," the President called on all relevant government agencies to "immediately take action, to the extent appropriate and consistent with applicable law, to require masks to be worn in compliance with CDC guidelines" on public-transportation systems. *Id.*

A few weeks later, the CDC issued the transportation mask order, which is the primary target of this litigation. *See* Ex. 2, CDC, *Order Under Section 361 of the Public*

Health Service Act, Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs, 86 Fed. Reg. 8025 (Feb. 3, 2021). Generally, the transportation mask order requires persons to "wear masks over the mouth and nose when traveling on conveyances into and within the United States" and "at transportation hubs." *Id.* at 8026. The order's objectives are:

- Preservation of human life;
- Maintaining a safe and secure operating transportation system;
- Mitigating the further introduction, transmission, and spread of COVID-19 into the United States and from one state or territory into any other state or territory; and
- Supporting response efforts to COVID-19 at the Federal, state, local, territorial, and tribal levels.

Id. at 8027.

The scientific justifications are straightforward: "Masks help prevent people who have COVID-19, including those who are pre-symptomatic or asymptomatic, from spreading the virus to others." *Id.* at 8028. They "also provide personal protection to the wearer by reducing inhalation of" "virus-laden droplets." *Id.* "The community benefit of wearing masks . . . is due to the combination of these effects; individual prevention benefit increases with increasing numbers of people using masks consistently and correctly." *Id.*

The order also explains why mask-wearing is especially important on public transportation and in commercial air travel: "[t]raveling on multi-person conveyances increases a person's risk of getting and spreading COVID-19 by bringing persons in close contact with others, often for prolonged periods[.]" *Id.* at 8029. "Furthermore,

given how interconnected most transportation systems are across the nation and the world, local transmission can grow even more quickly into interstate and international transmission when infected persons travel on non-personal conveyances without wearing a mask and with others who are not wearing masks." *Id.* And in the context of commercial air travel in particular, "[s]ocial distancing may be difficult if not impossible." *Id.*

Beyond the obvious public-health goals, the order also explains that "[r]equiring masks will help us control this pandemic and aid in re-opening America's economy." *Id.* That is because "America's transportation systems" are "essential for America's economy and other bedrocks of American life"—whether to "carry life-saving medical supplies and medical providers into and across the nation to our hospitals, nursing homes, and physicians' offices," to "bring food and other essentials to our communities," or to "bring America's workforce to their jobs." *Id.*

The order exempts "child[ren] under the age of 2," and anyone "with a disability who cannot wear a mask, or cannot safely wear a mask," among others. *Id.* at 8027. It also exempts (among other things) "[p]rivate conveyances operated solely for personal, non-commercial use." *Id.* at 8028. And it does not apply "[w]hile eating, drinking, or taking medication, for brief periods." *Id.* at 8027. Although the order could theoretically be enforced through criminal penalties, "CDC does not intend to

rely primarily on . . . criminal penalties but instead strongly encourages and anticipates widespread voluntary compliance[.]" *Id.* at 8030 n.33.[3]

IV. <u>Litigation Background</u>

On July 12, 2021, almost six months after the CDC issued the transportation mask order, Plaintiffs—a Wyoming corporation headquartered in Idaho (Health Freedom Defense Fund, Inc.), and two Florida residents (Ana Carolina Daza and Sarah Pope)—filed this lawsuit. Compl., ECF No. 1. Plaintiffs filed an amended complaint on December 13, 2021, with Defendants' consent and the Court's leave, *see* ECF Nos. 36, 38, 39.

In their amended complaint (like their original complaint), Plaintiffs bring four claims challenging the CDC's transportation mask order: (1) that the order exceeds the CDC's statutory authority, *see* Am. Compl., ECF No. 39, ¶¶ 58-68 (Count I); (2) that it was issued in violation of the APA's notice-and-comment requirements, *id.* ¶¶ 69-74 (Count II); (3) that it is arbitrary and capricious, *id.* ¶¶ 75-81 (Count III); and (4) that, if the order does not exceed CDC's statutory authority, then Section 264 of the PHSA is an unconstitutional delegation of legislative authority, *id.* ¶¶ 82-84 (Count IV).

[3] The Transportation Security Administration (TSA) has also issued a series of Security Directives, through which TSA assists with the implementation and enforcement of the CDC's mask order. *See generally Corbett v. TSA*, 19 F.4th 478 (D.C. Cir. 2021) (holding that TSA Security Directives requiring masks in public-transportation systems are lawful); *see also id.* at 490 (Henderson, J., dissenting) (dissenting on the basis that plaintiff lacked standing, but also noting that, "[o]n the merits, this petition for review is a slam-dunk loser"). Unlike in other mask-related litigation, however, TSA is not a party here, and these Plaintiffs have not challenged any of the relevant TSA orders.

Plaintiffs also bring two constitutional claims that challenge Executive Order 13998 directly. *See id.* ¶¶ 85-95 (Counts V and VI).

Pursuant to a schedule agreed upon by the parties and ordered by the Court, ECF No. 38, Defendants answered the amended complaint on January 6, 2022, ECF No. 41, and now move for summary judgment on all claims.

ARGUMENT

Plaintiffs believe that masks are not just ineffective, but actually harmful. *See* Am. Compl. ¶¶ 35, 41. But a large and growing body of scientific data says otherwise, which is why the CDC issued an order that—temporarily, and with various exceptions, including for those who cannot safely wear a mask for medical reasons—generally requires masks for those traveling in our nation's public-transportation systems. CDC was doing exactly what Congress authorized it to do: to take actions that "in [its] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases" into and within the United States—in particular, "sanitation" measures, or "other measures" similar to "sanitation" measures. 42 U.S.C. § 264(a). And because CDC "reasonably considered the relevant issues and reasonably explained the decision," *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021), this Court should decline Plaintiffs' invitation to substitute its (or their) judgment for that of the agency.

I. The Transportation Mask Order is authorized by the Public Health Service Act (Count I)

a. Congress authorized the CDC to adopt "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 [of the United States], or from one State or possession into any other State or possession." 42 U.S.C. § 264(a). In doing so, 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." *Id.* Whatever the outer bounds of this authority, it plainly includes, at an absolute minimum, "sanitation" measures, or "other measures" akin to "sanitation" measures. *Id.*

Masking is a conventional "sanitation" measure. A leading modern dictionary defines "sanitation" as "the act or process of making sanitary" or "the promotion of hygiene and prevention of disease by maintenance of sanitary conditions." Sanitation, *Merriam-Webster.com Dictionary*, https://perma.cc/9ARR-YKYH. Dictionaries from the 1940s, published shortly before and after enactment of the PHSA, define the term similarly, or even more broadly.[4] Those dictionary definitions are all consistent with

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[4] *See, e.g.*, Ex. 3, FUNK & WAGNALLS NEW STANDARD DICTIONARY OF THE ENGLISH LANGUAGE 2172 (Isaac K. Funk et al. eds., 1946) (defining "sanitation" as "[t]he devising and applying of measures for preserving and promoting public health; the removal or neutralization of elements injurious to health; the practical application of sanitary science"); Ex. 4, WEBSTER'S NEW INT'L DICTIONARY OF THE ENGLISH LANGUAGE 2214 (William Allan Neilson et al. eds., 2d ed. 1942) (defining "sanitation" as the "use of sanitary measures," and defining "sanitary" as "[o]f or pert[aining] to health; for or relating to the preservation or restoration of health; occupied with

plain meaning and common usage—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. That is why "doctors have been wearing medical-grade N95 or surgical masks . . . during surgeries or patient interactions as part of their daily routines, for many decades." *Why Doctors Wear Masks* (Sept. 1, 2020), YALEMEDICINE.ORG, https://perma.cc/TE77-8PBH.

Even if there were doubt on this score, the temporary requirement to wear masks on public transportation is a comparable (or milder) imposition than the other examples enumerated in the statute, such as "inspection," "fumigation," "disinfection," "pest extermination," and "destruction." 42 U.S.C. § 264(a). It thus qualifies, at minimum, as an "other measure[]" that CDC has determined "may be necessary" "in [its] judgment," within the meaning of the second sentence of 42 U.S.C. § 264(a).[5] In other words, regardless of whether the Court interprets the first sentence of 42 U.S.C. § 264(a) broadly, as it is written (*i.e.*, to authorize any measure that "in [the CDC's] judgment [is] necessary to prevent the introduction, transmission, or spread of communicable diseases"), or rather adopts a narrower interpretation (*i.e.*, to authorize only measures that are akin to those listed in the second sentence, including "sanitation" measures), the CDC's transportation mask order is lawful.

measures or equipment for improving conditions that influence health; free from, or effective in preventing or checking, agencies injurious to health, esp[ecially] filth and infection; hygienic").

[5] Plaintiffs' complaint (and one of the opinions it relies on) excises the word "sanitation" from the statute, using an ellipsis. *See* Am. Compl. ¶ 65 (quoting *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, 2021 WL 2514138, at *19 (M.D. Fla. June 18, 2021)).

The Supreme Court's decision in *Alabama Association of Realtors v. HHS*, 141 S. Ct. 2485 (2021) ("*AAR*"), holding that the CDC's eviction moratorium was likely unlawful, is not to the contrary. To be sure, *AAR* does clarify that the second sentence of 42 U.S.C. § 264(a) at least "informs the grant of authority" in the first, "by illustrating the kinds of measures that could be necessary[.]" *Id.* at 2488. But if anything, that confirms that the text at least authorizes "sanitation" measures, along with other "kinds of measures" like sanitation measures. *Id.*; *see also id.* (the listed measures "directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself"). And whatever could be said about the CDC's eviction moratorium, there is nothing indirect about the mask order—a mask is literally a physical barrier that "directly" reduces viral transmission in real time.[6]

b. Even if the statute were ambiguous, the Court should defer to the agency's reasonable interpretation. Under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the Court first asks "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If so, both the Court and the agency "must give effect to the unambiguously expressed intent of Congress." *Id.* at 843. "If, however, the statute is ambiguous on the point, we assume that Congress delegated to the agency the authority to reasonably answer the question." *In re Gateway Radiology Consultants, P.A.*, 983 F.3d 1239, 1256 (11th Cir. 2020). So "[t]he

[6] Also, unlike here, *see infra* at 16-18, *Chevron* deference was not pressed before the Supreme Court in *AAR*, which was litigated in an emergency posture.

second *Chevron* step is to determine if the agency's interpretation of the statute is reasonable." *Id.*

The 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"—decisions that "involve[] difficult policy choices that agencies are better equipped to make than courts." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005). *Chevron* thus applies where "Congress delegated authority to the agency generally to make rules carrying the force of law, and . . . the agency interpretation . . . was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Courts must uphold the agency's interpretation "as long as it is a permissible construction of the statute, even if it differs from how the court would have interpreted the statute." *Sebelius v. Auburn Reg'l Med. Ctr.*, 568 U.S. 145, 158 (2013).

Those prerequisites are satisfied here. The PHSA reflects a congressional delegation to HHS to promulgate regulations with the force of law. The statute authorizes the Secretary "to make and enforce such regulations as in his judgment are necessary" to prevent the spread of disease. 42 U.S.C. § 264(a). It further allows the Secretary to "provide for . . . measures [that] in his judgment may be necessary" in order to "carry[] out and enforc[e] such regulations[.]" *Id.* And the implementing regulation paraphrases this language to authorize the CDC Director to "take such measures to prevent such spread of the diseases as he/she deems reasonably

necessary," provided he determines that state and local disease-control measures are inadequate. 42 C.F.R. § 70.2. The language clearly provides the agency authority to make binding regulations. *Accord Brand X*, 545 U.S. at 980-81 (analyzing a statute empowering an agency to "execute and enforce" an Act and "prescribe such rules and regulations as may be necessary in the public interest to carry out [its] provisions"). Finally, the mask order was issued pursuant to that authority, and has the force of law. *See* 86 Fed. Reg. at 8030.[7] Accordingly, even if the Court determines that this statutory-interpretation question is a close one, it should defer to CDC's reasonable interpretation.

c. Plaintiffs argue that accepting CDC's interpretation "would be 'tantamount to creating a general [federal] police power.'" Am. Compl. ¶ 62 (quoting *Skyworks, Ltd. v. CDC*, 524 F. Supp. 3d 745, 758 (N.D. Ohio 2021) (holding that the CDC's eviction moratorium exceeded its statutory authority)). That concern is misplaced. Unlike in some of the eviction-moratorium cases, Plaintiffs here bring no claim arguing that the federal government entirely lacks constitutional authority to regulate in this area. *See infra at* 39 n.14. For good reason: Congress may "regulate Commerce

[7] The fact that the agency invoked the good-cause exception to notice-and-comment rulemaking does not change this conclusion. *See Barnhart v. Walton*, 535 U.S. 212, 221 (2002) ("that the Agency previously reached its interpretation through means less formal than 'notice and comment' rulemaking, . . . does not automatically deprive that interpretation of the judicial deference otherwise its due"); *Mead*, 533 U.S. at 231 ("we have sometimes found reasons for *Chevron* deference even when no such administrative formality was required and none was afforded"). Instead, factors like the clear authority pursuant to which it was promulgated, the fact that the Order carries the force of law, its formality—the Order was published in the Federal Register—and the agency's public-health expertise demonstrate that deference is warranted. *See Mead*, 533 U.S. at 230-31; *see also NationsBank of N.C., N.A. v. Variable Annuity Life Ins. Co.*, 513 U.S. 251, 257-58 (1995) (deferring, under *Chevron*, to agency's reasonable position articulated in interpretive letters).

with foreign Nations, and among the several States," and "make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers." U.S. Const. art. I, § 8, cl. 3 and 18—power that plainly authorizes it to act to control an "interstate epidemic," *United States v. Comstock*, 560 U.S. 126, 134-35, 142, 148 (2010). 42 U.S.C. § 264(a) falls squarely in that wheelhouse: it authorizes measures that "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." As that text makes clear, this is a classic exercise of the interstate and foreign commerce powers (including as supplemented by the Necessary and Proper Clause, to the extent necessary).

d. Plaintiffs also argue (*see* Am. Compl. ¶¶ 63-64) that one of the regulations that CDC invoked here—42 C.F.R. § 70.2—imposes an additional requirement that does not appear in the statute: that CDC "determine[] that the measures taken by the health authorities of [a] State . . . are insufficient to prevent the spread of . . . disease." But CDC did so here. As it explained, "[i]ntrastate transmission of the virus" inevitably leads to "interstate and international spread of the virus, particularly on public conveyances and in travel hubs, where passengers who may themselves be traveling only within their state or territory commonly interact with others traveling between states or territories or internationally." 86 Fed. Reg. at 8029. Thus, the CDC reasonably determined 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 any other state or territory." *Id.* (emphasis added); *see also id.* at 8030 ("This Order shall not apply" where state or local "requirements . . . provide the same level of public health protection as—or greater protection than—the requirements listed herein."). Nothing in the statute or the regulation required CDC to do more, let alone to identify specific states (or state measures) by name. And tellingly, Plaintiffs do not contend that Florida—the only State with residents who have standing that are before this Court—has implemented comparable mask-wearing or other requirements adequate to stem the spread of COVID-19.[8]

*   *   *

"When Congress undertakes to act in areas fraught with medical and scientific uncertainties, legislative options must be especially broad and courts should be cautious not to rewrite legislation." *Marshall v. United States*, 414 U.S. 417, 427 (1974). Because Plaintiffs' interpretation would effectively rewrite the Public Health Service Act to give it an artificially narrow scope, Defendants are entitled to summary judgment on Count I.

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[8] Plaintiffs are also mistaken to suggest that the CDC improperly invoked 42 C.F.R. §§ 71.31(b) and 71.32(b) to support the order. Although it is unclear whether any of the individual Plaintiffs have imminent plans to travel internationally, *cf.* Am. Compl. ¶ 49 (noting Plaintiff Daza's *past* international travel plans), these longstanding regulations—which Plaintiffs seem not to dispute are consistent with the statute—permit the agency not only to detain arriving carriers, but alternatively to issue a "controlled free pratique" that "stipulat[es] what measures are to be met," 42 C.F.R. § 71.31(b), as a "condition" to "enter a U.S. port," *id.* § 71.1 (defining "controlled free pratique"); *see also id.* § 71.32(b) (authorizing "detention, disinfection, fumigation, or other related measures"). Requiring international passengers on arriving carriers to wear a mask is a permissible "measure" under these regulations for much the same reasons as explained above.

II. The Transportation Mask Order is not arbitrary and capricious (Count III).

Arbitrary and capricious review is "exceedingly deferential." *Sierra Club v. Van Antwerp*, 526 F.3d 1353, 1360 (11th Cir. 2008) (quotation omitted). Courts may not "substitute [their] judgment for the agency's as long as its conclusions are rational." *Miccosukee Tribe of Indians of Fla. v. United States*, 566 F.3d 1257, 1264 (11th Cir. 2009). "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 141 S. Ct. at 1158. Of particular relevance here, the Eleventh Circuit "give[s] an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise." *Nat'l Mining Ass'n v. Dep't of Labor*, 812 F.3d 843, 866 (11th Cir. 2016) (quotation omitted); *see also Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) (where an agency "is making predictions, within its area of special expertise, at the frontiers of science, . . . a reviewing court must generally be at its most deferential").

a. Plaintiffs' arbitrary-and-capricious claim is largely premised on their own contrarian view of the scientific evidence: that "[i]n addition to safety concerns, there are substantial reasons to doubt the efficacy of masks for controlling virus spread." Am. Compl. ¶¶ 35, 41. But the CDC has amply supported its determination that mask wearing "is one of the most effective strategies available for reducing COVID-19 transmission." 86 Fed. Reg. at 8026. And the CDC has "reasonably explained," *Prometheus Radio Project*, 141 S. Ct. at 1158, that masks both (1) "help prevent people

who have COVID-19, including those who are pre-symptomatic or asymptomatic, from spreading the virus to others," and (2) "also provide personal protection to the wearer by reducing inhalation of" "virus-laden droplets." 86 Fed. Reg. at 8028. Under bedrock principles of administrative law, that is more than enough—even if there were room for reasonable scientists to disagree.

That said, even a cursory review of the administrative record shows that CDC's judgment aligns with the widespread medical consensus that masks work to slow the spread of COVID-19. *See id.* ("Seven studies have confirmed the benefit of universal masking in community level analyses," each of which "demonstrated that, following directives . . . for universal masking, new infections fell significantly."). And new evidence continues to pile up.[9]

The scientific consensus supporting mask-wearing to reduce transmission of COVID-19 is presumably why "[a] person not wearing a mask . . . will not be allowed in—or will be directed to leave—a courthouse" in the Middle District of Florida. Ex. 5, No. 3:20-mc-00023, ECF No. 4, COVID-19 Order (M.D. Fla. July 30, 2021) (Corrigan, C.J.). And in the context of commercial air travel in particular, "[s]ocial distancing may be difficult if not impossible," 86 Fed. Reg. at 8029, and there is a long history of federal regulation—including to protect passengers from being exposed to airborne contaminants. *Cf. Competitive Enter. Inst. v. Dep't of Transp.*, 863 F.3d 911, 919

[9] *See, e.g.*, Bagheri et al., *An upper bound on one-to-one exposure to infectious human respiratory particles*, PROCEEDINGS OF THE NAT'L ACADEMY OF SCIENCES (Dec. 2, 2021), https://perma.cc/3R3Q-838Y; Adam Taylor, WASH. POST, *Massive randomized study is proof that surgical masks limit coronavirus spread, authors say* (Sept. 1, 2021), https://perma.cc/M2E4-7E3Q.

(D.C. Cir. 2017) ("[E]-cigarette vapor in confined aircrafts could harm non-users. Especially due to the involuntary nature of secondhand exposure on aircrafts, where individuals are often assigned seats, . . . [t]hose seated next to users may not want to expose themselves (or their babies or older children) to even small risks[.]" (citations omitted)).

Plaintiffs point to a smattering of other sources, *see* Am. Compl. ¶¶ 35-46, which they interpret to be inconsistent with the CDC's judgment about the safety and efficacy of masks. But even accepting the (dubious) premise that there is significant uncertainty about either the efficacy or safety of mask-wearing during a global pandemic of an airborne respiratory virus, the APA does not require unanimity or certainty in the scientific literature before an agency can act. *Cf. Prometheus Radio Project*, 141 S. Ct. at 1160 ("[T]he FCC did not have perfect empirical or statistical data. Far from it. But that is not unusual in day-to-day agency decisionmaking within the Executive Branch."). Instead, especially "[i]n an area characterized by scientific and technological uncertainty," the Court "must proceed with particular caution, avoiding all temptation to direct the agency in a choice between rational alternatives." *Am. Wildlands v. Kempthorne*, 530 F.3d 991, 1000 (D.C. Cir. 2008).

b. Plaintiffs—none of whom allege that they are young children—also argue that CDC "provide[d] no epidemiological basis for drawing the line for exemptions for children at age 2 and under, whereas the WHO recommends against masking children age 5 and under[.]" Am. Compl. ¶ 79. As a threshold matter, it is not clear

how adult Plaintiffs could even have Article III standing to make this argument, which seeks to second-guess the CDC's age cutoff for young children—after all, "standing is not dispended in gross." *Lewis v. Casey*, 518 U.S. 343, 358 n.6 (1996). "To the contrary, a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought." *Town of Chester, N.Y. v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017). Likewise, the fact that Plaintiffs have standing to raise other claims is irrelevant: "If the right to complain of *one* administrative deficiency automatically conferred the right to complain of *all* administrative deficiencies, any citizen aggrieved in one respect could bring the whole structure of state administration before the courts for review." *Lewis*, 518 U.S. at 358 n.6.; *see also, e.g.*, *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352-53 (2006) (similar); *McGowan v. Maryland*, 366 U.S. 420, 429 (1961) (similar).

In any event, "[a]n agency has wide discretion in making line-drawing decisions" and "is not required to identify the optimal threshold with pinpoint precision." *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214-15 (D.C. Cir. 2013) (quotation marks omitted); *see also Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) ("[T]he same capacious grant of authority that empowers [the agency] to make these determinations leaves its discretion equally unchecked in other areas, including the ability to identify and create exemptions from its own Guidelines."). The line drawn need only be "within a zone of reasonableness." *Nat'l*

Shooting Sports Found., 716 F.3d at 214. Here, it is—even if these particular Plaintiffs would prefer the approach of the World Health Organization to that of the CDC.[10]

c. Plaintiffs argue that the FDA (a non-party) has exhibited "uncertainty regarding the efficacy of masks for the general public." Am. Compl. ¶ 79. But agency uncertainty is neither unusual nor problematic under the APA. *See, e.g.*, *Prometheus Radio Project*, 141 S. Ct. at 1160; *Kempthorne*, 530 F.3d at 1000. In any event, the premise is faulty: an FDA document that Plaintiffs attached to the amended complaint makes clear that, from the FDA's perspective, "face masks are authorized for use by the general public to cover their noses and mouths, in accordance with CDC recommendations." ECF No. 39-3, at 2. And the FDA has issued a series of other guidance documents (both before and after issuance of the CDC order at issue), all with the goal of encouraging mask-wearing by the general public.[11]

d. Plaintiffs assert that the CDC "disregarded the fact that a protocol already exists under the Federal Aviation Act, and regulations promulgated thereunder by the Federal Aviation Administration (the 'FAA'), which address an air carrier's ability to refuse boarding to a passenger based on a threat of communicable disease." Am. Compl. ¶ 77 (citing 49 U.S.C. § 44902(b); 14 C.F.R. §§ 382.21 and 382.19(c)(1)-(2)).

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[10] In the alternative, any error on this score would also be harmless, as it could not possibly have caused prejudice to *these* Plaintiffs—none of whom allege that they are children between the ages of three and five. *See infra* at 31-32 (discussing the APA's harmless-error rule).

[11] *See, e.g.*, FDA, *Enforcement Policy for Face Masks, Barrier Face Coverings, Face Shields, Surgical Masks, and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency*, at 2-3 (Sept. 2021), https://perma.cc/TVD3-NVKN ("FDA believes the policy set forth in this guidance may help address [] urgent public health concerns by clarifying the regulatory landscape of face masks . . . , and helping to expand the availability of these devices for use by the general public . . . .").

It is not clear why Plaintiffs would prefer to be refused boarding altogether, rather than permitted to board with a mask. Nor is it clear why it matters to the legality of the *CDC's* actions that the *FAA* theoretically could also regulate in this area (though, importantly, only with respect to air travel) but has not.

In any event, this argument ignores the applicable standard of review. Under the APA, "[a] court is not to ask whether a regulatory decision is the best one possible or even whether it is better than the alternatives." *FERC v. Elec. Power Supply Ass'n*, 577 U.S. 260, 292 (2016). And an agency is not held to account for every conceivable policy alternative; it need only "explain [the] rejection of an alternative that was 'within the ambit of the existing Standard' and shown . . . to be effective." *Clinton Mem'l Hosp. v. Shalala*, 10 F.3d 854, 859 (D.C. Cir. 1993) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48-51 (1983)). Plaintiffs' proposal that the CDC instead call on the FAA to prevent the boarding of some (entirely unidentified) category of passengers fails this test many times over. It concerns a different authority, administered by a separate agency. It would cover only a subset of public-transportation conveyances (*i.e.*, commercial airlines). And even with respect to air travel, it would likely fail to identify a significant proportion of contagious passengers. Refusing travel would also represent far greater government entanglement with the day-to-day travel plans of the American people than the order that CDC actually issued—which allows *anyone* to fly, without any advance approval

from the government, as long as they wear a mask or obtain an exemption from the airlines.

e. Plaintiffs suggest that the mask order "fails to take into account persons such as Plaintiffs Daza and Pope, who suffer from anxiety, headaches, and shortness of breath when wearing a mask." Am. Compl. ¶ 79. Not so. The order explicitly exempts any "person with a disability who cannot wear a mask, or cannot safely wear a mask, because of the disability[.]" 86 Fed. Reg. at 8027. It is not clear from the record whether any of the Plaintiffs fall within that definition. Nor is it clear whether any Plaintiff has ever actually attempted to obtain a mask exemption. *See* Am. Compl. ¶¶ 49-50; *see also* Order, ECF No. 35, at 9 ("Nor do they claim that they applied for and were denied an exemption from the mandate."). But, to the extent Plaintiffs are suggesting that they "cannot safely wear a mask" for some medical reason, 86 Fed. Reg. at 8027, then the order does not even apply to them.

Similarly, to the extent Plaintiffs allege that they sometimes experience "shortness of breath when wearing a mask," Am. Compl. ¶ 79, they appear to have overlooked that the order already provides relief in that exact circumstance: "Persons who are experiencing difficulty breathing or shortness of breath or are feeling winded may remove the mask temporarily until able to resume normal breathing with the mask." 86 Fed. Reg. at 8027 n.7.

It seems that Plaintiffs would have preferred the CDC to adopt a slightly broader medical exemption provision. But, just as with the age cutoff for young children, *see*

supra at 23-25, the agency's approach to this issue falls well within the "zone of reasonableness." *Prometheus Radio Project*, 141 S. Ct. at 1158; *see also Little Sisters*, 140 S. Ct. at 2380 (absent some statutory limitation, agencies have broad discretion in crafting exemptions). Under the APA, that is enough.

e. Plaintiffs argue that the CDC "ignore[d] the fact that the travel industry was, up until the time of the Mask Mandate, effectively self-regulating," Am. Compl. ¶ 80—presumably a reference to the fact that many airlines had voluntarily adopted mask requirements of their own. This argument is self-defeating. To the extent Plaintiffs are suggesting that all airlines would issue identical mask requirements even in the absence of the CDC's order, then a victory in this case would give them nothing, and Plaintiffs lack Article III standing. *See, e.g.*, *Renal Physicians Ass'n v. HHS*, 489 F.3d 1267, 1278 (D.C. Cir. 2007) (no redressability if "the undoing of the governmental action will not undo the harm, because the new status quo is held in place by other forces"). To the extent that some or all airlines would *not* do so, then, in the agency's reasonable judgment, the industry is *not* "effectively self-regulating." Am. Compl. ¶ 80. And as long as they are reasonable, it is the agency's policy preferences that matter—not Plaintiffs', and not those of commercial airlines.

* * *

Under well-settled principles of administrative law, it is Plaintiffs' burden to show that "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an

explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. Because Plaintiffs cannot meet that "exceedingly deferential" standard, *Van Antwerp*, 526 F.3d at 1360, Defendants are entitled to summary judgment on Plaintiffs' arbitrary-and-capricious claim.[12]

III. The Transportation Mask Order is exempt from the APA's notice-and-comment requirements (Count II)

a. The APA's notice-and-comment rulemaking procedures are not required "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). This exception streamlines APA procedures in emergency situations, or where delay could result in serious harm. *United States v. Dean*, 604 F.3d 1275, 1281 (11th Cir. 2010).

Plaintiffs allege that the mask order was issued "[w]ithout specifically citing the 'good cause' exception" in the APA. Am. Compl. ¶ 71. That is incorrect: CDC

[12] In other litigation challenging the CDC's order, some have argued that the widespread availability of effective vaccines—a development that largely post-dates issuance of the order—undermines the agency's rationale. *See* Compl., ECF No. 1, *Wall v. CDC*, No. 6:21-cv-0975-PGB-DCI (M.D. Fla. June 7, 2021). Plaintiffs here, by contrast, have explicitly disclaimed and affirmatively waived that argument, in explicit representations that this Court relied upon in denying Defendants' motion to transfer. *See* Order, ECF No. 35 at 9-10 ("[T]hey do not ground their objections to the agency action in their vaccination status. . . . Plaintiffs' Complaint in this action does not mention vaccination at all."); Pls.' Opp'n to Defs.' Mot. to Transfer, ECF No. 26 at 10 ("Plaintiffs here have not raised vaccination status at all, let alone as a material consideration in determining who should be required to wear a mask on a public conveyance."). So this Court need not (and should not) consider that argument here.

explicitly concluded that "there is good cause to dispense with prior public 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 . . . to delay the issuance and effective date of this Order." 86 Fed. Reg. at 8030. CDC thus acted quickly given the "public safety justification[s]" at stake, *Dean*, 604 F.3d at 1281, just as the APA permits. If the good-cause exception does not apply to temporary public-health measures to protect our transportation systems during a pandemic that has already killed more than 847,000 Americans, it is hard to imagine when it would.

Plaintiffs claim that CDC cannot rely on the good-cause exception because any COVID-related "emergency had long passed by early 2021." Am. Compl. ¶ 74 (citing *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, --- F. Supp. 3d ----, 2021 WL 2514138 (M.D. Fla. June 18, 2021)). That is factually incorrect, but also irrelevant—Plaintiffs' narrow conception of the good-cause exception is foreclosed by binding precedent. In the Eleventh Circuit, to invoke the good-cause exception, "there does not need to be an emergency situation." *Dean*, 604 F.3d at 1281. Instead, the agency "only has to show that there is good cause to believe that delay would do real harm." *Id.*; *compare Florida v. Becerra*, 2021 WL 2514138, at *44 (relying on out-of-circuit cases about the good-cause exception applying only in an "emergency situation"). Here, CDC made that common-sense finding, which is amply supported by the record. *See* 86 Fed. Reg. at 8030.

In any event, even accepting the upshot of Plaintiffs' argument (and the holding in *Florida v. Becerra*)—*i.e.*, that the CDC could have issued this order *earlier* in the pandemic, when the emergency was newer—that would not be any reason to block a rule that will still reduce the spread of a dangerous disease in the coming weeks and months. Indeed, just last week, the Supreme Court rejected a virtually identical argument, holding that the government appropriately invoked the good-cause exception in a COVID-related rule issued in November of 2021. *See Biden v. Missouri*, 595 U.S. ---, No. 21A240 (Jan. 13, 2022) (per curiam), Slip op. at 8-9 (agency may "forgo notice and comment" for a vaccination requirement intended to "reduce COVID-19 infections, hospitalizations, and deaths" among healthcare workers).

b. In the alternative, any notice-and-comment error was harmless. The APA provides that "due account shall be taken of the rule of prejudicial error," 5 U.S.C. § 706, which is like "an administrative law harmless error rule," *Little Sisters*, 140 S. Ct. at 2385 (alteration and citation omitted). Accordingly, "[i]f the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand[.]" *PDK Labs., Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004). "The party claiming injury bears the burden of demonstrating harm; the agency need not prove its absence." *Combat Veterans for Cong. Political Action Comm. v. FEC*, 795 F.3d 151, 157 (D.C. Cir. 2015); *see also Shinseki v. Sanders*, 556 U.S. 396, 409-11 (2009) (explaining that the "burden of showing that an error is harmful normally falls upon the party attacking the agency's determination").

Here, Plaintiffs never even attempt to explain what they would have said during a comment process, let alone how that could have made a difference to the outcome, given the emergency that CDC was (and is) facing in responding to COVID-19. *See, e.g.*, *Am. Bankers Ass'n v. NCUA*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999) ("[The D.C.] Circuit has found harmless error where a petitioner did 'not explain what it would have said had it been given' an opportunity to respond." (quoting *Air Transp. Ass'n of Am. v. Civil Aeronautics Bd.*, 732 F.2d 219, 224 n.11 (D.C. Cir. 1984)). And presumably, any comments would have focused primarily on the dubious assertions that masks are ineffective, dangerous, or both. *See* Am. Compl. ¶¶ 35, 41 Accordingly, "it would be senseless to vacate and remand," *PDK Labs.*, 362 F.3d at 799, given the likelihood that CDC would reach the same conclusion—particularly now, given the spread of the highly transmissible Delta and Omicron variants, and the substantial evidence that masks work to slow the spread of COVID-19.

IV. Plaintiffs' non-delegation claims are meritless (Count IV).

Plaintiffs argue in the alternative that, if 42 U.S.C. § 264 is broad enough to sustain the CDC's order, then it is necessarily an unconstitutionally broad delegation of legislative power. But "Congress does not violate the Constitution merely because it legislates in broad terms." *Touby v. United States*, 500 U.S. 160, 165 (1991). Instead, as long as Congress provides "an intelligible principle to which" the agency "is directed to conform, such legislative action is not a forbidden delegation of legislative power."

J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928). 42 U.S.C. § 264 easily clears that low bar.

Over the past century, the Supreme Court has repeatedly upheld far broader (and vaguer) standards than this one. *See, e.g.*, *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475-76 (2001) ("protect the public health"); *Touby*, 500 U.S. at 165 ("imminent hazard to the public safety" (citation omitted)); *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 216 (1943) ("public interest"). In fact, the Supreme Court has not invalidated a statute on nondelegation grounds since 1935, *Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality opinion), *reh'g denied*, 140 S. Ct. 579; the CDC's authority to issue public-health orders necessary to prevent the spread of disease during a global pandemic should not be the first. *See, e.g.*, *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 447 (5th Cir. 2020) (rejecting nondelegation challenge under existing Supreme Court precedent, because it is not the province of the lower courts to "reexamine or revive the nondelegation doctrine"), *cert. denied* 141 S. Ct. 2746 (2021).

In any event, the Supreme Court's decision in *AAR* suggests that the scope of 42 U.S.C. § 264(a) is at least "inform[ed]" by the statute's list of six specifically authorized measures. 141 S. Ct. at 2488. So, even if there were any arguable non-delegation problem with this statute, that resolves it.

V. <u>Plaintiffs lack Article III standing to challenge Executive Order 13998, and in any event those challenges are meritless (Counts V and VI).</u>

Before considering the merits of any of Plaintiffs' claims, the Court must first assure itself that Plaintiffs have carried their burden to demonstrate subject-matter

jurisdiction. Although Defendants do not dispute that at least some Plaintiffs have Article III standing to challenge the CDC's transportation mask order (which imposes a legal obligation on the individual Plaintiffs to wear masks when using public transportation), all Plaintiffs lack standing to challenge Executive Order 13998 (which imposes no obligations on them at all).

a. Standing is a "threshold question in every federal case, determining the power of the court to entertain the suit." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). To establish standing, a plaintiff must show: (1) an "injury in fact," that is, a violation of a legally protected interest that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical"; (2) a causal connection between the injury and the defendant's conduct; and (3) that it is "likely, as opposed to merely speculative that the injury will be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992) (citation omitted). "In plainer language, the plaintiff needs to show that the defendant harmed him, and that a court decision can either eliminate the harm or compensate for it." *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 924 (11th Cir. 2020). "[S]tanding is not dispensed in gross," but rather "a plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought." *Town of Chester*, 137 S. Ct. at 1650. Plaintiffs lack standing for their claims challenging Executive Order 13998, *see* Am. Compl. Counts V & VI, because Plaintiffs' alleged injury is not fairly traceable to the Executive Order and their claims are not redressable by the Court.

b. On these claims, Plaintiffs' alleged injuries—arising from being required to wear a mask when traveling on public-transportation conveyances or at transportation hubs, *see* Am. Compl. ¶¶ 47-50, 53—are not "fairly traceable to the challenged action," *Hollywood Mobile Ests. Ltd. v. Seminole Tribe of Fla.*, 641 F.3d 1259, 1265 (11th Cir. 2011). Crucially, contrary to Plaintiffs' assertion that "[t]he Executive Order mandates the wearing of masks on" various "modes of transportation," Am. Compl. ¶ 23, in fact, the Executive Order does not impose *any* obligations on *anyone* outside of the Executive Branch. Instead, as relevant here, President Biden directed *his subordinates* at all "executive departments and agencies . . . that have relevant regulatory authority" to "take action, to the extent appropriate and consistent with applicable law, to require masks to be worn in compliance with CDC guidelines in or on" various "forms of public transportation." E.O. 13998 § 2(a), *Promoting COVID 19 Safety in Domestic and Int'l Travel*, 86 Fed. Reg. 7205 (Jan. 26, 2021). Because the CDC's order—rather than the Executive Order—imposes the legal obligations that allegedly cause Plaintiffs harm, their "immediate gripe" is with the CDC order and not with the Executive Order, which is fatal to their standing to challenge the Executive Order. *Support Working Animals, Inc. v. Governor of Fla.*, 8 F.4th 1198, 1203 (11th Cir. 2021); *Lewis v. Governor of Ala.*, 944 F.3d 1287, 1301-02, 1306 (11th Cir. 2019) (en banc); *see also Fla. Wildlife Fed'n, Inc. v. S. Fla. Water Mgmt. Dist.*, 647 F.3d 1296, 1305 (11th Cir. 2011) (injury not fairly traceable to the challenged action where it "did not impose any new duty or condition upon the EPA's existing obligations"); *Jacobson v. Fla. Sec'y of State*,

974 F.3d 1236, 1254 (11th Cir. 2020) (plaintiff failed to demonstrate standing where "a different, independent official" had control over the action which allegedly harmed the plaintiff).

c. "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court." *Steel Co. v. Citizens for a Better Envt.*, 523 U.S. 83, 107 (1998). Rather, "[t]he element of redressability requires that 'it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Hollywood Mobile*, 641 F.3d at 1266 (quoting *Lujan*, 504 U.S. at 561); *see also Mulhall v. UNITE HERE Local 355*, 618 F.3d 1279, 1290 (11th Cir. 2010) ("Redressability is established when a favorable decision would amount to a significant increase in the likelihood that the plaintiff would obtain relief that directly redresses the injury suffered.") (internal quotation marks and citation omitted).

The alleged harms suffered by Plaintiffs would not be redressed by a favorable decision from this Court on Plaintiffs' claims challenging the Executive Order. Again, it is the subsequent CDC order—also challenged in this case—that imposes the legal obligations that allegedly cause Plaintiffs' harm, not the Executive Order. Indeed, even absent the Executive Order, the CDC order would stand independently, and Plaintiffs' obligation to wear a mask (or obtain a medical exemption) would be unchanged. Thus, a favorable decision with regards to the Executive Order could not redress Plaintiffs' alleged injuries. *See, e.g.*, *Support Working Animals*, 8 F.4th at 1205 ("Even if we were to issue a decision in the plaintiffs' favor, § 32 would remain on the

books, the plaintiffs' businesses would remain illegal, and they would remain in the same position they were in when they filed the operative complaint."); *Lewis*, 944 F.3d at 1301-05 (it would be "impermissibly speculative" to conclude that Plaintiff had demonstrated redressability, where plaintiffs' "immediate gripe" was with another party); *Fla. Wildlife Fed'n*, 647 F.3d at 1306 ("Even if this court reversed the district court's decision approving the 2009 Consent Decree, the unchallenged 2009 Determination and the water-quality standards promulgated under it would still stand. The Appellants would thus still be subjected to the same numeric criteria that they face under the current circumstances.").[13]

d. Even if Plaintiffs had standing to challenge the Executive Order, their claims still fail on the merits. Plaintiffs' claim in Count V—that the Executive Order is "an unconstitutional exercise of legislative power" because it constitutes a "nationwide edict . . . mandat[ing] that every citizen" wear a mask when traveling—rests on a material misunderstanding of the Executive Order. Am. Compl. ¶¶ 86-90. As explained above, in fact, the Executive Order does not impose obligations on anyone outside of the Executive Branch, instead simply directing "executive departments and

[13] Because Plaintiffs lack Article III standing to challenge the Executive Order, the President should be dismissed as a Defendant in this case, regardless of how the Court resolves Plaintiffs' claims against the CDC. That result would avoid risking a needless separation-of-powers controversy, because where (unlike here) "[t]he only apparent avenue of redress for plaintiffs' claimed injuries would be injunctive or declaratory relief against . . . the President himself . . . [s]uch relief is unavailable." *Newdow v. Roberts*, 603 F.3d 1002, 1013 (D.C. Cir. 2010); *cf. Franklin v. Massachusetts*, 505 U.S. 788, 827 (1992) (Scalia, J., concurring in part and concurring in the judgment) ("It is incompatible with [the President's] constitutional position that he be compelled personally to defend his executive actions before a court.").

agencies . . . that have relevant regulatory authority" to "take action, to the extent appropriate and consistent with applicable law, to require masks to be worn in compliance with CDC guidelines in or on" various "forms of public transportation." E.O. 13998 § 2(a). And to the extent that the Executive Order directs the CDC to take action, it directs the CDC to do so only "to the extent appropriate and consistent with applicable law." *Id.*

None of this is unusual, let alone unconstitutional. The President's "faithful execution of the laws enacted by the Congress . . . ordinarily allows and frequently requires the President to provide guidance and supervision to his subordinates." *Bldg. & Const. Trades Dep't, AFL-CIO v. Allbaugh*, 295 F.3d 28, 32 (D.C. Cir. 2002). And, by definition, directing executive agencies to take action *to the extent consistent with applicable law* cannot be interpreted as an order to violate the constitution. *See, e.g.*, *id.* at 33 ("[H]ad President Truman merely instructed the Secretary of Commerce to secure the Government's access to steel '[t]o the extent permitted by law,' *Youngstown* would have been a rather mundane dispute over whether the Secretary had statutory authority to act as he did."); *Common Cause v. Trump*, 506 F. Supp. 3d 39, 47 (D.D.C. 2020) (Katsas, J.) ("We cannot ignore these repeated and unambiguous qualifiers imposing lawfulness and feasibility constraints on implementing the memorandum.").

Plaintiffs' Tenth Amendment claim (Count VI)—which asserts that the Executive Order violates the Tenth Amendment by "imped[ing] on the traditionally-recognized prerogative of the States to protect the public health of their inhabitants

under their general police power," Am. Compl. ¶ 93—fares no better. Similar to Count V, the fact that the Executive Order does not impose any obligations outside of the Executive Branch—and merely instructs executive agencies to take some subsequent action, which may itself be subject to legal challenge (as the CDC order is here)—is fatal. The Executive Order cannot violate the Tenth Amendment when it merely directs that further agency action be taken consistent with applicable law.

In any event, the only relevant agency action that actually applies to Plaintiffs—the CDC order—is entirely consistent with the Tenth Amendment.[14] The Tenth Amendment "is essentially a tautology," in that it "confirms that the power of the Federal Government is subject to limits that may, in a given instance, reserve power to the States." *New York v. United States*, 505 U.S. 144, 157 (1992). Those limits on federal power, however, are "not derived from the text of the Tenth Amendment itself," but rather derive from all of the other "limitations contained in the Constitution." *Id.* at 156. As discussed in detail *supra* (at 14-20), the CDC has exercised authority properly delegated by Congress. And there is no doubt that Congress has the constitutional authority to legislate to mitigate the spread of communicable disease—as it did in the Public Health Service Act—pursuant to the Commerce Clause and (if necessary) the Necessary and Proper Clause. U.S. Const., art. I, § 8, cls. 3 and 18; *see also supra* at 18-19.

[14] To be clear, Plaintiffs do not actually bring any Tenth Amendment challenge to the CDC order. Count VI—Plaintiffs' sole Tenth Amendment claim—challenges only the Executive Order, and in fact does not even mention the CDC order. *See* Am. Compl. ¶¶ 91-95. Thus, the Court need not address whether the CDC order violates the Tenth Amendment.

Plaintiffs' amended complaint does not suggest otherwise. Rather, Plaintiffs merely assert that "[t]he Executive Order impedes on the . . . prerogative of the States to protect the public health . . . under their general police power." Am. Compl. ¶ 93. But even ignoring (again) Plaintiffs' material misinterpretation of the Executive Order, this is not a viable Tenth Amendment theory: "The Court long ago rejected the suggestion that Congress invades areas reserved to the States by the Tenth Amendment simply because it exercises its authority under the Commerce Clause in a manner that displaces the States' exercise of their police powers." *Hodel v. Va. Surface Mining & Reclamation Ass'n, Inc.*, 452 U.S. 264, 291 (1981).

CONCLUSION

For these reasons, summary-judgment should be entered for Defendants on all claims.

Dated: January 18, 2022

Respectfully submitted,

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