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No. 21-11287

United States Court of Appeals for the 11th Circuit

AUG 08 2022

ATLANTA GA

HEALTH FF

HEALTH FREEDOM DEFENSE FUND, ANA DAZA, & SARAH POPE, Appellees/Plaintiffs

v.

JOSEPH BIDEN, XAVIER BECERRA, CENTERS FOR DISEASE CONTROL & PREVENTION, DEPARTMENT OF HEALTH & HUMAN SERVICES, ROCHELLE WALENSKY, MARTIN CETRON, & UNITED STATES OF AMERICA, Appellants/Defendants

Appeal from the United States District Court for the Middle District of Florida
No. 8:21-cv-1693

BRIEF OF AMICI CURIAE 3 INDUSTRIAL HYGIENE EXPERTS IN SUPPORT OF APPELLEES URGING AFFIRMANCE

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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 Appellants' Opening Brief (Brief at C-1 & C-2) 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 appellees' arguments that the Federal Transportation Mask Mandate ("FTMM or "Mask Mandate") imposed by Appellants Centers for Disease Control & Prevention ("CDC") and Department of Health & Human Services ("HHS") is arbitrary and capricious. Also, these government agencies did follow the Administrative Procedure Act ("APA") notice-and-comment requirements before adopting the FTMM Order that requires 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 & 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 the district court's judgment that the FTMM is ultra vires and

should be vacated worldwide. Health Freedom Defense Fund v. Biden, No. 8:21-cv-1693 (M.D. Fla. April 18, 2022) ("HFDF"). Although CDC, HHS, the Transportation Security Administration ("TSA") have temporarily suspended all mask dictates due to the decision below, it is critical that this Court enjoin all federal agencies from ever reissuing any directives forcing passengers and transportation workers to don face masks.

We obtained consent of Alisa Klein, counsel for the government appellants, and Brant Hadaway, counsel for the 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.

¹ CDC and HHS claim a staggering power to require passengers on airplanes over foreign/international airspace and ships sailing in international waters to cover their faces – places clearly well outside U.S. jurisdiction.

V. STATEMENT OF THE ISSUES

We participate in this case (and the related action *Wall v. CDC*, No. 22-11532) 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 – issues that were not directly raised by the appellees/plaintiffs below and therefore not properly addressed in the district court's judgment.

We sent a letter Feb. 22, 2022, to Appellant 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. Ex. 1. 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 USCA11 Case: 22-11287 Date Filed: 08/08/2022 Page: 10 of 91

deeply flawed studies to come to the conclusion that masking everyone in the transport sector would "slow the spread."

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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 this case 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 the related *Wall* 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, which is not an issue in this case). Mr. Wall introduced 228 scientific and medical studies, articles, and videos into evidence (indexed at https://lucas.travel/masksarebad) totaling thousands of pages. Unfortunately appellees/plaintiffs in this case did not present such evidence to contradict CDC's false findings, and therefore Judge Mizelle did not have

reason to consider the mountain of science that contradicts pretty much everything CDC and HHS tell the public about masks. Supplementing the record in this case would have allowed Judge Mizelle to expand her inquiry into the arbitrary and capricious nature of the Mask Mandate and would have further illustrated why there was no "good cause" to forego notice and comment on a highly controversial government mandate not based in science.

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 Mizelle's ruling shall be affirmed, Judge Byron's decision must be reversed, and the Court must permanently enjoin CDC and HHS from ever again issuing a Mask Mandate unless Congress passes a new law specifically allowing them to do so.²

² It's questionable, however, whether Congress would have the constitutional authority to mandate masks in the transportation sector as this policy greatly infringes on the constitutional right to travel, the Fifth Amendment, and the 10th Amendment, issues that sadly were not argued below.

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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. CDC has minimal qualifications to regulate industrial hygiene. Doing so makes the Mask Mandate arbitrary and capricious, as the government experts in this field work for the Occupational Health & Safety Administration in the Department of Labor, whose regulations the FTMM violate.

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.³

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 was preventing the respirator from capturing a seal to the face. If healthcare professionals made these terrible errors putting on face coverings, one can

³ https://tinyurl.com/2uhpwrth

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 for 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 HHS did not even mention OSHA's respirator regulations when they hurriedly issued their FTMM Order to please a new president who demanded a Mask Mandate to fulfill one of his key campaign pledges, even though he admitted the federal government lacks the constitutional authority to require Americans to don face masks.

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 government didn't listen.

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)⁵ – 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.

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

⁴ https://tinyurl.com/yay6hxx2

⁵ 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 coronavirus. So how exactly do face coverings prevent the transmission of COVID-19?

mask and your face."6

Here we have CDC and HHS 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. When agencies ignore enormous scientific evidence and 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 3½ months with

⁶ https://tinyurl.com/pab7k8cy

no reports of COVID-19 hotspots in America's transportation sector since Judge Mizelle vacated the FTMM. Courts have also recognized that the evidence does not support mask mandates.

"There is no way to understand plaintiffs' trial evidence as establishing COVID-19 infections are "certainly impending" in schools without mask mandates, but not in schools mandating masks. ... At the time of trial, two of plaintiffs' seven schools were maskoptional (in compliance with [Texas Executive Order] GA-38), and five mandated masks (in violation of GA-38). The two maskoptional schools had positivity rates of 1.9 and 3.0%. The five schools with mask mandates measured at 0.3, 1.1, 2.3, 4.9, and 5.4% – higher, lower, and in between the rates from the maskoptional schools. Moreover, plaintiffs did nothing to control for their schools' various other efforts to reduce COVID-19 infections, and hence did nothing to prove the relative efficacy of mask mandates in the five law-violating schools. ... In light of widely available vaccines and the schools' other mitigation efforts, 'the odds' of any particular plaintiff contracting COVID-19 and subsequently suffering complications are 'speculative,' and 'the time (if ever) when any such [infection] would occur is entirely uncertain." E.T. v. Paxton, No. 21-51083, 2022 WL 2914732, at *3 (5th Cir. July 25, 2022) (dismissing challenge to Texas' ban on governmental mask mandates because, inter alia, the seven disabled students could not prove any injury from attending schools that didn't require muzzling kids and teachers).

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 as they saw the Omicron variant sicken thousands of their employees last winter despite everyone being masked. A

But the government continues pushing masks today, 2½ years into the pandemic (which many consider to be over now as COVID-19 is mostly 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. The FTMM did not reduce COVID-19 spread in the transportation sector, as we've seen with no evidence of new outbreaks aboard planes or other transit modes since the *vacatur* occurred April 18, 2022.

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." 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 to see how truly worthless they are (warnings include that the mask is not a product designed to prevent any illness or disease).

Former presidential COVID-19 adviser Michael Osterholm admitted that

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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.

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. 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 HHS 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 affirm the judgment below that declared the FTMM unlawful and set it aside because CDC and HHS violated the APA's notice-and-comment requirements. 5 USC § 553.

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 HHS 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).

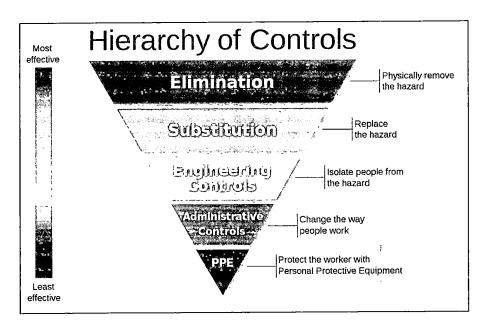


Figure 1-A: Hierarchy of Controls

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

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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 HHS 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.

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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. 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.

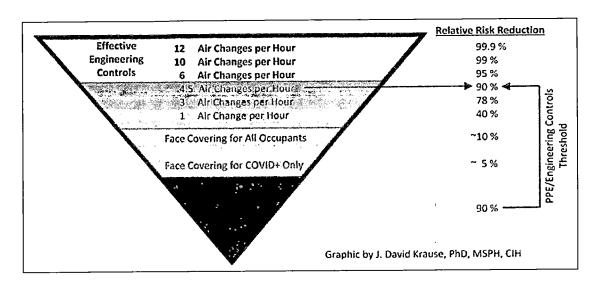


Figure 1-B: AIHA Reducing the Risk of COVID-19 Using Engineering Controls Graphic

CDC and HHS 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 HHS 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.* demonstrated⁷ that that the vast majority of COVID particles emitted during illness are aerosols, not droplets. Figure 2-A.

⁷ https://www.pnas.org/content/118/8/e2021830118

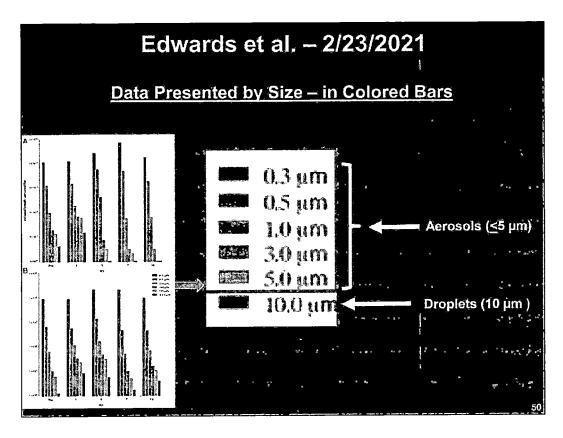


Figure 2-A: Edwards *et al.*, 2021 – Particle Size Emissions by Size & Time

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 HHS 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.

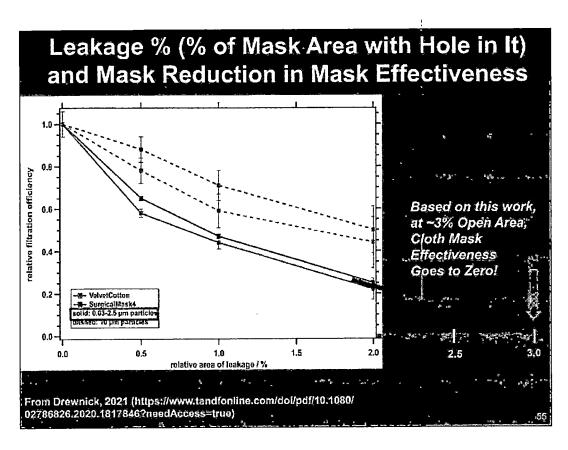


Figure 2-B: Loss of Mask Effectiveness in the Real World

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 the FTMM does 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?

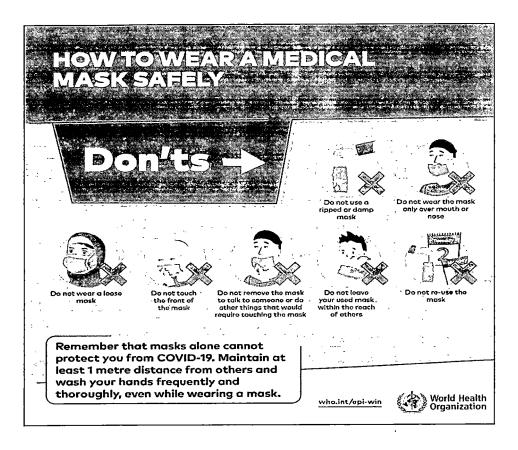


Figure 3-A: WHO Mask Safety Sheet - Don'ts

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. 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 HHS continue to push universal masking as some kind of "silver bullet."

A Brownstone paper by Paul Alexander⁸ 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.

The Fifth Circuit last week recognized these limitations:

"[P]laintiffs failed to identify any increased risk of contracting COVID-19 resulting from the prohibition on mask mandates, and any increased risk of suffering complications from a hypothetical COVID-19 infection is even more attenuated. But even assuming plaintiffs could show those increased risks, they could be attributed to any number of variables that have nothing to do with mask mandates. Those include innumerable differences in the way plaintiffs' schools - each an independent actor - have chosen to address COVID-19. ... All of this presumably explains why the entirety of the district court's factual finding on this point is this: 'the use of masks may decrease the risk of COVID infection in group settings.' That finding fails to support plaintiffs' contention that mask mandates are the only way they can adequately reduce the risks of COVID-19. It says nothing about allowing but not requiring masks. It says nothing about masks' relative efficacy vis-à-vis other mitigation measures. And it says nothing

⁸ https://tinyurl.com/mw2t6z6z

about school environments generally or plaintiffs' schools specifically. It therefore warrants no weight." E.T. at *6 (emphasis original).

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 Mizelle's decision didn't mention a single harm of masking, when experts have identified more than 70.

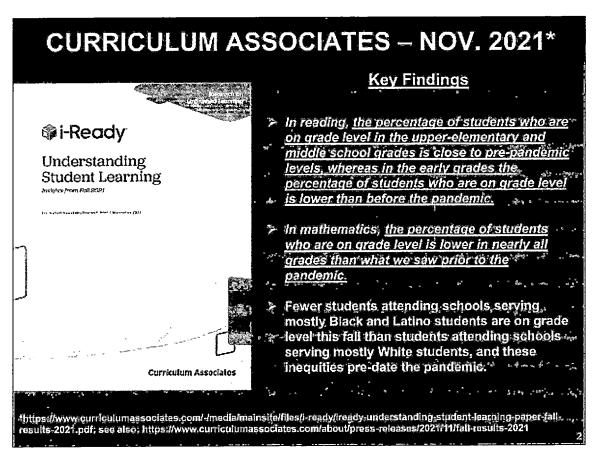


Figure 3-B: Curriculum Associates, Nov. 2021 - Title Page

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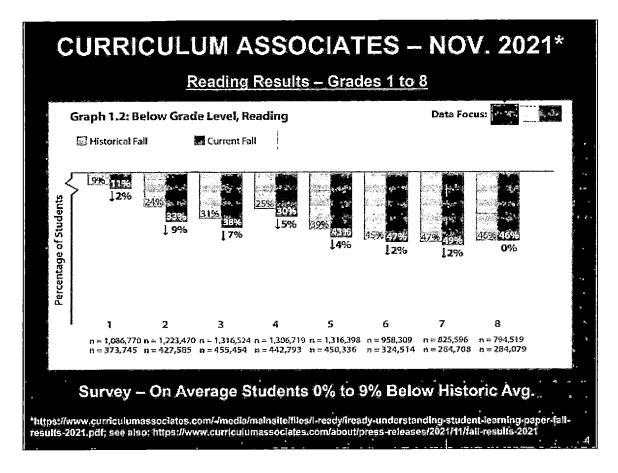


Figure 3-C: Curriculum Associates – Reading Deficits in 2021 vs. Prior Years

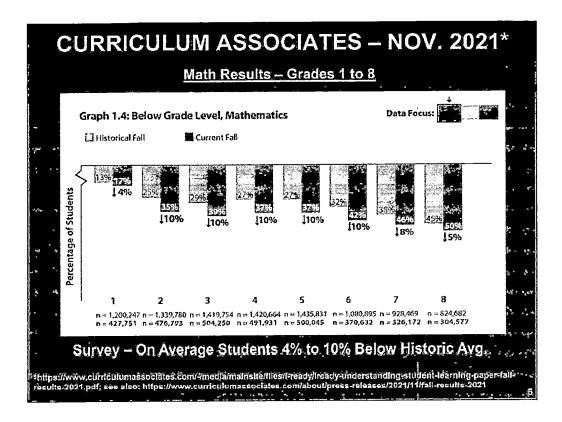


Figure 3-D: Curriculum Associates – Math Deficits in 2021 vs. Prior Years

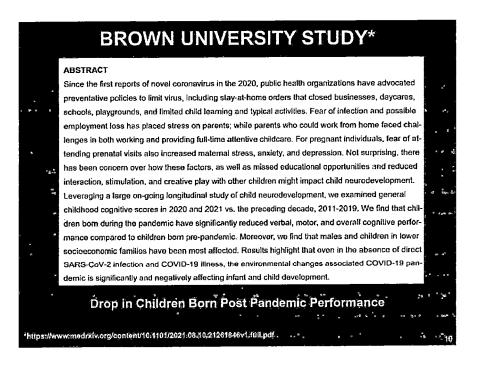


Figure 3-E: Brown University - Cognitive Deficits

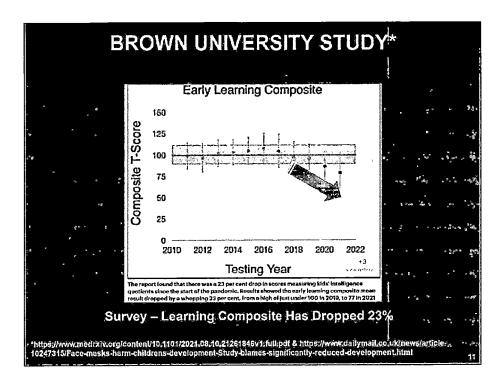


Figure 3-F: Brown University Study – Learning Loss of 23% for Children Born Since Pandemic

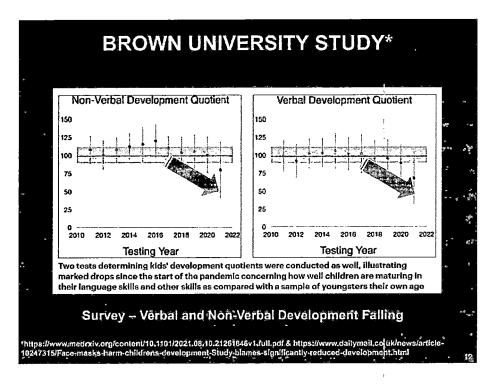


Figure 3-G: Brown University Study – Non-Verbal & Verbal Development Losses

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January 2022 England Dept. of Education Study – Masks Negatively Affected Learning

The review acknowledged the use of face coverings are harmful:

"A survey conducted by the Department for Education in April 2021 found that <u>almost all secondary leaders and teachers (94%) thought that wearing face coverings has made communication between teachers and students more difficult, with 59% saying it has made it a lot more difficult"</u>

"Wearing face coverings may have <u>physical side effects</u> and impair face identification, verbal and non-verbal communication between teacher and learner."

Evicance Summary

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

OTHER NEGATIVE EFFECTS OF WEARING MASKS

increased risk of adverse effects when using masks:

<u>internal diseases</u>

COPD

Sleep Apnea Syndrome advanced renal Failure

Obesity

Cardiopulmonary Dysfunction

Asthma

Psychiatric Illness

Claustrophobia Panic Disorder

Personality Disorders Dementia

Schizophrenia helgiess Patients

fixed and sedated Patients

Neurological Diseases

Migraines and Headache Sufferers Patients with intracranial Masses

Epicosy

Pediatric Diseases

Asthma

Respiratory diseases Cardiopulmonary Diseases

Neuromuscular Diseases

Ep#epsy

ENT Diseases

Vocal Cord Disorders

Rhinitis and obstructive Diseases

Dermatological Diseases

Acne Atopic Occupational Health Restrictions moderate / heavy physical Work

Gynecological restrictions

Pregnant Women

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

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There has been a bombardment by policymakers such as those at CDC and HHS 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.

This Court should not buy the propaganda CDC sold the American public, nor its efforts to overturn Judge Mizelle's decision here. The agency made numerous false claims in the FTMM Order such as that it 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." The government hasn't ever provided any evidence to support this hypothesis.

These are keystone observations to make when critically examining the measly seven studies CDC cited to justify President Biden's call for a Mask Mandate:

 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:

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.

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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 55 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 (56). 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 CO₂ with any type of face mask would appear to pose more problems for individuals with underlying cardiopulmonary disease. Other drawbacks for such individuals with tace-mask weating indy include anxiety and greater dyspines (60, 61 for the face performance (62), possible cognitive effects as a result of slight CO₂ retention and milicip increased hypoxemia, and increased Wb (63).

Increased temperature around the face (64) and a 0.5°C body-temperature elevation with loss of normal respiratory heat dissipation (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 (66, 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 CO₂ retention, resulting from potential small increases in dead space with a face mask.

Figure 3-L: Id.

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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 VO₂ 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 ²⁹—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 failure³⁰ and asthma. ³¹ Future research should examine cognitive capacity to tasks while wearing a mask during exercise, as well as the relationship between VO₂ 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 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."

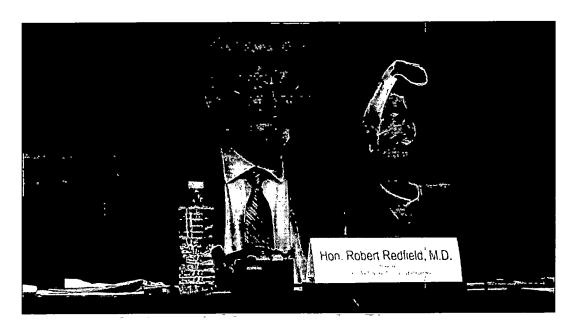


Figure 4-A: Dr. Robert Redfield testifying about masks before the Senate Appropriations Committee

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

⁹ https://www.sciencedirect.com/science/article/pii/S2590238520303647

- 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 HHS 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 for kids. Figure 4-C.

¹⁰ https://www.tyscienceguy.com/mask-documentary-series.html

¹¹ 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

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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.
- 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.
- 5) 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 puncture's 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 811OS only).
- 7) 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.
- 8) Dispose of used product in accordance with applicable regulations.

Use Limitations

- 1) 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.
- 3) Do not alter, wash, abuse or misuse this respirator.
- 4) 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 Appellant Walensky to educate and assist her team in rescinding this publication and instead implementing strategies that are low risk and yield positive results. Ex. 1. 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. 2) 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. Ex. 1. 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" brief¹² 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. 3.

¹² 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 April 2022 and the Fifth Circuit's recent decision in *E.T. v Paxton*. We hope this brief will help the Court understand how CDC's Mask Mandate is arbitrary and capricious, not to mention all the other legal problems raised by Health Freedom Defense Fund such as the agency not having statutory authority to require face coverings as well as lack of notice and comment.

Because "our system does not permit agencies to act unlawfully even in pursuit of desirable ends," the Court must affirm Judge Mizelle's decision declaring unlawful CDC's FTMM Order. *Ala. Ass'n of Realtors v. HHS*, 141 S.Ct. 2485, 2490 (2021). We also ask the Court to permanently enjoin the appellants 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 two individual travelers before the Court in this case. *Barr v. Am. Ass'n of Pol. Consultants*, 140 S.Ct. 2335, 2351 (2020).

Respectfully submitted this 2nd day of August 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 6,492 words as measured by Microsoft Word.

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X. CERTIFICATE OF SERVICE

I certify that on Aug. 2, 2022, I e-mailed this brief to these Court clerks for uploading into the 11th Circuit's Case Management/Electronic Case Filing system:

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

I also certify that I e-mailed this brief Aug. 2 to counsel for the parties and other *amici curiae*:

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Exhibit 1

February 22, 2022

Rochelle P. Walensky, MD, MPH Director, Centers for Disease Control and Prevention 1600 Clifton Road, NE Atlanta, GA 30333

Anthony S. Fauci, MD
Director, National Institute of Allergy and Infectious Diseases
National Institutes of Health
31 Center Dr # 7A03
Bethesda, MD 20892

Honorable Senator Ronald H. Johnson 328 Hart Senate Office Building Washington DC 20510

Douglas L. Parker, Assistant Secretary of Labor for Occupational Safety and Health Occupational Safety & Health Administration 200 Constitution Ave NW Washington, DC 20210

Mr. Jeffrey Zients
Coordinator and Counselor to the President
COVID-19 Pandemic Response
The White House
1600 Pennsylvania Ave. NW
Washington, DC 20500

Sent via US Mail Certified Return Receipt and e-mail

Re: Request for Immediate Corrections to the CDC Guidance on Masks and Respirators

Dear Dr. Walensky, Dr. Fauci, Senator Johnson, Mr. Parker, and Mr. Zients:

We the undersigned, professional experts in the field of industrial hygiene, with combined experience of nearly 150 years, are highly concerned with the inaccurate and misleading guidance being promoted by the CDC on its website regarding efficacy of masking to prevent COVID-19 and now similar guidance regarding respirators and request for immediate correction to said guidance. The guidance is overly broad, inaccurate, and especially inappropriate for children and the general public.

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For reference, the field of industrial hygiene is defined as:

"That science and art devoted to the anticipation, recognition, evaluation, and control of those environmental factors or stressors arising in or from the workplace, which may cause sickness, impaired health and well-being, or significant discomfort among workers or among of the citizens of the community" (https://www.aiha.org/about-ih/Pages/default.aspx).

The AIHA defines an Industrial Hygienist (https://www.aiha.org/ih-careers/discover-industrial-hygiene) as:

"Scientists and engineers committed to protecting the health and safety of people in the workplace and the community."

Thus, our profession is dedicated, in part, to providing controls to exposures and rely upon what is known as the hierarchy of controls. The hierarchy of controls was first developed by the National Safety Council (NSC) in 1950. This guides us as to the most effective to least effective exposure controls (see Figure 1):

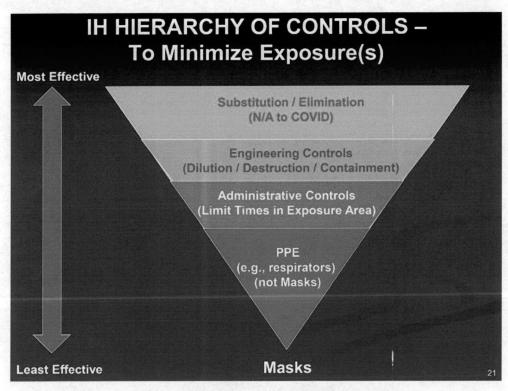


Figure 1: Hierarchy of Controls

Note that masks do not fit into the hierarchy of controls simply because they are not even personal protective equipment. This is recognized in the recent ASTM Face Covering (mask) Standard [ASTM F3502-21 – Standard Specification for Barrier Face Coverings (BFCs)] illustrated in Figure 2:

3.1.8 *respirator*, *n*—personal protective equipment (PPE) designed to protect the wearer from inhalation of hazardous contaminants.

3.1.8.1 *Discussion*—Barrier face coverings are not designed to meet the performance requirements of NIOSH-approved respirators. For the purpose of this specification, healthcare

Figure 2: ASTM 2021 BFC Standard – Masks Not PPE (Respirators)

The best industrial hygiene solution has for decades been engineering controls of dilution with fresh air, filtration, and/or destruction – all of which are readily available technologies.

Given this background, we the undersigned have been increasingly concerned about the mis-information provided by the CDC to the public; often reflected by inappropriately conclusive language that *omits technical limitations and documented negative effects associated with masks and face coverings*. Examples of our concerns follow:

Issue #1: Recommending N-95 type masks is inappropriate for the general population and children:

The CDC's January 14, 2021 and January 28, 2021 webpage language have instructed people to move away from masks and toward N95-type respirators (see for example https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html), including KN95 respirators (Figure 3):

Respirators

When choosing a respirator, look at how well it fits and read the manufacturer instructions. These instructions should include information on how to wear, store, and clean or properly dispose of the respirator. Respirators have markings printed on the product to indicate they are authentic, see appropriate N95 markings

and KN95 markings.

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in and out around the edges of the respirator. Gaps can be caused by choosing the wrong size or type of respirator or when a respirator is worn with facial hair. For Information about how to use your N95 correctly, see How to Use Your N95 Respirator. The information on this page is about N95 respirators but also applies to international respirators, like KN95 respirators.

Most publicly available respirators are disposable and should be discarded when they are dirty, damaged, or difficult to breathe through.

More information on these two types of respirators is provided below.

Figure 3: CDC January 14 & January 28, 2022 Guidance on Respirators - pgs. 4-5

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Under the topic of respirators, the CDC lists both N95 and KN95 respirators.

Moreover, as the CDC knows, persons or entities providing respirators in the workplace (unlike masks) must follow OSHA's Personal Protective Equipment Standard (OSHA 29 CFR 1910.132) to establish the nature of the hazard (Hazards Assessment) and the Respiratory Protection Standard (RPS) requirements (29 CFR 1910.134). Non-employees must also follow the RPS under the manufacturers' instructions (as we shall show later). These RPS requirements are substantial and include factors such as:

- Written RPS Plan
- Medical Clearance
- Initial Fit Test
- Annual Fit Test
- Training by a professional such as an IH on fit testing, cleaning, storage, and changeout.

As the CDC knows, or should know, movement from masks to respirators comes with significant requirements or as the manufacturers such as 3M state on their instructions, improper usage "may result in sickness or death".

In this context, we have recently been provided by the following request, and rejection by OSHA, to investigate improper usage of KN respirators by an employer (Figure 4):

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U.S. Department of Labor

Occupational Safety and Health Administration Toledo Area Office 420 Madison Ave, Suite 600 Toledo, OH 43604



February 9, 2022



RE: OSHA Complaint No. 1864651



The Occupational Safety and Health Administration (OSHA) has received your notice of alleged workplace hazard(s) against notified Gun Lake Casino. After careful review we have decided not to conduct an inspection because:

On the basis of the information provided to our office during our phone conversation the employer has provided and is requiring employees to wear KN95 masks which are not NIOSH certified respirators and would not be covered by OSHA's respiratory protection standard.

If you do not agree with this decision, you may contact me for a clarification of the matter at (419) 259-7542.

Section 11(c) of the OSH Act provides protection for employees against discrimination because of their involvement in protected safety and health related activity. If you believe you are being treated differently or action is being taken against you because of your safety or health activity, you may file a complaint with OSHA. You should file this complaint as soon as possible, since OSHA normally can accept only those complaints filed within 30 days of the alleged discriminatory action.

Thank you for your concern for a safe and healthful workplace.

Respectfully,

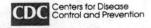
Daniladipo

Todd Jensen Area Director

Figure 4: OSHA February 9, 2022 Response Letter to Gun Lake Casino Complaint

OSHA rejected the employee complaint on a technicality that the employer was not following the OSHA RPS because the respirator was a KN95 rather than an N95. And, as shown in Figure 5, NIOSH does not approve KN95's:

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NIOSH-approved N95 Particulate Filtering Facepiece Respirators

This list is reviewed and updated weekly.

Manufacturers Listed from A to Z - L

The N95 respirator is the most common of the seven types of particulate filtering facepiece respirators. This product filters at least 95% of airborne particles but is not resistant to oil-based particles.

This web page provides a table of NIOSH-approved N95 respirators listed by manufacturer from A-Z. You can find a specific manufacturer by clicking on the first letter of their name on the index below. Web links in the table go to the NIOSH Approval Holder's website. See the Notes section for information about private labels.

NIOSH entered a Memorandum of Understanding [4] (MOU) in 2018 with the Food and Drug Administration (FDA). This MOU granted NIOSH the authority to approve surgical N95 filtering facepiece respirators. Prior to this MOU, both NIOSH and FDA approved and cleared surgical N95s. The **Model Number/Product Line in bold text followed by (FDA)** indicates these surgical N95 respirators in the table below. NIOSH also provides a table of the surgical N95 respirators approved prior to the MOU. Surgical N95 respirators approved under the MOU do not require FDA's 510(k) clearance. These NIOSH-approved surgical N95 respirators are only on the Certified Equipment List (CEL).

A respirator labeled as a KN95 respirator is expected to conform to China's GB2626 standard. NIOSH does not approve KN95 products or any other respiratory protective devices certified to international standards. For more information, view Factors to Consider When Planning to Purchase Respirators from Another Country.

Figure 5: NIOSH Language Regarding Approval of KN95 Respirators

So, in an obvious case of deception, the CDC recommends the usage of N95 and KN95 respirators (see Figure 3) yet must know they are not approved by NIOSH and that OSHA will not enforce the RPS. The irony here is that NIOSH is part of the CDC (see Figure 5 letterhead), so the CDC clearly knows this. Note that it is known that KN95 respirators from China are known to be less expensive than those made with the N95 designation and find widespread usage; this too was known, or should have been known, by the CDC.

Thus, the CDC pushes KN95 respirators as part of the move toward respirators, knowing they are not approved by their sub-agency NIOSH, which allows employers to make employees wear respirators without the protections of OSHA's Respiratory Protection Standard (RPS). This is an unconscionable breach of the public health function and should be corrected immediately.

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Issue #2: CDC has issued harmful guidance for masking children that contradicts manufacturers' recommendations, world-wide standard practice and CDC's own guidance, and without appropriate risk-benefit analysis:

The CDC's January 28, 2021 webpage language misleadingly implies respirators are acceptable for children yet knows that this is not the case simply based on manufacturer instructions, they link the reader to https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html – see Figure 6:

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.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html

Figure 6: Misleading CDC Language Regarding Children Wearing Masks and Respirators

As illustrated in detail below, the CDC provided language in its January 28, 2022 guidance for children that is particularly misleading by obfuscating and omitting information readily known, or likely to have been known by the CDC.

"The benefits of mask-wearing are well-established:"

First, the benefits of children, or anyone for that matter, of wearing masks being well

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established is simply false. A Brownstone paper by Paul Elias Alexander published December 21, 2021 (https://brownstone.org/articles/more-than-150-comparative-studies-and-articles-on-mask-ineffectiveness-and-harms/) shows both the effectiveness of masks and their harms, citing 150 studies. One of these author's testified in the Western District Court of Michigan on September 28, 2021, in a half-dozen interviews (e.g., Jeff Hayes Films: https://rumble.com/vrfoox-covid-revealed-episode-8b-bonus-video-stephen-petty.html), in his own podcasts (https://rumble.com/c/PettyPodcasts) and in the Liberty Dispatch in Canada (https://podcasts.apple.com/us/podcast/episode-99-masks-dont-work-an-interview-with-ppe/id1559570986?i=1000550149187). During this testimony it was shown that the nearly 50 studies cited by the CDC purportedly showing masks are effective did not support statements made by the CDC and most suffered from a lack of a control group (group similar to the mask study group not wearing masks) or cofounding factors (multiple factors such as changes in HVAC systems, distancing, quarantining, and masks) wherein one cannot determine the specific contribution by masking.

But the most egregious part of this statement is that it only addresses supposed benefits, not liabilities. Even the WHO - UNICEF (https://www.who.int/publications/i/item/WHO-2019-nCoV-IPC_Masks-Children-2020.1) understands that risk-rewards analysis should be done before recommending unproven, unscientifically-supported policies before masking them. Remember – do no harm – is the overarching principle (Figures 7 & 8):

Advice to decision makers on the use of masks for children in the community

Overarching guiding principles

Given the limited evidence on the use of masks in children for COVID-19 or other respiratory diseases, including limited evidence about transmission of SARS-CoV-2 in children at specific ages, the formulation of policies by national authorities should be guided by the following overarching public health and social principles:

- Do no harm: the best interest, health and well-being of the child should be prioritized.
- The guidance should not negatively impact development and learning outcomes.
- The guidance should consider the feasibility of implementing recommendations in different social, cultural and geographic
 contexts, including settings with limited resources, humanitarian settings and among children with disabilities or specific
 health conditions.

Figure 7: WHO UNICEF Recommendations for Children and Masks

From Figure 7, the overarching guiding principle is to do no harm.

Advice on the use of masks in children

WHO and UNICEF advise decision makers to apply the following criteria for use of masks in children when developing national policies, in countries or areas where there is known or suspected community transmission of SARS-CoV-2 and in settings where physical distancing cannot be achieved.

- Based on the expert opinion gathered through online meetings and consultative processes, children aged up to five years should not wear masks for source control. This advice is motivated by a "do no harm" approach and considers:
 - childhood developmental milestones^{b 41}
 - · compliance challenges and
 - · autonomy required to use a mask properly.

The experts (following the methods described above) recognized that the evidence supporting the choice of the age cut-off is limited (see above, section related to transmission of COVID-19 in children), and they reached this decision mainly by consensus. The rationale included consideration of the fact that by the age of five years, children usually achieve significant developmental milestones, including the manual dexterity and fine motor coordination movements needed to appropriately use a mask with minimal assistance.

In some countries, guidance and policies recommend a different and lower age cut-off for mask use⁴²⁻⁴⁵. It is recognized that children may reach developmental milestones at different ages and children five years of age and under may have the dexterity needed to manage a mask. Based on the do no harm approach, if the lower age cut-off of two or three years of age is to be used for recommending mask use for children, appropriate and consistent supervision, including direct line of sight supervision by a competent adult and compliance need to be ensured, especially if mask wearing is expected for an extended period of time. This is both to ensure correct use of the mask and to prevent any potential harm associated with mask wearing to the child.

Children with severe cognitive or respiratory impairments who have difficulties tolerating a mask should, under no circumstances, be required to wear masks.

Other IPC, public health and social measures should be prioritized to minimize the risk of SARS-CoV-2 transmission for children five years of age and under; specifically maintaining physical distance of at least 1 meter where feasible, educating children to perform frequent hand hygiene and limiting the size of school classes. It is also noted that there may be other specific considerations, such as the presence of vulnerable persons or other local medical and public health advice that should be considered when determining if children five years of age and under need to wear a mask.

- For children between six and 11 years of age, a risk-based approach should be applied to the decision to use of a mask. This approach should take into consideration:
 - intensity of transmission in the area where the child is and updated data/available evidence on the risk of infection and transmission in this age group;
 - social and cultural environment such as beliefs, customs, behaviour or social norms that influence the community
 and population's social interactions, especially with and among children;
 - the child's capacity to comply with the appropriate use of masks and availability of appropriate adult supervision;
 - potential impact of mask wearing on learning and psychosocial development; and
 - additional specific considerations and adaptions for specific settings such as households with elderly relatives, schools, during sport activities or for children with disabilities or with underlying diseases.
- Advice on mask use in children and adolescents 12 years or older should follow the WHO guidance for mask use in adults¹ and/or the national mask guidelines for adults.

Even where national guidelines apply, additional specific considerations (see below) and adaptions for special settings such as schools, during sport, or for children with disabilities or with underlying diseases will need to be specified.

Figure 8: WHO UNICEF Recommendations for Children and Masks by Age

Note that from Figure 8, WHO recommends against masking below age 6 and that children ages 6 to 11 may be masked upon completion of a risk assessment. England has similar guidance. But the CDC requires masks for children down to age 2 against WHO guidance and based on extensive reviews, has yet to perform any risk assessment on the net benefits of children wearing masks.

Specifically, it is well established that significant harms (i.e., reduced learning and development and physical, emotional, and social harms) have been reported in the literature (Figures 9-18):

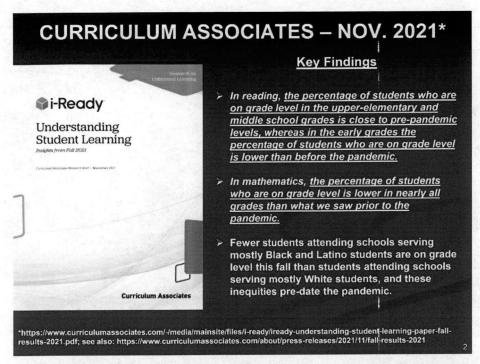


Figure 9: Curriculum Associates - Nov. 2021 - Title Page

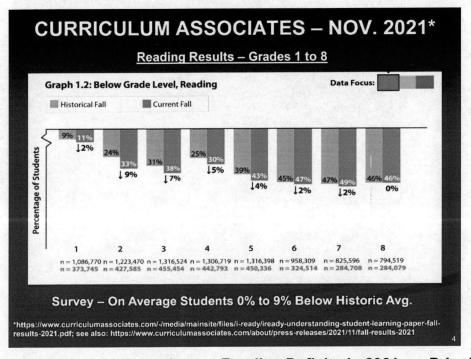


Figure 10: Curriculum Associates - Reading Deficits in 2021 vs. Prior Years

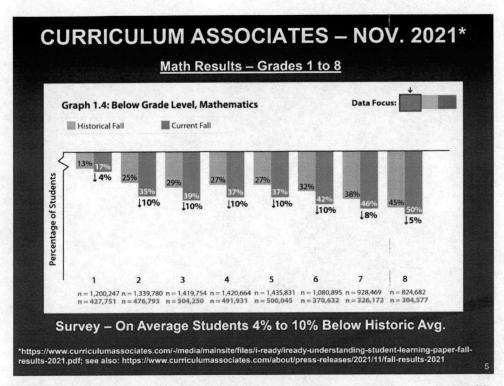


Figure 11: Curriculum Associates - Math Deficits in 2021 vs. Prior Years

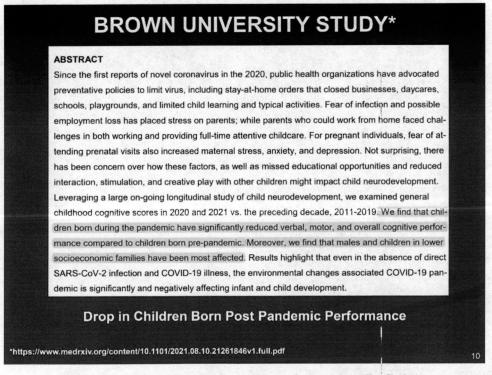


Figure 12: Brown University - Cognitive Deficits

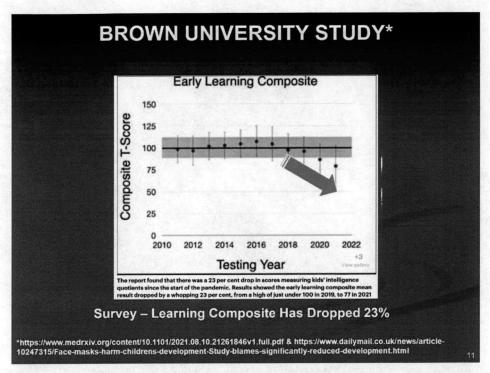


Figure 13: Brown University Study – Learning Loss of 23% for Children Born Since Pandemic

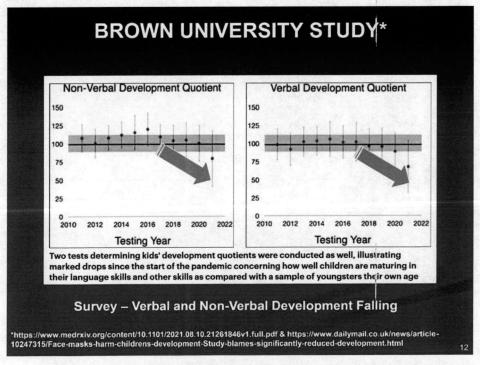


Figure 14: Brown University Study – Non-Verbal and Verbal Development Losses

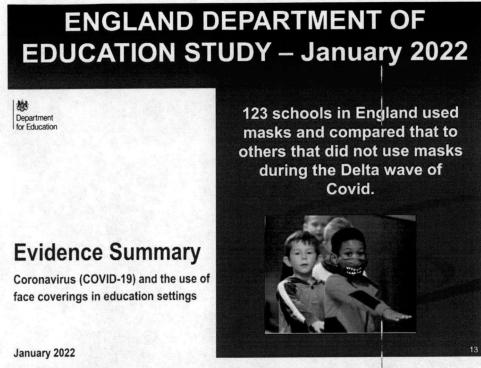


Figure 15: England Department of Education

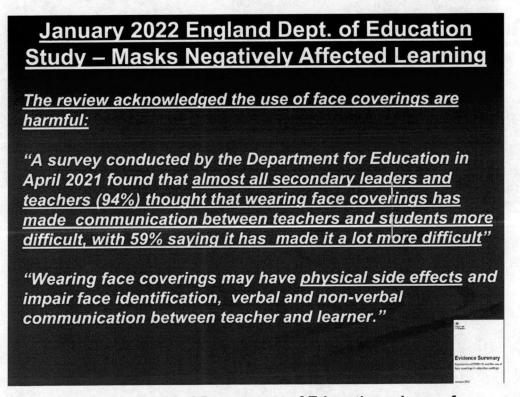


Figure 16: England Department of Education – Loss of Communication and Physical Effects

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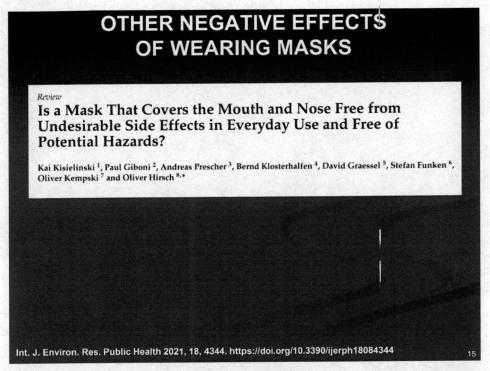


Figure 17: Kisielinski et al. – Mask Meta Study – Reviewed 1,226 Studies

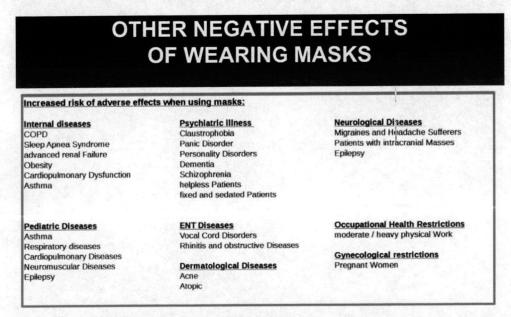


Figure 5. Diseases/predispositions with significant risks, according to the literature found, when using masks. Indications for weighing up medical mask exemption certificates.

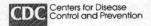
Int. J. Environ. Res. Public Health 2021, 18, 4344. https://doi.org/10.3390/ijerph18084344

Figure 18: Kisielinski et al., – Areas of Quantitated Adverse Effects on Children and Adults

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Clearly, the CDC has not conducted a net risk assessment and should have, and must do so to avoid continuing harms to children.

Even more disturbing, in their innocent looking, new Guidance for Children (Learn the Signs, Act Early) the CDC has in part, extended the timeframes for children to achieve learning outcomes (https://www.cdc.gov/ncbddd/actearly/milestones/index.html). Regarding these changes – Figure 19, CDC refers the reader to an American Academy of Pediatrics (AAP) webpage (https://publications.aap.org/pediatrics/article-abstract/doi/10.1542/peds.2021-052138/184748/Evidence-Informed-Milestones-for-Developmental?redirectedFrom=fulltext):



CDC's Developmental Milestones

CDC's milestones and parent tips have been updated and new checklist ages have been added (15 and 30 months). Due to COVID-19, updated photos and videos have been delayed but will be added back to this page in the future. For more information about the recent updates to CDC's developmental milestones, please view the *Pediatrics* journal article describing the updates.

Figure 19: CDC Learn the Signs, Act Early New Webpage - Reference to AAP

The headlines for the reference paper are reproduced as Figure 20:

Evidence-Informed Milestones for Developmental Surveillance Tools | Pediatrics | American Acade

SPECIAL ARTICLE | FEBRUARY 08 2022

Jennifer M. Zubler, MD ≤; Lisa D. Wiggins, PhD; Michelle M. Macias, MD; Toni M. Whitaker, MD; Judith S. Shaw, EdD, MPH, RN; Jane K. Squires, PhD; Julie A. Pajek, PhD; Rebecca B. Wolf, MA; Karnesha S. Slaughter, MPH; Amber S. Broughton, MPH; Krysta L. Gerndt, MPH; Bethany J. Mlodoch; Paul H. Lipkin, MD

Address correspondence to Jennifer M. Zubler, MD, National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, 4770 Buford Hwy NE, MS S106-4, Atlanta, GA 30341. E-mail: wyv4@cdc.gov

Figure 20: CDC Referenced AAP Paper by Zubler (CDC) et al. Dated February 8, 2022

Zubler et al., write in part:

^{*} Contributed equally as co-senior authors.

"The Centers for Disease Control and Prevention's (CDC) Learn the Signs. Act Early. program, funded the American Academy of Pediatrics (AAP) to convene an expert working group to revise its developmental surveillance checklists. The goals of the group were to identify evidence-informed milestones to include in CDC checklists, clarify when most children can be expected to reach a milestone (to discourage a wait-and-see approach), and support clinical judgment regarding screening between recommended ages. Subject matter experts identified by the AAP established 11 criteria for CDC milestone checklists, including using milestones most children (≥75%) would be expected to achieve by specific health supervision visit ages and those that are easily observed in natural settings. A database of normative data for individual milestones, common screening and evaluation tools, and published clinical opinion was created to inform revisions. Application of the criteria established by the AAP working group and adding milestones for the 15and 30-month health supervision visits <u>resulted in a 26.4% reduction</u> and 40.9% replacement of previous CDC milestones. One third of the retained milestones were transferred to different ages; 67.7% of those transferred were moved to older ages. Approximately 80% of the final milestones had normative data from ≥1 sources. Socialemotional and cognitive milestones had the least normative data. These criteria and revised checklists can be used to support developmental surveillance, clinical judgment regarding additional developmental screening, and research in developmental surveillance processes. Gaps in developmental data were identified particularly for socialemotional and cognitive milestones.

Thus, at least 22.3% [67.7% of 33%] of the CDC child developmental milestones in place for ~18 years, were moved from a younger age to an older age in February 2022.

One must conclude the CDC, rather than acknowledging the harms being done to children's development by their COVID policies, including masking, is simply moving the goalposts for what constitutes normal child development rather than admitting and moving away from failed policies.

Statements under "Respirators" and "Selecting Masks":

- 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.
- Masks and respirators should not be worn by children younger than 2 years.
- 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.

This language may be the most misleading and egregious given that the links CDC provides to manufacturers' instruction state that their N95s are not for use with children – the CDC has to know this.

The links to manufacturers' instructions from the January 28, 2022 mask and January 25, 2022 How to Use Your N95 Respirator are shown in Figures 21 and 22 respectively:

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Related Pages

- > Your Guide to Masks
- > Improve How Your Mask Protects You
- How to Use Your N95 Respirator

Last Updated Jan. 28, 2022

Figure 21: CDC January 28, 2022 Link – Bottom of Page and CDC January 25, 2022 Link to Manufacturers' Guidance and Warnings

The "How to Use Your N95 Respirator" is at the bottom of the CDC January 28, 2022 webpage.

COVID-19

How to Use Your N95 Respirator

Updated Jan. 25, 2022

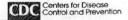
Wear Your N95 Properly So It Is Effective

- N95s must form a seal to the face to work properly. This is especially important for people at increased risk for severe disease. Wearing an N95 can make it harder to breathe. If you have heart or lung problems, talk to your doctor before using an N95.
- Some N95s may contain latex in the straps. If you have natural rubber latex allergies, see the manufacturers' website for information about your specific model.

For specific manufacturer's instructions for your N95 model, see Free N95 Respirator Manufacturers.

Figure 22: CDC January 15, 2022 Link to How to Use Your N-95 Respirator – Link to Manufacturers

The link in turn takes one to the following page (https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/free-n95-manufacturers.html) (Figure 23):





COVID-19

Free 1933 Respirator Manufacturers

Distributed from the Strategic National Stockpile Updated Jan. 25, 2022

What You Need to Know

- The Strategic National Stockpile has distributed N95 respirators to pharmacy distribution centers throughout the country.
- You can find specific manufacturer's instructions for your N95 model below.

For information about how to use your N95 correctly, see How to Use Your N95 Respirator.

3M



MODEL

3M Model 8210+

NIOSH APPROVAL

TC-84A-0007

General and Occupational/Workplace 8210, 81105, 8210Plus N95 Particulate Respirator User Instructions (3m.com) ■ ☑



MODEL

3M Model 8110S

NIOSH APPROVAL

TC-84A-0007

General and Occupational/Workplace 8210, 8110S, 8210Plus N95 Particulate Respirator User Instructions (3m.com) ■ ☑

MODEL

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/free-n95-manufacturers.htm

Figure 23: CDC January 15, 2022 Link to How to Use Your N-95 Respirator – Link to Manufacturers – pg. 1

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From this webpage, four manufacturers are listed representing 12 respirators:

- > 3M (6 models)
- Drager (1 model)
- Honeywell (2 models)
- Moldex (3 models).

For each model, the link can be clicked to get directly to the manufacturers' instructions for each respirator. For 3M and Moldex, major suppliers, only one set of instructions is used for each of their individually listed respirators. In other words, the same instructions were provided for each of the manufacturers' listed products.

Both 3M and Moldex explicitly state that their masks are not to be use by children (Figure 24).

Occupational/Workplace Use: 3M™ 8210, 8110S, 8210Plus N95 User Instructions

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.
- The particles which can be dangerous to your health include those so small that you cannot see them.
- 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).
- 7) 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

- 1) 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.
- 3) Do not alter, wash, abuse or misuse this respirator.
- 4) 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).
- 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.
- 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 24: 3M Instructions for CDC Listed 3M N95 Respirators – Not Designed to be Used by Children

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Note the following observations from Figure 24:

- This respirator is not designed to be used by children!
- The respirator is only intended to be used for occupational or professional adults properly trained (e.g., under the RPS).
- Failure to follow instructions may result in sickness or death.
- A written respiratory protection plan, under the requirements of 29 CFR 1910.134 (RPS) must be in place prior to use of this respirator.

The Moldex instructions are essentially the same.

Moreover, 3M warns it is not protective against infectious diseases (Figure 25):

Biological Particles

This respirator can help reduce inhalation exposures to certain airborne biological particles (e.g. mold, *Bacillus anthracis*, *Mycobacterium tuberculosis*, etc.) but cannot eliminate the risk of contracting infection, illness or disease. OSHA and other government agencies have not established safe exposure limits for these contaminants.

5

Figure 25: 3M Instructions for CDC Listed 3M N95 Respirators – Not Protective Against Infection, Illness, or Disease

Note that anthrax and TB are much larger particles than virus particles like the COVID-19 virus.

In light of this discussion, the CDC should immediately correct their webpage stating explicitly that respirators, according to manufacturers' instructions, "Are not designed to be used by Children" and that anyone using a respirator must be doing so under a written respiratory protection plan that follows the OSHA RPS.

Issue #3: The CDC continues to ignore the fact that COVID-19 is primarily spread by aerosols (not droplets) making mask use mostly ineffective:

The CDC continues to make the misleading argument that masks stop COVID droplets. This is misleading because while masks do stop some droplets (> 50 to 10 micron), the vast majority of COVID particles are smaller aerosols (≤ 5 microns) – see Figure 26:

Types of Masks and Respirators

Masks are made to contain droplets and particles you breathe, cough, or sneeze out. If they fit closely to the face, they can also provide you some protection from particles spread by others, including the virus that causes COVID-19.

Respirators are made to protect you by filtering the air and fitting closely on the face to filter out particles, including the virus that causes COVID-19. They can also contain droplets and particles you breathe, cough, or sneeze out so you do not spread them to others.

Figure 26: CDC - Misleading Guidance on Masks and Droplets

We are not the only ones who have written you regarding this issue. On February 15, 2001, the following scientists wrote a lengthy memo to you regarding your misleading language in this area and asked you to correct it:

- Rick Bright, PhD, Former Director of BARDA, Dept of Health and Human Services
- Lisa M. Brosseau, ScD, CIH, University of Minnesota CIDRAP
- Lynn R. Goldman, MD, MS, MPH, George Washington University
- Céline Gounder, MD, ScM, NYU Grossman School of Medicine & Bellevue Hospital Center
- Jose Jimenez, PhD, University of Colorado at Boulder
- Yoshihiro Kawaoka, DVM, PhD, University of Wisconsin-Madison and University of Tokyo
- Linsey Marr, PhD, Virginia Tech
- David Michaels, PhD, MPH, George Washington University
- Donald K. Milton, MD, DrPH, University of Maryland
- Michael Osterholm, PhD, MPH, University of Minnesota CIDRAP
- Kimberly Prather, PhD, University of California San Diego
- Robert T. Schooley, MD, University of California San Diego
- Peg Seminario, MS, AFL-CIO (retired)

They wrote in part:

"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 <u>small inhalable particles</u> 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, followed by respiratory protection...

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. (https://www.pnas.org/content/118/8/e2021830118) demonstrated that that the vast majority of COVID particles emitted during illness are aerosols not droplets (see Figure 27):

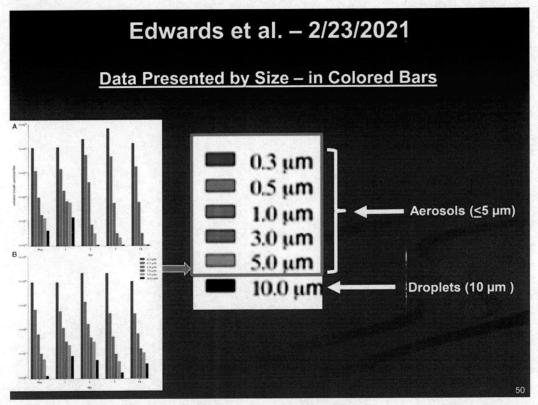


Figure 27: Edwards et al., 2021 - Particle Size Emissions by Size and Time

Edwards et al. concluded their paper with the following statements:

- Our finding that <u>the proportion of small respiratory droplets (i.e., aerosols) were the majority of particles exhaled in all subjects</u>.
- There may be an elevated risk of the airborne transmission of SARS CoV 2 by way of the very small droplets (aerosols) that transmit through conventional masks and traverse distances far exceeding the conventional social distance of 2 m (~7').
- Exhaled aerosol numbers appear to be not only an indicator of disease progression, but a marker of disease risk in non-infected individuals.

While the mask may contain droplets, they only do so for a period. As the masks are exposed to heat and moisture they suffer from degradation within a few hours.

We ask that the CDC immediately suspend misleading statements in all their public information that masks stop droplets when the vast majority of particles are smaller aerosols that stay suspended for days to weeks (vs. minutes for droplets), readily pass through gaps around the masks, and can reach deep into the lungs (see for example Fennelly, Kevin, P., 2020, Particle sizes of infectious aerosols: implications for infection control, Lancet Respir Med 2020; 8: 914–24).

Issue #4: CDC's position for masks used by the general public lacks proper scientific justification and creates potential harm based on a false sense of security:

Statements that a mask can provide protection are false and mislead the public into a false sense of security. Industrial Hygiene solutions seek a more than 90% relative risk reduction, and this publication continues to focus on the lowest form of non-protection that does not meet the least desirable mode of protection (PPE) in the Hierarchy of Controls with PPE. The September 9, 2020 guidance from AIHA illustrated this concept of the need for a super reduction in relative risk, not a minor one (https://aiha-assets.sfo2.digitaloceanspaces.com/AIHA/resources/Guidance-Documents/Reducing-the-Risk-of-COVID-19-using-Engineering-Controls-Guidance-Document.pdf - pg. 4).

Moreover, the CDC continues to provide guidance that gaps in masks can be eliminated; in the real world that never happens (Figure 28):

Choosing a Mask or Respirator for Different Situations

Masks and respirators (i.e., specialized filtering masks such as "N95s") can provide different levels of protection depending on the type of mask and how they are used. 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.

Whatever product you choose, it should provide a good fit (i.e., fitting closely on the face without any gaps along the edges or around the nose) and be comfortable enough when worn properly (covering your nose and mouth) so that you can keep it on when you need to. Learn how to improve how well your mask protects you by visiting CDC's Improve How Your Mask Protects You page.

A respirator has better filtration, and if worn properly the whole time it is in use, can provide a higher level of protection than a cloth or procedural mask. A mask or respirator will be less effective if it fits poorly or if you wear it improperly or take it off frequently. Individuals may consider the situation and other factors when choosing a mask or respirator that offers greater protection.

Do NOT wear cloth masks with

- · Gaps around the sides of the face or nose
- Exhalation valves, vents, or other openings (see example)
- · Single-layer fabric or those made of thin fabric that don't block light
- · Wet or dirty material

Figure 28: CDC Guidance Suggesting Gaps in Masks Can be Eliminated

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The CDC statement that masks should not be worn if gaps cannot be eliminated is meaningless because this cannot occur; only properly selected and fitted respirators can accomplish this.

Masks cannot ever obtain a perfect fit to the face and efficiencies of masks when worn in real world scenarios (day-long usage). When the mask has more than a 3% gap, it offers effectively zero protection (Figure 29):

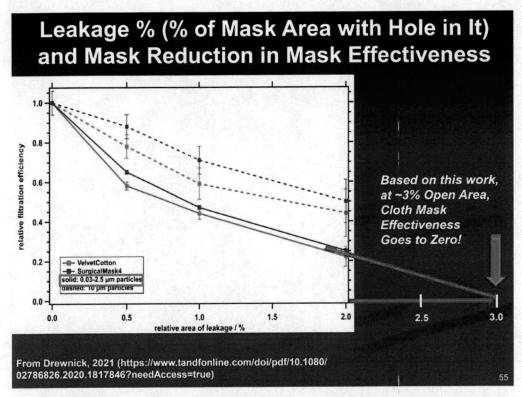


Figure 29: Loss of Mask Effectiveness in the Real World

Thus, the core issue with masks, and even respirators, is the seal – small gap areas effectively render these devices ineffective.

The American Society for Testing and Materials (ASTM) Standard Specification for Barrier Face Coverings F3502-21 Note 2 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."

As well as, importantly, Note 5, "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."

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Every breath increases atmospheric viral load, or the amount of viral matter held aloft in an enclosed space. In instances when it does not take very much of an airborne pathogen for vulnerable individuals to get sick, a contagious individual should not wear a mask or respirator that creates a concentrated plume of aerosols, thinking they are protecting others from their respiratory emissions.

Explosive force-generating events, such as coughs and sneezes, increase the pressure behind exhaled matter. Masks can exacerbate the spread of airborne pathogens by creating focused plumes of fine particulates, in turn increasing emission trajectory, with the added concern of aerosolization of droplets through the mask membrane.

Finally, what is now most concerning, is that public entities are taking CDC guidance and making respirators available for free (Figure 30):





Figure 30: "Free" Open Contaminated N95s Being Given Away to the Public at Grocery Stores

These entities, based on CDC guidance, likely and/or unknowingly, do not address the requirements of the Respiratory Protection Standard and causing additional harm to the public by such a lack of understanding. Inevitably, this practice will result in harm and liability to their employees and customers for improper distribution and storage of respirators under the RPS.

Conclusion:

The CDC has built a series of recommendations for masking that are inconsistent with the technical and medical literature. The policy and procedural recommendations exaggerate the benefits, while ignoring the limitations and harms, especially for children and the general population. In addition, the CDC has taken a policy position of "it might work" and "it can't hurt" and use selective and weak observational data in the place of actual controlled scientific study to justify inappropriate recommendations for masks and face coverings.

Recently, the CDC has deployed a respiratory protection policy (i.e., masks to N95s) that dismisses the key principles in any Safety and Health program regarding the use of respirators – namely the Respiratory Protection Program. There is no mention of potential risks if the respirator is not properly used or fitted correctly. Moreover, it is clear that respirators are not intended for use with children. In our profession, if PPE and respiratory protection guidance was to ever be delivered without risk identification, fit testing, and training, we would be liable for putting personnel in a high-risk scenario, which is what the CDC is doing with their policy.

We would ask the CDC to accept these basic industrial hygiene facts that we have presented, update their public guidance accordingly regarding the issue of droplets vs. aerosols, stop confusing the public regarding the effectiveness of masks, and stop implying respirators are acceptable for children, and to be given generally to the public. In addition, it is clear the CDC knows, or should know, that gaps between the face and mask are a major problem for real mask effectiveness and could never have met our industry's requirement of 90% relative risk reduction.

The CDC is doing enormous damage to science and scientists by allowing politics to dictate public health policy rather than actual science. Increasingly, and for good reason as we have illustrated, the public does not trust the CDC and its science; this must change.

We recognize that it is easy to judge from afar and know that you and your team are under tremendous stress during this period. Our desire is to see the CDC and our country succeed in these efforts. As such, instead of just being critical, we want to offer our time to your organization to find solutions together. We would be willing to collaborate in the creation of a competent plan that will be based on the Hierarchy of Controls and will be tailored to various work and living environments. We will also help develop data points we can use to monitor and measure this program to enable proper adjustments as needed.

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We look forward to your responses to our concerns as we continue to work to protect the public.

Sincerely:

Stephen E. Petty, P.E., C.I.H., C.S.P.*

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Exhibit 2

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

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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.

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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.

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Exhibit 3

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.