

**No. 22-11287**

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

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**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

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**BRIEF OF AMICUS CURIAE CHILDREN'S HEALTH DEFENSE  
IN SUPPORT OF PLAINTIFFS-APPELLEES HEALTH FREEDOM  
DEFENSE FUND, INC.**

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Dated: August 2, 2022

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

Children's Health Defense (CHD) is a national non-profit 501(c)(3) organization. CHD has no parent corporation. No publicly held company has a 10 percent or greater ownership interest. CHD's mission is to end the epidemic of children's chronic health conditions by working aggressively to eliminate harmful exposures to environmental toxins via education, to obtain justice for those already injured, and to promote protective safeguards for all of society, including children.

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Proposed Amicus certifies that, to the best of their knowledge, the Certificate of Interested Persons filed by Plaintiffs-Appellees in their August 1, 2022 Answer Brief contains a correct complete list of the people and entities that have an interest in the outcome of this appeal, other than the following additions:

Children's Health Defense

Mary Holland, President, Children's Health Defense.

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## I. INTEREST OF AMICUS CURIAE<sup>1</sup>

Amicus offers this brief to explain why the Centers for Disease Control and Prevention's (CDC) "mask mandate for children on transportation conveyances and in transportation hubs" (hereinafter "Mask Mandate") is both ineffective and harmful. Under the CDC's February 2, 2021 Agency Order, all persons aged two and older are required to wear a homemade or manufactured mask covering the nose and mouth when traveling on any public transportation conveyance, including airplanes, interstate and local railroads and buses, boats and ships, and private taxis and "ride-share" automobiles, as well as at any transportation hub within the United States. The CDC has allowed exemptions from the masking requirement for a narrow class of people with disabilities, and has provided guidelines allowing for the removal of masks under certain circumstances, while using these same public conveyances.<sup>2</sup> The Order asserted that the CDC had authority to impose

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<sup>1</sup> Children's Health Defense has received written permission from Appellee's Counsel Brant Hadaway and Appellant's Counsel Solicitor General Brian J. Springer to file this brief. The parties received notice of the intention to file this brief at least 10 days prior to filing. No person or entity other than the named amicus, its members or counsel has (i) paid in whole or in part for the preparation of this brief or (ii) authored in whole or in part this brief.

<sup>2</sup> CENTERS FOR DISEASE CONTROL, *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*, fn 33.  
[https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC\\_GMTF\\_01-29-21-p.pdf](https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC_GMTF_01-29-21-p.pdf).

unspecified criminal penalties, although the agency opted to rely on civil penalties and voluntary compliance.

Masks are not government-approved for children to prevent them from contracting SARS-CoV-2, the virus associated with COVID-19, nor do they offer any measurable benefit for the prevention of viral transmission. On the contrary, masks cause children to suffer serious harms. Masks, along with polymerase chain reaction (PCR) tests intended to detect SARS-CoV-2 infection, are granted Emergency Use Authorization (EUA) only and have not been approved or licensed. In fact, just two years ago, the CDC declared that PCR test mandates were illegal and unethical, firmly declaring: "If a school is implementing a testing strategy, testing should be ordered on a voluntary basis. It is unethical and illegal to test someone who does not want to be tested, including students whose parents or guardians do not want them to be tested."<sup>3</sup> Mandating an EUA product, including tests and masks, violates federal law since they are by definition experimental. Since masks are merely EUA-authorized, not approved or licensed by the Food and Drug Administration (FDA), it is illegal and unethical for the CDC to mandate masks for children.

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<sup>3</sup> CENTERS FOR DISEASE CONTROL, *Interim Considerations for Testing for K-12 School Administrators and Public Health Officials, Centers for Disease Control And Prevention* (updated Dec. 4, 2020). <https://www.cdc.gov/coronavirus/2019-cov/community/schoolschildcare/k-12-testing.html>.

American children today are on the receiving end of a confusing bombardment of un-scientific, psychological signals from both the government and media that are damaging their physical and mental health irreparably.

There has never been any scientific evidence that proves masks provide any protection to prevent the spread of SARS-CoV-2. On the contrary, mask mandates were implemented without ever being properly tested or evaluated for efficacy. Now, accumulating research shows that masks do not protect, but instead, can make individuals sick.<sup>4,5</sup> Rather than having their intended effect, mask mandates, particularly for children, are causing not only significant physical and psychological harm, but are also interfering with child development. Simple common sense demonstrates that pointlessly blocking people's airflow exposes the utter disregard for their health, safety, and well-being in furtherance of petty goals, causing long-lasting physical and psychological harm to children.

Children's Health Defense amicus brief rejects the notion that facemasks provide any meaningful protection for children and even adults because masks are functionally useless in preventing the spread of viral infection. Facemasks are

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<sup>4</sup> Fögen, Zacharias, *The Foegen effect*, MEDICINE, February 18, 2022 - Volume 101 - Issue 7 - p e28924 doi: 10.1097/MD.00000000000028924. <https://pubmed.ncbi.nlm.nih.gov/35363218/>.

<sup>5</sup> Chandra, Ambarish, Høeg, Tracy Beth, *Revisiting Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1—October 20 2021*. THE LANCET, May 22, 2022. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4118566](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4118566).

unnecessary burdens on children who are merely trying to live their lives without unreasonable, illegal and illogical government mandates conditioning them into submission at the whim of government bureaucrats.

Without continued judicial intervention to counter this physiological and psychological damage to toddlers, children, and teens, including the threat of criminal sanctions, government overreach will go unchecked. As such, we urge the Court uphold the Mask Mandate injunction and to disallow re-implementation under the unsupported guise of public health. The Mask Mandate provides no protection for passengers and instead, causes real harm, particularly to children. Masks merely promote a false sense of security and in no way protect against the viral transmission of SARS-CoV-2.

## **II. SUMMARY OF ARGUMENT**

In January 2021, on his second day in office and one year after his predecessor President Trump declared a public health emergency under the Public Health Service Act, President Biden issued Executive Order 13998 for "Immediate Action to Require Mask-Wearing on Certain Domestic Modes of Transportation."

The Order specified:

- (a) Mask Requirement. The Secretary of Labor, the Secretary of Health and Human Services (HHS) to immediately take action "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.

Within weeks, on February 3, 2021, the CDC, a federal agency under the U.S. Department of Health and Human Services (HHS), announced an Agency Order<sup>6</sup> requiring persons, aged two and above (with some exemptions for disabilities and medical conditions)<sup>7</sup>, to wear a manufactured or homemade mask<sup>8</sup> over the mouth and nose when traveling on any conveyance or in a transportation hub within the United States and when entering or leaving the U.S.

These Executive and CDC actions occurred despite the complete lack of scientific data supporting the claim that masks prevent transmission of SARS-CoV-2, the virus associated with Covid-19. Further, the utilization of masks as “personal protective equipment (PPE)” is based on the Emergency Use Authorization (EUA) of masks as PPE. Yet masks have not been formally approved as PPE, nor is there evidence that masks worn as directed by the CDC are safe for wearers or effective in preventing viral transmission. Indeed, under the

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<sup>6</sup> CENTERS FOR DISEASE CONTROL, *Requirement for Persons To Wear Masks While on Conveyances and at Transportation Hubs*, 86 FR 8025, 8027 (Feb. 3, 2021). [https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC\\_GMTF\\_01-29-21-p.pdf](https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC_GMTF_01-29-21-p.pdf).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*



EUA statute governing “emergency authorization,” no legal claims of the safety or effectiveness of masks are valid.<sup>9</sup>

Even if universal compliance with the mask-wearing were achieved, the CDC Agency Order exempts from mask requirements children under two years of age as well as certain people with disabilities. Further, even for those required to wear masks, the CDC permits removal of masks when eating, drinking or to facilitate communication where necessary. Later in 2021, the CDC amended the Agency Order to permit the removal of masks in outdoor settings, even in outdoor transportation hubs and rail platforms.

The CDC has not only failed to provide any scientific evidence that mask-wearing in children is safe or effective in limiting the spread of SAR-CoV-2, but its order ignores the potential and known detrimental effects of mask-wearing, particularly for children. Contrary to the empty platitudes and pronouncements in CDC's Appellant brief, there is no persuasive “science” that universal masking (or even less than universal, as is the case here) can provide any significant protection for children (or those around them) against viral infection.

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<sup>9</sup> *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff*, FOOD AND DRUG ADMINISTRATION (Revised May 2020), at pp. 7-8. <https://www.fda.gov/media/136449/download>.

### III. ARGUMENT

#### A. MASKS DO NOT PREVENT THE SPREAD OF SARS-COV-2 OR ANY OTHER VIRUS.

##### 1. There Has Never Been a Scientific Basis for the Claim That Face Coverings Prevent the Spread of Viral Infection.

There is no scientific evidence that face coverings, whether cloth masks, surgical masks, or N95-style face coverings (known in the industry as “respirators”), prevent or even limit the spread of SAR-CoV-2 viral infection in the community. In fact, prior to April 2020, the broad scientific consensus was exactly the opposite, *i.e.* that face coverings had never been proven to prevent the spread of respiratory viruses like influenza or pneumonia, even in hospital settings or in medical offices, locations where mask usage was most prevalent before 2020.

##### 2. The Physical Properties of Masks Establish That They Cannot Prevent Virus Spread.

Although face mask design varies, the properties of a disposable face mask simply cannot contain the SARS-CoV-2 virus nor prevent it from exiting the nose and mouth of infected individuals into the air around them to be breathed in by others. Research shows that the SARS-CoV-2 virus has a diameter of 60 nm to 140 nm nanometers (a billionth of a meter).<sup>10</sup> The 0.3-10 micron pore size of standard surgical face masks is much larger than coronavirus (0.1  $\mu\text{m}$ ), and these

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<sup>10</sup> Bar-On et al, *SARS-CoV-2 (COVID-19) by the numbers*, ELIFE, Apr. 2, 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7224694/#bib70>.

masks incompletely form-fit the face.<sup>11</sup> A nanometer used in the measurement of SARS-CoV-2 virus particular is 1,000 times smaller than a micrometer since 1 micrometer ( $\mu\text{m}$ ) = 1,000 nanometers. Due to the difference in sizes between SARS-CoV-2 diameter and facemasks thread diameter, SARS-CoV-2 can easily pass through any facemask just as a mosquito or dust can pass through a chain link fence.

In September 2019, the World Health Organization (WHO) published a comprehensive report on ten randomized controlled trials addressing the effectiveness of face masks against influenza-like illness (ILI). None of the trials found a statistically significant benefit by wearing facemasks.<sup>12</sup>

An April 2020 scientific review of 31 research studies assessing facemask effectiveness in preventing respiratory illnesses, including SARS-CoV-2, found:

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<sup>11</sup> Liu, Yuangang et al, *Proposed Approach for Reusing Surgical Masks in Covid-19 Pandemic*, Department of Dermatology, Oregon Health & Science University. [https://www.ohsu.edu/sites/default/files/2020-03/Proposed%20Solution%20for%20face%20mask%20reuse\\_Final%20\(web\).pdf](https://www.ohsu.edu/sites/default/files/2020-03/Proposed%20Solution%20for%20face%20mask%20reuse_Final%20(web).pdf).

<sup>12</sup> *Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza*, WORLD HEALTH ORGANIZATION, Technical Document, September 19, 2019. <https://www.who.int/publications/i/item/non-pharmaceutical-public-health-measuresfor-mitigating-the-risk-and-impact-of-epidemic-and-pandemic-influenza>.

“In conclusion, there is a limited evidence base to support the use of masks and/or respirators in healthcare or community settings.”<sup>13</sup>

In May 2020, a literature review published on the government medRxiv website entitled “Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review” evaluated ten randomized controlled trials (RCTs) conducted between 1946 and 2018 evaluating the effectiveness of facemasks in preventing influenza, a respiratory infection similar to Covid-19. The authors reported: “There is limited evidence for their [masks’] effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found no significant effect of face masks on transmission of laboratory-confirmed influenza.”<sup>14</sup>

### **3. Government Officials Initially Confirmed that Masks Cannot Prevent Virus Spread.**

Notably, all public health officials supported this scientific consensus before mid-2020, discouraging mask wearing by the general public to prevent viral

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<sup>13</sup> Brainard, J. et al, *Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review*, MEDRXIV (April 6, 2020). <https://www.medrxiv.org/content/10.1101/2020.04.01.20049528v1>.

<sup>14</sup> Xiao, J., Shiu, et al, *Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures*. EMERGING INFECTIOUS DISEASES, 26(5), 967-975, May 2020. <https://doi.org/10.3201/eid2605.190994>.

spread. Dr. Anthony Fauci of the National Institutes of Health (NIH) stated in a televised interview on CBS's "Sixty Minutes" on March 8, 2020: "People feel a little bit better and it [a mask] might even block a droplet, but it's not providing the perfect protection that people think that it is."<sup>15</sup> CDC Director Robert Redfield on February 27, 2020<sup>16</sup> echoed this view. On the same day, then-U.S. Surgeon General Jerome Adams noted: "What the World Health Organization and the CDC have reaffirmed in the last few days is that they do not recommend the general public wear masks."<sup>17</sup>

**4. Government Officials Summarily Reversed Course, Declaring Masks Prevent Virus Spread Despite Previous Statements and Evidence to the Contrary.**

By April 3, 2020, the CDC dramatically changed course, now recommending that people wear facemasks to prevent the spread of infection with SARS-CoV-19. As National Public Radio reported: "U.S. health authorities had discouraged healthy Americans from wearing facial coverings for weeks, saying

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<sup>15</sup> Anthony Fauci television interview, *60 Minutes* (March 8, 2020). <https://www.youtube.com/watch?v=jwCynEjFt8E>.

<sup>16</sup> Langlois, Sean, *Surgeon general wants you to stop buying masks to protect yourself from coronavirus: 'They are NOT effective'*, MARKET WATCH, March 1, 2020. <https://www.marketwatch.com/story/surgeon-general-wants-you-to-stop-buying-masks-to-protect-yourself-from-coronavirus-they-are-not-effective-2020-03-01>.

<sup>17</sup> S. Fitzgerald, *Surgeon General Doubles Down: Masks Increase Virus Risk*, NEWSMAX (Feb. 27, 2020). <https://www.newsmax.com/us/surgeon-general-adams-masks/2020/03/31/id/960679/>.

they were likely to do more harm than good in the fight against the coronavirus — but now, as researchers have learned more about how the highly contagious virus spreads, officials have changed their recommendations.”<sup>18</sup>

But the CDC never provided a scientific basis for its abrupt change, failing to publish any new scientific data or studies conducted during the previous month that contradicted prior research or that supported the reversal in masking recommendations. The CDC did not sponsor RCTs or any targeted research to evaluate the need for masking or for this change. In fact, the only large RCT on the issue of masking effectiveness in the context of Covid-19 was conducted by Danish researchers in May and June 2020, with 6,000 participants. The results, published in the *Annals of Internal Medicine*, found no statistically significant effect for the use of high-quality medical face masks against SARS-CoV-2 infection in a community setting.<sup>19</sup>

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<sup>18</sup> Dwyer, C., Aubrey, A, *CDC Now Recommends Americans Consider Wearing Cloth Face Coverings In Public*, NATIONAL PUBLIC RADIO, April 3, 2020. <https://www.npr.org/sections/coronavirus-live-updates/2020/04/03/826219824/president-trump-says-cdc-now-recommends-americans-wear-cloth-masks-in-public>.

<sup>19</sup> Henning Bundgaard et al, *Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers*, ANNALS OF INTERNAL MEDICINE, March 2021. <https://www.acpjournals.org/doi/10.7326/M20-6817>. Notably, due to political pressures, three medical journals refused to publish the results of the Danish study. *See On the Suppressed Danish Mask Study*, SWISS POLICY RESEARCH, October 24, 2020. <https://swprs.org/the-suppressed-danish-mask-study/>.

The April 2020 CDC reversal implied a significant difference in the effectiveness of masking to prevent viral spread in the COVID-19 context, yet provided no evidence. Facemasks had already been amply demonstrated to lack effectiveness in preventing the spread of influenza viruses. The actual scientific evidence, most often produced outside the U.S., demonstrated an absence of scientific support for widespread masking in community settings. The European Centre for Disease Prevention (ECDC) in fact noted in February 2021, “Evidence for the effectiveness of non-medical face masks, face shields/visors and respirators in the community is scarce and of very low certainty.”<sup>20</sup>

After months of experience and data collection on facemasks during 2020-2021, it became clear that mask requirements had no impact on the spread of SARS-CoV-2 virus.<sup>21</sup> A May 2021 comprehensive data analysis study, published in August 2021 in the *International Research Journal of Public Health*, found “no association between mask mandates or use and reduced COVID-19 spread in US

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<sup>20</sup> EUROPEAN CENTER FOR DISEASE PREVENTION AND CONTROL, *Using face masks in the community: first update - Effectiveness in reducing transmission of COVID-19*, February 15, 2021. <https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-face-masks-community-first-update.pdf>.

<sup>21</sup> Chandra, Ambarish, Høeg, Tracy Beth, *Revisiting Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1—October 20 2021*. THE LANCET, May 22, 2022. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4118566](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4118566).

states.”<sup>22</sup> Yet the CDC continued to promote face masks to prevent the spread of SARS-CoV-2, providing at best only anecdotal and observational studies to support masking guidance.<sup>23</sup> Notably, the CDC formally rescinded that guidance on February 25, 2022 [when the District Court enjoined the mandate], again without reference to updated scientific data.

### 5. Masks are Not Safe and Effective for Children.

In January 2022, the CDC updated some of its mask guidance, finally recognizing cloth masks offer the least protection:

Loosely woven cloth products provide the least protection, layered finely woven products offer more protection, well-fitting disposable surgical masks and KN95s offer even more protection, and well-fitting NIOSH-approved respirators (including N95s) offer the highest level of protection.<sup>24</sup>

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<sup>22</sup> Damian D.Guerra, Daniel J.Guerra. *Mask mandate and use efficacy for COVID-19 containment in US States*. INTERNATIONAL RESEARCH JOURNAL OF PUBLIC HEALTH, 2021; 5:55. DOI: 10.28933/irjph-2021-08-1005. <https://escipub.com/irjph-2021-08-1005/>.

<sup>23</sup> See CDC, *Science Brief: Use of Masks to Control the Spread of SARS-CoV-2* (Dec. 6, 2021), <https://bit.ly/3utvxOA>. The Brief selects eight observational studies to support its claims for the effectiveness of facemasks, and a single RCT conducted in Bangladesh in 2020 that was the subject of strong refutation, finding that the “primary outcome of the study is insignificant.” Chikina, Maria et al, *A note on sampling biases in the Bangladesh mask trial*. STAT.AP, Dec. 2, 2021. <https://arxiv.org/pdf/2112.01296.pdf>.

<sup>24</sup> CDC, *Types of Masks and Respirators* (updated January 24, 2022). <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html>.



In its most recent (February 25, 2022) guidance on masking, the CDC offered this instruction for children:

*Children ages 2 years and older can wear masks or respirators to protect themselves and others from COVID-19.*

*Choose a well-fitting and comfortable mask or respirator that your child can wear properly.*

Yet the FDA continues to advise against N95 respirators for children (or even for people with facial hair), noting:

N95 respirators are not designed for children or people with facial hair. Because a proper fit cannot be achieved on children and people with facial hair, the N95 respirator may not provide full protection.<sup>25</sup>

In a CDC document addressing counterfeit N95 masks, the CDC notes that one way to identify a counterfeit N95 is if it makes “Claims for the approval [of the mask] for children (NIOSH does not approve any type of respiratory protection for children).”<sup>26</sup>

Florida's Surgeon General Dr. Joseph Ladapo exposed the CDC's lack of scientific basis for its position on masking:

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<sup>25</sup> U.S. FOOD AND DRUG ADMINISTRATION, *N95 Respirators, Surgical Masks, Face Masks, and Barrier Face Coverings*, July 19, 2021. <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-face-masks-and-barrier-face-coverings#cdc>.

<sup>26</sup> CDC, *Counterfeit Respirators / Misrepresentation of NIOSH-Approval*, March 17, 2022. <https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html>.

“What did the two randomized clinical trials that we’ve done during the pandemic,<sup>27</sup> what did they show? Ask them that when they tell you that these things save lives,” Ladapo said. “One found nothing, zero benefit. The other found a small benefit, like a tiny benefit that’s a little bit methodologically shaky. And by the way, none of them found a benefit in young people. **Not a single one found a benefit in young people.** That’s the highest-quality evidence, that’s what it showed.” (Emphasis added.)

“It’s a lie and it needs to stop and people need to un-believe it,” Ladapo said, holding up the mask he’d brought with him, before leaving the podium.<sup>28</sup>

## 6. Facemasks Cause Harm.

Although the CDC ignores it, scientists have provided mounting evidence over the last two years that widespread public facemask wearing is not only ineffective in preventing viral transmission but can and does cause serious harm. In 2021, a group of German researchers conducted a large literature review of more than 65 scientific research documents housed on the NIH PubMed site to examine “adverse effects and risks of different types of mouth–nose-covering masks.”<sup>29</sup> The

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<sup>27</sup> Dr. Ladapo is referring to the Danish RCT (FN 20) and the Bangladesh RCT referenced in this brief. See FN23.

<sup>28</sup> Sachs, *S*, *Unbelieve the lie: Florida surgeon general says masks ‘never’ saved lives during pandemic*. NEWS CHANNEL 8, March 4, 2022. <https://www.wfla.com/news/politics/unbelieve-the-lie-florida-surgeon-general-says-masks-never-saved-lives-during-pandemic/>.

<sup>29</sup> Kisielinski K et al, *Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?* Int J Environ Res Public Health. 2021 Apr 20;18(8):4344. doi: 10.3390/ijerph18084344.

survey found studies confirming highly significant evidence of harm from mask-wearing:

- Five cited studies found that "[b]esides the shift in blood gases towards hypercapnia (increase in CO<sub>2</sub>) and hypoxia (decrease in O<sub>2</sub>) ... masks also restrict the cognitive abilities of the individual ... accompanied by a decline in psycho-motoric abilities and consequently a reduced responsiveness as well as an overall reduced performance capability."
- Four studies<sup>30</sup> found that people with certain psychological conditions should not wear masks: "People undergoing treatment for dementia, paranoid schizophrenia, personality disorders with anxiety and panic attacks, but also panic disorders with claustrophobic components, are difficult to reconcile with a mask requirement, because even small increases in CO<sub>2</sub> can cause and intensify panic attacks."

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PMID: 33923935; PMCID: PMC8072811. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8072811/#sec3dot1-ijerph-18-04344>.

<sup>30</sup> See for example, Gorman J.M et al, *Response to Hyperventilation in a Group of Patients with Panic Disorder*, AM. J. PSYCHIATRY, July 1984;141:857–861. doi: 10.1176/ajp.141.7.857 <https://ajp.psychiatryonline.org/doi/abs/10.1176/ajp.141.7.857>.

- Three studies<sup>31</sup> found that “[p]oor filtration performance and incorrect use of surgical masks and community masks, as well as their frequent reuse, imply an increased risk of infection” for mask-wearers.
- One study included the following long list of conditions as criteria for childhood exemptions from mask requirements: “[A]ny cardiopulmonary disease including but not limited to: asthma, bronchitis, cystic fibrosis, congenital heart disease, emphysema; any condition that may be aggravated by physical exertion, including but not limited to: exercise-induced asthma; lower respiratory tract infections (pneumonia, bronchitis within the last 2 weeks), anxiety disorders, diabetes, hypertension or epilepsy/attack disorder; any physical disability due to medical, orthopedic or neuromuscular disease; any acute upper respiratory illness or symptomatic rhinitis (nasal obstruction, runny nose or sneezing); any condition with deformity that affects the fit of the mask (e.g., increased facial hair, craniofacial deformities, etc.).”<sup>32</sup>

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<sup>31</sup> See for example MacIntyre C.R. et al, *Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers*. BMJ OPEN, 2015, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4420971/>.

<sup>32</sup> 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/>.

**7. The Government Concedes that Facemasks are not Safe or Effective Because They are Emergency Use Authorized Only.**

Face masks used as personal protection were granted EUA status from the FDA<sup>33</sup> on April 18, 2020.<sup>34</sup> On April 24, 2020, the FDA clarified the EUA to emphasize that face masks, including cloth face coverings, are only authorized for use by the general public and health care personnel as “source control.”<sup>35</sup> 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.”<sup>36</sup>

The FDA’s revised EUA letter on April 24, 2020 specified: **“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**

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<sup>33</sup> See 21 U.S. Code § 360bbb-3 - *Authorization for medical products for use in emergencies.*

<sup>34</sup> 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, Feb. 7, 2020.

<sup>35</sup> U.S. FOOD AND DRUG ADMINISTRATION, *Letter to Manufacturers of Face Masks; Health Care Personnel; Hospital Purchasing Departments and Distributors; and Any Other Stakeholders*, April 24, 2020. <https://www.fda.gov/media/137121/download>.

<sup>36</sup> *Id.*

**pandemic.”**<sup>37</sup> Although authorized and strongly promoted for emergency use, the FDA barred any claims that the facemasks were either safe or effective in preventing infection.

Similarly, in its document *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)*<sup>38</sup> the FDA stated clearly that face masks are not intended to reduce or prevent infection:

The product is not intended for any use that would create an undue risk in light of the public health emergency, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.<sup>39</sup>

Because the FDA has not approved or licensed facemasks, any use of a facemask under such an emergency authorization must be voluntary and recipients must be informed “of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the

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<sup>37</sup> *Id.*

<sup>38</sup> U.S. FOOD AND DRUG ADMINISTRATION, *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff*, revised September 2021. <https://www.fda.gov/media/136449/download>.

<sup>39</sup> *Id.* at pp 7-8.

alternatives to the product that are available and of their benefits and risks.”<sup>40</sup> Yet the CDC attempts to require that all transportation riders, under penalty of criminal sanction, wear these experimental products for which claims of safety or effectiveness are legally prohibited.

Further, the CDC recommends that children not wear N95 respirators. It therefore mandates that children wear (clean, dry) cloth masks, which it has admitted are ineffective at preventing viral transmission. To compensate for this ineffectiveness and the dangers to children from wearing cloth masks, and to somehow navigate around the CDC’s contradictory guidance, mask advocates offer the nonsensical advice that young children should wear multiple masks. The CDC admits that cloth masks are ineffective for purposes of preventing viral transmission, as are all facemasks and respirators, so for "extra protection" the CDC recommends wearing two masks.<sup>41</sup>

#### **8. Face Masks May Increase Death Rates as well as Fail to Protect Wearers and the Broader Community from the Transmission of SAR-CoV-2.**

As early as August 2020, a study by German scientists found little evidence demonstrating the effectiveness of mask requirements for reducing the spread of SARS-CoV-2. They concluded: “Upon our critical review of the available

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<sup>40</sup> 21 U.S. Code § 360bbb–3(e)(1)(ii)(III).

<sup>41</sup> CDC, *Types of Masks and Respirators* updated January 28, 2022. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html>.

literature, we found only weak evidence for wearing a face mask as an efficient hygienic tool to prevent the spread of a viral infection.”<sup>42</sup>

A follow-up European study in April 2022 confirmed the conclusions of the 2020 German scientists: “These findings indicate that countries with high levels of mask compliance did not perform better than those with low mask usage.”<sup>43</sup>

Biologists at the University of Louisville, Kentucky in May 2021 assessed whether statewide mask mandates and compliance had any effect on the spread of COVID-19. They concluded: “We found little to no association between COVID-19 case growth and mask mandates or mask use at the state level. These findings suggest that statewide mandates and enhanced mask use did not detectably slow COVID-19 spread.”<sup>44</sup>

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<sup>42</sup> Matuschek C et al, *Face masks: benefits and risks during the COVID-19 crisis*. Eur J MED RES. 2020 Aug 12;25(1):32. doi: 10.1186/s40001-020-00430-5. PMID: 32787926; PMCID: PMC7422455. <https://pubmed.ncbi.nlm.nih.gov/32787926/>.

<sup>43</sup> Spira B. *Correlation Between Mask Compliance and COVID-19 Outcomes in Europe*. CUREUS. 2022 Apr 19;14(4):e24268. doi: 10.7759/cureus.24268. PMID: 35607577; PMCID: PMC9123350. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9123350/>.

<sup>44</sup> Guerra, D et al, *Mask mandate and use efficacy in state-level COVID-19 containment*, MEDRXIV, May 25, 2021. <https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v1.full.pdf>.



In May 2022, independent researchers attempted to replicate a widely circulated CDC study<sup>45</sup> that claimed a reduction in pediatric COVID-19 cases where school mask mandates were in place. The CDC study examined data from 565 U.S. counties with and without school mask requirements, six weeks before and two weeks after school openings in 2021. The CDC study found that, on average, non-masking counties had 30 additional COVID-19 cases per 100,000 students. In attempting to replicate the CDC analysis, the independent researchers expanded data collection to 1,832 counties, while also examining data from the CDC’s 565 targeted counties for a longer period than the CDC’s study period. The independent study disproved the CDC’s original results: “[i]ncorporating a larger sample and longer period showed no significant relationship between mask mandates and case rates.”<sup>46</sup>

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<sup>45</sup> Budzyn SE et al, *Pediatric COVID-19 cases in counties with and without school mask requirements—United States, July 1–September 4, 2021*. MORBIDITY AND MORTALITY WEEKLY REPORT. Oct 1, 2021. 1;70(39):1377. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8486393/>.

<sup>46</sup> Chandra, Ambarish and Høeg, Tracy Beth, *Revisiting Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements—United States, July 1—October 20 2021*. Available at SSRN: <https://ssrn.com/abstract=4118566> or <http://dx.doi.org/10.2139/ssrn.4118566>.

Alarming, a February 2022 comprehensive study from every Kansas county<sup>47</sup> found that not only were mask requirements ineffective to reduce COVID-19 spread, **they actually correlated with higher death rates.** The study author noted, “[C]ounties with a mask mandate had significantly higher case fatality rates than counties without mask mandates.”

Results from this study strongly suggest that mask mandates actually caused about 1.5 times the number of deaths or ~50% more deaths compared to no mask mandates. This means that the risk for the individual wearing the mask should even be higher, because there is an unknown number of people in MMC [Mask Mandated Counties] who either do not obey mask mandates, are exempted for medical reasons or do not go to public places where mask mandates are in effect. These people do not have an increased risk and thus the risk on the other people under a mask mandate is actually higher.

Citing the German PubMed survey study, an article in the American Medical Association journal *JAMA Pediatrics* on June 30, 2021<sup>48</sup> examined the impact on children of elevated oxygen levels in inhaled air while wearing a mask:

Most of the complaints reported by children can be understood as consequences of elevated carbon dioxide levels in inhaled air. This is because of the dead-space volume of the masks,

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<sup>47</sup> Fögen, Zacharias, *The Foegen effect*, MEDICINE, February 18, 2022 - Volume 101 - Issue 7 - p e28924 doi: 10.1097/MD.00000000000028924. <https://pubmed.ncbi.nlm.nih.gov/35363218/>.

<sup>48</sup> Walach H et al. *Experimental Assessment of Carbon Dioxide Content in Inhaled Air With or Without Face Masks in Healthy Children: A Randomized Clinical Trial*. JAMA PEDIATR. June 30, 2021. doi:10.1001/jamapediatrics.2021.2659. <https://jamanetwork.com/journals/jamapediatrics/fullarticle/2781743> [retracted post-publication].

which collects exhaled carbon dioxide quickly after a short time. This carbon dioxide mixes with fresh air and elevates the carbon dioxide content of inhaled air under the mask, and **this was more pronounced in this study for younger children.**

This leads in turn to impairments attributable to hypercapnia. A recent review [citation omitted] concluded that there was ample evidence for adverse effects of wearing such masks. We suggest that decision-makers weigh the hard evidence produced by these experimental measurements accordingly, **which suggest that children should not be forced to wear face masks.** (Emphasis added)

#### **9. CDC's Mask Mandate is not Based on Scientific Evidence.**

Appellants recognize that courts traditionally prefer not to rule on the basis of science, as scientific experts often have widely divergent opinions. Fortunately for this Court, the Appellant CDC has not provided expert opinions or scientific data to support any of its claims, offering only festooned platitudes and pronouncements. Appellants simply assert without evidence that “masks are a longstanding means to prevent the spread of communicable disease.” (Appellants’ brief p. 19) Without citing any actual scientific data, Appellants claim: “The CDC amply satisfied its obligation to ‘examine the relevant data and articulate a satisfactory explanation for’ its judgment that the mask order is necessary to prevent the spread of COVID-19 in transportation corridors.” (Appellants’ brief p. 20.)

The District Court was unimpressed with the CDC’s arguments.

The agency must consider the essential aspects of the problem and act reasonably, as the government claims that the CDC did. That is necessary, but not sufficient alone. It must also explain its decision with enough particularity that a reviewing court can determine that it used its discretion appropriately. The CDC did not do that. *See Regents of the Univ. of Cal.*, 140 S. Ct. at 1913 ("The fact that there may be a valid reason . . . does not establish that [the agency] considered [it] . . ."). It didn't even try to explain.

*Health Freedom Def. Fund, Inc. v. Biden*, 8:21-cv-1693-KKM-AEP (M.D. Fla. Apr. 18, 2022) 2022 U.S. Dist. LEXIS 71206, \*58.

The CDC failed to provide any “particularity” for its conclusions and thus lost in the trial court.

**10. Even Though the CDC Cannot Justify the Mask Mandate, it May Impose Criminal Penalties.**

The CDC normally issues “guidance” that is not binding and does not have the force of law. Consistent with this practice, the CDC's Mask Mandate is guidance advising children and preschoolers that "Wearing a well-fitting mask consistently and correctly reduces the risk of spreading the virus that causes COVID-19."<sup>49</sup> Yet the CDC may not legally make this claim in light of the FDA's

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<sup>49</sup> CDC, *Operational Guidance for K-12 Schools and Early Care and Education Programs to Support Safe In-Person Learning*, updated May 27, 2022 <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-childcare-guidance.html>.

Note that the CDC is not legally permitted to make such a claim in light of the FDA's admonition that “No printed matter, including advertising or promotional materials, relating to the use of the authorized face mask may represent or suggest

prohibition: “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.”<sup>50</sup> Typically such unscientific “guidance” is followed at the local level where state and local public health officials enact mandates with the force of law based on the CDC’s guidance.

In this instance, the CDC uncharacteristically reserves the right to enforce the mask mandate directly through criminal penalties,<sup>51</sup> although the CDC failed even to justify its policy to the District Court. The Court found:

The CDC does not "articulate a satisfactory explanation"—or any explanation at all—"for its action" and fails to include a "rational connection between the facts found and the choices made." *Motor Vehicle Mfrs.*, 463 U.S. at 43 (quotation omitted). Instead, it simply announces the exceptions.

*Health Freedom Def. Fund, Inc. v. Biden*, 8:21-cv-1693-KKM-AEP (M.D. Fla. Apr. 18, 2022) 2022 U.S. Dist. LEXIS 71206, \*55.

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that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.” (FN 33.)

<sup>50</sup> See FN 33.

<sup>51</sup> FN 33 CDC, *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*, fn 33. [https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC\\_GMTF\\_01-29-21-p.pdf](https://www.cdc.gov/quarantine/pdf/Mask-Order-CDC_GMTF_01-29-21-p.pdf).

#### IV. CONCLUSION

With the 2021 inauguration of President Joe Biden, the CDC promised to “follow the science” in its COVID-19 policies. Yet its actual practices do not follow the science. The CDC has repeatedly cited dubious research, usually long after it issues guidance, without scientific transparency or credibility. At its heart, science requires verification of results, which the CDC has failed to do. CDC's scientism erodes trust in the institution and public health generally.

Since the CDC issued its February 2, 2021 Order requiring masks in transportation settings, it has yet to provide any legitimate scientific basis for its claims that masks are safe and prevent the spread of infection. Instead, the CDC overstepped its authority and required all Americans two years and older to wear facemasks, proclaiming that these experimental devices are “safe and effective” when in fact, no such claims are even legally permissible.

When the District Court issued its injunction, scenes of jubilant adults and children appeared on newscasts nationwide.<sup>52</sup> Indeed, adults have bristled against mask mandates, particularly on airplanes, for months, with more than 4,500

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<sup>52</sup> *You May Remove Your Mask: Plane Passengers Cheer as Mandate Lifted Mid-Flight*, YAHOO NEWS, April 18, 2022. <https://www.yahoo.com/entertainment/may-remove-mask-plane-passengers-024635785.html>.

incidents reported to the Federal Aviation Administration (FAA) in 2021 alone.<sup>53</sup> Sadly, children mostly have suffered in silence, enduring serious medical and psychological harms without any demonstrable benefit from suffocating mask requirements in schools, transportation and other settings. Vulnerable children have limited ability to challenge these nonsensical policies on their own.

For the foregoing reasons, and on behalf of millions of children forced to comply with the CDC's unscientific and irrational Mask Mandate,<sup>54</sup> Children's Health Defense respectfully requests that the Court affirm the District Court's ruling.

Dated: August 2, 2022

Respectfully submitted,



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<sup>53</sup> *Will the End of the Mask Mandate Curb Air Passenger Violence?* TRAVEL POST, April 19, 2022. <https://www.travelpulse.com/news/airlines/will-the-end-of-the-mask-mandate-curb-air-passenger-violence.html>.

<sup>54</sup> For in-depth analyses of science on masks, please see <https://childrenshealthdefense.org/the-science-of-masks/>.

**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 5,989 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.

Dated: August 2, 2022

A handwritten signature in blue ink, appearing to read "Ray L. Flores II", with a long horizontal flourish extending to the right.

RAY L. FLORES II



**CERTIFICATE OF SERVICE**

I hereby certify that on August 2, 2022, a true and accurate copy of the foregoing certificate was electronically filed with the Court using the CM/ECF system. Service on counsel for all parties will be accomplished through the Court's electronic filing system.

Date: August 2, 2022

/s/ Ray L. Flores II