UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

| HEALTH FREEDOM DEFENSE FUND, INC., a Wyoming Not-for-Profit Corporation, ANA CAROLINA DAZA, and SARAH POPE, individuals, | Case No COMPLAINT FOR DECLARATORY RELIEF |
|---|--|
| Plaintiffs, | DEMAND FOR JURY TRIAL |
| VS. | |
| JOSEPH R. BIDEN, JR., President of the | |
| United States; XAVIER BECERRA, | |
| Secretary of Health and Human Services, in | |
| his official capacity; THE DEPARTMENT | |
| OF HEALTH AND HUMAN SERVICES; | |
| THE CENTERS FOR DISEASE CONTROL; | |
| ROCHELLE P. WALENSKY, MD, MPH, | |
| Director of the Centers for Disease Control | |
| and Prevention, in her official capacity; and | |
| MARTIN S. CETRON, MD, Director, | |
| Division of Global Migration and | |
| Quarantine, Centers for Disease Control | |
| and Prevention, in his official capacity; The | |
| UNITED STATES OF AMERICA, | |
| Defendants. | |

Plaintiffs, Health Freedom Defense Fund, Inc. ("HFDF"), Ana Carolina Daza, and Sarah Pope, by and through their undersigned counsel, sue Defendants, Joseph R. Biden, Jr., in his official capacity as the President of the United States of America, Xavier Becerra in his official capacity as Secretary of the Department of Health and Human Services, The Department of Health and Human Services ("HHS"), The Centers for Disease Control ("CDC"), Rochelle P. Walensky, MD MPH, in her official capacity as the Director of the CDC, Martin S. Cetron, MD, in his official capacity as the Director of the CDC's Division of Global Migration and Quarantine, and The United States of America, and allege as follows:

INTRODUCTION

1. Plaintiffs challenge the validity of Executive Order Number 13998 issued by Defendant Biden on January 21, 2021 entitled Executive Order on Promoting COVID-19 Safety in Domestic and International Travel (the "Executive Order"), 86 Fed. Reg. 7205, a true and correct copy of which is attached hereto as Exhibit A, and the subsequent order issued by the CDC, a department of HHS, on January 29, 2021, entitled, "Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs" (the "Mask Mandate"), 86 Fed. Reg. 8025, a true and correct copy of which is attached hereto as Exhibit B.

2. The Executive Order, in pertinent part, directs all relevant federal agencies to take action to require that masks be worn on all forms of public transportation in accordance with CDC guidelines.

3. Shortly thereafter, the CDC issued the Mask Mandate, pursuant to 42 U.S.C. § 264(a) and 42 C.F.R. §§ 70.2, 71.31(b), and 71.32(b), without allowing comments under the Administrative Procedure Act.

4. The Mask Mandate requires that, when traveling on conveyances and at transportation hubs, all persons (with limited exceptions) must wear masks. The

Mask Mandate also requires conveyance operators and hub operators to make sure that all passengers are wearing masks, except in very limited circumstances.

5. Plaintiffs challenge the Mask Mandate pursuant to 5 U.S.C. § 706(2) of the Administrative Procedure Act (the "APA") on grounds that it:

- a. is not in accordance with and exceeds the CDC's statutory and regulatory authority under 42 U.S.C. § 264(a) and 42 C.F.R. §§ 70.2, 71.31(b), and 71.32(b);
- b. is a rule that was enacted without observance of notice and comment procedures required by the APA; and/or
- c. is arbitrary and capricious, in that it exempts children under age 2 without regard to scientific evidence of the impact of prolonged mask use on persons of all ages.

6. Alternatively, if the Mask Mandate does not exceed Defendants' statutory and regulatory authority, then 42 U.S.C. § 264(a) constitutes an unlawful delegation of legislative authority.

7. As well, Plaintiffs challenge the Executive Order on grounds that it constitutes an improper exercise of legislative authority by the Executive Branch, and that it further improperly asserts a general police power that has traditionally been relegated to the States, in derogation of the Separation of Powers under the United States Constitution.

PARTIES

8. Plaintiff Health Freedom Defense Fund (hereinafter, "HFDF") is a notfor-profit public benefit Wyoming corporation with its headquarters in Sandpoint, Idaho. HFDF is a member organization that seeks to advocate for and educate the public on the topics of medical choice, bodily autonomy, and self-determination, and that opposes laws and regulations that force individuals to submit to the administration of medical products, procedures, and devices against their will.

9. Plaintiff Ana Carolina Daza is domiciled in Pinellas County, Florida and is *sui juris*.

10. Plaintiff Sarah Pope is domiciled in Hillsborough County, Florida and is *sui juris*.

11. Plaintiffs Daza and Pope are referred to herein as the "Individual Plaintiffs".

12. Allegations regarding "Plaintiffs" hereinbelow shall be deemed to include the Individual Plaintiffs and Plaintiff HFDF.

13. Defendant Biden is the President of the United States and is sued in his official capacity only.

14. Defendant The United States of America is sued herein under 5 U.S.C. §§ 702–03 and 28 U.S.C. § 1346.

15. Defendant the Centers for Disease Control and Prevention ("CDC")

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 5 of 28 PageID 5

issued and is implementing the Mask Mandate, 86 Fed. Reg. 8025. *See* Ex. B. The CDC is a component of Defendant the Department of Health & Human Services ("HHS").

16. Defendant Becerra is the Secretary of HHS, and is sued in his official capacity.

17. Defendant Walensky is the Director of the Centers for Disease Control and Prevention and is sued in her official capacity.

18. Defendant Cetron is the Director of the CDC's Division of Global Migration and Quarantine and is sued in his official capacity.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1346, and 5 U.S.C. §§ 702-03.

20. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) and (e)(1). A substantial part of the events giving rise to this claim occurred and continue to occur in this District, the Individual Plaintiffs and declarants in support of Plaintiff HFDF all reside within the Middle District and within this Division, and each Defendant is an officer of the United States sued in his or her official capacity, or an agency of the United States, or the United States.

21. This Court has the authority to grant the relief requested herein pursuant to 5 U.S.C. § 706 and 28 U.S.C. §§ 2201-02.

FACTS COMMON TO ALL COUNTS

22. Upon taking office on January 20, 2021, President Biden issued a series of executive orders addressing the COVID-19 pandemic. President Biden issued the subject Executive Order on his second day in office, January 21, 2021. *See* Exhibit A.

23. The Executive Order mandates the wearing of masks on modes of transportation, including "(i) airports; (ii) commercial aircraft; (iii) trains; (iv) public maritime vessels, including ferries; (v) intercity bus services; and (vi) all forms of public transportation as defined in section 5302 of title 49, United States Code." *Id.*; 86 Fed. Reg. 7205.

24. The Executive Order cites no statutory authority to support its broad, sweeping mandate, and does not expressly refer to any national emergency.

25. Pursuant to the directive of the Executive Order, Defendant Cetron, acting on behalf of CDC in his official capacity and with the approval of Defendants HHS, Becerra, and Walensky, issued the Mask Mandate on January 29, 2021, just eight days after the Executive Order. *See* Exhibit B. The Mask Mandate took effect at 11:59 p.m. on February 1, 2021.

26. Specifically, the Mask Mandate in part 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." 86 Fed. Reg. at 8026. Those best efforts include, *inter alia*,

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 7 of 28 PageID 7

"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).

27. The latter directive constitutes an outright fabrication, as no such "Federal law" exists.

28. The Mask Mandate cites as its statutory authority 42 U.S.C. 264(a), and as regulatory authority 42 C.F.R. §§ 70.2, 71.31(b), and 71.32(b). As further discussed below, none of those authorities provides a legal basis for the Mask Mandate.

29. From January 30, 2020, when the World Health Organization declared a "public health emergency of international concern" over the global outbreak of COVID-19, until the date of the Executive Order (a period of nearly one year), the United States government took no action to mandate the wearing of masks on travel conveyances.

30. Nevertheless, the Mask Mandate provides that it "is not a rule within the meaning of" the APA, "but is rather an emergency action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 70.2, 71.31(b), 71.32(b)." 86 Fed. Reg. 8030.

31. The Mask Mandate further provides that, even if a court determines that it qualifies as a rule under the APA:

notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and comment and the opportunity to

comment on this Order and the delay in effective date. Considering the public health emergency caused by COVID-19, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Order."

Id.

32. Thus, even though the CDC had taken no action to publish any rule or other agency action of this sort for nearly an *entire year* since the COVID-19 pandemic was declared as a public health emergency, Defendants sought to justify bypassing the normal rule-making procedures required by the APA – thus claiming a sweeping police power over every person seeking to board a public conveyance or even enter a transportation hub - by calling it an *emergency*.

33. As a consequence, Defendants require every person who enters a transportation hub or public conveyance in the United States, and every person onboard a conveyance arriving at or departing from a U.S. port of entry, to wear, at all times and with limited exceptions, a face-covering that covers the nose and mouth.

34. The practical result is that a traveler must wear a mask for hours, with very little respite except when actively eating or drinking. A typical transcontinental flight, for example, lasts for approximately five hours or more. The additional time spent entering an airport, checking in, clearing security, waiting for departure, deplaning, and retrieving luggage easily increases the time spent wearing a mask to

at *least* seven hours or more. Non-direct flights that require a connection can add at least one to three hours to that total. A person flying non-direct from Tampa to San Francisco, for example, could easily end up having to spend ten hours or more wearing a mask.

35. The potential adverse health effects from this cannot be casually dismissed. Even healthcare workers who are trained in the use of masks have been susceptible to adverse effects from prolonged mask use during the COVID-19 pandemic:

Headaches related to prolonged mask use can be attributed to mechanical factors, hypercapnia, and hypoxemia. Tight straps and pressure on superficial facial and cervical nerves are mechanical features causing headaches. Cervical neck strain from donning PPE, sleep deprivation, irregular mealtimes, and emotional stress are other sources of healthcare headaches among professionals during prolonged mask use. Tight fitting masks cause inadequate ventilation and increased levels of carbon dioxide (CO₂) known as hypercapnia. As CO₂ is a known respiratory stimulant, a buildup of exhaled CO₂ between the mask and face will cause increased lung ventilation and respiratory activity. Symptoms of hypoxemia such as chest discomfort and tachypnea are also noted in healthcare professionals with prolonged mask use. Exhaled CO₂ builds up between the mask and face, and increased levels of CO₂ cause confusion, impaired cognition, and disorientation.¹

¹ See Adverse Effects of Prolonged Mask Use among Healthcare Professionals during COVID-19 (Journal of Infectious Diseases and Epidemiology), available at <u>https://clinmedjournals.org/articles/jide/journal-of-infectious-diseases-and-epidemiology-jide-6-130.php?jid=jide</u> (last viewed on July 10, 2021) (footnotes omitted). See also 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), available at

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 10 of 28 PageID 10

36. Among the limited exemptions to the Mask Mandate are children under the age of 2 years. Defendants provide no epidemiological basis for this arbitrary cut-off age, and offer no discussion of the impact of prolonged mask-wearing on children of all ages, let alone adults.

37. By comparison, the WHO takes the position that children age 5 and under should not be required to wear masks at all, and that the use of masks for children aged 6 to 11 should be only under limited circumstances.² Recent evidence indicates that even short-term mask-wearing in children of all ages causes them to incur unacceptably high concentrations of CO2 in their blood.³ Defendants' selection of age 2 as the cut-off for an age exemption is thus completely arbitrary.

38. More broadly, the Federal Food and Drug Administration's position on the efficacy of masks in preventing the spread of COVID-19 for people of all ages has been equivocal. On the FDA's website regarding face masks, surgical masks,

https://pubmed.ncbi.nlm.nih.gov/34028470/ (last viewed in July 10, 2021).

² See <u>https://www.who.int/news-room/q-a-detail/q-a-children-and-masks-related-to-covid-19</u> (last viewed on July 7, 2021).

³ A recently-published study of the effects of masks on children in Germany showed that, after only three minutes of breathing with a mask, children of ages ranging from 6 to 17 years accumulated CO2 levels that far exceeded acceptable levels established by the German government. *See* Experimental Assessment of Carbon Dioxide Content in Inhaled Air With or Without Face Masks in Health Children (JAMA Pediatrics June 30, 2021), available at https://jamanetwork.com/journals/jamapediatrics/fullarticle/2781743?appId=scweb (last viewed on July 7, 2021).

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 11 of 28 PageID 11

and respirators, it states that "[m]asks *may* help prevent people who have COVID-19 from spreading the virus to others.... Wearing a face mask *may* limit exposure to respiratory droplets and large particles and *may* help prevent people who have COVID-19 from spreading the virus."⁴ (emphasis added).

39. In its umbrella Emergency Use Authorization ("EUA") for face masks to be used by the general public in response to COVID-19, the FDA recites that "the authorized face masks *may* be effective as source control to help prevent the spread of" COVID-19. *See* EUA dated April 24, 2020, attached hereto as Exhibit "C", at 3 (emphasis added). But even here, the FDA hedges its bet by prohibiting manufacturers of non-surgical masks from labeling their product:

> in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction.

Id. at 4.

40. To make things more confusing, the FDA has revoked its EUAs for non-NIOSH⁵-approved respirator masks – i.e., the kn95 masks that became widely

⁴ See <u>https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/face-masks-including-surgical-masks-and-respirators-covid-19#:~:text=Source%20control%20refers%20to%20use,spread%20of%20respiratory%20secretions (updated on June 30, 2021).</u>

⁵ National Institute for Occupational Safety and Health.

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 12 of 28 PageID 12

available and are often used by members of the public.⁶ Even a well-informed consumer would find it difficult, if not impossible, to understand what types and brands of face masks have been authorized or approved, and for what purposes they can or should be used and, most significantly, which – *if any* – are regarded as safe to use for extended periods of time by the National Institute for Occupational Safety and Health. The Mask Mandate shows no indication that these concerns were considered and, if so, whether they were accorded any weight.

41. In addition to safety concerns, there are substantial reasons to doubt the efficacy of masks for controlling virus spread. A study published in the Emerging Infectious Disease Journal in May 2020 found that ten randomized controlled trials of the use of face masks to control the influenza virus, which is essentially the same size as the SARS-CoV-2 virus, showed no significant reduction in influenza transmission.⁷

42. Similarly, as study of nearly two thousand United States Marine Corp recruits published in the New England Journal of Medicine in November 11, 2020,

⁶ See <u>https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#china</u> (last viewed on July 8, 2021).

⁷ See Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings – Personal Protective and Environmental Measures - Volume 26, Number 5 – May 2020 - Emerging Infectious Diseases journal - CDC, available at <u>https://wwwnc.cdc.gov/eid/article/26/5/19-</u> 0994_article (last viewed on July 8, 2021).

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 13 of 28 PageID 13

indicated that masks did not reduce or prevent the spread of SARS-CoV-2.8

43. As recently as December 2020, two months before the Mask Mandate

was issued, the WHO announced:

At present, there is only limited and inconsistent scientific evidence to support the effectiveness of masking of healthy people in the community to prevent infection with respiratory viruses, including SARS-CoV-2. A large randomized community-based trial in which 4862 healthy participants were divided into a group wearing medical/surgical masks and a control group found no difference in infection with SARS-CoV-2.⁹

44. Cloth masks, such as those generally used by the public, are particularly problematic according to a randomized controlled trial conducted with regard to the influenza virus in 2015. The study concluded that due to moisture retention, reuse of cloth masks and poor filtration, cloth masks may result in increased risk of infection.¹⁰

45. Thus, the FDA – the very agency charged with researching and understanding the efficacy of medical devices – has never been able to state whether

See SARS-CoV-2 Transmission among Marine Recruits during Quarantine | NEJM, available at <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2029717</u> (last viewed on July 8, 2021).

⁹ World Health Organization, Mask use in the context of COVID-19. Geneva, Switzerland, 1 December, 2020, available at <u>https://apps.who.int/iris/bitstream/handle/10665/337199/WHO-2019-nCov-IPC_Masks-2020.5-eng.pdf?sequence=1&isAllowed=y</u> (last viewed on July 9, 2021).

¹⁰ See A cluster randomised trial of cloth masks compared with medical masks in healthcare workers - PubMed (nih.gov), available at <u>https://pubmed.ncbi.nlm.nih.gov/25903751/</u> (last viewed on July 8, 2021).

the kinds of face masks being used by the general public provide any benefit for preventing the spread of a virus such as COVID-19.

46. Yet, with the stroke of a pen, Defendants imposed their sweeping Executive Order and Mask Mandate on nearly every traveler in the country.

Plaintiffs' Standing to Seek Declaratory and Injunctive Relief

47. As alleged above, Plaintiff HFDF is a not-for-profit, membership organization that seeks to advocate for and educate the public on the topics of medical choice, bodily autonomy, and self-determination, and that opposes laws and regulations that force individuals to submit to the administration of medical products, procedures, and devices against their will. Several of HFDF's members travel, or wish to travel, on interstate conveyances as defined by the Mask Mandate, are domiciled in the Middle District of Florida, Tampa Division, and are directly affected by the Mask Mandate, as more fully set out in the Declarations attached hereto and made a part hereof as Composite Exhibit "D". HFDF's members therefore would have standing in their own right to bring the causes of action asserted by HFDF.

48. The interests at stake in this case are germane to HFDF's purpose, and neither the claims asserted nor the relief requested by HFDF require the individual participation of HFDF's members. HFDF therefore has standing to bring this case on behalf of its members, which presents a justiciable issue for the Court.

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 15 of 28 PageID 15

49. Plaintiff Ana Carolina Daza resides in Pinellas County. She has traditionally flown annually to visit family and to attend to family property in Colombia, and is subject to the mask mandate. Because of international travel restrictions instituted as a result of the COVID pandemic and the resulting, multiple flight cancellations, Ms. Daza has not flown since February 2020. However, she is planning to travel to see her family in Colombia in August 2021. She understands that she will be required to wear a mask on the flight, but strenuously objects to being required to do so. Ms. Daza suffers from anxiety when wearing a mask, feels like she cannot breathe, and suffers from an overwhelming urge to remove the mask. She also gets headaches and suffers shortness of breath when wearing a mask – i.e., the very same symptoms that have been found to affect healthcare workers due to prolonged mask use (see supra, ¶35 & fn. 1). Her physician has diagnosed her as having anxiety and has provided a note, but her disability does not qualify her for a disability exemption under the Mask Mandate.

50. Plaintiff Sarah Pope resides in Hillsborough County. She still regularly flies to Virginia to see her elderly mother, and wears a mask when required to do so, but she now avoids long-haul flights because cannot tolerate wearing a mask for extended periods of time. She had to forego joining her family on a trip to Hawaii because the thought of wearing a mask for such a long flight gave her anxiety, and she is concerned about having panic attacks if she attempts to do so. She thus

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 16 of 28 PageID 16

strongly objects to the Mask Mandate, and wants to see it lifted so that she might have an opportunity to join her family on a long-haul flight, again.

51. Plaintiffs thus have Article III standing to bring this lawsuit, as their dispute is concrete and not conjectural or hypothetical. Their injuries are fairly traceable to the Executive Order and the Mask Mandate, and are redressable by this Court.

52. To the extent applicable, Plaintiffs have statutory standing under the Administrative Procedure Act, 5 U.S.C. § 706, because their claims at least arguably fall within the zone of interests implicated by the statutory violations asserted herein.

53. Plaintiffs have no adequate remedy at law for the ongoing violations and usurpations of constitutional and statutory authority alleged herein.

54. All conditions precedent to bringing this lawsuit have been performed, excused, or waived.

COUNT I

Agency action not in accordance with law and in excess of authority

(Violation of the APA)

55. Plaintiffs incorporate the allegations of paragraphs 1 through 54, and further allege:

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 17 of 28 PageID 17

56. Under the APA, a court must "hold unlawful and set aside agency action" that is "in excess of statutory . . . authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

57. The Mask Mandate purports to derive its statutory and regulatory authority from 42 U.S.C. § 264(a) and 42 C.F.R. §§ 70.2, 71.31(b), and 71.32(b). Ex. B.

58. The Mask Mandate exceeds that authority in several ways.

59. *First*, neither 42 U.S.C. § 264, nor 42 C.F.R. § 70.2, nor 42 C.F.R. §§ 71.31(b) or 71.32(b) authorizes the CDC to institute such a broad sweeping mandate requiring every person who travels on a public conveyance to don some type of garment or device. To hold otherwise would be "tantamount to creating a general police power." *Skyworks, Ltd. v. CDC,* Case No. 5:20-cv-2407, 2021 U.S. Dist. LEXIS 44633 at *31 (N.D. Ohio March 10, 2021).

60. *Second,* Sections 264 and 70.2 permit the CDC to act only if it first "determines that the measures taken by" a state "are insufficient to prevent the spread" of a communicable disease "from such State . . . to any other State." 42 C.F.R. § 70.2. But here, the CDC has made no such determination. Rather, the Mask Mandate recites a broad statement:

Any state or territory without sufficient mask-wearing requirements for transportation systems within its jurisdiction has not taken adequate measures to prevent the spread of COVID-19 from such state or territory to any other state or territory. 86 Fed. Reg. 8029.

61. This utterly fails to identify measures taken by a particular state, or any state at all, much less how those measures are insufficient.

62. Third, the CDC's reading of its authority under 42 U.S.C. § 264 is divorced from context. The statute gives the CDC the authority 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." 42 U.S.C. § 264(a). However, the next sentence of the statute clarifies that to "carry[] out and enforc[e]" those regulations, the CDC is authorized to conduct "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 such measures, as in [CDC's] judgment may be necessary." Id. This "second sentence [of Section 264(a)] operates to limit CDC's enforcement and implementation authority to only those actions resembling 'inspection, fumigation, disinfection, . . . [and] pest extermination." Florida v. Becerra, Case No. 8:21-cv-839, 2021 U.S. Dist. LEXIS 114297, *55 (M.D. Fla. June 18, 2021) (Merryday, D.J.) As such, the second sentence "discloses, illustrates, exemplifies, and limits to measures

similar in scope and character the measures contemplated and authorized by Congress when enacting the statute." *Id.* (citing *Yates v. United States*, 574 U.S. 528, 546 (2015)). Clearly, mandating that every person setting foot in an airport, bus terminal, train station, aircraft, bus, train, or ship wear a mask over his or her nose and mouth exceeds the scope of that limiting language.

63. *Fourth*, 42 C.F.R. §§ 71.31(b) and 71.32(b), rather than assist Defendants' sweeping power grab, only serve to illustrate the limited scope of the CDC's statutory and regulatory authority. Section 71.31(b) provides:

The [CDC] may require 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. The [CDC] may issue a controlled free pratique to the carrier stipulating what measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.

64. But again, the Mask Mandate divorces this provision from context. The meaning of this section is clarified by Section 71.31(a), which addresses a carrier's "arrival at a U.S. port. . . ." It is further clarified by the reference in Section 71.31(b) to a "controlled free pratique," which means "permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions." 42 C.F.R. § 71.1(b). Clearly, then, Section 71.31(b) refers to the CDC's authority to detain a carrier that is suspected of harboring persons, articles, or things that present a risk

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 20 of 28 PageID 20

of communicable disease, or to grant leave to the carrier to enter a U.S. port under certain conditions. That is a far cry from authorizing the CDC to require every person entering a conveyance, anywhere in the U.S., or anywhere in the world where a person is *en route* to the U.S., to wear a mask.

65. Section 71.32(b) provides that, whenever the CDC "has reason to believe that any arriving carrier or article or thing on board the carrier is or may be contaminated with a communicable disease," the CDC "may require detention, disinfection, disinfestation, fumigation, or other related measures. . . ." This clearly relates back to the second sentence of 42 U.S.C. § 264(a) – *i.e.*, it illustrates how narrow and limited the CDC's authority actually is. It certainly does not confer the broad, sweeping power assumed by Defendants in regard to the Mask Mandate.

COUNT II

Failure to Provide Notice and Comment

(Violation of the APA)

66. Plaintiffs incorporate the allegations of paragraphs 1 through 54, and further allege:

67. Even if the Mask Mandate falls within the CDC's statutory authority under 42 U.S.C. § 264(a), the APA required Defendants to provide notice of, and receive comment on, the Mask Mandate. *See* 5 U.S.C. § 533.

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 21 of 28 PageID 21

68. Without specifically citing the "good cause" exception of 5 U.S.C. § 553(b)(B), Defendants lean on the year-old "emergency" of COVID-19 to claim that the Mask Mandate is not a "rule" within the meaning of the APA. 86 Fed. Reg. at 8030. As a result, Defendant did not even invite comments, much less provide for a notice and comment interval.

69. *First,* the Mask Mandate is clearly a "rule" within the meaning of the APA, because it prescribes law (the Mandate *literally* instructs carriers and transportation hub operators to inform passengers that failure to properly wear a mask constitutes a "*violation of Federal law*," 86 Fed. Reg. at 8026, even though no corresponding statute exists), and marks the consummation of an agency decision-making process that determines rights or obligations and/or constitutes action from which legal consequences will flow. *See* 5 U.S.C. § 551(4); *Florida v. Becerra*, 2021 Dist. LEXIS 114297 at *110 (citations omitted).

70. *Second*, the "good cause" exception of 5 U.S.C. § 553(b)(B), which Defendants have only tacitly invoked, is to be "narrowly construed and only reluctantly countenanced," and only "excuses the APA's notice-and-comment procedures in an 'emergency situation.'" *Becerra, supra* at *123 (citations omitted).

71. Good cause does not exist when the agency has sufficient time to provide notice and comment. HHS declared COVID-19 a public health emergency early in 2020, and yet did not promulgate the Mask Mandate until early 2021,

practically a year later. If the COVID-19 pandemic presented a national emergency in early 2020, that emergency had long passed by early 2021. As noted by this Court in *Becerra*, "[i]f the existence of a communicable disease alone permitted CDC to find 'good cause,' CDC would seldom, if ever, need to comply with the statutory requirement for 'good cause' to dispense with notice and comment." *Becerra*, *supra* at *126.

COUNT III

Arbitrary and Capricious Agency Action

(Violation of the APA)

72. Plaintiffs incorporate the allegations of paragraphs 1 through 54, and further allege:

73. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary [or] capricious," as Defendants' actions are here. 5 U.S.C. § 706(2)(A).

74. *First*, Defendants 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. *See* 49 U.S.C. § 44902(b); 14 C.F.R. §§ 382.21 and 382.19(c)(1)-(2). The regulatory regime promulgated by the FAA is comprehensive, and the FAA – which is responsible for

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 23 of 28 PageID 23

interpreting and enforcing statutes governing flight operations – apparently did not deem it necessary to update or amend those regulations during the nearly one-year period from the onset of the COVID-19 pandemic to the date of the Mask Mandate.

75. *Second*, an agency "must examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Here, Defendants failed to articulate why the Mask Mandate was needed, what specific State measures were inadequate, and why the exemptions under the Mask Mandate were not arbitrarily selected.

76. As noted above, for example, Defendants provide 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, and recommends that children ages 6-11 wear masks only under limited circumstances. The Mask Mandate also fails to articulate whether any safety data respecting the effects of long-term mask use for persons of all ages was considered. The Mandate's only exemption for disabilities is for persons "who cannot wear a mask, or cannot safely wear a mask, because of the disability...." 86 Fed. Reg. at 8027. This 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. Defendants also fail to address the FDA's own uncertainty regarding the efficacy of masks for the general

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 24 of 28 PageID 24

public, as well as concerns regarding the safety of wearing masks for extended periods of time.

77. Defendants also ignore the fact that the travel industry was, up until the time of the Mask Mandate, effectively self-regulating, and the Mask Mandate contains no finding to the contrary. The Mandate forecloses carriers from adjusting to changing circumstances, and from offering alternative solutions.

78. *Third,* the Mask Mandate fails to show that Defendants considered less burdensome alternatives. For example, existing Federal Air Regulations provide guidance for airlines to determine whether they may deny boarding to a passenger based on a "direct threat" of infectious disease. *See* 14 C.F.R. §§ 382.21 and 382.19(c)(1)-(2).

COUNT IV

Unconstitutional Delegation of Legislative Power

(Violation of U.S. Const. Art. I, § 1 as to the Mask Mandate)

79. Plaintiffs incorporate the allegations of paragraphs 1 through 54, and further allege:

80. Article I, Section 1 of the U.S. Constitution provides that "[a]ll legislative powers herein granted shall be vested in a Congress of the United States." In other words, only Congress can make laws.

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 25 of 28 PageID 25

81. If the Mask Mandate does not exceed Defendants' authority under 42 U.S.C. § 264 and its related regulations, then Section 264 constitutes an unconstitutional delegation of legislative authority to the Executive Branch, which afforded the CDC the power to determine the rights of every person engaged in interstate travel, and to make a sweeping policy decision without any meaningful accountability to the electorate.

COUNT V

Unconstitutional Exercise of Legislative Power

(Violation of U.S. Const. Art. I, § 1 as to the Executive Order)

82. Plaintiffs incorporate the allegations of paragraphs 1 through 54 and 80, and further allege:

83. The Executive Order constitutes an unconstitutional exercise of legislative power by the Executive Branch, in that it is not authorized by any statute, and indeed does not even deign to cite any statutory basis.

84. The Executive Order does not cite any national emergency, nor could it. No such emergency existed at the time that the Executive Order was entered. By then, the COVID-19 pandemic had affected travel in the United States for nearly a year.

85. Congress could have enacted legislation requiring the wearing of masks on public conveyances during the year that preceded the Executive Order, but

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 26 of 28 PageID 26

Congress did not do so. No provision of Article II allows a President to enact nationwide edicts, merely because the Legislative Branch has failed to enact legislation that the President would prefer.

86. The Executive Order is unprecedented in its breadth and impact. Never before has a President of the United States entered an executive order mandating that every citizen of the Republic be required to don a type of garment or device, whether when traveling or otherwise, for any reason whatsoever.

87. The Executive Order contains no expiration date or sunset provision, and fails to provide any guidance as to when or under what conditions it may be deemed to have expired.

<u>COUNT VI</u>

Violation of Separation of Powers

(Violation of Amendment X to the United States Constitution)

88. Plaintiffs incorporate the allegations of paragraphs 1 through 54, and further allege:

89. The Tenth Amendment to the United States Constitution provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the People." U.S. Const. Am. X.

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 27 of 28 PageID 27

90. The Executive Order impedes on the traditionally-recognized prerogative of the States to protect the public health of their inhabitants under their general police power. The public health power, including the power to quarantine, is still understood as a function of state police power, with the federal role being limited to measures that are "distinctly limited in time, scope, and subject matter." *Becerra, supra* at *43-44.

91. The Executive Order contains no finding that the public health authority of the States has been somehow inadequate, and contains no finding explaining why, at this late stage in the pandemic, action by the Federal government is suddenly warranted or necessary.

92. As such, the Executive Order violates the Separation of Powers between the States and the Federal Government.

PRAYER FOR RELIEF

For the foregoing reasons, Plaintiffs ask the Court to:

- a) Enter a declaratory judgment holding the Mask Mandate as unlawful and/or unconstitutional, and set it aside.
- b) Enter a declaratory judgment holding the Executive Order as unconstitutional, and set it aside.
- c) Award Plaintiffs their reasonable costs and attorney's fees.
- d) Award such other relief as the Court deems equitable and just.

Case 8:21-cv-01693 Document 1 Filed 07/12/21 Page 28 of 28 PageID 28

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury for all matters so triable.

Filed this 12th day of July, 2021.

HADAWAY, PLLC 2425 Lincoln Ave. Miami, FL 33133 Tel: (305) 389-0336

<u>/s/ Brant C. Hadaway</u> Brant C. Hadaway, B.C.S. Florida Bar No. 494690 Email: <u>bhadaway@davillierlawgroup.com</u>

and

George R. Wentz, Jr. *Pro Hac Vice Application to be filed* The Davillier Law Group, LLC 935 Gravier Street, Suite 1702 New Orleans, Louisiana 70112 Email: <u>gwentz@davillierlawgroup.com</u> Tel: (504) 582-6998

Attorneys for Plaintiffs