

No. 22-11287

**IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT**

**HEALTH FREEDOM DEFENSE FUND, INC., et al.,
Plaintiffs-Appellees,
v.
JOSEPH R. BIDEN, JR., President of the United States, et al.,
Defendants-Appellants.**

**On Appeal from the United States District Court for the Middle District of
Florida,
No. 8:21-cv-1693, Hon. Kathryn Kimball Mizelle, Presiding**

***Amicus Curiae* Brief of America's Frontline Doctors
In Support of Plaintiffs-Appellees and Affirmance**

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August 8th, 2022

**CORPORATE DISCLOSURE STATEMENT,
CERTIFICATE OF INTERESTED PERSONS**

Proposed *Amicus Curiae* is America's Frontline Doctors ("AFLDS"), a non-partisan, not-for-profit organization of hundreds of member physicians who come from across the country, representing a range of medical disciplines and practical experience on the front lines of medicine. AFLDS' programs focus on a number of critical issues discussed below. No publicly held company has a 10 percent or greater ownership interest in America's Frontline Doctors.

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for proposed *Amicus Curiae* certifies that, to the best of their knowledge, the Certificate of Interested Persons filed by Plaintiffs-Appellees in their August 1st, 2022 Answer Brief and in the Amicus Brief filed on August 2nd, 2022 by Children's Health Defense contain a correct complete list of the people and entities that have an interest in the outcome of this appeal, other than the following additions from AFLDS: **Joey Gilbert**

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Identifying airborne transmission as the dominant route for the spread of COVID-
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Contributed by Mario J. Molina, May 16, 2020 (sent for review May 14, 2020;
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SUMMARY OF ARGUMENT

An objective and dispassionate review of the medical and scientific literature surrounding mask wearing reveals that masks are ineffective for preventing infection from COVID-19 or other viruses. Masks are also ineffective in preventing transmission of the COVID-19 or other viruses to others. There is no measurable beneficial effect as will be seen below. This is because the tiny virus micro-particles are so much smaller than the mask pore openings. It is akin to the oft-cited analogy of putting up a chain link fence in the vain hopes of keeping out mosquitos.

Indeed, ineffective masks have been found to have measurably harmful effects such as increased incidents of life-threatening bacterial pneumonia, decreased oxygen levels in the brains of mask-wearers, and speech deficits in children. Masks are also unsanitary, and function as bacteria-collectors.

“Mandatory” mask wearing has also become the source of numerous disruptive and sometimes violent conflicts between passengers and transportation workers, and among transportation workers themselves, creating veritable chaos in the skies¹.

¹Wall, et al. v Transportation Security Agency, Brief of *Amici Curiae* 309 Pilots & Flight Attendants in Support of Petitioners, pgs. 12-21, 21-1220, 1221, 1225, 1236, 1237, 1258, 4-18-2022, CADC

Furthermore, face masks are considered medical devices, which are only in use subject to an Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA).² As such, their use is subject to the ethical and legal principles of fully informed and voluntary patient consent, which includes the requirement that the patient be advised “of the option to accept or refuse administration of the product”.³ In contrast, the federal transportation mask mandate invalidated by the District Court herein relied upon a form of coercion to enforce compliance with wearing ineffective and potentially dangerous masks. Being denied access to necessary transportation services as a penalty for declining the experimental medical device is a form of coercion which invalidates voluntary patient consent.

Finally, regardless of the ineffectiveness and potential dangers of “mandatory” mask wearing, the President and the CDC lack the constitutional and statutory authority to issue such a sweeping edit on such a major question affecting millions of travelers, which major question demands legislative authorization.

The District Court correctly followed *Alabama Ass’n of Realtors v. Dep’t of*

²<https://www.fda.gov/media/137121/download>,
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorization-face-masks-non-surgical>

³21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)

Health and Human Svc's, 141 S. Ct. 2485 (2021) (per curiam), and rejected the CDC's claim of authority, which CDC claimed stemmed from the word "sanitation", found in the Public Health Service Act of 1944 (PHSA) § 361(a), as codified at 42 U.S.C. § 264(a).

Finally, the CDC neglected to follow the notice and comment procedures as required by the Administrative Procedures Act, (APA), 5 U.S.C. §§ 551-559. As many courts have recognized, the pandemic public health emergency was first introduced in 2020 and has long since passed, removing the justification for an emergency exception to the APA.

ARGUMENT

A. MASKS DON'T WORK

The claim that masks are safe and effective against viral micro-particulates is inaccurate. Masks are ineffective, unsanitary, and in many ways they harm the wearer physically and psychologically. In fact, coercing or requiring a person to wear a mask without his or her consent sets the stage for contracting a virus more likely, overrides patient consent, and makes the consequences of that infection worse.

All studies **prior to the outbreak** of the alleged severe acute respiratory syndrome coronavirus (SARS-CoV-2), or cause of the coronavirus disease,

colloquially known as COVID-19, did not show a benefit of masks in preventing viral spread.⁴ In fact, during the pandemic, although 80% of U.S. states mandated masks, research showed that masks did not reduce the spread of the virus.⁵ No masks have been shown to protect against small particle viruses.⁶ Coronaviruses are 0.1 to 0.125 microns – 100 times smaller than fine dust particles. CDC July 2020 statistics show that 85% of people who were sick with COVID-19 reported “always” or “usually” wearing a mask. Only 3.9% of COVID-19 victims reported never wearing a mask. These numbers were nearly identical in the control group – i.e., those not getting sick with COVID-19.⁷

Another study done on active-duty U.S. Marines required that the Marines be pre-screened, quarantined in barracks, wear masks (except when sleeping and eating), practice social distancing, and disinfect their environment. Furthermore, they were supervised to ensure compliance. None of this had any effect on the

⁴Renyi Zhang, Yixin Li, Annie L. Zhang, Yuan Wang, and Mario J. Molina Identifying airborne transmission as the dominant route for the spread of COVID-19_ PNAS June 30, 2020 117 (26) 14857-14863; first published June 11, 2020 Contributed by Mario J. Molina, May 16, 2020 (sent for review May 14, 2020; reviewed by Manish Shrivastava and Tong Zhu:. <https://www.pnas.org/doi/10.1073/pnas.2018637117>

⁵<https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v1.full.pdf>

⁶Masking Lack of Evidence with Politics, The Center for Evidence Based Medicine, July 23, 2020: <https://www.cebm.net/COVID-19/masking-lack-of-evidence-with-politics/>

⁷Erratum: Vol. 69, No. 36. MMWR Morb Mortal Wkly Rep 2020;69:1380. DOI: <http://dx.doi.org/10.15585/mmwr.mm6938a7>

development of disease or transmission. The Center for Evidenced Based Medicine in Oxford England reviewed all the controlled studies on mask wearing and came to the same conclusion that showed there was no statistical benefit to masks.⁸

Schools in Sweden were kept open for 1.95 million children, ages 15 and younger and masks were not enforced. As reported in the New England Journal of Medicine, Sweden had zero COVID-19 deaths among students, and teachers did not have an excess infection risk.⁹

In general, the death curve of Sweden, which did none of the mandated actions, had the same appearance as the seasonal death curve of England, which undertook every possible measure. Moreover, Dr. Fauci, the current director of the National Institute of Allergy and Infectious Diseases (NIAID) and the president's chief medical adviser, has stated that masks don't work. In a February 5, 2020 email to former Health and Human Services Secretary Sylvia Burwell, he stated, "masks are really for infected people to prevent them from spreading infection to people who are not infected rather than protecting uninfected people from acquiring infection. The typical mask you buy in the drug store is not really

⁸Letizia MD, A., Ramos PhD, Irene et al. Sars-CoV-2 Transmission Among Marine Recruits During Quarantine. NEJM, 11 Nov 2020: <https://pubmed.ncbi.nlm.nih.gov/33176093/>

⁹ Open Schools, COVID-19, and Child and Teacher Morbidity in Sweden; NEJM Letter to the Ed. 6 Jan 2021: <https://pubmed.ncbi.nlm.nih.gov/33176093/>

effective in keeping out virus, which is small enough to pass through the material.”¹⁰ One month later in a March 8, 2020 interview on “60 Minutes”, Dr. Fauci again publicly stated, “people should not be walking around with a mask, there’s no reason.”¹¹

Surgical masks are worn by medical health care workers because they are designed to protect the patient from the doctors’ respiratory droplets and to protect the doctor from blood and bodily secretions. The wearer, however, is not protected from other people’s airborne particles. Numerous studies conclude that masks do not prevent virus respiratory illness and only offer a false sense of security as they do not prevent transmission of viral particles. The following demonstrates the ineffectiveness of the majority of masks worn by the general public and condoned by the CDC. The size of a particle in barrier intervention matters. Viruses are smaller than bacteria and are approximately 0.1 micrometers (μm). In comparison, wood smoke particles are 0.4-0.7 micrometers and easily penetrate cloth masks. Even a properly fitted N95 mask will block 95% of air particles only down to 0.3

¹⁰ <https://twitter.com/GraduatedBen/status/1399942256723963904>

¹¹ March 2020: Dr. Anthony Fauci talks with Dr Jon LaPook about COVID-19, https://www.youtube.com/watch?v=PRa6t_e7dgl

µm from reaching the wearer's face.¹²

Further, a randomized controlled study of masks done of hospital personnel (who were supervised and controlled in the mask wearing) showed cloth mask wearers are six (6) times more likely to contract a respiratory illness than those without a mask.¹³

Additionally, surgical masks are not efficient at preventing emissions from infected patients, as they are designed to protect patients from a surgeon's respiratory droplets, and are not effective at blocking particles smaller than 100 µm.¹⁴ For example, a 2011 randomized Australian clinical trial of standard medical and surgical masks showed that medical masks offered no protection at all from influenza.¹⁵

¹² Carr-Locke DL, Soetikno R, Shah S, Kaltenbach T, Shergill A. I Smell Smoke-The Must Know Details About the N95. *Am J Gastroenterol*. 2020 Oct;115(10):1562-1565. doi: 10.14309/ajg.0000000000000785. PMID: 32796175; PMCID: PMC7447000; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7447000/>

¹³ C Raina MacIntyre, Holly Seale, Tham Chi Dung, et al. A cluster randomized trial of cloth masks compared with medical masks in healthcare workers. *Infectious Diseases Research BMJ Open*, 2015: <https://bmjopen.bmj.com/content/5/4/e006577>

¹⁴ Disposable N95 Respirators and Surgical Masks: A Comparison: <https://multimedia.3m.com/mws/media/1841759O/respirators-and-surgical-masks-contrast-technical-bulletin-anz.pdf>

¹⁵ A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in health care workers: <https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1750-2659.2011.00198.x>

A virus is transmitted through respiratory droplets produced when an infected person coughs, sneezes, or talks. Larger respiratory droplets (5 μm) remain in the air for only a short time and travel only short distances, generally one meter. They fall to the ground quickly.¹⁶

Wearing a mask outside of a surgical or health care facility offers little, if any, protection from infection. Public health authorities define a significant exposure to COVID-19 as one that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes). It is scientific nonsense that wearing a mask when entering a medical office or restaurant is necessary, but considered safe to remove it while being examined or seated at a table.

As pointed out by Physics PhD Professor Dennis Rancourt, “Such small particles (2.5 μm) are part of air fluidity, are not subject to gravitational sedimentation, and would not be stopped by long-range inertial impact. This means that the slightest (even momentary) facial misfit of a mask or respirator renders the design filtration norm of the mask or respirator entirely irrelevant.”¹⁷

¹⁶ Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1: <https://www.nejm.org/doi/pdf/10.1056/NEJMc2004973?articleTools=true>

¹⁷ Rancourt PhD, Denis. “Masks Don’t Work: A Review of Science Relevant to COVID-19 Social Policy”: <https://www.rcreader.com/commentary/masks-dont-work-covid-a-review-of-science-relevant-to-covide-19-social-policy>

The World Health Organization stated: “At the present time, the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence and there are potential benefits and harms to consider.”¹⁸ The Center for the National Center for Immunization and Respiratory Diseases states: “We don’t routinely recommend the use of face masks by the public to prevent respiratory illness. And we certainly are not recommending them at this time for this new virus.”¹⁹

Masks cannot prevent viruses from spreading. The overall evidence is clear: Standard cloth and surgical masks offer next to no protection against virus-sized particles or small aerosols.²⁰

B. MASKS ARE UNSANITARY AND CAUSE HARMS

Little attention seems to be paid to the plethora of unsanitary aspects of

¹⁸ World Health Organization. (2020) . Advice on the use of masks in the context of COVID-19: interim guidance, 5 June 2020. World Health Organization. <https://apps.who.int/iris/handle/10665/332293>. License: CC BY-NC-SA 3.0 IGO: <https://apps.who.int/iris/handle/10665/332293>

¹⁹ Transcript for CDC Media Telebriefing: Update on 2019 Novel Coronavirus (2019-nCoV): <https://www.cdc.gov/media/releases/2020/t0131-2019-novel-coronavirus.html>

²⁰Clapp PW, Sickbert-Bennett EE, Samet JM, et al. Evaluation of Cloth Masks and Modified Procedure Masks as Personal Protective Equipment for the Public During the COVID-19 Pandemic. JAMA Intern Med. 2021;181(4):463–469. doi:10.1001/jamainternmed.2020.8168: <https://pubmed.ncbi.nlm.nih.gov/33300948/>

mask wearing, including harmful repercussions to a person's physical health. There are many adverse psychological effects of mask wearing as well, and disruptions to normal socialization and interactions among individuals and society as a whole.

A recent study published in July 2022 concluded that both sides of a mask get quickly contaminated with pathogenic bacteria, growing fungi colonies that can be a direct source of infection to the respiratory and digestive tracts and skin.²¹ Additionally, toxic mold, fungi, and bacteria can pose a significant threat to the immune system by potentially weakening it. And alarming reports reveal that extremely dangerous graphene, fiberglass, and plastic fibers from masks are being absorbed into the lungs.²² In essence, masks are potentially dangerous medical devices that can put an individual at risk for viral infection, and, if so, they will have a far worse outcome.²³

²¹Park, AM., Khadka, S., Sato, F. et al. Bacterial and fungal isolation from face masks under the COVID-19 pandemic. *Sci Rep* 12, 11361 (2022): <https://doi.org/10.1038/s41598-022-15409-x>

²² Paul E. Alexander. “,” American Institute for Economic Research, April 9, 2021, <https://www.aier.org/article/the-dangers-of-masks/>

²³Russell Blaylock, Id. (quoting Sheharde H et al. Cutting edge: Hypoxia-Inducible Factor-1 negatively regulates Th 1 function *J Immunol* 2015;195:1372-1376). See also: Westendorg AM et al. Hypoxia enhances immunosuppression by inhibiting CD4+ effector T cell function and promoting Treg activity. *Cell Physiol Biochem* 2017;41:1271-84. See further: Sceneay J et al. Hypoxia-driven immunosuppression contributes to the pre-metastatic niche. *Oncoimmunology* 2013;2:1 e22355.

According to some researchers, masks actually increase COVID-19 deaths. A study by Dr. Zacharias Fögen conducted in Kansas revealed that counties with a mask mandate had significantly higher case fatality rates than counties without a mask mandate. Dr. Fögen coined this phenomenon the “Foegen effect.” He explained that deep re-inhalation of droplets and virions caught in masks may make COVID-19 infection more likely or severe.²⁴

Breathing is adversely affected by masks, as shown by researchers in Germany who showed that cardiopulmonary performance is impaired by masks.²⁵ Even simple cloth masks can cause shortness of breath especially during activity. The Occupational Safety and Health Administration (OSHA) assesses safe CO₂ limits to be 2000 ppm. However, recent measurements of CO₂ inside cloth masks revealed levels of 10,000 ppm in some cases.²⁶ This is especially important for anyone with underlying cardiopulmonary insufficiency. Increased CO₂ levels have also been shown to alter expression of genes in bronchial cells

²⁴ Fögen, Zacharias MD . The Foegen effect: A mechanism by which facemasks contribute to the COVID-19 case fatality rate. *Medicine*: February 18, 2022 - Volume 101 - Issue

²⁵ Fikenzer S, Uhe T, Lavall D, Rudolph U, Falz R, Busse M, Hepp P, Laufs U. Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity. *Clin Res Cardiol*. 2020 Dec;109(12):1522-1530. doi: 10.1007/s00392-020-01704-y. Epub 2020 Jul 6. PMID: 32632523; PMCID: PMC7338098: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7338098/>

²⁶ Jane Orient MD, Personal Communication also: <https://aapsonline.org/COVID-19-and-air-pollution/>

adversely affecting “innate immune response, host defense, lung edema clearance”, and is an independent risk factor for death for pneumonia.²⁷ This propensity of masks to quickly become infectious bacteria traps illustrates that masks are unsanitary.

Sanitary mask disposal is also a major problem. It is estimated by some researchers that millions of surgical masks can be consumed worldwide in one (1) day.²⁸ Thus, discarding a single-use mask could, under ambient conditions, slowly degrade into smaller particles (5 mm) and form a new source of microplastics causing environment pollution and threatening living organisms.²⁹ This huge consumption of surgical masks contributes to microplastic pollution in the land environment and possibly universally permeates the aquatic ecosystem as

²⁷Casalino-Matsuda SM, Wang N, Ruhoff PT, Matsuda H, Nlend MC, Nair A, Szleifer I, Beitel GJ, Sznajder JI, Sporn PHS. Hypercapnia Alters Expression of Immune Response, Nucleosome Assembly and Lipid Metabolism Genes in Differentiated Human Bronchial Epithelial Cells. *Sci Rep.* 2018 Sep 10;8(1):13508. doi: 10.1038/s41598-018-32008-x. PMID: 30202079; PMCID: PMC6131151: <https://pubmed.ncbi.nlm.nih.gov/30202079/>, Goh DYT et al, A randomised clinical trial to evaluate the safety, fit, comfort of a novel N95 mask in children. *SCI REP.* 2019 Dec 12;9(1):18952. doi: 10.1038/s41598-019-55451-w. PMID: 31831801; PMCID: PMC6908682. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6908682/>.

²⁸ Li T, Liu Y, Li M, Qian X, Dai SY. Mask or no mask for COVID-19: A public health and market study. *PloS One.* 2020 Aug 14;15(8):e0237691. doi: 10.1371/journal.pone.0237691. PMID: 32797067; PMCID: PMC7428176.

²⁹ O.O. Fadare, E.D. Okoffo, COVID-19 face masks: a potential source of microplastic fibers in the environment *Sci. Total Environ.*, 737 (2020), p. 140279: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7297173/>

well.

Thus, it is ironic that the CDC seized on the word “sanitation”, found in the Public Health Service Act of 1944 (PHSA) § 361(a) as codified at 42 U.S.C. § 264(a), as the CDC’s justification for assuming sweeping powers to compel travelers to wear masks. Masks are inherently unsanitary. Masks are a sanitation problem, not a sanitation solution.

C. REGARDLESS OF MASK INEFFECTIVENESS AND HARMS, THE PRESIDENT AND THE CDC LACK THE NECESSARY CONSTITUTIONAL AND LEGISLATIVE AUTHORIZATION TO ISSUE A TRANSPORTATION MASK MANDATE

Regardless of the ineffectiveness and potential dangers of “mandatory” mask wearing, the President and the CDC lack the constitutional and statutory authority to issue such a sweeping edit on such a major question affecting millions of travelers, which major question demands legislative authorization under the major questions doctrine. This view of the major questions doctrine was recently adopted by the United States Supreme Court under both *West Virginia v. EPA*, 597 U.S. ___, Case No. 20-1530 (June 30, 2022), Slip Op. revised (July 13, 2022), and under *Alabama Ass’n of Realtors v. Dep’t of Health and Human Svc’s*, 141 S. Ct. 2485 (2021) (per curiam), which the District Court properly followed. Also see “Nat’l Fed’n of Indep. Bus. V. OSHA, 595 U.S. ___, 142 S. Ct. 661 (2022).

The CDC's claim that its' authority stemmed from the word "sanitation", found in the Public Health Service Act of 1944 (PHSA) § 361(a), as codified at 42 U.S.C. § 264(a) is particularly incorrect, inasmuch as masks pose a sanitation problem, and not a sanitation solution.

The CDC neglected to follow the notice and comment procedures as required by the Administrative Procedures Act, (APA), 5 U.S.C. §§ 551-559. As many courts have recognized, the pandemic public health emergency was first introduced in 2020 and has long since passed, removing the justification for an emergency exception to the APA.

The Plaintiffs-Appellees are also correct in their assertion that, although it may not be necessary to reach this issue in this case, the CDC's transportation mask mandate also violated the non-delegation doctrine.

Finally, masks are medical devices being used under an FDA EUA. As such they are a form of medical treatment. Courts have consistently upheld the patient's right to refuse medical treatments on constitutional grounds for decades. See *Mills v. Rogers*, 457 U.S. 291, 102 S.Ct. 2442, 73 L.Ed.2d 16 (1982), *Guardianship of Roe*, 383 Mass. 415, 421 N.E.2d 40 (1981), *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, 280 (1990), *Washington v. Harper*, 494 U.S.

210, 110 S.Ct. 1028, 108 L.Ed.2d 178 (1990), *Riggins v. Nevada*, 504 U.S. 127, 112 S.Ct. 1810, 118 L.Ed.2d 479 (1992), and *Sells v. United States*, 539 U.S. 166 (2003). Preservation of the absolute right of informed patient consent and medical freedom is a paramount consideration.

CONCLUSION

It has been shown that masks neither protect the mask-wearer from infection, nor prevent a mask-wearer from infecting others. Therefore, the transportation mask mandate is fundamentally irrational at its core, as the mandate in no way accomplishes its intended purpose. Masks are also actually harmful and unsanitary in many ways. Further, the President and the CDC lack the constitutional and statutory authority to enact such a mandate on this major question affecting millions of travelers, and for the other reasons enumerated herein. The “mandatory” wearing of masks is anathema to our system of informed patient consent and medical freedom. The District Court’s Order should be affirmed.

s/ David A. Dalia
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CERTIFICATE OF COMPLIANCE WITH RULE 32(g)

I hereby certify that the foregoing brief complies with Fed. R. App. P. 32(a)(7)(B) and Fed. R. App. P. 29(a)(5) because it contains 2,453 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and 11th Cir. R. 32 4.

I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced font in Microsoft Word using 14 point Times New Roman.

s/ David A. Dalia
David A. Dalia

CERTIFICATE OF SERVICE

I hereby certify that on August 8th, 2022, I electronically filed the foregoing Amicus Curiae Brief of America's Frontline Doctors in Support of Plaintiffs-Appellees and Affirmance with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit via the Court's CM/ECF system, which will automatically serve all counsel of record via CM/ECF notice.

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