

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

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

HEALTH FREEDOM DEFENSE FUND,
INC., a Wyoming Not-for-Profit
Corporation, ANA CAROLINA DAZA,
and SARAH POPE, individuals,

Plaintiffs,

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.

**AMENDED COMPLAINT FOR
DECLARATORY RELIEF**

DEMAND FOR JURY TRIAL

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 not-for-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”) 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*, “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 headaches among healthcare 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

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.

<https://clinmedjournals.org/articles/jide/journal-of-infectious-diseases-and-epidemiology-jide-6-130.php?jid=jide> (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 <https://pubmed.ncbi.nlm.nih.gov/34028470/> (last viewed in July 10, 2021).

² See <https://www.who.int/news-room/q-a-detail/q-a-children-and-masks-related-to-covid-19> (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 Healthy Children (JAMA Pediatrics June 30, 2021), available at <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2781743?appId=scweb> (last viewed on July 7, 2021).

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, 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.

⁴ See <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).

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 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

⁵ National Institute for Occupational Safety and Health.

⁶ See <https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#china> (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 https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article (last viewed on July 8, 2021).

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, 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

⁸ See SARS-CoV-2 Transmission among Marine Recruits during Quarantine | NEJM, available at <https://www.nejm.org/doi/full/10.1056/NEJMoa2029717> (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 https://apps.who.int/iris/bitstream/handle/10665/337199/WHO-2019-nCov-IPC_Masks-2020.5-eng.pdf?sequence=1&isAllowed=y (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 <https://pubmed.ncbi.nlm.nih.gov/25903751/> (last

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

viewed on July 8, 2021).

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.

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 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 believe and therefore allege that, to date, not a single person has been cited, charged, fined, or otherwise penalized strictly for the “offense” of not wearing a mask on a passenger aircraft. Rather, passengers who become rude or disruptive, or who physically assault or intimidate crewmembers, are being fined by the FAA for interfering with a crewmember in the performance of the crewmember’s duties, pursuant to, *inter alia*, 14 C.F.R. §§ 91.11, 121.580, 125.328, and 135.120; and/or 49 U.S.C. § 46318. While some of these incidents are referred to as “mask-related,” none have involved a passenger who was cited solely for failure to wear a mask.

52. Plaintiffs believe and therefore allege that the Mask Mandate is not actually being enforced on passenger flights because no “Federal law” exists that requires passengers to wear masks. However, the Mask Mandate instructs carriers

to tell passengers that it is a “violation of Federal law,” subject to fines, not to wear a mask onboard an aircraft.¹¹

53. While Plaintiffs have no desire to disrupt a flight or to be rude or abusive towards an air crew, and would never condone such behavior, Plaintiffs are uncertain of their rights in the event that they should be accused of not properly wearing a mask in conformity with “Federal law.”

54. 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.

55. 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.

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

¹¹ Anyone who has traveled by air in the U.S. since January 2021 has heard the spiel, that “it is a violation of federal law” not to wear a mask while onboard the aircraft.

57. 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)

58. Plaintiffs incorporate the allegations of paragraphs 1 through 57, and further allege:

59. 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).

60. 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.

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

62. *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).

63. *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.

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

65. *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.

66. *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.

67. 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 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.

68. 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)

69. Plaintiffs incorporate the allegations of paragraphs 1 through 57, and further allege:

70. 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.

71. 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.

72. *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).

73. *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).

74. 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)

75. Plaintiffs incorporate the allegations of paragraphs 1 through 57, and further allege:

76. 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).

77. *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 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.

78. *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.

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

80. 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.

81. *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)

82. Plaintiffs incorporate the allegations of paragraphs 1 through 57, and further allege:

83. 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.

84. 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)

85. Plaintiffs incorporate the allegations of paragraphs 1 through 57 and 83, and further allege:

86. 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.

87. 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.

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

89. 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.

90. 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.

COUNT VI

Violation of Separation of Powers

(Violation of Amendment X to the United States Constitution)

91. Plaintiffs incorporate the allegations of paragraphs 1 through 57, and further allege:

92. 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.

93. 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.

94. 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.

95. 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.

JURY TRIAL DEMAND

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

Filed this 13th day of December, 2021.

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Attorneys for Plaintiffs

Exhibit A:

Executive Order 13998

Presidential Documents

Executive Order 13998 of January 21, 2021

Promoting COVID–19 Safety in Domestic and International Travel

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.* Science-based public health measures are critical to preventing the spread of coronavirus disease 2019 (COVID–19) by travelers within the United States and those who enter the country from abroad. The Centers for Disease Control and Prevention (CDC), the Surgeon General, and the National Institutes of Health have concluded that mask-wearing, physical distancing, appropriate ventilation, and timely testing can mitigate the risk of travelers spreading COVID–19. Accordingly, to save lives and allow all Americans, including the millions of people employed in the transportation industry, to travel and work safely, it is the policy of my Administration to implement these public health measures consistent with CDC guidelines on public modes of transportation and at ports of entry to the United States.

Sec. 2. *Immediate Action to Require Mask-Wearing on Certain Domestic Modes of Transportation.*

(a) *Mask Requirement.* The Secretary of Labor, the Secretary of Health and Human Services (HHS), the Secretary of Transportation (including through the Administrator of the Federal Aviation Administration (FAA)), the Secretary of Homeland Security (including through the Administrator of the Transportation Security Administration (TSA) and the Commandant of the United States Coast Guard), and the heads of any other executive departments and agencies (agencies) that have relevant regulatory authority (heads of agencies) shall immediately 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:

- (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.

(b) *Consultation.* In implementing this section, the heads of agencies shall consult, as appropriate, with interested parties, including State, local, Tribal, and territorial officials; industry and union representatives from the transportation sector; and consumer representatives.

(c) *Exceptions.* The heads of agencies may make categorical or case-by-case exceptions to policies developed under this section, consistent with applicable law, to the extent that doing so is necessary or required by law. If the heads of agencies do make exceptions, they shall require alternative and appropriate safeguards, and shall document all exceptions in writing.

(d) *Preemption.* To the extent permitted by applicable law, the heads of agencies shall ensure that any action taken to implement this section

does not preempt State, local, Tribal, and territorial laws or rules imposing public health measures that are more protective of public health than those required by the heads of agencies.

(e) *Coordination.* The Coordinator of the COVID-19 Response and Counselor to the President (COVID-19 Response Coordinator) shall coordinate the implementation of this section. The heads of agencies shall update the COVID-19 Response Coordinator on their progress in implementing this section, including any categorical exceptions established under subsection (c) of this section, within 7 days of the date of this order and regularly thereafter. The heads of agencies are encouraged to bring to the attention of the COVID-19 Response Coordinator any questions regarding the scope or implementation of this section.

Sec. 3. Action to Implement Additional Public Health Measures for Domestic Travel.

(a) *Recommendations.* The Secretary of Transportation (including through the Administrator of the FAA) and the Secretary of Homeland Security (including through the Administrator of the TSA and the Commandant of the Coast Guard), in consultation with the Director of CDC, shall promptly provide to the COVID-19 Response Coordinator recommendations concerning how their respective agencies may impose additional public health measures for domestic travel.

(b) *Consultation.* In implementing this section, the Secretary of Transportation and the Secretary of Homeland Security shall engage with interested parties, including State, local, Tribal, and territorial officials; industry and union representatives from the transportation sector; and consumer representatives.

Sec. 4. Support for State, Local, Tribal, and Territorial Authorities. The COVID-19 Response Coordinator, in coordination with the Secretary of Transportation and the heads of any other relevant agencies, shall promptly identify and inform agencies of options to incentivize, support, and encourage widespread mask-wearing and physical distancing on public modes of transportation, consistent with CDC guidelines and applicable law.

Sec. 5. International Travel.

(a) *Policy.* It is the policy of my Administration that, to the extent feasible, travelers seeking to enter the United States from a foreign country shall be:

- (i) required to produce proof of a recent negative COVID-19 test prior to entry; and
- (ii) required to comply with other applicable CDC guidelines concerning international travel, including recommended periods of self-quarantine or self-isolation after entry into the United States.

(b) *Air Travel.*

(i) The Secretary of HHS, including through the Director of CDC, and in coordination with the Secretary of Transportation (including through the Administrator of the FAA) and the Secretary of Homeland Security (including through the Administrator of the TSA), shall, within 14 days of the date of this order, assess the CDC order of January 12, 2021, regarding the requirement of a negative COVID-19 test result for airline passengers traveling into the United States, in light of subsection (a) of this section. Based on such assessment, the Secretary of HHS and the Secretary of Homeland Security shall take any further appropriate regulatory action, to the extent feasible and consistent with CDC guidelines and applicable law. Such assessment and regulatory action shall include consideration of:

(A) the timing and types of COVID-19 tests that should satisfy the negative test requirement, including consideration of additional testing immediately prior to departure;

(B) the proof of test results that travelers should be required to provide;

(C) the feasibility of implementing alternative and sufficiently protective public health measures, such as testing, self-quarantine, and self-isolation on arrival, for travelers entering the United States from countries where COVID-19 tests are inaccessible, particularly where such inaccessibility of tests would affect the ability of United States citizens and lawful permanent residents to return to the United States; and

(D) measures to prevent fraud.

(ii) The Secretary of HHS, in coordination with the Secretary of Transportation (including through the Administrator of the FAA) and the Secretary of Homeland Security (including through the Administrator of the TSA), shall promptly provide to the President, through the COVID-19 Response Coordinator, a plan for how the Secretary and other Federal Government actors could implement the policy stated in subsection (a) of this section with respect to CDC-recommended periods of self-quarantine or self-isolation after a flight to the United States from a foreign country, as he deems appropriate and consistent with applicable law. The plan shall identify agencies' tools and mechanisms to assist travelers in complying with such policy.

(iii) The Secretary of State, in consultation with the Secretary of HHS (including through the Director of CDC), the Secretary of Transportation (including through the Administrator of the FAA), and the Secretary of Homeland Security, shall seek to consult with foreign governments, the World Health Organization, the International Civil Aviation Organization, the International Air Transport Association, and any other relevant stakeholders to establish guidelines for public health measures associated with safe international travel, including on aircraft and at ports of entry. Any such guidelines should address quarantine, testing, COVID-19 vaccination, follow-up testing and symptom-monitoring, air filtration requirements, environmental decontamination standards, and contact tracing.

(c) *Land Travel.* The Secretary of State, in consultation with the Secretary of HHS, the Secretary of Transportation, the Secretary of Homeland Security, and the Director of CDC, shall immediately commence diplomatic outreach to the governments of Canada and Mexico regarding public health protocols for land ports of entry. Based on this diplomatic engagement, within 14 days of the date of this order, the Secretary of HHS (including through the Director of CDC), the Secretary of Transportation, and the Secretary of Homeland Security shall submit to the President a plan to implement appropriate public health measures at land ports of entry. The plan should implement CDC guidelines, consistent with applicable law, and take into account the operational considerations relevant to the different populations who enter the United States by land.

(d) *Sea Travel.* The Secretary of Homeland Security, through the Commandant of the Coast Guard and in consultation with the Secretary of HHS and the Director of CDC, shall, within 14 days of the date of this order, submit to the President a plan to implement appropriate public health measures at sea ports. The plan should implement CDC guidelines, consistent with applicable law, and take into account operational considerations.

(e) *International Certificates of Vaccination or Prophylaxis.* Consistent with applicable law, the Secretary of State, the Secretary of HHS, and the Secretary of Homeland Security (including through the Administrator of the TSA), in coordination with any relevant international organizations, shall assess the feasibility of linking COVID-19 vaccination to International Certificates of Vaccination or Prophylaxis (ICVP) and producing electronic versions of ICVPs.

(f) *Coordination.* The COVID-19 Response Coordinator, in consultation with the Assistant to the President for National Security Affairs and the Assistant to the President for Domestic Policy, shall coordinate the implementation of this section. The Secretary of State, the Secretary of HHS, the Secretary of Transportation, and the Secretary of Homeland Security shall

update the COVID-19 Response Coordinator on their progress in implementing this section within 7 days of the date of this order and regularly thereafter. The heads of all agencies are encouraged to bring to the attention of the COVID-19 Response Coordinator any questions regarding the scope or implementation of this section.

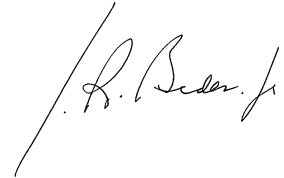
Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
January 21, 2021.

Exhibit B:

CDC Mask Mandate

The rapidly changing nature of the pandemic requires not only that CDC act swiftly, but also deftly to ensure that its actions are commensurate with the threat. This necessarily involves assessing evolving conditions that inform CDC's determinations.

The conditions that existed on September 4, 2020 have only worsened. As of January 21, 2021, there have been over 24,400,000 cases and over 400,000 deaths. Data collected by Princeton University show that eviction filings are occurring; it is therefore expected that large numbers of evictions would be processed if the Order were to expire. [<https://evictionlab.org/eviction-tracking>]. Without this Order, there is every reason to expect that evictions will increase significantly, resulting in further spread of COVID-19. It is imperative to act quickly to protect the public health, and it would be impracticable and contrary to the public interest to delay the issuance and effective date of the Order pending notice-and-comment rulemaking.

Similarly, if this Order qualifies as a rule under the APA, the Office of Information and Regulatory Affairs (OIRA) has determined that it would be a major rule under the Congressional Review Act (CRA). But there would not be a delay in its effective date. The agency has determined that for the same reasons, there would be good cause under the CRA to make the requirements herein effective immediately.

If any provision of this Order, or the application of any provision to any persons, entities, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any persons, entities, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

This Order shall be enforced by federal authorities and cooperating state and local authorities through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 70.18. However, this Order has no effect on the contractual obligations of renters to pay rent and shall not preclude charging or collecting fees, penalties, or interest as a result of the failure to pay rent or other housing payment on a timely basis, under the terms of any applicable contract.

Criminal Penalties

Under 18 U.S.C. 3559, 3571; 42 U.S.C. 271; and 42 CFR 70.18, a person violating this Order may be subject to a fine of no more than \$100,000 if the violation does not result in a death, or a fine of no more than \$250,000 if the

violation results in a death, or as otherwise provided by law. An organization violating this Order may be subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law. The U.S. Department of Justice may initiate criminal proceedings as appropriate seeking imposition of these criminal penalties.

Notice to Cooperating State and Local Officials

Under 42 U.S.C. 243, the U.S. Department of Health and Human Services is authorized to cooperate with and aid state and local authorities in the enforcement of their quarantine and other health regulations and to accept state and local assistance in the enforcement of Federal quarantine rules and regulations, including in the enforcement of this Order.

Notice of Available Federal Resources

While this Order to prevent eviction is effectuated to protect the public health, the states and units of local government are reminded that the Federal Government has deployed unprecedented resources to address the pandemic, including housing assistance.

The Department of Housing and Urban Development (HUD) has informed CDC that all HUD grantees—states, cities, communities, and nonprofits—who received Emergency Solutions Grants (ESG) or Community Development Block Grant (CDBG) funds under the CARES Act may use these funds to provide temporary rental assistance, homelessness prevention, or other aid to individuals who are experiencing financial hardship because of the pandemic and are at risk of being evicted, consistent with applicable laws, regulations, and guidance.

HUD has further informed CDC that:

HUD's grantees and partners play a critical role in prioritizing efforts to support this goal. As grantees decide how to deploy CDBG—CV and ESG—CV funds provided by the CARES Act, all communities should assess what resources have already been allocated to prevent evictions and homelessness through temporary rental assistance and homelessness prevention, particularly to the most vulnerable households.

HUD stands at the ready to support American communities take these steps to reduce the spread of COVID-19 and maintain economic prosperity. Where gaps are identified, grantees should coordinate across available Federal, non-Federal, and philanthropic funds to ensure these critical needs are

sufficiently addressed and utilize HUD's technical assistance to design and implement programs to support a coordinated response to eviction prevention needs. For program support, including technical assistance, please visit www.hudexchange.info/program-support. For further information on HUD resources, tools, and guidance available to respond to the COVID-19 pandemic, state and local officials are directed to visit <https://www.hud.gov/coronavirus>. These tools include toolkits for Public Housing Authorities and Housing Choice Voucher landlords related to housing stability and eviction prevention, as well as similar guidance for owners and renters in HUD-assisted multifamily properties.

Similarly, the Department of the Treasury has informed CDC that the funds allocated through the Coronavirus Relief Fund and the Emergency Rental Assistance Program may be used to fund rental assistance programs to prevent eviction. Visit <https://home.treasury.gov/policy-issues/cares/state-and-local-governments> for more information about the Coronavirus Relief Fund and <https://home.treasury.gov/policy-issues/cares/emergency-rental-assistance-program> for more information about the Emergency Rental Assistance Program..

Effective Date

This Order is effective on January 31, 2021 and will remain in effect, unless extended, modified, or rescinded, through March 31, 2021.

Authority

The authority for this Order is Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 70.2.

Dated: January 29, 2021.

Sherri Berger

Acting Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021-02243 Filed 1-29-21; 4:15 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirement for Persons To Wear Masks While on Conveyances and at Transportation Hubs

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of Agency Order.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), announces an Agency Order requiring persons to wear masks over the mouth and nose when traveling on any conveyance (e.g., airplanes, trains, subways, buses, taxis, ride-shares, ferries, ships, trolleys, and cable cars) into or within the United States. A person must also wear a mask on any conveyance departing from the United States until the conveyance reaches its foreign destination. Additionally, a person must wear a mask while at any transportation hub within the United States (e.g., airport, bus terminal, marina, train station, seaport or other port, subway station, or any other area that provides transportation within the United States). Furthermore, operators of conveyances and transportation hubs must use best efforts to ensure that persons wear masks as required by this Order.

DATES: This Order takes effect at 11:59 p.m. Monday February 1, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16-4, Atlanta, GA 30329. Email: dgmqpolicyoffice@cdc.gov.

SUPPLEMENTARY INFORMATION: The virus that causes COVID-19 spreads very easily and sustainably between people who are in close contact with one another (within about 6 feet) mainly through respiratory droplets produced when an infected person coughs, sneezes, or talks. These droplets can land in the mouths, eyes, or noses of people who are nearby and possibly be inhaled into the lungs. Some people without symptoms also spread the virus. In general, the more closely a person interacts with others and the longer that interaction, the higher the risk of COVID-19 spread.

This Order is issued to preserve human life; maintain a safe and operating transportation system; mitigate 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 support response efforts to COVID-19 at the Federal, state, local, territorial, and tribal level.

Appropriately worn masks reduce the spread of COVID-19—particularly given the evidence of pre-symptomatic and asymptomatic transmission of COVID-19. Masks are most likely to reduce the spread of COVID-19 when they are widely used by people in public

settings. Using masks along with other preventive measures, including social distancing, frequent handwashing, and cleaning and disinfecting frequently touched surfaces, is one of the most effective strategies available for reducing COVID-19 transmission.

This Order will remain in effect unless modified or rescinded based on specific public health or other considerations, or until the Secretary of Health and Human Services rescinds the determination under section 319 of the Public Health Service Act (42 U.S.C. 247d) that a public health emergency exists.

A copy of the Order is provided below and a copy of the signed order can be found at <https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html>

CENTERS FOR DISEASE CONTROL AND PREVENTION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ORDER UNDER SECTION 361

OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. 264)

AND 42 CODE OF FEDERAL REGULATIONS 70.2, 71.31(b), 71.32(b)

REQUIREMENT FOR PERSONS TO WEAR MASKS

WHILE ON CONVEYANCES AND AT TRANSPORTATION HUBS

SUMMARY:

Notice and Order; and subject to the limitations under “Applicability,” pursuant to 42 U.S.C. 264(a) and 42 CFR 70.2, 71.31(b), and 71.32(b):

(1) Persons¹ must wear² masks over the mouth and nose when traveling on conveyances into and within the United States. Persons must also wear masks at transportation hubs as defined in this Order.

(2) A conveyance operator transporting persons into and within the United States³ must require all persons onboard to wear masks for the duration of travel.

(3) A conveyance operators operating a conveyance arriving at or departing from a U.S. port of entry must require all persons on board to wear masks for

the duration of travel as a condition of controlled free pratique.⁴

(4) Conveyance operators must use best efforts to ensure that any person on the conveyance wears a mask when boarding, disembarking, and for the duration of travel. Best efforts include:

- Boarding only those persons who wear masks;
- instructing persons that Federal law requires wearing a mask on the conveyance and failure to comply constitutes a violation of Federal law;
- monitoring persons onboard the conveyance for anyone who is not wearing a mask and seeking compliance from such persons;
- at the earliest opportunity, disembarking any person who refuses to comply; and
- providing persons with prominent and adequate notice to facilitate awareness and compliance of the requirement of this Order to wear a mask; best practices may include, if feasible, advance notifications on digital platforms, such as on apps, websites, or email; posted signage in multiple languages with illustrations; printing the requirement on transit tickets; or other methods as appropriate.

(5) Operators of transportation hubs must use best efforts to ensure that any person entering or on the premises of the transportation hub wears a mask. Best efforts include:

- Allowing entry only to those persons who wear masks;
- instructing persons that Federal law requires wearing a mask in the transportation hub and failure to comply constitutes a violation of Federal law;
- monitoring persons on the premises of the transportation hub for anyone who is not wearing a mask and seeking compliance from such persons;
- at the earliest opportunity, removing any person who refuses to comply from the premises of the transportation hub; and
- providing persons with prominent and adequate notice to facilitate awareness and compliance with the requirement of this Order to wear a mask; best practices may include, if feasible, advance notifications on digital platforms, such as on apps, websites, or

⁴ As a condition of this controlled free pratique to commence or continue operations in the United States, conveyance operators must additionally require all persons to wear masks on board conveyances departing from the United States and for the duration of their travel until the conveyance arrives at the foreign destination if at any time any of the persons on the conveyance (passengers, crew, or conveyance operators) will return to the United States while this Order remains in effect. This precaution must be followed regardless of scheduled itinerary.

¹ As used in this Order, “persons” includes travelers (i.e., passengers and crew), conveyance operators, and any workers or service providers in the transportation hub.

² To “wear a mask” means to wear a mask over the nose and mouth.

³ This includes international, interstate, or intrastate waterways, subject to the jurisdiction of the United States.

email; posted signage in multiple languages with illustrations; printing the requirement on transit tickets; or other methods as appropriate.

DEFINITIONS:

Controlled free pratique shall have the same definition as under 42 CFR 71.1, meaning “permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.”

Conveyance shall have the same definition as under 42 CFR 70.1, meaning “an aircraft, train, road vehicle,⁵ vessel . . . or other means of transport, including military.” Included in the definition of “conveyance” is the term “carrier” which under 42 CFR 71.1 has the same definition as conveyance under 42 CFR 70.1.

Conveyance operator means an individual operating a conveyance and an individual or organization causing or authorizing the operation of a conveyance.

Mask means a material covering the nose and mouth of the wearer, excluding face shields.⁶

Interstate traffic shall have the same definition as under 42 CFR 70.1, meaning

“(1):

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a state or possession—

(ii) From a point of origin in any state or possession to a point of destination in any other state or possession; or

(iii) Between a point of origin and a point of destination in the same state or possession but through any other state, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country or loading persons or property for transportation to a foreign country.

⁵ This includes rideshares meaning arrangements where passengers travel in a privately owned road vehicle driven by its owner in connection with a fee or service.

⁶ A properly worn mask completely covers the nose and mouth of the wearer. A mask should be secured to the head, including with ties or ear loops. A mask should fit snugly but comfortably against the side of the face. Masks do not include face shields. Masks can be either manufactured or homemade and should be a solid piece of material without slits, exhalation valves, or punctures. Medical masks and N-95 respirators fulfill the requirements of this Order. CDC guidance for attributes of acceptable masks in the context of this Order is available at: <https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html>.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.”

Intrastate traffic means the movement of any conveyance or the transportation or movement of persons occurring solely within the boundaries of a state or territory, or on tribal land.

Possession shall have the same definition as under 42 CFR 70.1 and 71.1, meaning a “U.S. territory.”

State shall have the same definition as under 42 CFR 70.1, meaning “any of the 50 states, plus the District of Columbia.”

Territory shall have the same definition as “U.S. territory” under 42 CFR 70.1 and 71.1, meaning “any territory (also known as possessions) of the United States, including American Samoa, Guam, the [Commonwealth of the] Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.”

Transportation hub means any airport, bus terminal, marina, seaport or other port, subway station, terminal (including any fixed facility at which passengers are picked-up or discharged), train station, U.S. port of entry, or any other location that provides transportation subject to the jurisdiction of the United States.

Transportation hub operator means an individual operating a transportation hub and an individual or organization causing or authorizing the operation of a transportation hub.

U.S. port shall have the same definition as under 42 CFR 71.1, meaning any “seaport, airport, or border crossing point under the control of the United States.”

STATEMENT OF INTENT:

This Order shall be interpreted and implemented in a manner as to achieve the following objectives:

- 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.

APPLICABILITY:

This Order shall not apply within any state, locality, territory, or area under the jurisdiction of a Tribe that (1) requires a person to wear a mask on conveyances; (2) requires a person to wear a mask at transportation hubs; and (3) requires conveyances to transport only persons wearing masks. Such

requirements must provide the same level of public health protection as—or greater protection than—the requirements listed herein.

In addition, the requirement to wear a mask shall not apply under the following circumstances:

- While eating, drinking, or taking medication, for brief periods;
- While communicating with a person who is hearing impaired when the ability to see the mouth is essential for communication;
- If, on an aircraft, wearing of oxygen masks is needed because of loss of cabin pressure or other event affecting aircraft ventilation;
- If unconscious (for reasons other than sleeping), incapacitated, unable to be awakened, or otherwise unable to remove the mask without assistance;⁷ or
- When necessary to temporarily remove the mask to verify one’s identity such as during Transportation Security Administration screening or when asked to do so by the ticket or gate agent or any law enforcement official.

This Order exempts the following categories of persons:⁸

- A child under the age of 2 years;
- A person with a disability who cannot wear a mask, or cannot safely wear a mask, because of the disability as defined by the Americans with Disabilities Act (42 U.S.C. 12101 *et seq.*).⁹

⁷ 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. Persons who are vomiting should remove the mask until vomiting ceases. Persons with acute illness may remove the mask if it interferes with necessary medical care such as supplemental oxygen administered via an oxygen mask.

⁸ Operators of conveyances or transportation hubs may impose requirements, or conditions for carriage, on persons requesting an exemption from the requirement to wear a mask, including medical consultation by a third party, medical documentation by a licensed medical provider, and/or other information as determined by the operator, as well as require evidence that the person does not have COVID-19 such as a negative result from a SARS-CoV-2 viral test or documentation of recovery from COVID-19. CDC definitions for SARS-CoV-2 viral test and documentation of recovery are available in the Frequently Asked Questions at: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-international-air-travelers.html>. Operators may also impose additional protective measures that improve the ability of a person eligible for exemption to maintain social distance (separation from others by 6 feet), such as scheduling travel at less crowded times or on less crowded conveyances, or seating or otherwise situating the individual in a less crowded section of the conveyance or transportation hub. Operators may further require that persons seeking exemption from the requirement to wear a mask request an accommodation in advance.

⁹ This is a narrow exception that includes a person with a disability who cannot wear a mask

• A person for whom wearing a mask would create a risk to workplace health, safety, or job duty as determined by the relevant workplace safety guidelines or federal regulations.

This Order exempts the following categories of conveyances, including persons on board such conveyances:

- Private conveyances operated solely for personal, non-commercial use;
- Commercial motor vehicles or trucks as these terms are defined in 49 CFR 390.5, if the driver is the sole occupant of the vehicle or truck;
- Conveyances operated or chartered by the U.S. military services provided that such conveyance operators observe Department of Defense precautions to prevent the transmission of COVID-19 that are equivalent to the precautions in this Order.

This Order applies to persons on conveyances and at transportation hubs directly operated by U.S. state, local, territorial, or tribal government authorities, as well as the operators themselves. U.S. state, local, territorial, or tribal government authorities directly operating conveyances and transportation hubs may be subject to additional federal authorities or actions, and are encouraged to implement additional measures enforcing the provisions of this Order regarding persons traveling onboard conveyances and at transportation hubs operated by these government entities.

To the extent permitted by law, and consistent with President Biden's Executive Order of January 21, 2021 (Promoting COVID-19 Safety in Domestic and International Travel),¹⁰ Federal agencies are required to implement additional measures enforcing the provisions of this Order.

BACKGROUND:

There is currently a pandemic of respiratory disease (coronavirus disease 2019 or "COVID-19") caused by a novel coronavirus (SARS-CoV-2). As of January 27, 2021, there have been 99,638,507 confirmed cases of COVID-19 globally, resulting in more than 2,141,000 deaths. As of January 27, 2021, there have been over 25,000,000 cases identified in the United States and over 415,000 deaths due to the disease. New SARS-CoV-2 variants have emerged in recent weeks, including at

for reasons related to the disability. CDC will issue additional guidance regarding persons who cannot wear a mask under this exemption. <https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html>.

¹⁰ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-promoting-covid-19-safety-in-domestic-and-international-travel/>.

least one with evidence of increased transmissibility.¹¹

The virus that causes COVID-19 spreads very easily and sustainably between people who are in close contact with one another (within about 6 feet) mainly through respiratory droplets produced when an infected person coughs, sneezes, or talks. These droplets can land in the mouths, eyes, or noses of people who are nearby and possibly be inhaled into the lungs. Infected people without symptoms (asymptomatic) and those in whom symptoms have not yet developed (pre-symptomatic) can also spread the virus. In general, the more closely an infected person interacts with others and the longer those interactions, the higher the risk of COVID-19 spread. COVID-19 may be transmitted by touching surfaces or objects that have the virus on them and then touching one's own or another person's eyes, nose, or mouth.

Masks help prevent people who have COVID-19, including those who are pre-symptomatic or asymptomatic, from spreading the virus to others.¹² Masks are primarily intended to reduce the emission of virus-laden droplets, *i.e.*, they act as source control by blocking exhaled virus.¹³ This is especially relevant for asymptomatic or pre-symptomatic infected wearers who feel well and may be unaware of their infectiousness to others, and who are estimated to account for more than 50% of transmissions.^{14 15} Masks also provide personal protection to the wearer by reducing inhalation of these droplets, *i.e.*, they reduce wearers' exposure through filtration.¹⁶ The community benefit of wearing masks for SARS-CoV-2 control is due to the combination of these effects; individual prevention benefit increases with increasing

numbers of people using masks consistently and correctly.

Appropriately worn masks reduce the spread of COVID-19—particularly given the evidence of pre-symptomatic and asymptomatic transmission of COVID-19. Seven studies have confirmed the benefit of universal masking in community level analyses: in a unified hospital system,¹⁷ a German city,¹⁸ a U.S. State,¹⁹ a panel of 15 U.S. States and Washington, DC,^{20 21} as well as both Canada²² and the United States²³ nationally. Each analysis demonstrated that, following directives from organizational and political leadership for universal masking, new infections fell significantly. Two of these studies^{24 25} and an additional analysis of data from 200 countries that included localities within the United States²⁶ also demonstrated reductions in

¹⁷ Wang X, Ferro EG, Zhou G, Hashimoto D, Bhatt DL. Association Between Universal Masking in a Health Care System and SARS-CoV-2 Positivity Among Health Care Workers. *JAMA*. 2020;10.1001/jama.2020.12897. <https://www.ncbi.nlm.nih.gov/pubmed/32663246>.

¹⁸ Mitze T., Kosfeld R., Rode J., Wälde K. *Face Masks Considerably Reduce COVID-19 Cases in Germany: A Synthetic Control Method Approach*. IZA—Institute of Labor Economics (Germany); 2020. ISSN: 2365-9793, DP No. 13319. <http://ftp.iza.org/dp13319.pdf>.

¹⁹ Gallaway MS, Rigler J, Robinson S, et al. Trends in COVID-19 Incidence After Implementation of Mitigation Measures—Arizona, January 22–August 7, 2020. *MMWR Morb Mortal Wkly Rep*. 2020;69(40):1460–1463.10.15585/mmwr.mm6940e3. <https://www.ncbi.nlm.nih.gov/pubmed/33031366>.

²⁰ Lyu W, Wehby GL. Community Use Of Face Masks And COVID-19: Evidence From A Natural Experiment Of State Mandates In The US. *Health Aff (Millwood)*. 2020;39(8):1419–1425.10.1377/hlthaff.2020.00818. <https://www.ncbi.nlm.nih.gov/pubmed/32543923>.

²¹ Hatzius J, Struyven D, Rosenberg I. Face Masks and GDP. *Goldman Sachs Research* <https://www.goldmansachs.com/insights/pages/face-masks-and-gdp.html>. Accessed January 20, 2021.

²² Karaivanov A., Lu SE, Shigeoka H., Chen C., Pamplona S. *Face Masks, Public Policies and Slowing the Spread of Covid-19: Evidence from Canada* National Bureau of Economic Research 2020. Working Paper 27891. <http://www.nber.org/papers/w27891>.

²³ Chernozhukov V, Kasahara H, Schrimpf P. Causal Impact of Masks, Policies, Behavior on Early Covid-19 Pandemic in the U.S. *J Econom*. 2021 Jan;220(1):23–62. doi: 10.1016/j.jeconom.2020.09.003. Epub 2020 Oct 17.

²⁴ Hatzius J, Struyven D, Rosenberg I. Face Masks and GDP. *Goldman Sachs Research* <https://www.goldmansachs.com/insights/pages/face-masks-and-gdp.html>. Accessed January 20, 2021.

²⁵ Chernozhukov V, Kasahara H, Schrimpf P. Causal Impact of Masks, Policies, Behavior on Early Covid-19 Pandemic in the U.S. *J Econom*. 2021 Jan;220(1):23–62. doi: 10.1016/j.jeconom.2020.09.003. Epub 2020 Oct 17.

²⁶ Leffler CT, Ing EB, Lykins JD, Hogan MC, McKeown CA, Gzybowski A. Association of country-wide coronavirus mortality with demographics, testing, lockdowns, and public wearing of masks. *Am J Trop Med Hyg*. 2020 Dec;103(6):2400–2411. doi: 10.4269/ajtmh.20-1015. Epub 2020 Oct 26.

¹¹ <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/scientific-brief-emerging-variants.html>.

¹² <https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html>.

¹³ Leung NHL, Chu DKW, Shiu EYC, et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. *Nature Medicine*. 2020;26(5):676–680. <https://dx.doi.org/10.1038/s41591-020-0843-2>.

¹⁴ Moghadas SM, Fitzpatrick MC, Sah P, et al. The implications of silent transmission for the control of COVID-19 outbreaks. *Proc Natl Acad Sci U S A*. 2020;117(30):17513–17515.10.1073/pnas.2008373117. <https://www.ncbi.nlm.nih.gov/pubmed/32632012>.

¹⁵ Johansson MA, Quandelacy TM, Kada S, et al. SARS-CoV-2 Transmission From People Without COVID-19 Symptoms. *Johansson MA, et al. JAMA Netw Open*. 2021 Jan 4;4(1):e2035057. doi: 10.1001/jamanetworkopen.2020.35057.

¹⁶ Ueki H, Furusawa Y, Iwatsuki-Horimoto K, et al. Effectiveness of Face Masks in Preventing Airborne Transmission of SARS-CoV-2. *mSphere*. 2020;5(5):10.1128/mSphere.00637–20. <https://www.ncbi.nlm.nih.gov/pubmed/33087517>.

mortality. An economic analysis using U.S. data found that, given these effects, increasing universal masking by 15% could prevent the need for lockdowns and reduce associated losses of up to \$1 trillion or about 5% of gross domestic product.²⁷

Wearing a mask especially helps protect those at increased risk of severe illness from COVID-19²⁸ and workers who frequently come into close contact with other people (e.g., at transportation hubs). Masks are most likely to reduce the spread of COVID-19 when they are widely used by people in public settings. Using masks along with other preventive measures, including social distancing, frequent handwashing, and cleaning and disinfecting frequently touched surfaces, is one of the most effective strategies available for reducing COVID-19 transmission.

Traveling 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, and exposing them to frequently touched surfaces. Air travel often requires spending time in security lines and crowded airport terminals. Social distancing may be difficult if not impossible on flights. People may not be able to distance themselves by the recommended 6 feet from individuals seated nearby or those standing in or passing through the aircraft's aisles. Travel by bus, train, vessel, and other conveyances used for international, interstate, or intrastate transportation pose similar challenges.

Intrastate transmission of the virus has led to—and continues to lead 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. Some states, territories, Tribes, and local public health authorities have imposed mask-wearing requirements within their jurisdictional boundaries to protect public health.²⁹

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

Therefore, I have determined that the mask-wearing requirements in this Order are reasonably necessary to prevent the further introduction, transmission, or spread of COVID-19 into the United States and among the states and territories. Individuals traveling into or departing from the United States, traveling interstate, or traveling entirely intrastate, conveyance operators that transport such individuals, and transportation hub operators that facilitate such transportation, must comply with the mask-wearing requirements set forth in this Order.

America's transportation systems are essential. Not only are they essential for public health, they are also essential for America's economy and other bedrocks of American life. Those transportation systems carry life-saving medical supplies and medical providers into and across the nation to our hospitals, nursing homes, and physicians' offices. Trains, planes, ships, and automobiles bring food and other essentials to our communities and to our homes. Buses bring America's children and teachers to school. Buses, trains, and subways, bring America's workforce to their jobs.

Requiring masks on our transportation systems will protect Americans and provide confidence that we can once again travel safely even during this pandemic. Therefore, requiring masks will help us control this pandemic and aid in re-opening America's economy.

The United States and countries around the world are currently embarking on efforts to vaccinate their populations, starting with healthcare personnel and other essential workers at increased risk of exposure to SARS-

CoV-2 and people at increased risk for severe illness from the virus. While vaccines are highly effective at preventing severe or symptomatic COVID-19, at this time there is limited information on how much the available COVID-19 vaccines may reduce transmission in the general population and how long protection lasts.³⁰ Therefore, this mask requirement, as well as CDC recommendations to prevent spread of COVID-19,³¹ additionally apply to vaccinated persons. Similarly, CDC recommends that people who have recovered from COVID-19 continue to take precautions to protect themselves and others, including wearing masks;³² therefore, this mask requirement also applies to people who have recovered from COVID-19.

ACTION:

Until further notice, under 42 U.S.C. 264(a) and 42 CFR 70.2, 71.31(b), and 71.32(b), unless excluded or exempted as set forth in this Order, a person must wear a mask while boarding, disembarking, and traveling on any conveyance into or within the United States. A person must also wear a mask at any transportation hub that provides transportation within the United States.

Conveyance operators traveling into or within the United States may transport only persons wearing masks and must use best efforts to ensure that masks are worn when embarking, disembarking, and throughout the duration of travel. Operators of transportation hubs must use best efforts to ensure that any person entering or on the premises of the transportation hub wears a mask.

As a condition of receiving controlled free pratique under 42 CFR 71.31(b) to enter a U.S. port, disembark passengers, and begin operations at any U.S. port of entry, conveyances arriving into the United States must require persons to wear masks while boarding, disembarking, and for the duration of travel. Conveyance operators must also require all persons to wear masks while boarding and for the duration of their travel on board conveyances departing from the United States until the conveyance arrives at the foreign destination, if at any time any of the persons onboard (passengers, crew, or conveyance operators) will return to the United States while this Order remains in effect. These travel conditions are

²⁷ Hatzius J, Struyven D, Rosenberg I. Face Masks and GDP. *Goldman Sachs Research* <https://www.goldmansachs.com/insights/pages/face-masks-and-gdp.html>. Accessed January 20, 2021.

²⁸ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>.

²⁹ Based on internet sources, 37 states plus DC and Puerto Rico mandate the wearing of masks in public. Among the jurisdictions that have imposed mask mandates, variations in requirements exist. For example, exemptions for children range in cutoff age from 2 to 12, but masks are generally required in indoor public spaces such as restaurants and stores, on public transit and ride-hailing services, and outdoors when unable to maintain 6

feet of distance from others. See <https://www.aarp.org/health/healthy-living/info-2020/states-mask-mandates-coronavirus.html> (accessed January 28, 2021).

³⁰ <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>.

³¹ <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>.

³² <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>.

necessary to mitigate the harm of further introduction of COVID-19 into the United States.

Requiring a properly worn mask is a reasonable and necessary measure to prevent the introduction, transmission and spread of COVID-19 into the United States and among the states and territories under 42 U.S.C. 264(a) and 42 CFR 71.32(b). Among other benefits, masks help prevent dispersal of an infected person's respiratory droplets that carry the virus. That precaution helps prevent droplets from landing in the eye, mouth, or nose or possibly being inhaled into the lungs of an uninfected person, or from landing on a surface or object that an uninfected person may then touch and then touch his or her own or another's eyes, nose, or mouth. Masks also provide some protection to the wearer by helping reduce inhalation of respiratory droplets.

This Order shall not apply within any state, locality, territory, or area under the jurisdiction of a Tribe, where the controlling governmental authority: (1) Requires a person to wear a mask on conveyances; (2) requires a person to wear a mask at transportation hubs; and (3) requires conveyances to transport only persons wearing masks. Those requirements must provide the same level of public health protection as—or greater protection than—the requirements listed herein.

In accordance with 42 U.S.C. 264(e), state, local, territorial, and tribal authorities may impose additional requirements that provide greater public health protection and are more restrictive than the requirements in this Order. Consistent with other federal, state, or local legal requirements, this Order does not preclude operators of conveyances or transportation hubs from imposing additional requirements, or conditions for carriage, that provide greater public health protection and are more restrictive than the requirements in this Order (*e.g.*, requiring a negative result from a SARS-CoV-2 viral test or documentation of recovery from COVID-19 or imposing requirements for social distancing or other recommended protective measures).

This Order is not a rule within the meaning of the Administrative Procedure Act ("APA") but rather is an emergency action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 70.2, 71.31(b), 71.32(b). In the event that a court determines this Order 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. Similarly, the Office of Information and Regulatory Affairs has determined that if this Order were a rule, it would be a major rule under the Congressional Review Act, but there would not be a delay in its effective date as the agency has determined that there would be good cause to make the requirements herein effective immediately under the APA.

This order is also an economically significant regulatory action under Executive Order 12866 and has therefore been reviewed by the Office of Information and Regulatory Affairs of the Office of Management and Budget. The agency is proceeding without the complete analysis required by Executive Order 12866 under the emergency provisions of 6(a)(3)(D) of that Order.

If any provision of this Order, or the application of any provision to any carriers, conveyances, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, conveyances, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

To address the COVID-19 public health threat to transportation security, this Order shall be enforced by the Transportation Security Administration under appropriate statutory and regulatory authorities including the provisions of 49 U.S.C. 106, 114, 44902, 44903, and 46301; and 49 CFR part 1503, 1540.105, 1542.303, 1544.305 and 1546.105.

This Order shall be further enforced by other federal authorities and may be enforced by cooperating state and local authorities through the provisions of 18 U.S.C. 3559, 3571; 42 U.S.C. 243, 268, 271; and 42 CFR 70.18 and 71.2.³³

EFFECTIVE DATE:

This Order shall enter into effect on February 1, 2021, at 11:59 p.m. and will

³³ While this Order may be enforced and CDC reserves the right to enforce through criminal penalties, CDC does not intend to rely primarily on these criminal penalties but instead strongly encourages and anticipates widespread voluntary compliance as well as support from other federal agencies in implementing additional civil measures enforcing the provisions of this Order, to the extent permitted by law and consistent with President Biden's Executive Order of January 21, 2021 (Promoting COVID-19 Safety in Domestic and International Travel).

remain in effect unless modified or rescinded based on specific public health or other considerations, or until the Secretary of Health and Human Services rescinds the determination under section 319 of the Public Health Service Act (42 U.S.C. 247d) that a public health emergency exists.

Dated: February 1, 2021.

Sherri Berger,

Acting Chief of Staff, Centers for Disease Control and Prevention.

[FR Doc. 2021-02340 Filed 2-1-21; 4:15 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX20EG31DW50100; OMB Control Number 1028-New]

Agency Information Collection Activities; Hydrography Addressing tool

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Geological Survey (USGS) are proposing a new information collection. **DATES:** Interested persons are invited to submit comments on or before April 5, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to gs-info_collections@usgs.gov. Please reference OMB Control Number 1028-xxxx in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Michael Tinker by email at mdtinker@usgs.gov or by telephone at 303-202-4476.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below.

Exhibit C:

April 2020 Emergency Use Authorization for Face Masks



April 24, 2020

To: Manufacturers of Face Masks;
Health Care Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders.

On April 18, 2020, in response to concerns relating to insufficient supply and availability of face masks,^{1,2} the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) authorizing the use of face masks for use by members of the general public, including health care personnel (HCP)³ in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States

¹ A face mask is a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks).

² Surgical masks are not covered within the scope of this authorization. Surgical masks are masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are regulated under 21 CFR 878.4040 as class II devices requiring premarket notification. Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. More information on the distinction is provided in FDA guidance, titled "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" available at <https://www.fda.gov/media/136449/download>.

³ HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

citizens living abroad, and that involves the virus that causes COVID-19.⁴ Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.⁵

On April 24, 2020 in response to questions and concerns that have been received by FDA since issuance of the April 18, 2020 letter of authorization and having concluded that revising the April 18, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the April 18, 2020 letter in its entirety with amendments⁶ incorporated. Specifically, FDA is clarifying through this re-issued letter that facemasks, including cloth face coverings, are authorized to be used by HCP only as source control^{7,8} in accordance with CDC recommendations under this EUA.⁹ As stated in the April 18 letter, face masks are authorized for use by the general public to cover their noses and mouths, in accordance with CDC recommendations.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of face masks for use in accordance with CDC recommendations, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

For the most current CDC recommendations on the use of face masks by the general public during COVID-19, please visit CDC's webpage: [Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission](#) For the most recent recommendations on use of face masks by HCPs in a healthcare setting, see: [Strategies to Optimize the Supply of PPE and Equipment](#).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of face masks in accordance with CDC recommendations as source control as described in the Scope of Authorization (Section II) to

⁴ U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 7, 2020)

⁵ U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 17335 (March 27, 2020).

⁶ The amendments to the April 18, 2020 letter clarify that the eligible facemasks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for filtering face piece respirators or for surgical face masks. This reissued EUA does not change any aspects of the April 18, 2020 letter with respect to the use of face masks by the general public.

⁷ Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.

⁸ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>

⁹ In addition, health care employers should refer to standards of the Occupational Safety and Health Administration (OSHA) that apply to PPE to protect workers and infectious disease hazards. See 29 CFR 1910 subpart I.

help prevent spread of the virus during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face masks may be effective as source control to help prevent the spread of SARS-CoV-2 by infected individuals who may or may not have symptoms of COVID-19 during the COVID-19 pandemic, and that the known and potential benefits of face masks, when used in accordance with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of face masks for source control by the general public and for HCPs to help prevent the spread of the virus due to face mask shortages during the COVID-19 pandemic.^{10,11}

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as HCP in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of the SARS-CoV-2 during the COVID-19 pandemic. The facemasks are not intended to be used by HCPs as PPE, meaning they are neither substitutable for respiratory protective devices such as filtering face piece respirators, nor for surgical face masks. This use is consistent with face masks regulated as Class I 510(k)-exempt face masks under 21 CFR 878.4040.

Authorized Face Masks

Face masks are authorized under this EUA when they are intended for use as source control, by members of the general public as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

¹⁰ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

¹¹ Providing authorization for the introduction into interstate commerce of face masks by manufacturers that do not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. In addition, increased availability of face masks helps meet the needs for source control for the general population, reserving FDA-cleared surgical masks and FDA-cleared or -authorized N95 and N95 equivalent Face Filtering Respirators for use by HCP. Providing HCP who are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled 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;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and
6. The product is not labeled for use in high risk aerosol generating procedures.¹²

Manufacturers of face masks that are used as described above and meet the above requirements (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>, serves as face mask manufacturers' notification of authorization.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of face masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that face masks may be effective as described within this section (the Scope of Authorization, Section II) of this letter, pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of this letter, and concludes that face masks (as described in this section, the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of face masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), face masks, as source control, are authorized for use by members of the general public, as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.

¹² Examples of aerosol generating procedures in healthcare settings may be found at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html>

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under sections 520(f)(1). FDA grants that waiver, including the quality system requirements under 21 CFR Part 820 and labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements in 21 CFR Part 830 and 21 CFR 801.20, except that face masks must include the labeling elements specified in the Conditions of Authorization (Section IV).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers and Distributors of Authorized Products¹³

- A. Manufacturers and Distributors will make face masks available with labeling that includes a description of the product as a face mask, including a list of the body contacting materials (which does not include any drugs or biologics).
- B. Manufacturers and Distributors of authorized products shall not label the product: 1) as a surgical mask, to provide liquid barrier protection; 2) for use in a clinical setting where the infection risk level through inhalation exposure is high; 3) for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses; 4) as a respiratory protective device; or 5) for high risk aerosol-generating procedures.
- C. Manufacturers must make the required labeling available to each end user or end user facility (each hospital) in hard copy or in an alternative format (e.g., electronic labeling on the manufacturer's website). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.
- D. Manufacturers and Distributors will include instructions for recommended cleaning and/or disinfection materials and processes, if applicable, for their authorized product(s). Manufacturers must provide these instructions, if applicable, to each end user or end user facility (e.g., each hospital) in hard copy or in an alternative format (e.g., electronic instructions). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

¹³ The requirements under 21 CFR Part 806 (Reports of Corrections and Removals) and 21 CFR Part 807 (Registration and Listing) do not apply to products authorized under an EUA. As such, compliance with these regulations are not required under this EUA.

- E. Manufacturers will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. See FDA's webpage "[Medical Device Reporting \(MDR\): How to Report Medical Device Problems](#)"¹⁴ for reporting requirements and procedures.¹⁵
- F. Manufacturers and distributors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- G. Through a process of inventory control, manufacturers and distributors will maintain records of the entities to which they distribute the face masks and the numbers of each such product they distribute.
- H. Manufacturers and distributors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

- I. All printed matter, including advertising and promotional materials, relating to the use of the authorized face mask shall be consistent with the labeling elements listed in Section II of this EUA, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- J. No printed matter, including advertising or promotional materials, relating to the use of the authorized face mask may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.
- K. All advertising and promotional descriptive printed matter relating to the use of the product shall clearly and conspicuously state that
 - The product has not been FDA cleared or approved
 - The product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic.
 - This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices,

¹⁴ FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

¹⁵ Also refer to FDA guidance, titled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic" available at <https://www.fda.gov/media/72498/download>.

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during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Exhibit D:

Declarations

**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,

Plaintiffs,

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.

Case No. _____

DECLARATION OF KELLY PRATT

DECLARATION OF KELLY PRATT

I, Kelly Pratt, hereby declare under penalty of perjury as follows:

1. I am of sound mind and of the age of majority, and capable of testifying to the information sworn to herein.
2. I make this Declaration based on my own personal knowledge.
3. I am a citizen of the United States of America, and I am domiciled in Manatee

DECLARATION OF KELLY PRATT

County, Florida.

4. I am a member of Health Freedom Defense Fund, Inc.

5. Since the pandemic and the restrictions surrounding the pandemic have been implemented, I have not been able to see my now ninety-three-year-old mother who has recently been relocated from Seattle, Washington to an assisted living facility in San Francisco, California.

6. Prior to the pandemic, I would visit my mother at least once a year. The trip from Tampa is a minimum of eight hours total travel time, including time spent in airports.

7. The last time I saw my beloved mother was in November of 2019 when she came to visit me in Bradenton, Florida. Unfortunately, she is physically unable to travel alone now.

8. I have put off traveling to see my mother because I cannot fathom wearing a mask for a minimum of eight hours. When I put a mask on, I find it much more difficult to breath, and I experience overwhelming anxiety. I believe that wearing a mask for extended periods of time is harmful to one's health.

9. I feel an incredible amount of guilt knowing that any day might be the day that my mother is no longer around, and I may never get a chance to see her again due to these tyrannical edicts.

10. I object to the government choosing for me when and where I have the freedom to live and move about freely without a facial covering. I object to others using their power to dictate when and where I can come and go without covering my face.

11. I am adamantly opposed to this illegal mask ordinance. No one in this country has the right to dictate what I must put over my mouth and nose.

12. Although I could have filed a lawsuit on my own behalf, since I am a member of Health Freedom Defense Fund, I am relying on the Health Freedom Defense Fund to represent

me and protect my health freedoms.

I hereby declare under penalty of perjury that the foregoing is a true and correct statement, and that this declaration was executed on the 9th day of July, 2021.

Kelly Pratt

KELLY PRATT

Signature: Kelly Pratt
Kelly Pratt (Jul 10, 2021 14:33 EDT)

Email: kpcats@live.com

**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,

Plaintiffs,

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.

Case No. _____

DECLARATION OF PAULA JAGER

DECLARATION OF PAULA JAGER

I, Paula Jager, hereby declare under penalty of perjury as follows:

1. I am of sound mind and of the age of majority, and capable of testifying to the information sworn to herein.
2. I make this Declaration based on my own personal knowledge.

Signature: 
Paula Jager (Jul 9, 2021 17:29 EDT)

Email: g.i.jane@verizon.net

3. I am a citizen of the United States of America, and I am domiciled in Hillsborough County, Florida.

4. I am a member of Health Freedom Defense Fund, Inc.

5. Because of the mandate to wear a mask while flying, I have been unable to attend fitness conferences, which has negatively affected my business in the cross-fit arena.

6. I normally travel a couple times per year for pleasure and have been unable to since this policy has been implemented.

7. When I wear a mask, I feel like I cannot breathe, not to mention the chaffing that occurs from the mask.

8. Being forced to wear a mask is personally offensive to my dignity. I feel like I am being dehumanized.

9. I object to the government choosing for me when and where I have the freedom to live and move about freely without a facial covering. I object to others using their power to dictate when and where I can come and go without covering my face.

10. I am adamantly opposed to this illegal mask ordinance. No one in this country has the right to dictate what I must put over my mouth and nose.

11. Although I could have filed a lawsuit on my own behalf, since I'm a member of Health Freedom Defense Fund, I am relying on the Health Freedom Defense Fund to represent me and protect my health freedoms.

I hereby declare under penalty of perjury that the foregoing is a true and correct statement, and that this declaration was executed on the 9th day of July, 2021.

Paula Jager

PAULA JAGER

**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,

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vs.

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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.

Case No. _____

**DECLARATION OF PETER
KENNEDY**

DECLARATION OF PETER KENNEDY

I, Peter Kennedy, hereby declare under penalty of perjury as follows:

1. I am of sound mind and of the age of majority, and capable of testifying to the information sworn to herein.
2. I make this Declaration based on my own personal knowledge.

Signature: Peter D. Kennedy
Peter D. Kennedy (Jul 9, 2021 19:23 EDT)

Email: pete.foodlaw@gmail.com

3. I am a citizen of the United States of America, I am domiciled in the State of Florida, and I reside in Sarasota County, Florida.
4. I am a member of the Health Freedom Defense Fund, Inc.
5. Prior to the pandemic, I traveled on average twelve times per year.
6. Since the lockdowns and restrictions have been instituted, I have not traveled by airplane at all in part due to my unwillingness to be forced to wear a mask. The resulting inability to fly has caused irreparable harm.
7. I have done extensive research on the efficacy masks provide against a virus, and the potential health risks around masking, and it is my belief that masks are ineffective and a health hazard.
8. I object to the government choosing for me when and where I have the freedom to live and move about freely without a facial covering. I object to others using their power to dictate when and where I can come and go without covering my airway and impeding my ability to breathe.
9. I am adamantly opposed to this illegal mask ordinance. No one in this country has the right to dictate what I must put over my mouth and nose.
10. Although I could have filed a lawsuit on my own behalf, since I am a member of the Health Freedom Defense Fund, I am relying on the Health Freedom Defense Fund to represent me and protect my health freedoms.

I hereby declare under penalty of perjury that the foregoing is a true and correct statement, and that this declaration was executed on the 9th day of July 2021.

Peter D. Kennedy

PETER KENNEDY