No. 21-11532-BB

# United States Court of Appeals for the 11th Circuit

LUCAS WALL,
Appellant/Plaintiff

v.

CENTERS FOR DISEASE CONTROL & PREVENTION, DEPARTMENT OF HEALTH & HUMAN SERVICES, TRANSPORTATION SECURITY ADMINISTRATION, DEPARTMENT OF HOMELAND SECURITY, & DEPARTMENT OF TRANSPORTATION, Appellees/Defendants

Appeal from the United States District Court for the Middle District of Florida
No. 6:21-cv-975

# BRIEF OF AMICI CURIAE 3 INDUSTRIAL HYGIENE EXPERTS IN SUPPORT OF APPELLANT URGING REVERSAL

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# I. CERTIFICATE OF INTERESTED PERSONS

Pursuant to 11th Cir. R. 26.1-2(b), we certify that the CIP contained in Appellant's Opening Brief (Brief at 1-32) is correct and complete except for the additions of ourselves:

- David Howard, Amicus Curiae
- Stephen Petty, Amicus Curiae
- Tyson Gabriel, Amicus Curiae

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#### IV. AMICI'S INTEREST IN THE CASE

Friends of the Court are three experts in the fields of industrial hygiene as well as occupational safety and health. We write in support of Appellant Lucas Wall's arguments that the Federal Transportation Mask Mandate ("FTMM or "Mask Mandate") imposed by Appellees Centers for Disease Control & Prevention ("CDC"), Department of Health & Human Services ("HHS"), Transportation Security Administration ("TSA"), and Department of Homeland Security ("DHS") is arbitrary and capricious. Also, these government agencies did follow the Administrative Procedure Act ("APA") notice-and-comment requirements before adopting the CDC/HHS FTMM Order, and TSA/DHS' three "Security Directives" and one Emergency Amendment that require all transportation passengers and workers nationwide to wear face masks.

Had notice and comment been provided, we and many others in our profession would have advised these agencies that masks do not stop the spread of respiratory viruses such as COVID-19 and that Occupational Safety &

<sup>&</sup>lt;sup>1</sup> We agree with Mr. Wall that TSA's Mask Mandate has nothing to do with transportation security, therefore we adopt his use of the term "Health Directives" throughout the remainder of this brief to more appropriately describe TSA's orders.

Health Administration ("OSHA") regulations require any company mandating N95 respirators (masks) to follow strict protocols including medical examination and fit testing. Also, we are personally subject to the Mask Mandate (which the CDC conflates N95 respirators with) every time we fly or use other modes of public transportation.

We support Mr. Wall's arguments that all components of the FTMM are *ultra vires* and should be vacated worldwide, as a different judge did for the CDC/HHS portion in the case of *Health Freedom Defense Fund v. Biden*, No. 8:21-cv-1693 (M.D. Fla. April 18, 2022) ("*HFDF*"). Although CDC, HHS, TSA, and DHS have temporarily suspended all mask dictates due to the decision in *HFDF* (currently on appeal to this Court; No. 22-11287), it is critical that this Court enjoin all four agencies from ever reissuing any directives forcing passengers and transportation workers to don face masks.

We obtained consent of Appellant Lucas Wall and Brian Springer, counsel for the government appellees, to file this brief. FRAP 29(a)(2).

No party's counsel authored this brief in whole or part. No party or their counsel contributed money that was intended to fund preparing or submitting the brief. No person other than those signing this brief contributed money that was intended to fund preparing or submitting this document.

#### V. STATEMENT OF THE ISSUES

We participate in this case to ensure the Court has a true understanding of the science: Face masks do not stop the spread of a respiratory virus but harm human health in many ways, as Mr. Wall has corrected pointed out. We are proud that he introduced into evidence below our Feb. 22, 2022, letter to Dr. Rochelle Walensky, CDC director; Anthony Fauci, chief medical adviser to President Biden; Sen. Ronald Johnson; Douglas Parker, assistant secretary of labor for occupational health and safety; and Jeffrey Zients, White House COVID-19 Pandemic Response coordinator. App. 959-985. We authored that letter along with five other colleagues in the fields of industrial hygiene as well as occupational health and safety to bring these government officials' attention to the fact that they have been misleading the public about the efficacy of face coverings as a tool to reduce transmission of coronavirus.

As we will explore below, the federal government has constantly lied to the American public about masks being a critical tool to slow down COVID-19 infections. In this case, the administrative record is virtually nonexistent when it comes to being supported by science. CDC and HHS cited only seven deeply flawed studies to come to the conclusion that masking everyone in the transport sector would "slow the spread." TSA and DHS cited not a single scientific study to justify their FTMM Health Directives.

#### VI. ARGUMENT SUMMARY

There are only two lawsuits we are aware of in the nation where a judgment has been issued on a challenge to the FTMM Order issued by CDC and HHS, and both happen to be from the Middle District of Florida and currently on appeal to this Court. Judge Mizelle in *HFDF* correctly held that the Mask Mandate was issued beyond CDC's statutory authority and was also *ultra vires* because the agency failed to provide notice and allow comments, and the policy is arbitrary and capricious. We are disappointed Judge Mizelle's well-reasoned opinion did not discuss the government's false claims that masks are an effective tool to curtail transmission of a respiratory virus when used by an untrained general public such as transit passengers and employees.

In this case, Judge Byron came to the exact opposite legal conclusions of Judge Mizelle and brushed off many of Mr. Wall's solid arguments against the legality of the FTMM (as well as the International Traveler Testing Requirement, a part of the case we do not address). Mr. Wall introduced 228 scientific and medical studies, articles, and videos into evidence below (indexed at <a href="https://lucas.travel/masksarebad">https://lucas.travel/masksarebad</a>) totaling thousands of pages, not a single one of which Judge Byron considered in his misguided ruling that CDC and HHS have the legal authority to mandate masks, that "good cause"

excused the APA's notice-and-comment requirement, and that the FTMM isn't arbitrary and capricious because it was issued without any basis in science or medicine. Judge Byron should have considered all the evidence Mr. Wall presented to rebut the findings of CDC and HHS.

The administrative "record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency." *AT&T Info. Sys. v. GSA*, 810 F.2d 1233, 1236 (D.C. Cir. 1987). Supplementation of the administrative record is appropriate when an agency has deliberately or negligently excluded certain documents from the record, such as in this case. Mr. Wall's evidence helps the Court determine that the agencies failed to consider most relevant factors.

We hope the arguments and evidence we offer the Court will help it come to the correct conclusion in this case and the related appeal: Judge Byron's decision must be reversed, Judge Mizelle's ruling shall be affirmed, and the Court must permanently enjoin CDC, HHS, TSA, and DHS from ever again issuing a Mask Mandate unless Congress passes a new law specifically allowing them to do so.

#### VII. ARGUMENT

# A. The Mask Mandate must be vacated and enjoined from ever being reissued because it is arbitrary and capricious.

There have been two responses to the COVID-19 pandemic: a medical response and an exposure-mitigation response. Many have inacurately assumed that the medical industry has expertise in both areas but this is incorrect. The medical industry is unschooled in exposure science and is in fact a customer to the exposure-science industry known as "industrial hygiene." This is the area where we offer expertise to the Court. A transportation security agency certainly has no qualifications to regulate industrial hygiene. Doing so makes the Mask Mandate arbitrary and capricious. If CDC's part of the Mask Mandate qualifies as such, then clearly TSA's portion does too. *HFDF*. The district court was wrong to dismiss Mr. Wall's claims against TSA and its parent department, DHS, because their mask directives do not involve security matters, therefore the "exclusive jurisdiction" of the Court of Appeals does not apply.

The medical response consists of learning about the pathogen and how it travels, how it affects and enters the body, the pathogen's structure and weaknesses, and what treatments work after exposure to the pathogen has occurred. Exposure-mitigation sciences will initially take the medical science to specifically evaluate possible options for combating the virus. Then, each

occupied space will be evaluated to identify current hazards and ensure a customized approach to each exposure will be met to ensure the occupants have optimal safety and health results.

We work in concert to mitigate various exposures in every single industry. You will find us in construction, mining, manufacturing, law enforcement, the military, insurance, food service, government, consumer shopping, and yes we serve the medical industry too!

OSHA sums up industrial hygiene as the "science and art devoted to the anticipation, recognition, evaluation, and control of those environmental factors or stresses arising in or from the workplace, which may cause sickness, impaired health and well-being, or significant discomfort among workers or among the citizens of the community." The American Industrial Hygiene Association ("AIHA") defines an industrial hygienist as "scientists and engineers committed to protecting the health and safety of people in the workplace and the community."

The Department of Labor defines a "qualified" person as one who by possession of a recognized degree, certificate, or professional standing, or who by extensive knowledge, training, and experience, has successfully demonstrated the ability to solve or resolve problems relating to the subject matter, the work, or the project. While we recognize the obvious significance

that medical science is required for a competent pandemic response, we disagree with the assumption that medical specialists are the qualified people to recommend exposure-mitigation strategies.

History has shown this before but the public and media did not catch these past mistakes. An example of the inept training of control measures in the medical field occurred during the Ebola outbreak in 2014. A hospital in Dallas, Texas, took in Ebola patients and found itself completely unprepared. The medical professionals got on the Internet and unprofessionally used some Personal Protective Equipment ("PPE"). As a result, nurses were exposed and became infected. Moreover, it can be assumed that the nurses were not fit tested for respirator use and no training on their control plan was provided. Thankfully, the nurses survived but court proceedings revealed bungled measures taken.<sup>2</sup>

Even early in the current pandemic, we witnessed firsthand the lack of training in the medical field on PPE use. Petite nurses were wearing large disposable N95 respirators (clearly not fit tested). In some cases, they took the bottom strap off, while others had their disposable N95 respirator on upside down. In addition, doctors were wearing a surgical mask with a disposable N95 respirator on top of it. This is improper use because the face mask

<sup>&</sup>lt;sup>2</sup> <u>https://tinyurl.com/2uhpwrth</u>

was preventing the respirator from capturing a seal to the face. If healthcare professionals made these terrible errors putting on face coverings, one can only image that many members of the traveling public did so too because of having to comply with the Mask Mandate.



Dr. Wenliang Li preventing his N95 respirator from gaining a seal by wearing a surgical mask underneath

The inadequacies in the medical industry's comprehension of exposure mitigation are further illustrated in that around 90% of the OSHA citations that involve the pandemic are in the medical industry. The administration's citations consistently revolve around violations of the regulatory standards in PPE (29 CFR § 1910.132) and Respiratory Protection (29 CFR § 1910.134). It is such a profound issue that OSHA is in the process of creating regulatory standards for the medical industry as it relates to COVID-19.

Some disagree with our position that travelers and transit workers fall under the Code of Federal Regulations' requirements for masks. This is inaccurate for two reasons. First, the N95 is at the forefront of the mask debate and the N95 is a respirator, not a traditional mask. The "95" means the filter has 95% efficiency, which means it can only achieve that by being used correctly every single time. Further, it seals to the face, which qualifies it as a respirator. As such, N95 manufacturers require that the wearer should adhere to the Respiratory Protection Standard for safe use. CDC and TSA did not even mention OSHA's respirator regulations when they hurriedly issued their FTMM Order and Health Directives.

Second, government agencies are forcing people to wear a mask because of purported safety and health concerns. So, the logical starting point should be to use established science related to the safety and health professions to build from. Therefore, it is important for professionals in our industry to be engaged in this debate to ensure the bar for safety and health sciences is not lowered by the unqualified. Dr. Mark Gendreau is among many aviation health specialists who said when the pandemic began that masks "won't work against contracting a virus in flight" and "they don't stop someone from breathing in a virus droplet." The appellees didn't listen.

<sup>&</sup>lt;sup>3</sup> https://tinyurl.com/yay6hxx2

And sadly neither did Judge Byron. His opinion is full of extremely misguided statements buying CDC's contention that masks are effective. "In fact, the CDC correctly pointed out that the FTMM helps prevent the imposition of economic burdens by stymying the spread of COVID-19 and, consequently, avoiding future lockdowns and resulting losses." App. 461. There is no evidence to support this conclusion.

Given the government's own data, how are we to believe that masks have been effective in its goal of reducing COVID-19 transmission when TSA itself admits that 22,812 of its employees (35% of its workforce) 4 – all of whom were forced to wear masks for more than a year – have tested positive for COVID-19?

Government lawyers like to defend the FTMM by claiming doctors have worn N95 or surgical masks during surgeries or patient interactions as part of their daily routines for many decades. But they fail to explain that medical professionals wear masks to stop bodily fluid sprays and splashes from entering their orifices, not to prevent the transmission of respiratory droplets.

<sup>&</sup>lt;sup>4</sup> Because so many COVID-19 cases are mild, health authorities estimate only half of infections are confirmed by testing. This means it's quite likely an astounding **70%** of TSA's 65,000 employees have been infected with coro-

navirus. So how exactly do face coverings prevent the transmission of COVID-19?

The Food & Drug Administration ("FDA"), a unit of HHS, admits this:

"While a surgical mask may be effective in blocking splashes and large-particle droplets, a face mask, by design, it does not filter or block very small particles in the air that may be transmitted by coughs, sneezes, or certain medical procedures. Surgical masks also do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the mask and your face." 5

Here we have CDC and TSA requiring masks in no sector of the nation except transportation, without showing a single scientific study identifying this sector as being more vulnerable to coronavirus spread.

"[T]he government has the burden to establish that the challenged law satisfies strict scrutiny. ... [N]arrow tailoring requires the government to show that measures less restrictive of the [constitutionally protected] activity could not address its interest in reducing the spread of COVID. Where the government permits other activities to proceed with precautions, it must show that the [constitutionally protected] exercise at issue is more dangerous than those activities even when the same precautions are applied. Otherwise, precautions that suffice for other activities suffice for [constitutionally protected] exercise too." *Tandon v. Newsom*, 141 S.Ct. 1294 (2021).

It's important for the Court to understand that there has **never** been scientific evidence that supports universal mask use. This has been concocted by the Biden Administration to support the president's political objectives. App. 1,020-1,032. When agencies ignore enormous scientific evidence and

<sup>&</sup>lt;sup>5</sup> <u>https://tinyurl.com/pab7k8cy</u>

fail to even give the public the chance to comment on a proposed directive, the law demands it be set aside.

It's not just our judgment that masks are ineffective in reducing COVID-19 spread; it's the widespread view of tens of thousands of experts worldwide. And notably our judgment has been proven true in the past 2½ months with no reports of COVID-19 hotspots in America's transportation sector since Judge Mizelle vacated the FTMM in *HFDF*.

As Mr. Wall notes, air travel is already equipped to provide a safe experience (App. 1,091-1,115), the use of Personal Protective Equipment by untrained people creates more risk, and mask guidance continues to come from unqualified scientists talking outside their lane of expertise.

After initially supporting the FTMM, leaders across the airline and travel industries came to realize the Mask Mandate did nothing but cause numerous disruptions as angry customers fought for their right to breathe freely. Their views on the science evolved (App. 1,058-1,098) as they saw the Omicron variant sicken thousands of their employees despite everyone being masked. App. 1,033-1,057. But the government continues pushing masks today, 2½ years into the pandemic (which many consider to be over now as COVID-19 is a mild illness that will continue circulating until more effective

vaccines are developed), failing to admit the science was never there to support such a mandate and it did not reduce COVID-19 spread in the transportation sector, as we've seen with no evidence of new outbreaks since the *vacatur* occurred April 18, 2022, in *HFDF*.

Dr. Leana Wen, who had been one of the nation's most forceful and prominent mask advocates, conceded late last year that "Cloth masks are little more than facial decorations. There's no place for them in light of omicron." App 765. Many others who previously believed in mask efficacy, including a former FDA chief, have come to the same conclusion.

New studies, articles, and expert testimony come out each month adding to the large and growing body of scientific data illustrating that masks have not stopped the spread of COVID-19 but are harmful to human health. The Court need only read the labels on boxes of masks for sale that Mr. Wall offered as evidence below to see how truly worthless they are. App. 1,000.

Former presidential COVID-19 adviser Michael Osterholm admitted that most masks are ineffective: "We know today that many of the face cloth coverings that people wear are not very effective in reducing any of the virus movement in or out," said Osterholm, director of the University of Minnesota's Center for Infectious Disease Research & Policy. App. 744.

We're disturbed that the government presented no evidence below that

CDC and TSA are using the existing Do Not Board and Lookout systems to stop passengers who have tested positive for COVID-19 from embarking aircraft. App. 605-609. Targeting travelers who are a genuine threat to public health – those who are infected – can be done without infringing on the freedom to travel for everyone else.

"Not only is there no evidence that the applicants have contributed to the spread of COVID-19 but there are many other less restrictive rules that could be adopted to minimize the risk to public interests. Finally, it has not been shown that granting the applications will harm the public. As noted, the State has not claimed that attendance at the applicants' services has resulted in the spread of the disease. And the State has not shown that public health would be imperiled if less restrictive measures were imposed." *Roman Catholic Diocese of Brooklyn v. Cuomo*, No. 20A87 (U.S. Nov. 25, 2020).

# B. The COVID-19 mitigation strategy of supposed public-health officials and TSA has not been prioritized in accordance with the Hierarchy of Controls. Had notice been given and our industry had the opportunity to comment, we would have raised concerns.

CDC and TSA issued the challenged Mask Mandate without giving notice and considering public comments. Had the agency done so, industrial hygienists and workplace-safety experts such as ourselves would have objected and offered our knowledge. A tribunal must "hold unlawful and set aside agency action ... found to be ... without observance of procedure required by law." 5 USC § 706(2)(D). This Court should hold unlawful and set aside the

Mask Mandate because CDC and TSA violated the APA's notice-and-comment requirements. 5 USC § 553. *HFDF*.

TSA asserts that notice and comment are waived when it must respond to an urgent transportation security threat and issues what it calls a "Security Directive." But because the so-called "Security Directives" at issue here are actually Health Directives, this exception to the APA doesn't apply – and the district court had jurisdiction.

We have been in several conversations with doctors and school administrators on COVID-19 exposure-mitigation tactics and have been met with the strawman argument that nobody really knows which exposure-control measures are working and which ones work better than others.

As occupational safety and health professionals, we affirm that our profession consists of trained experts in evaluating an environment for risks and exposure with the ability to measure the determined exposures and devise a mitigation plan. We use a long-standing, proven scientific system called the Hierarchy of Controls (Figure 1-A) that was introduced by the National Safety Council ("NSC") in 1950 to layer our exposure-mitigation strategies. This system also enables us to prioritize the mitigating efforts to better educate our customers as to which strategies are going to work the best. The

record shows CDC and TSA did not engage in any Hierarchy of Controls analysis or explain why they had good cause not to. "Besides its brief reference to the pandemic, the Mandate makes no effort to explain its reasoning that there was an exceptional circumstance at the time it implemented the rule." *HFDF*.

A decision to vacate that "maintains the separation of powers and ensures that a major new policy undergoes notice and comment" is in the public interest. *Texas v. United States*, 787 F.3d 733, 768 (5th Cir. 2015).

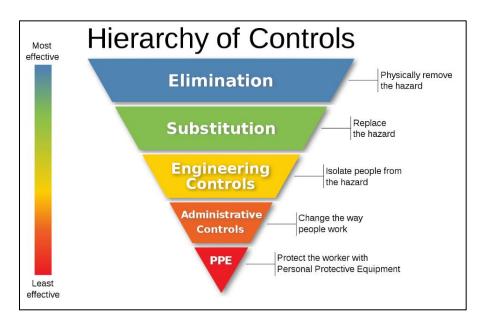


Figure 1-A: Hierarchy of Controls

The human interaction with a control, while it is engaged with the risk or contamination, is a primary difference between the class of controls on the high end of the hierarchy and those at the low end. In any compliance program, the most critical component of whether it will succeed or not is human

behavior. Human behavior as it relates to compliance with safety and health measures is such a juggernaut that we have entire education courses on Behavioral-Based Safety, which is why we always seek solutions that have a foundation in engineering controls.

If an agency order is based on scientific or other technical data, that data and the methodology used to obtain it should be included in the notice to allow meaningful comment. *Lloyd Noland Hosp. & Clinic v. Heckler*, 762 F.2d 1561 (11th Cir. 1985). But CDC provided no notice at all of the FTMM.

CDC (and TSA) should have received public comments that engineering controls isolate people from the hazard while the design and function of an administrative control is maintained by specific consistent proper execution of the procedural control. Any deviation from that then becomes contamination behavior and is deteriorating or downgrading its effectiveness.

At the bottom of the effectiveness chain is the Personal Protective Equipment category of controls. With PPE there is complete reliance on human use and interaction to maintain its designed scope of protection. In our careers, we have experienced personnel failing to use their PPE due to a lack of comfort, poor training, or myths they carried with them from a previous employer.

Masks do not seal to the face and cannot offer protection. They can reduce exposure to blood splatter for medical professionals at best, but they are not deemed a true protective piece. Therefore, a mask can in no way scientifically be considered a primary solution to an exposure issue as many doctors, government agencies, and politicians have claimed. A competent response would be focused on dilution, filtration, and destruction of the pathogen.

Airplanes provide state-of-the-art ventilation systems that provide fresh air to the cabin typically every few minutes and push the air in a laminar motion to reduce cross contamination. App. 1,091-1,115. This is important to understand because the American Industrial Hygiene Association conducted a study in 2020 (Figure 1-B) that found engineering controls (such as a ventilation system) provide the optimal solution for human protection. It produced a graph demonstrating a 95-99.9% risk reduction for exposure by simply having 6-12 air changes per hour.

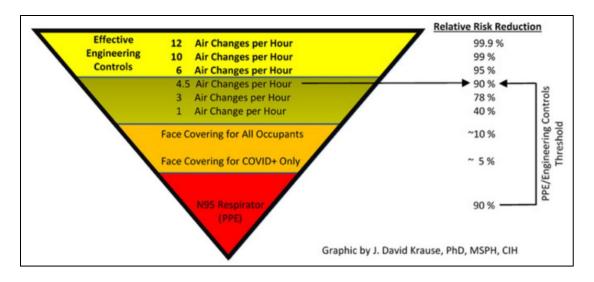


Figure 1-B: AIHA Reducing the Risk of COVID-19 Using Engineering Controls Graphic

CDC and TSA conducted no studies regarding mask efficacy. The N95's optimal performance is based on the user's adherence to the Respiratory Protection Standard as well as the manufacturer's requirements for discarding the N95 after 2-4 hours of use. But many flights, bus trips, and train rides are much longer than four hours.

"[A]n utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure." Sugar Cane Growers Coop. of Fla. v. Veneman, 289 F.3d 89, 96 (D.C. Cir. 2002). The APA provides that people and organizations being regulated must be afforded the opportunity to participate and provide information and suggest alternatives so the agency is educated about the impact of the proposed rule and can make an informed decision. NLRB v. Wyman-Gordon,

394 U.S. 759 (1969). By giving affected parties an opportunity to comment and develop evidence in the record to support their view and objections, notice improves the quality of judicial review. *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506 (D.C. Cir. 1983).

The "Absence of Apparent Transmission of SARS-CoV-2 from 2 Stylists after Exposure at a Hair Salon with a Universal Face Covering Policy in Springfield, Missouri, May 2020" study has been a foundational piece used by public-health officials to make the false claim that face masks are an added value when deployed in a community. We investigated this study, which CDC cites to justify the FTMM. Here is an overview of our findings:

- The study insinuates that 139 clients were not infected but the researchers in fact cannot make that claim. The sample size was 139, but the researchers were only able to collect factual evidence on 67 clients. Of the others, 37 clients refused to be tested and were self-reporting during a period when people had an incentive not to report themselves being sick due to quarantine and isolation policies. Another 35 clients were not contacted and did not receive a test, nor did they participate in self-reporting. Only 48% of the sample size was factually evaluated, while 52% had no data.
- The study admitted limitations in administrative controls of limiting

services, and stylists and clients not facing each other during services. By not facing one another, clients and hair stylists made their experience significantly safer by making the flow of potential virus transmission more difficult. This was a significantly missed opportunity by the research team to demonstrate multiple measures people can take to prevent transmission. This might be evidence of a bias of the research team in attempting to demonstrate the need for mask use. Regardless, by not properly evaluating all forms of controls in accordance with the well-established hierarchy demonstrates a significant lack of knowledge of this subject matter. Those involved in this defective study often cited by CDC are unable to properly evaluate such event.

The study did not admit limitations by not evaluating sanitization efforts. The CDC falsely claims masks are a sanitation measure. Not true. *HFDF*. Sanitation of surfaces is a combination of administrative and engineering controls. These are administrative controls because of the consistent processes for surface cleaning efforts. They are also engineering controls because the cleaning agents utilized end the flow of contamination. These are higher forms of controls in mitigat-

ing the risk of exposure. By not properly evaluating all forms of controls in accordance with the well-established hierarchy demonstrates a significant lack of knowledge of this subject matter.

The study did not admit the limitation of not evaluating the Heating, Ventilation, & Air Conditioning ("HVAC") system. By having an active HVAC system, airborne aerosols that carry infectious disease will be mitigated from the occupied space and prevent others from being exposed. Other than eliminating the hazard, the HVAC system is the first line of defense and the most critical exposure prevention method in a building. A focused emphasis should have been placed on evaluating this critical defense mechanism.

This study is not evidence-based science that should drive a public-health policy such as creating a Federal Transportation Mask Mandate. But despite its numerous flaws, it is still used by public-health officials around the world to push universal masking.

# C. CDC and TSA continue to mislead the public on masks and droplets.

On Feb. 15, 2021, 13 scientists wrote a lengthy memo regarding the federal government's misleading language in these areas and requested that it be

corrected. They wrote: "To address and limit transmission via inhalation exposure and prevent COVID infections and deaths, we urge the Biden administration to take the following immediate actions:

- Update and strengthen CDC guidelines to fully address transmission via inhalation exposure to small inhalable particles from infectious sources at close, mid, and longer range. Updated guidelines should be informed by a risk assessment model that focuses on source and pathway (ventilation) controls first.
- Issue an OSHA emergency standard on COVID-19 that recognizes the importance of aerosol inhalation, includes requirements to assess risks of exposure, and requires implementation of control measures following a hierarchy of controls."

Edwards *et al.* demonstrated<sup>6</sup> that that the vast majority of COVID particles emitted during illness are aerosols, not droplets. Figure 2-A.

<sup>6</sup> https://www.pnas.org/content/118/8/e2021830118

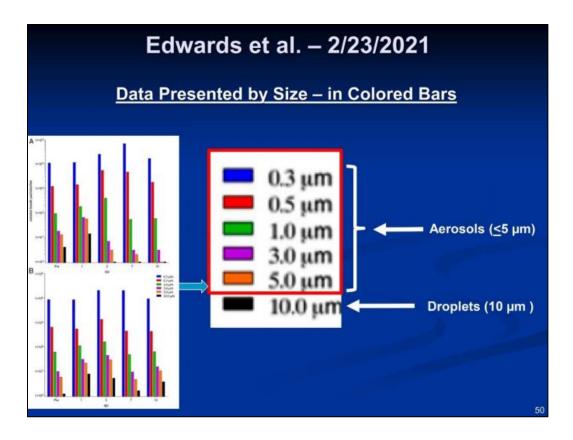


Figure 2-A: Edwards *et al.*, 2021 – Particle Size Emissions by Size & Time

While a mask might contain some droplets, it only does so for a period. As the mask is exposed to heat and moisture, it suffers from degradation within a few hours. Most importantly – a factor CDC and TSA did not consider – is that masks are not designed to stop aerosols.

Masks can't ever obtain a perfect fit to the face and efficiencies of masks are extremely low when worn in real-world scenarios (such as day-long usage by transportation workers or long-haul flyers). When the mask has more than a 3% gap, it effectively offers zero protection. Figure 2-B.

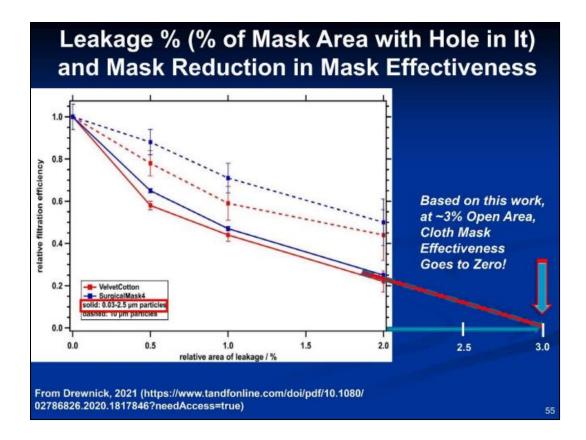


Figure 2-B: Loss of Mask Effectiveness in the Real World

The foundational debate around masks is their capability to protect the wearer and offer source control. Therefore, the critical issue to understand is how well does the mask seal to the face to offer such solutions? What's clear is small gap areas effectively render these devices ineffective.

The American Society for Testing & Materials ("ASTM") Standard Specification for Barrier Face Coverings F3502-21 states:

• "There are currently no established methods for measuring outward leakage from a barrier face covering, medical mask, or respirator.

Nothing in this standard addressed or implied a quantitative assessment of outward leakage and no claims can be made about the degree to which a barrier face covering reduces emission of human-generated particles." Note 2.

There are currently no specific accepted techniques that are available to measure outward leakage from a barrier face covering or other products. Thus, no claims may be made with respect to the degree of source control offered by the barrier face covering based on the leakage assessment." Note 5.

# D. Universal mask policies such as the Federal Transportation Mask Mandate are adding risk.

Every mask experiment on CDC's website only shows how water droplets land in a mask. Then the experiments stop. There is no exploration of where the infectious material goes next. If a person has a mask on their face for several hours a day, that is significant time and opportunity for contamination build-up.

"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." *HFDF*, quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Every mask case study on CDC's website is predicated on the notion that masks are an engineering control – supposing that when placed on a face, they are then working at 100% efficiency, as though one is turning a light switch on. An important distinction between engineering controls and Personal Protective Equipment is that when a contamination is interacting with an engineering control, it is doing its work automatically and the human is rarely influencing the engineering control. With PPE, the human and the control are always in contact with the risk, thus the human can always influence the control, and always be exposed to the risk.

When PPE is used in the professional environment it was designed for, it is accompanied by strict behavioral processes for the purpose of reducing contamination. That's what it takes for a mask to succeed in its roll. This critical mechanism of mask functionality has been entirely removed in the public use of masks.

Why did the doctors who are prescribing public deployment of masks think masks would somehow magically work without compensating for contamination behavior? If we are going to be scientifically consistent, we must be able to reproduce this in all settings.

The message from doctors influencing public policy is clearly that behavior is not important to the protective function of a mask. That concept conflicts with our training and how we strive to execute strategies in the safety and industrial hygiene professions.

As mentioned before, a mask's ability to function properly is presumptive upon being worn properly, fit tightly, not touched, not adjusted, and cleaned. But TSA's Health Directives do not require any of this, rendering forced masking worthless – and therefore arbitrary and capricious. If a mask is not worn, fitted, cleaned, or touched properly, it is not working. If such concerns did not exist, why did the World Health Organization ("WHO") produce this list of "Don'ts"? Figure 3-A. And why did CDC and TSA ignore this list?



Figure 3-A: WHO Mask Safety Sheet - Don'ts

If there are no correlating safe behaviors with the deployment of masking (just as with any PPE policy), the mask cannot work and causes harm. App. 797, 808-852, & 958. Safety data for decades shows that at minimum 90% of the population will participate in the "Don'ts" list and nullify any possible benefit of mask use.

As safety and industrial hygiene professionals, we seek solutions that offer 90% or more protection for those we are tasked to protect. This simple data would quash the use of a mask in a typical professional setting, yet CDC and TSA continue to push universal masking as some kind of "silver bullet."

A Brownstone paper by Paul Alexander<sup>7</sup> published Dec. 21, 2021, shows the harms of masks, citing more than 150 studies. One of these authors testified in the Western District of Michigan court Sept. 28, 2021, that the small number of studies cited by CDC purportedly showing masks are effective did not support statements made by the agency, and most suffered from a lack of a control group (group similar to the mask study group not wearing masks) or cofounding factors (such as changes in HVAC systems, distancing, quarantining, and masks) wherein one can't determine the specific contribution of masking.

Now society has 2½ years of well-established data that significant harms of universal masking adds risk such as reduced learning and development as well as physical, emotional, and social harms (*see* Figures 3-B to 3-I). Yet Judge Byron's decision didn't mention a single harm of masking, when experts have identified more than 70. There is so scientific support whatsoever for Judge Byron's conclusion that:

"In other words, masks have two functions: (1) they protect the wearer from breathing in harmful air particles ... and (2) they prevent the wearer from breathing out harmful air particles ... In this way, masks (to varying degrees) promote the public health by checking the transmission of airborne viruses, such as SARS-CoV-2, and thus fit within the definitions of 'sanitation.'" App. 470.

<sup>7</sup> https://tinyurl.com/mw2t6z6z

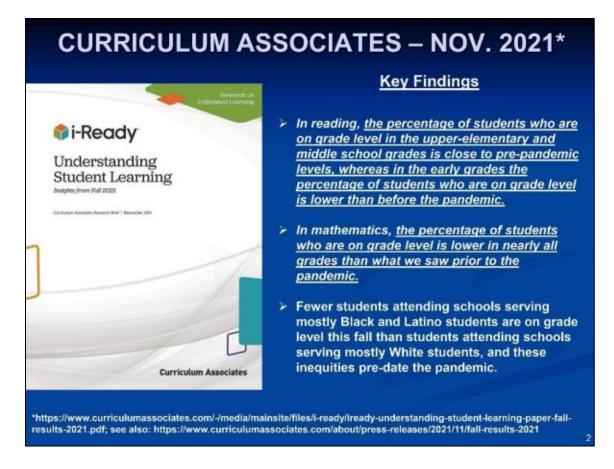


Figure 3-B: Curriculum Associates, Nov. 2021 - Title Page

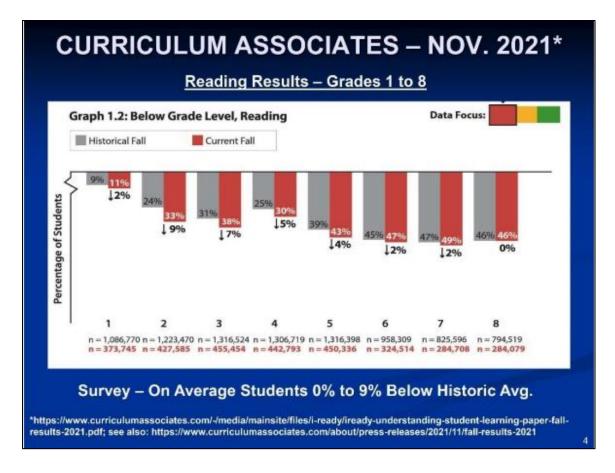


Figure 3-C: Curriculum Associates – Reading Deficits in 2021 vs. Prior Years

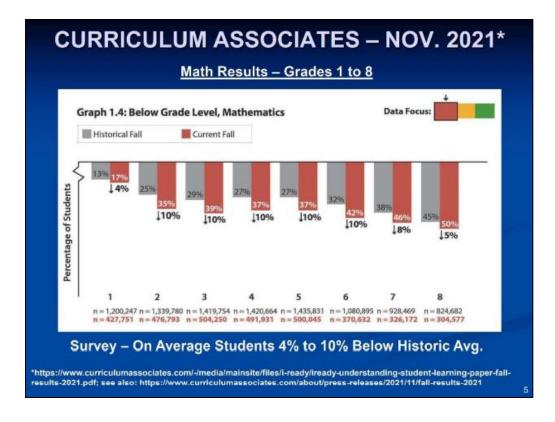


Figure 3-D: Curriculum Associates – Math Deficits in 2021 vs. Prior Years

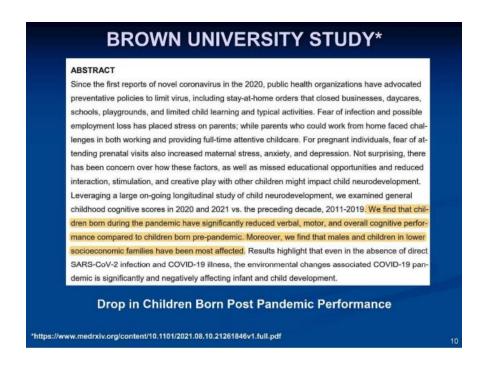


Figure 3-E: Brown University – Cognitive Deficits

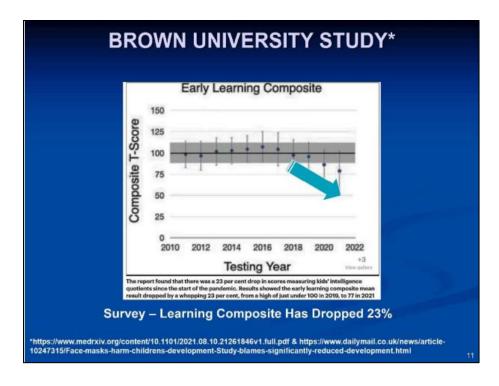


Figure 3-F: Brown University Study – Learning Loss of 23% for Children Born Since Pandemic

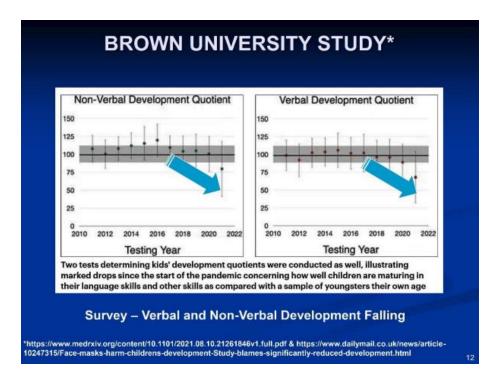


Figure 3-G: Brown University Study – Non-Verbal & Verbal Development Losses

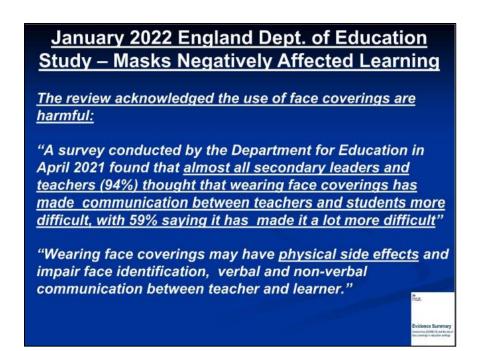


Figure 3-H: England Department of Education – Loss of Communication and Physical Effects



Figure 3-I: Kisielinski *et al.*, Areas of Quantitated Adverse Effects on Children & Adults

There has been a bombardment by policymakers such as those at CDC and TSA for the traveling public to "follow the science." However, the curious thing about that is even CDC's science does not actually say what we have been told it says. There is no research that offers a comparison to the real-life daily activities that both adults and children are engaged in such as flying or using public transit.

Again Judge Byron bought the propaganda CDC sold the American public, failing to critically analyze false claims such as "CDC relied on an economic analysis of American data to support its prediction that the masking requirement could 'prevent the need for lockdowns and reduce associated losses of up to \$1 trillion or about 5% of the gross domestic product." App. 472-473. The government hasn't ever provided any evidence to support this hypothesis.

These are keystone observations to make when critically examining CDC's health studies, which TSA relied on in issuing the Health Directives requiring mask use:

• The participants are typically in perfect health, whereas the public at large is typically unhealthy over a broad spectrum; and

In each of CDC's mask-risk experiments, measurable clinical numbers always move or fluctuate. However, none of the studies bother to explore the continued rate of measurables beyond the chosen time limits of the study. This is a critically important omission as people in society are engaged in life activities for hours at a time, day after day, for weeks on end.

The following studies demonstrated some of these before-mentioned issues and negate the one-size-fits-all approach recommended by CDC and adopted by TSA in the Health Directives:

Beyond the larger sample size, advantages of our study include testing cloth facemasks that are actually being used by people in day-to-day life during the current pandemic, not excluding subjects with common co-morbidities like asthma [15], and measuring ventilation and not just oxygenation [12]. Our study has limitations that could be addressed in future work. First, our sample size is modest, though notably larger than many prior studies assessing gas exchange while wearing masks. Second, the duration of each study phase was 10 minutes, which was chosen to provide adequate time to observe physiologic changes but not require people to volunteer more than 90 minutes of their time. Though the substantial increase in heart rate with walking supports that the duration and intensity were sufficient, future studies may consider a longer duration and/or higher intensity of physical activity. Similarly, the rigor of the activity could be better controlled by using a treadmill. Third, the order of testing could be randomized to make sure that vitals obtained during the last phases (i.e. wearing the surgical mask) were not influenced by the subjects being tired from the prior phases. However, each subject had a 10 minute period of rest (sitting) before each walking phase during which their heart rate returned to baseline, so it is unlikely that the slight increase in heart rate observed with surgical masks was due to subject fatigue. Fourth, we used transcutaneous measurements of CO2 tension rather than arterial blood sampling in order to minimize pain for the subjects, which may be a less accurate method of measurement. However, the SenTec monitor is validated as a surrogate for arterial blood sampling [16] and the measurements taken in triplicate in our study subjects were very consistent (almost always within 1-2 mmHg of each other).

### Conclusion

In conclusion, facemasks did not impair oxygenation or ventilation among 50 adults at rest or during physical activity. No episodes of hypoxemia or hypercarbia occurred with either cloth or surgical masks, both at rest and while walking briskly. The risk of pathologic gas exchange impairment with cloth masks and surgical masks is near-zero in the general adult population.

Figure 3-J: "The Effects of Wearing Facemasks on Oxygenation & Ventilation at Rest & During Physical Activity" Authors: Shein SL, Whitticar S, Mascho KK, Pace E, Speicher R, et al.

#### **Pediatrics**

There are important differences in respiratory physiology in infants and young children as compared with adults (*see* Reference <u>55</u> for review). Infants and young children have underdeveloped accessory muscles of respiration and thus rely more on the diaphragm for most of the Wb. An increase in respiratory muscle work is largely accomplished by an increase in the respiratory rate, and the diaphragm can become fatigued more quickly than in adults. Children under the age of 6 years have proportionally more extrathoracic anatomical dead space owing to the larger ratio of head size to body size (<u>56</u>). These anatomical differences combined with an inherently higher basal metabolic rate place infants and young children at greater risk of respiratory failure than adults from various significant health threats. These differences decrease as children age, and other than in children younger than 2 years and those with significant respiratory or neurological conditions, there are no significant differences in respiratory physiology for older children and adolescents that are expected to substantially alter the effects of masks as described above, but additional data are needed to clarify this issue.

# Figure 3-K: "Face Masks & the Cardiorespiratory Response to Physical Activity in Health & Disease" Authors: Hopkins SR, Dominelli PB, Davis CK, et al.

On the surface, the addition of a small increase in the Wb and reinspiration of low concentrations of CO<sub>2</sub> with any type of face mask would appear to pose more problems for individuals with underlying cardiopulmonary disease. Other drawbacks for such individuals with face-mask wearing may include anxiety and greater dyspnea (60, 61), reduced fine-motor performance (62), possible cognitive effects as a result of slight CO<sub>2</sub> retention and mildly increased hypoxemia, and increased Wb (63).

Increased temperature around the face ( $\underline{64}$ ) and a 0.5°C body-temperature elevation with loss of normal respiratory heat dissipation ( $\underline{65}$ ) may also have effects. Patients with mild-to-moderate pulmonary disease will likely tolerate cloth/surgical masks with an acceptable extent of discomfort, but with advanced disease, this may become more burdensome because of the effects of mask wearing described above ( $\underline{66}$ ,  $\underline{67}$ ). More efficient filtering masks will be difficult for almost anyone with severe nonasthmatic lung disease and may warrant closer monitoring of symptoms and arterial saturation with oximetry. Patients with altered ventilatory control and blunted drives to breathe, such as those with obesity hypoventilation syndrome, may also warrant monitoring for greater hypoxemia and increased  $CO_2$  retention, resulting from potential small increases in dead space with a face mask.

Figure 3-L: Id.

### Limitations and future research

It is important to note the study limitations. Our sample reflects young, apparently healthy, physically active adults, and thus results may not be applicable to other populations (eg. children, older adults, sedentary population, individuals with medical conditions). Next, despite following a thorough process for pretest mask fit, leakage may have occurred during the CPET, especially at higher workloads/stages when ventilation increased. Additionally, while we standardised the cloth face mask for the purposes of the study, there is significant variability in masks used by the public (eg. size, shape, material, design), each of which may impact the effect of masks on exercise responses. Further, resting measurements of dyspnoea would provide insight into the effect of wearing a cloth face mask at rest and measurement of lactate would provide insight into the explanation of reduced VO<sub>2</sub> to account for differences associated with effort versus physiological limitations. Finally, participants did not undergo a 'preparatory' exercise test, nor were the study team blinded to masked or unmasked conditions (eg., use of a sham). Future research should examine the effect of those specific mask configurations on exercise performance and related physiological variables and whether 'acclimatisation'—or even improved exercise performance<sup>29</sup>—to wearing masks during exercise occurs, as well as quantitative resting rates of dyspnoea. Further, increased RPE and dyspnoea across all stages during the masked condition warrant future investigation of implications for individuals with history of conditions such as chronic obstructive lung disease, chronic heart failure<sup>30</sup> and asthma. Future research should examine cognitive capacity to tasks while wearing a mask during exercise, as well as the relationship between VO<sub>2</sub> data and CPET stages.

### Conclusion

Our data suggest that wearing a cloth face covering negatively impacts exercise performance in healthy adults during a maximal treadmill test. As both physiological and perceptual factors were negatively impacted, coaches, trainers and athletes should be aware of the effect of cloth face coverings as the population continues to exercise safely during the global pandemic.

Figure 3-N "Effects of Wearing a Cloth Face Mask on Performance, Physiological & Perceptual Responses During a Graded Treadmill Running Exercise Test" Authors: Driver S, Reynolds M, Brown K, et al.

E. Public-health agencies and those without any such expertise such as TSA continue to use unqualified scientists to provide masking guidance and continue to embarrass themselves by using scientific research that is not evidence-based. The Mask Mandate violates OSHA regulations for mask use.

In March 2020, Dr. Anthony Fauci went before the nation and professed that universal masking should not occur. Then in April 2020, he and other public-health officials reversed course, suddenly claiming there was scientific evidence to support their new guidance. Yet this went against decades of

tested science that has been utilized to protect U.S. workers. The "science" used to guide these new directives was flawed as mentioned *supra*.

Yet unqualified scientists continue to pose to the American public as "experts" or "qualified" individuals when in fact they are not. One of the most profound experiences in this buffoonery came on Sept. 16, 2020, when then-CDC Director Robert Redfield went before the Senate Appropriations Committee and testified, "These facemasks are the important, powerful publichealth tool we have. ... I might even go so far as to say that this facemask is more guaranteed to protect me against COVID that when I take a COVID vaccine."



Figure 4-A: Dr. Robert Redfield testifying about masks before the Senate Appropriations Committee

To illustrate the concerns the Court should have about government "scientists" providing these ridiculous and false statements about masking, we investigated the research they used to come to these conclusions. The study Dr. Redfield relied on to form his opinion was called "Quantitative Method for Comparative Assessment of Particle Removal Efficiency of Fabric Masks as Alternatives to Standard Surgical Masks for PPE." Here are some of our findings:

- The Portacounts (equipment used for the study) were not calibrated before the study.
- The research team changed the original preprint title of this study. A significant difference in the original preprint and the preprint utilized by the research team (which became the official study name) was that the initial admission of the Portacounts being out of calibration was removed.
- To determine a fit, the mask is required to be tested against real-world scenarios of body movement. 29 CFR § 1910.134 App. A § 14. This study decided that because of social-distancing practices, this was not necessary, and they had their single test subject not move her head, not breathe out of her mouth, and only breathe from her nose. It falsely

<sup>8</sup> https://www.sciencedirect.com/science/article/pii/S2590238520303647

assumed that people in public, transportation workers, and those aboard transit conveyances would not move their heads and talk while wearing a mask.

- The masks had to be manipulated and a nylon layer was used to obtain a performance suitable to justify mask use. But "All personal protective equipment shall be of safe design and construction for the work to be performed." 29 CFR § 1910.132.
- Researchers made no mention of the need for people to have a medical evaluation before using respiratory devices that can achieve a high level of filter efficiency. But "Using a respirator may place a physiological burden on employees that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee." 29 CFR § 1910.134(e).

It was astonishing when we made these discoveries. Professionally speaking, Dr. Redfield embarrassed himself that day and damaged his credibility. CDC used this fraudulent study to proclaim to the country that masks offer protection, when in fact, scientifically they do not.

Congress assigned statutory authority to OSHA, in the Department of Labor, to regulate workplace safety. All transportation hubs and conveyances covered by the Mask Mandate are workplaces. Therefore, this requires CDC

and TSA to adhere to the Code of Federal Regulations enforced by OSHA such as 29 CFR §§ 1910.132 & 1910.134.

"The Mandate did not differentiate between kinds of masks based on their efficacy at blocking transmission." *HFDF*.

In July 2021, *amicus curiae* Tyson Gabriel published a video documentary showing many of the deficiencies in CDC's mask experiments. We respectfully ask the Court to examine the evidence presented therein. We demonstrate where numerous studies manipulated results through adjusting mechanisms or ignoring their own data. In addition, the presentation helps clarify how the mask studies are unfinished low-level, starter studies, not the robust data that should be used to influence public policy.

On Jan. 28, 2022, CDC published new mask guidance called "Types of Masks and Respirators." This was amazingly incoherent to established safety and health experts. In fact, this guidance significantly lowered the bar. An example can be found on Page 6. It insinuates that N95 respirators are safe for children. Figure 4-B. But in fact, most manufacturers such as 3M and Moldex clearly state that the N95s are not designed kids. Figure 4-C.

<sup>9</sup> https://www.tyscienceguy.com/mask-documentary-series.html

<sup>10</sup> https://tinyurl.com/yck9syfd

### Considerations for Children

### Masks

Anyone ages 2 years or older who is not vaccinated or not up to date on vaccines should wear masks in indoor public spaces. This recommendation also applies to people who are up to date on their vaccines when they are in an area of substantial or high transmission. CDC also currently recommends universal indoor masking for all teachers, staff, students, and visitors to K-12 schools, regardless of their vaccination status or the area's transmission rates. The benefits of mask-wearing are well-established.

### Respirators

Parents and caregivers may have questions about NIOSH-approved respirators (such as N95s) for children. Although respirators may be available in smaller sizes, they are typically designed to be used by adults in workplaces, and therefore have not been tested for broad use in children.

### **Selecting Masks**

- · Masks and respirators should not be worn by children younger than 2 years.
- Choose a well-fitting and comfortable mask or respirator that your child can wear properly. A poorly fitting or uncomfortable mask or respirator might be worn incorrectly or removed often, and that would reduce its intended benefits.
  - Choose a size that fits over the child's nose and under the chin but does not impair vision.
- Follow the user instructions for the mask or respirator. These instructions may show how to make sure the product fits properly.
- Some types of masks and respirators may feel different if your child is used to wearing a regular cloth or disposable procedure masks.

Figure 4-B: Misleading CDC Language Regarding Children Wearing Masks & Respirators

### Use Instructions

- 1) Failure to follow all instructions and limitations on the use of this respirator and/or failure to wear this respirator during all times of exposure can reduce respirator effectiveness and may result in sickness or death.
- 2) In the U.S., before occupational use of this respirator, a written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134, such as training, fit testing, medical evaluation, and applicable OSHA substance specific standards. In Canada, CSA standard Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. Follow all applicable local regulations.
- 3) The particles which can be dangerous to your health include those so small that you cannot see them.
- 4) Leave the contaminated area immediately and contact supervisor if dizziness, irritation, or other distress occurs.
- Store the respirator away from contaminated areas when not in use.
- 6) Inspect respirator before each use to ensure that it is in good operating condition. Examine all the respirator parts for signs of damage including the two headbands, attachment points, nose foam, and noseclip. The respirator should be disposed of immediately upon observation of damaged or missing parts. Filtering facepieces are to be inspected prior to each use to assure there are no holes in the breathing zone other than the punctures around staples and no damage has occurred. Enlarged holes resulting from ripped or torn filter material around staple punctures are considered damage. Immediately replace respirator if damaged. Staple perforations do not affect NIOSH approval (For 8110S only).
- Conduct a user seal check before each use as specified in the Fitting Instructions section. If you cannot achieve a proper seal, do not use the respirator.
- Dispose of used product in accordance with applicable regulations.

### **Use Limitations**

- This respirator does not supply oxygen. Do not use in atmospheres containing less than 19.5% oxygen.
- 2) Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown or when concentrations exceed 10 times the permissible exposure limit (PEL) or according to specific OSHA standards or applicable government regulations, whichever is lower.
- Do not alter, wash, abuse or misuse this respirator.
- Do not use with beards or other facial hair or other conditions that prevent a good seal between the face and the sealing surface of the respirator.
- Respirators can help protect your lungs against certain airborne contaminants. They will not prevent entry through other
  routes such as the skin, which would require additional personal protective equipment (PPE).
- 6) This respirator is designed for occupational/professional use by adults who are properly trained in its use and limitations.
  This respirator is not designed to be used by children.
- 7) Individuals with a compromised respiratory system, such as asthma or emphysema, should consult a physician and must complete a medical evaluation prior to use.

### Figure 4-C: 3M Instructions for N95 Respirators – Not Designed for Children

We wrote our Feb. 22, 2022, letter to CDC Director Walensky to educate and assist her team in rescinding this publication and implementing strategies that are low risk and yield positive results. App. 959-985. In its response, CDC dodged the question of why the agency would recommend N95s for children when the manufacturers warn against it. CDC's position continues to be that masks work if they are used "properly" (i.e. glued to the face with no

gaps), which is never the case in the real world, especially with an untrained public. CDC and other agencies continue to cite "research" such as the fraudulent Bangladesh mask study (Ex. 1 and App. 892-900) and the erroneous "SARS-CoV-2 Incidence in K-12 School Districts with Mask-Required Versus Mask-Optional Policies — Arkansas, August-October 2021" study as continued validation for their "masks are great" policies.

Our same letter was sent to Mr. Zients at the White House. It appears he might have taken our guidance and pushed for engineering controls as the main solution. On March 23 (31 days after our letter was received), the White House posted the "Let's Clear the Air on COVID" brief<sup>11</sup> that communicates engineering control technologies as the best solution to mitigate exposure.

Yet CDC continues clinging to its false narrative that masks are effective and do not harm human health: "CDC recommends that everyone aged 2 and older – including passengers and workers – properly wear a well-fitting mask or respirator over the nose and mouth in indoor areas of public transportation (such as airplanes, trains, etc.) and transportation hubs (such as airports, stations, etc.)." CDC Statement of May 3, 2022; Ex. 2.

<sup>11</sup> https://tinyurl.com/2p8rha6x

### VIII. CONCLUSION

It is astonishing to those of us who carry expertise in the safety and industrial hygiene fields that this universal masking nonsense has gone on for more than two years. Much of that has to do with courts not having the courage and integrity to listen and act upon information that is not carried in the media and in mainstream public-health circles. We're glad to see that is finally starting to change with Judge Mizelle's outstanding opinion in *HFDF* in April 2022. We hope this brief will help the Court understand how CDC's and TSA's Mask Mandate are arbitrary and capricious, not to mention all the other legal problems raised by Mr. Wall such as the agencies not having statutory authority to require face coverings, lack of notice and comment, violation of federal laws, and constitutional problems.

Because "our system does not permit agencies to act unlawfully even in pursuit of desirable ends," the Court must declare unlawful and vacate CDC's FTMM Order, TSA's three Health Directives, and TSA's Emergency Amendment. *Ala. Ass'n of Realtors v. HHS*, 141 S.Ct. 2485, 2490 (2021). We also ask the Court to award Mr. Wall his demanded relief of permanently enjoining CDC, HHS, TSA, and DHS from ever issuing any other orders requiring that transportation passengers and workers don face masks unless specific

authority is enacted into law by Congress (although even then the constitutional problems would remain).

"[W]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated – not that their application to the individual petitioners is proscribed." Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1409 (D.C. Cir. 1998). When "a provision is declared invalid," that provision "cannot be lawfully enforced against others" – not just against the one traveler before the Court in this case. Barr v. Am. Ass'n of Pol. Consultants, 140 S.Ct. 2335, 2351 (2020).

Respectfully submitted this 5th day of July 2022.

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### IX. CERTIFICATE OF COMPLIANCE

We certify that this brief complies with FRAP 29(a)(5) & 32(a)(5)(A) because it has been prepared in 14-point Georgia, a proportionally spaced font, and this document complies with the 6,500-word limit because the Argument section contains 6,380 words as measured by Microsoft Word.

### X. CERTIFICATE OF SERVICE

I certify that on July 5, 2022, I e-mailed this brief to these Court clerks for uploading into the 11th Circuit's Case Management/Electronic Case Filing system:

Eleanor Dixon Eleanor\_Dixon@ca11.uscourts.gov

Tony Richardson@ca11.uscourts.gov

I also certify that I am mailing four paper copies to the Court as required.

I also certify that I e-mailed this brief July 5 to the parties:

Lucas Wall Appellant Lucas.Wall@yahoo.com

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Alisa Klein Counsel for Appellees CDC and HHS Alisa.Klein@usdoj.gov

Tyson D. Gabriel

Lead Amicus Curiae

stevekirsch.substack.com

## We've asked Science to retract the Bangladesh mask study

Steve Kirsch

6-8 minutes

May 2, 2022



### People think masks work, even though they don't

Even after the Federal transportation mask mandate was rescinded, judging by the behavior I observed in multiple airports, it appears that somewhere around half the public still thinks that masks work.

### The mask study in Finland showed if there is an effect, it's negative

The best science shows that, if anything, the masks are more likely to be harmful than helpful; see this excellent video by UCSF Professor Vinay Prasad on the mask study done in Finland.

## The Bangladesh study was widely hailed by experts as the definitive study that "proved" masks work

One of the key reasons that people think masks work is the <u>Bangladesh study</u> that was done by Stanford and Yale and was relied upon by both the <u>CDC</u> and <u>IDSA</u>. In fact, it's the only randomized study that we are aware of that claims masks work.

The other randomized trial, the one done in Denmark, was deliberately re-written to suggest masks

work because the medical journals wouldn't publish a negative study since it was counter-narrative. The BMJ courageously documented the scientific misconduct by the medical journals.

### What if the Bangladesh study proved nothing?

So if we can show that the Bangladesh mask study actually shows that masks DO NOT WORK and we can get the paper retracted, then we've made an incredible difference. We can:

- 1. Force the medical community to admit that it has some very serious systemic issues that need to be addressed regarding scientific integrity.
- 2. Destroy the credibility of the CDC to give even the simplest medical advice. Drugs are very complex. Masks are simple. But the CDC can't even get something simple like masks right. It follows that it doesn't have a prayer to get something more complex like vaccines right.
- 3. Destroy the credibility of all the medical experts who relied on the study (pretty much everyone in the medical community). Not a single mainstream academic spoke out that the study showed nothing. They all screwed up.
- 4. Show that the medical community is utterly incapable of policing itself. This study wasn't rocket science. It's basic statistics. Why is a British mathematician easily destroying this study while nobody in the US medical community speaks out at all. And even when the "misinformation spreaders" were saying "masks don't work" the medical community still ignored looking at the issue. What does it take to get their attention?
- 5. Destroy the credibility of the press for not doing their homework in talking to us (we've said from the beginning that masks can't work)
- 6. Show the world that they should stop using masks, especially on kids and in schools.
- 7. Reduce pollution and trash from all the unnecessary masks that are being made
- 8. Show the entire world they were manipulated into adopting an intervention which at best did nothing and more than likely helped increase infection. Once they realize they were fooled on masks, it opens up the possibility that they might also have been fooled by the COVID vaccines. And once they realize they were misled by the COVID vaccines, they become open to the possibility that they were misled on other vaccines as well. They then start to realize that there was a reason for the liability protection request of the drug companies: it is because they knew their products were unsafe.
- 9. Demonstrate that, if we are given an opportunity to challenge the authorities, the "misinformation spreaders" always win.
- 10. Put an end to self-appointed "mask police" (these are people who come up to you and demand to know "where is your mask?")

### The Bangladesh mask study actually didn't prove anything

We've shown that there is nothing shown by the Bangladesh study previously. We challenged the first author to defend his study and he failed. Badly.

But the nail in the coffin is this new analysis by UK Professor Norman Fenton.

Yale Professor of Economics Jason Abaluck, the first author of the Bangladesh study, reviewed Fenton's analysis. Abaluck self-determined that Fenton was incompetent so he could justify no longer talking to him.

Abaluck also noted that the reason they used cluster randomization in the trial is because they weren't testing whether masks worked on individuals, but whether community masking as a health policy would make a difference: would people comply and would it subsequently reduce the rate of infection. This subtle distinction is irrelevant. At the end of the day, Abaluck's cluster-randomization study showed that there wasn't any difference in infection rate between the groups.

In fact, Fenton showed that Abaluck's study was roughly equivalent to this experiment:

To give a feel for just how 'insignificant' the 52% figure is - if you wanted to use it to conclude that the seropositivity rate is lower in people receiving the mask intervention than those who do not - then this would be much like flipping 201 coins, observing 101 'heads' and 100 'tails' and concluding that all coins are more likely to land on heads than tails.

### Fenton asked Science to retract or correct the paper

On May 2, 2022, Fenton wrote to the journal that published the paper (Science) and requested that the Bangladesh mask study be either corrected or retracted since it incorrectly states that masks work.

Here is the conclusion of the paper:

A randomized-trial of community-level mask promotion in rural Bangladesh during the COVID-19 pandemic shows that the intervention increased mask usage and reduced symptomatic SARS-CoV-2 infections, demonstrating that promoting community mask-wearing can improve public health.

The only thing that is true is that the intervention to ask people to wear masks did, in fact, increase mask wearing. The rest is wrong and needs to be retracted.

### What happens next is the true test of character

Everyone makes mistakes. But what they do about the mistake after it is clearly pointed out is telling.

We will soon see how trustable the editors of Science are. If the journal does nothing, it will implicate the journal. Which means you shouldn't trust it in the future.

Secondly, the medical community (and mainstream media) should now quickly assess whether they made a mistake in promoting a false narrative. If they publicly fail to admit their mistake at this point, they are even more deplorable than I imagined.

What do you think will happen?

### Subscribe to Steve Kirsch's newsletter

I write about COVID vaccine safety and efficacy, corruption, censorship, mandates, masking, and early treatments. America is being misled by formerly trusted authorities.

### Exhibit 2

cdc.gov

### **Coronavirus Disease 2019**

3-4 minutes

5-3-22

At this time, CDC recommends that everyone aged 2 and older – including passengers and workers – properly wear a well-fitting <u>mask or respirator</u> over the nose and mouth in indoor areas of public transportation (such as airplanes, trains, etc.) and transportation hubs (such as airports, stations, etc.). When people properly wear a well-fitting mask or respirator, they protect themselves and those around them, and help keep travel and public transportation safer for everyone. Wearing a well-fitting mask or respirator is most beneficial in crowded or poorly ventilated locations, such as airport jetways. We also encourage operators of public transportation and transportation hubs to support mask wearing by all people, including employees.

This public health recommendation is based on the currently available data, including an understanding of domestic and global epidemiology, circulating variants and their impact on disease severity and vaccine effectiveness, current trends in COVID-19 Community Levels within the United States, and projections of COVID-19 trends in the coming months.

Along with staying up to date with COVID-19 vaccines, avoiding crowds, wearing a well-fitting <u>mask</u> <u>or respirator</u> is one of multiple prevention steps that people can take to protect themselves and others in travel and transportation settings.

For more information about safer travel during the pandemic, see <u>Domestic Travel During COVID-19</u> <u>CDC</u> and <u>International Travel | CDC</u>.

The following can be attributed to CDC Director Rochelle P. Walensky, MD, MPH:

CDC continues to recommend that all people—passengers and workers, alike—properly wear a well-fitting mask or respirator in indoor public transportation conveyances and transportation hubs to provide protection for themselves and other travelers in these high volume, mixed population settings. We now have a range of tools we need to protect ourselves from the impact of COVID-19, including access to high-quality masks and respirators for all who need them.

Additionally, it is important for all of us to protect not only ourselves, but also to be considerate of others at increased risk for severe COVID-19 and those who are not yet able to be vaccinated. Wearing a mask in indoor public transportation settings will provide protection for the individual and the community.

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### U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.