Exhibit 9

Masking: A Careful Review of the Evidence

Dr. Paul Alexander November 11, 2021

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Masking: A Careful Review of the Evidence

by Paul Alexander

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The question on whether to wear a face mask or not during the Covid-19 pandemic remains emotional and contentious. Why? This question about the utility of face coverings (which has taken on a talisman-like life) is now overwrought with steep <u>politicization</u> regardless of political affiliation (e.g. <u>republican or liberal/democrat</u>).

Importantly, the evidence just is and was not there to support mask use for asymptomatic people to stop viral spread during a pandemic. While the evidence may seem conflicted, the evidence (including the peer-reviewed evidence) actually does not support its use and leans heavily toward masks having no significant impact in stopping spread of the Covid virus.

In fact, it is not unreasonable at this time to conclude that surgical and cloth masks, used as they currently are, have absolutely no impact on controlling the transmission of Covid-19 virus, and current evidence implies that face masks can be actually harmful. All this to say and as so comprehensively documented by Dr. Roger W. Koops in a recent American Institute of Economic Research (AIER) publication, there is <u>no clear scientific evidence</u> that masks (surgical or cloth) work to mitigate risk to the wearer or to those coming into contact with the wearer, as they are currently worn in everyday life and specifically as we refer to Covid-19.

We present the evidence in full below. We also state that should adequate evidence emerge that supports the effectiveness of surgical and cloth masks in this Covid pandemic (or any similar type masks), then we will change our position and conclude otherwise. Our focus is on face

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any such evidence?

Orofecal transmission?

Understanding the transmission of this respiratory SARS-CoV-2 pathogen is also evolving given evidence of <u>orofecal spread</u> as having a potentially larger <u>contributor</u> role in <u>non-respiratory</u> <u>transmission</u> of Covid. As an example, a recent open-evidence review brief by Oxford researchers <u>(Jefferson, Brassey, Heneghan)</u> and its <u>publication in CEBM</u>, reveals the growing recognition that SARS-CoV-2 can infect and be shed from the gastrointestinal (GI) tract of humans. Orofecal spread demands urgent study and if orofecal spread is shown to be definitive and more consequential in Covid transmission, then this could impact mitigation strategies beyond those for respiratory transmission.

Where do we begin on masks? How about infection fatality rate/IFR?

Moreover, we are addressing here highly irrational, punitive, capricious, and groundless societal restrictions for a virus with an infection fatality rate (IFR), based on Stanford University John <u>Ioannidis's</u> calculations, of 0.05% in persons under 70 years old (across different global nations). Ioannidis's research was followed up recently by a reported non-institutionalized IFR in the state of Indiana (persons aged > 12 years) of 0.12% (95% CI 0.09 to 0.19) when age 40-59/60 years (reported in the <u>Annals of Internal Medicine</u>), and an IFR when < 40 years old of 0.01% (95% CI 0.01 to 0.02). Persons 60 or older had an IFR of 1.71% (overall IFR was 0.26%).

So why would we continue this way with these unsound and very punitive restrictive policies and for so long once the factual characteristics of this virus became evident and as alluded to above, we finally realized that its infection fatality rate (IFR) which is a more accurate and realistic reflection of mortality than CFR, was really no worse than annual influenza?

How did we get here?

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We lay heavy blame on our government leaders but argue that the so-called 'medical experts' who are part of Covid Task Forces and guidance panels have been largely unscientific, illogical, and irrational in their guidance and statements.

Untethered from the reality of things. In many instances just flat out misleading and wrong! The incessant campaign by the media that has worked to drive fear and hysteria in the public is also partly to blame. There appears to be an unholy alliance between the government bureaucrats, the aforementioned 'medical experts,' and a willing print and digital media. A vast lot of what these experts say on Covid makes no sense anymore, at times unhinged and lacking of any credibility.

In such incredibly important Covid-related input and guidance, these television medical experts and many government leaders have failed in profound and often unimaginable ways and we are left asking how they got things so very wrong. Is it that these medical experts do not read the science? Or maybe cannot understand the data or science? Which? They talk about following the science but seem blinded to it. They clearly don't follow the science else we would not be here. They seem to not understand the devastation they have visited upon the lives of so many.

We argue that the messaging by the media and medical experts initially suggested that all persons are of equal risk of severe illness from Covid infection. This is where it all went wrong and where societies were greatly deceived by those who should not have done that. We were never 'all' at equal risk. This was deeply flawed and has crippled the US and global nations since day one of this pandemic. This was and remains a flat-out falsehood (untrue) and it has driven irrational fear by the public. This clearly erroneous intimation has stuck in the minds of the public and severely impacted the public's perception of their risk and how they would move forward.

School closure policy mirrors face mask policy?

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low transmission rates and very low likelihood of spreading Covid virus among children (or of becoming severely ill from Covid), they have gone on and destroyed a year of the school lives of children due to these nonsensical medical experts and hysterical media and this will carry a huge long-term loss to our children. Who is going to pay for this?

What did CDC and NIH know about risk to children and when did they know it?

Did we have any data or science? Of course we did. <u>Quality research</u> "in the leading journal Nature estimated the Covid-19 survival rate to be approximately 99.995% in children and teens." We knew this very early on but that did not stop public health agencies and experts from deceiving or failing to inform about the true risk. A recent publication by CDC reported that among in excess of 90,000 students and staff in 11 <u>North Carolina school districts</u>, they found that in-school virus transmission was "very rare." A similar finding emerged in 17 <u>rural</u> <u>Wisconsin</u> schools.

<u>The Atlantic's Derek Thompson</u> wrote in January 2021 that "We've known for months that young children are less susceptible to serious infection and less likely to transmit the coronavirus. Let's act like it." This piece by Thompson was driven by CDC 'coming' out in the last week for school reopenings when the data was clear for a very long time that the risk was very low, if at all. Then we are, as is Thompson in his piece, provoked to ask, why did the media, our bureaucratic government leaders, and the medical experts seemingly collude to damage our children with their baseless school closures? Why did they deceive the public for so long? Catastrophic long-term losses for our children's educational but importantly, their social and emotional/psychological development has accumulated. We know that <u>suicides among children</u> have been escalating. <u>Parents are struggling</u> with the pandemic and homeschooling and children are failing out. This type of unfounded fear has been driven by the media "despite a <u>thousandfold</u> <u>difference</u> in risk between old and young." They always knew this but continued a bold-faced lie! As a result, this has underpinned an atmosphere of gross distrust of our government officials and medical experts.

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Why this substantially reduced risk? We are not yet entirely sure but preliminary research points to <u>less expression of ACE2 receptor proteins</u> on the surface of the nasal epithelium in children (4-9 years old). This is well known globally for many, many months that children are at <u>very low</u> <u>risk</u> of <u>spreading infection to their classmates</u>, to their adults, teachers, or <u>even taking it home</u>. Secondary transmission evidence is nonexistent. Based on a high-quality McMaster University review, researchers found that "<u>Transmission was traced back to community and home settings</u> <u>or adults</u>, rather than among children within daycares or schools, even in jurisdictions where schools remained open or have since reopened."

International research had been clear that there was <u>no consistent relationship</u> between inperson schooling for children and virus transmission. Any medical expert or agency implying otherwise that this is new science and 'we now understand the data' or 'the data is now available' is flat out duplicitous. But why has this happened to our children yet did not happen for seasonal influenza each year which is far more deadly than Covid for children? Or for H1N1 when it struck in 2009? Were decisions made based on evidence or other factors?

Who is at fault here? What was the reason for this very flawed policy? It surely is not based on science. Why has the CDC and other US health agencies such as the NIH been so slow to react to the known science (strong evidence from <u>Norway. Ireland</u>, <u>Singapore</u>, <u>North Carolina</u> etc.) and thus guide the optimal policy decisions based on this clear prior accumulated science (<u>Washington Post piece</u> September 2020, <u>The Atlantic</u>, October 2020)? These health agencies had the evidence but continued advocating devastatingly flawed school closure policies that have damaged our children. Just look at the repeated sparring between <u>Senator Rand Paul</u> and Dr. Anthony Fauci whereby the senator has been ongoingly <u>pilloried by the media</u> for calling out Dr. Fauci who has routinely <u>changed statements</u> and been confusing on a range of issues and particularly on the issue of <u>school closures</u>. Dr. Fauci replied: "We don't know everything about this virus, and we really ought to be very careful, particularly when it comes to children." Surely Dr. Fauci was aware of the global Covid data as it related to risk in children.

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arrogant, and nonsensical medical experts caused?

The truth also is that many children – and particularly those less advantaged, our minority, our African-American, Latino, and South Asian children – get their main needs met at school, including nutrition, eye tests and glasses, and hearing tests. Importantly, schools often function as a strong protective system or watchguard for children who are sexually or physically abused and the visibility of it declines with school closures.

Due to the lockdowns and the lost jobs, adult parents are very angry and bitter, and the stress and pressure in the home escalates due to lost jobs/income and loss of independence and control over their lives as well as the dysfunctional remote schooling that they often cannot optimally help with. Some are tragically reacting by lashing out at each other and <u>their children</u>. There are even reports that children are being taken to the ER with parents stating that they think they may have killed their child who is unresponsive.

In fact, since the Covid lockdowns were initiated in Great Britain as an example, it has been reported that incidence of abusive head trauma in children has risen by <u>almost 1.500%!</u> Similar catastrophic head trauma in babies that is linked to the Covid pandemic has been reported in <u>Canada</u>! There has been a devastating trend in Ottawa, Canada hospitals with a rise in the number of little children and babies being seen with catastrophic head injuries during the second wave of Covid-19. Covid-19 has cost lives and our government leaders and health agencies with television medical experts are partly to blame for their nonsensical and seemingly politicized decision-making that had no scientific basis. Look at what they have done!

Sadly, our children will bear the <u>catastrophic consequences</u> and <u>not just educationally</u>, of the <u>deeply flawed</u> school closure policy <u>for decades</u> to come (<u>particularly our minority</u> <u>children</u> who were least able to afford this). They have done this, the CDC, NIH etc. have cost children lives and done immeasurable damage to our children by increasingly recognized deeply destructive, and nonsensical policies.

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mask-use and other mandates. Are we to believe that all aspects of the pandemic's response i.e. lockdowns, masking, vaccine etc., are fraught with these policy irregularities and aberrancies that are devastating to the public? As an example, we have doctors presently trying to mainstream <u>early outpatient treatment</u> for Covid in high-risk patients using established safe, cheap, effective, and available drugs but getting pilloried by the nihilistic medical experts and establishment. Such early ambulatory sequenced and combination treatment is a potential option that may reduce hospitalization and death.

Questions on masking mirrors questions on social distancing?

Specifically, from what sources did the CDC rely upon to designate that a distance of 6 feet between individuals is needed to mitigate Covid viral spread? And why, for example, do Europeans from various countries only have to stand about 1 meter apart (<u>approximately 3 feet</u>)? Do they know something that we don't? Or were both values arrived at arbitrarily? Were these recommendations based on evidence or were they set arbitrarily? If the latter, then why not 4 feet, 10 feet or 20 feet? Turns out "the <u>World Health Organization</u> recommends a distance of "at least one meter (3.3 feet)." China, France, Denmark and Hong Kong went with one meter. South Korea opted for 1.4 meters; Germany, Italy and Australia for 1.5 meters.

The <u>CDC said 6 feet</u> and we still don't know how they arrived at this distance and yet this pandemic has been active since at least February 2020. Unfortunately, then we can similarly at best only make unsound and disingenuous statements in favor of the use of masks but which are not backed with evidence or data. Yet the issues at hand are so serious given large societal implications and reorganization that it is difficult to reconcile with logic the absence of any such studies.

Focusing on face masks

With a focus on facial masks, where do we stand? Well, our position is based on the science. We contend that surgical and cloth masks are basically facial coverings that lack any scientific data

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the filtration potential of a N95 mask is 150-300 nanometers. We also suggest that such fitting would actually be needed as a person places a fresh mask on their face, in order to retain functionality of the N95 respirator. Perhaps, it is important to note that the "N95" terminology means that the mask filters 95% of the particulate material. Moreover, prolonged use of fitted N95 type masks (particulate filtering facepiece respirators) are uncomfortable, and <u>can</u> <u>potentially cause harm</u>.

In light of the above we hold that most of the populace would favor the use of the typical surgical 'blue' masks (or worse; cloth masks or home-made cloth masks) and even considering the fit issues discussed here regarding N95 masks, they cannot provide similar protection (from being infected or passing on infection) as might N95s.

There is simply no defensible rationale to treat this pandemic other than using an age and risktargeted approach and fostering optimal hand washing hygiene. The vastly rational and sensible way is to target high-risk people (i.e. those at risk of developing severe disease and/or dying) and allow everyone else to get on with their lives. We ensure hospitals are well prepared (we hope) and we have had one year to do this as outlined by our governments when they asked us to help 'bend the curve,' and we simultaneously triple down on protecting the high-risk persons.

With this in place, we strive to safely and with sensible precautions, reopen society and schools in full. It is as simple as that, and on top of this, we have strong evidence of the use early on of repurposed existing, safe, cheap, and effective therapeutics in higher-risk Covid positive persons in private homes or nursing home settings who are showing initial symptoms. When used <u>early in</u> <u>the outpatient setting</u>, these drugs (sequenced combined antivirals, corticosteroids, and antithrombotic anti-clotting drugs) can help reduce isolation, mitigate transmission, and cut hospitalization and death significantly.

The implications of the policies like restrictions and masking are far-reaching and such policies must be based on evidence. The current policies cause crushing harms to our societies and cannot be based on the notion of stopping Covid at all costs. Stopping Covid at all costs without

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reliable data or research.

In an article published in <u>Nature Communications (November 2020) that studied 10 million eligible</u> <u>persons</u>, it was demonstrated that asymptomatic spread was not merely rare but in fact, does not appear to happen at all! Not one instance was found in the study whereby researchers reported that there were positive tests emerging even amongst close contacts of asymptomatic cases in this sample of 10 million. Why would we even consider then the need for universal masking when there is evidence like this of limited asymptomatic spread?

We also point out (and we also recognize and appreciate that this argument is far from being one based in strong evidence per se) that if ten's of studies or more are required to prove, one way or another, whether a procedure is effective or not (and to therefore lead to changes in standard of care), and there are still no reliable data, the effects are either minimal or nonexistent. Hence it can be reasoned that there is no meaningful effect in the first place; such an argument can be used for the masking dilemma.

All this is to say that there is and was no scientific justification to mandate or call for 'voluntary' masking of healthy people. None! And we also suggest that this straightforward reasoning can be applied to most of the other 'mitigation' efforts being implemented to date; specifically societal lockdowns, and school closures. In fact, we can find no definitive research-based evidence to support masking, societal lockdowns, or school closures at the time of writing this piece. We continue to argue that most of this has been arbitrarily construed by the government leaders and their medical experts.

These policies are not merely misguided, but they are also not without serious and adverse consequences; they have caused crushing harms and have been very injurious at a personal and societal level. Restrictive policies have not been thought through as to the implications at large! The benefits have not been assessed or considered alongside the potential (and documented) harms and this is a catastrophic omission from the perspective of sound public health policy and principles. In short, the bureaucracy has provided us with confused and often contradictory

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evidence-informed decision-making were ignored entirely.

Double masking?

Moreover, Dr. Anthony Fauci of the NIAID is now supporting (or at the least not discouraging) the call for the use of double masks! To paraphrase him, it makes 'common sense' to wear two masks instead of one. Yet this flies in the face of the extant data showing that the use of single masks has not provided any protection insofar as progress of the pandemic is concerned (in fact just the opposite... in virtually every jurisdiction in which mask wearing was mandated, there were very large increases in the rates of infection or at least PCR positivity to be more accurate). Despite this Dr. Fauci has responded by raising the double-mask approach, stating that <u>"it likely</u> <u>does"</u> work in relation to offering more protection.

What happened to "following the science" and the need for randomized controlled trials on the use of double masks? It seems that we follow the science only when it supports preconceived notions or goals. What was stated on double masking was utter nonsense. Dr. Fauci likely did not read the <u>marine recruit CHARM NEJM study</u> whereby the recruits consistently wore double layered masks yet there was still spread in the most heavily, monitored for compliance, and restricted to military environments.

Did Dr. Fauci also consider the possibility that with double masks, wearers will likely experience more difficulty in simply breathing comfortably? And what would be the consequences for those with pulmonary diseases, upper respiratory infections, others with difficulty breathing without a mask, and most importantly for children? Wearing a mask, let alone two, potentially simulates COPD/chronic obstructive pulmonary disease, akin to what smokers commonly get. Masks can make it difficult for one to breathe out, especially during stressful situations. We cannot say here because we don't know, absent scientific data, but neither does Dr. Fauci. At worst the advice regarding the use of double masking (why not triple or even four or five masks?) is arbitrary and has no scientific basis. Then why put it out there? This reflects a dissonance to anything that disrupts the set narrative that at this stage of the pandemic happens to be more political in our

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As noted above, the data show that Dr. Fauci's confusing about-faces concerning advice as to management of the pandemic issues, including on masking, was perhaps arbitrary at best. As regards to masking, it is simply impossible to understand ongoing recommendations for this when we know that there are multiple US States where it can be shown clearly that after implementing mask mandates (indoor and outdoor), the number of cases went up! We are not suggesting that the addition of mask mandates in any way caused case numbers to soar, but clearly they had no positive or beneficial effects either. There are <u>37 US states</u> including but not limited to California, Texas, Hawaii, <u>Maine, Delaware, Florida, Oregon, and Pennsylvania</u> that currently mandate face coverings in public. Outside of the USA, there are also global data showing that when <u>mask mandates</u> were implemented in Austria, Germany, France, Spain, UK, Belgium, Italy, to name only a few, case numbers went up, not down.

Moreover, the <u>EPOCH Times</u> reported that "in states (US) with a mandate in effect, there were 9,605,256 confirmed Covid-19 cases, which works out to an average of 27 cases per 100,000 people per day. When states didn't have a statewide order—including states that never had mandates, coupled with the period of time masking states didn't have the mandate in place—there were 5,781,716 cases, averaging 17 cases per 100,000 people per day; a notable reduction as compared to the number of cases observed during mask mandates! States with mandates in place produced <u>an average of 10 more reported infections per 100,000 people per day</u> than states without mandates." The blind acceptance of the current unsupported dogma that has become so entrenched that if cases do go up, the experts wedded to the universal use of masks claim that this is good news such that the masking prevented even more cases from occurring; this is truly incredible.

The reality is that there is significant evidence that masks are not effective for controlling a pandemic. To reiterate we agree, though, that within the context of a clinician treating an obviously infected patient (with any communicable disease), the use of masks is important but even then this must also be augmented by the use of other PPE (goggles, and even hazmat clothing with isolated oxygen supplies for example) and this simply cannot be compared to

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regard to the use of masks to prevent spread of disease, and we also argue that this evidence is very pertinent to the virus (SARS CoV-2) associated with Covid-19 disease.

Overall, the available research on the use of masks to mitigate transmission of pathogens in a pandemic is of very poor methodological quality using largely indirect unadjusted evidence, and not the optimal clinical research that is needed. A major limitation is the use of the same evidence base by all reviews and thus arrival at similar findings. However, this low-quality evidence is what we have and is, we believe, still useful enough to guide and inform us.

At the same time, we do recognize the urgent need for well-designed clinical research in order to address as definitively as possible questions pertaining to the utility of face masks in curtailing or stopping spread of Covid-19 (and future similar respiratory 'pandemic' pathogens). In fact, we find it remarkable that researchers have not been commissioned to develop adequate studies on the use of face masks to prevent the spread of SARS CoV-2 by asymptomatic people. It's also noteworthy that there have also been no reliable studies that can demonstrate one way or the other whether social distancing truly can be used to impede viral spread, especially in asymptomatic people.

It appears that this issue is now fraught with politics and agendas promulgated by a wide array of medical experts on television and the media as opposed to being related to a reliable base of knowledge. We suggest that various populations are being hurt by this type of 'academic sloppiness,' which feeds into what we would call the reckless behavior of many experts and illinformed media outlets who rely on these authorities. Conclusions around the use of masks during the Covid pandemic (and other actions that have been taken but are not addressed here in detail such as lockdowns and school closures) are often baseless and we submit that the research community has not studied the mask issue appropriately, principally because they are reticent and possibly even wary as to what the findings might reveal. After all, those who object to masking are often immediately labeled as 'deniers' and heretics.

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dismissive of mask use) under the notion that in fact the experts were intentionally saying these things so as to prevent runs on surgical masks that were in short supply at the time and needed by healthcare workers. We put forward the notion that this is not the case and that in fact at that time, the experts actually were relying on available data as alluded to above. All this is to say that such changes in advice provided by top medical experts only served to confuse a public desperately in need of honesty and optimal guidance.

In relation to the above we point out that the <u>World Health Organization (WHO)</u> stated that "the widespread use of masks by healthy people in the community setting is not yet supported by high quality or direct scientific evidence and there are potential benefits and harms to consider."

A strong argument against the use of masks in the current Covid-19 pandemic gained traction when a recent <u>CDC case-control study</u> reported that well over 80% of cases always or often wore masks. This CDC study further called into question the utility of masks in the Covid-19 emergency.

A recent publication asserts that face masks become nonconsequential and do not work after 20 minutes due to <u>saturation</u>. "Those masks are only effective so long as they are dry," said Professor Yvonne Cossart of the Department of Infectious Diseases at the University of Sydney." As soon as they become saturated with the moisture in your breath they stop doing their job and pass on the droplets." In a similar light, there are indications that wearing a mask <u>that is already used</u> is riskier that if one wore no mask.

Moreover, accumulating data and evidence *in toto* suggests a lack of evidence to support mask use (in adults or children) including any broad mask mandate. For example, the <u>CDC</u> in its examination of Nonpharmaceutical Measures (NPIs) for Pandemic Influenza in Nonhealthcare Settings, <u>Oxford's CEBM</u>, <u>CIDRAP and policy</u> questions unsound mask data, <u>Klompas (NEJM) and</u> <u>universal masking</u>, <u>Jefferson et al.</u>, <u>CDC 2</u>, Brainard et al.'s research on preventing respiratory illness (<u>Norwich School of Medicine</u>), <u>Marks's Covid-19 transmission clusters in</u>

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in the transmission of laboratory-confirmed influenza and we hold that these findings could be extrapolated to SARS-CoV-2.

Researchers from the University of Oxford's Center for Evidence-Based Medicine

(CEBM) examined the data regarding the effectiveness of the use of masks within the current highly charged backdrop of politics. They concluded that after nearly 20 years of preparedness for coming pandemics, the evidence on face mask use remains very conflicted. They <u>examined</u> <u>evidence</u> that revealed that "<u>masks alone have no significant effect in interrupting the spread of ILI or influenza in the general population, nor in healthcare workers.</u>" They ask why had the correct applicable comparative effectiveness research not been conducted and we agree, that is, until the recent marine study (<u>NEJM publication</u> (CHARM study) and <u>the Danish study published in the Annals of Internal Medicine</u> which we describe. The Oxford researchers also speculate that there is likely and elevated rate of harm (infection) when <u>using cloth face masks</u>. They looked specifically at 6 RCTs in 2010 that examined face masks in respiratory viruses whereby 2 studies were in healthcare employees and 4 were in family and student groups. The trials for ILI showed <u>very poor mask wearing compliance</u> and seldom reported the harms that might be associated with the use of masks (harm evidence to be presented later in this discussion). Taken together though this fits with the premise outlined above where we state that if masking could be used to effectively prevent viral spread, there would have been clear evidence by now.

In 2013, the <u>Canadian Agency for Drugs and Technologies in Health</u> (an Agency specializing in Systematic Review/Meta-Analysis), stated: "<u>No evidence was found</u> on the effectiveness of wearing surgical face masks to protect staff from infectious material in the operating room, no evidence was found to support the use of surgical face masks to reduce the frequency of surgical site infections, and guidelines recommend the use of surgical face masks by staff in the operating room to protect both operating room staff and patients (despite the lack of evidence)."

Similarly, <u>Jefferson et al.</u> studied physical interventions to interrupt or reduce the spread of respiratory viruses (updating a prior Cochrane review (2011) to include 15 RCTs (n=13,259 persons) exploring the impact of masks (14 trials) in healthcare workers, the general population and those

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was considered to be of 'low' quality based on included study limitation, even though these were RCTs, and they were plagued with serious methodological concerns.

<u>Marks et al. reported on transmission clusters of Covid-19 in Catalonia, Spain</u> (post-hoc analysis of data collected in the BCN PEP CoV-2 Study), looking at a cohort that was part of a RCT (314 patients with Covid-19, with 282 (90%) having at least one contact, 753 contacts in total, resulting in 282 clusters. Ninety (32%) of 282 clusters had at least one transmission event). Researchers reported no association of risk of transmission with mask usage by contacts.

The <u>New England Journal of Medicine (NEJM)</u> recently published an article on Covid-19 and masks which appeared to suggest that masks have become no more than a <u>psychological crutch</u>, and stated that "We know that wearing a mask outside health care facilities offers little, if any, protection from infection. Public health authorities define a significant exposure to Covid-19 as face-to-face contact within 6 feet with a patient with symptomatic Covid-19 that is sustained for at least a few minutes (and some say more than 10 minutes or even 30 minutes).

The chance of catching Covid-19 from a passing interaction in a public space is therefore minimal. In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic." <u>They also stated that</u> "it is also clear that masks serve symbolic roles. Masks are not only tools, they are also talismans that may help increase health care workers' 'perceived' sense of safety, well-being, and trust in their hospitals. Although such reactions may not be strictly logical, we are all subject to fear and anxiety, especially during times of crisis. One might argue that fear and anxiety are better countered with data and education than with a marginally beneficial mask."

A recent <u>WHO-sponsored systematic review and meta-analysis</u> published in the Lancet included 39 nonrandomized observational studies (weaker study designs) that were not always adjusted fully for confounders and reported that face masks *could* be effective. These studies had small sample sizes with small event numbers, and were plagued with potential selection bias and residual confounding bias. The body of evidence was judged to be of low quality and was also

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ii) failure to consider the randomized evidence

iii) 25 included studies are about the SARS-1 virus or the MERS coronavirus, both of which have very different transmission characteristics than SARS-CoV-2: they were transmitted almost exclusively by severely ill hospitalized patients and there was no assessment of community transmission; a serious concern in regard to the issues being discussed in this document

iv) of the 4 studies relating to the SARS-CoV-2, 2 were misinterpreted by the authors of the <u>Lancet meta-study</u>, 1 is inconclusive, and 1 focused on the impact of using N95 (FFP2) respirators which is irrelevant insofar as community transmission, especially in regard to asymptomatic people and also did not address the use of medical grade or cloth masks

v) this <u>review</u> is being used to guide global face mask policy for the general population whereby one included study was judged to be misclassified (relating to masks in a hospital environment), one showed no benefit of face masks, and one is a poorly designed retrospective study about SARS-1 in Beijing based on telephone interviews. None of the studies refer to SARS-CoV-2.

Similarly, a recent study published in <u>PNAS</u> surrounding airborne transmission and face masks has also provoked substantial consternation and argued to be a politically motivated study more than a scientific one. It has led to over 40 leading scientists calling for its withdrawal due to it being <u>very flawed</u> because of the use of very suboptimal statistical analyses.

A review by the <u>Norwich School of Medicine (preprint)</u> studied the effectiveness of wearing face masks and examined 31 published studies of all research designs. They reported that "the evidence is not sufficiently strong to support widespread use of face masks as a protective measure against Covid-19. However, there is enough evidence to support the use of face masks for short periods of time by particularly vulnerable individuals when in transient higher risk situations."

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impact of mask-use in regard to the rate of infection with SARS CoV-2.

Interestingly, these results emerged in a setting where social distancing and other public health measures were in effect, except for mask-wearing. In point of fact, the use of masks in this population was in general quite low. In any case, based on these findings it might be expected on the basis of this study alone that there would be serious doubt raised as to the need for the initiation and maintenance of mandatory use of masks in the public domain. Unfortunately, as of this date, this does not seem to be the case and is inexplicable quite frankly.

Additionally, with a focus on cloth face masks, recent reports suggest that they should never be used as a protective barrier as they offer no transmission protection (as PPE or as source control; see <u>Tokyo report</u> and <u>BMJ study</u>).

In the <u>BMJ cluster randomized study</u>, researchers sought to compare the efficacy of cloth masks to medical masks in hospital workers (in 14 Vietnamese hospitals utilizing 1,607 workers over 18 years of age). Wards were randomized so that in some, medical masks were worn while in other wards cloth masks were used. Another ward was assigned as a control group for 'usual practice' which included the use of masks on every shift for 4 consecutive weeks. The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% Cl 1.69 to 100.07) compared with the medical mask arm. There were also significantly higher rates of ILI in the cloth mask group as compared with the control arm.

An analysis by mask use showed that ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth mask group compared with the medical mask group. Researchers found that penetration of the cloth masks by particles was in the range of 97% (filtering out only 3% of viral particles) and for medical masks, it was still only 44%. This being the first RCT of cloth masks, the researchers cautioned against the use of cloth masks. There is extensive moisture retention and poor filtration with reuse which results in

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respiratory symptoms who are not in near contact with people who are known to be infected."

In a May 2020 communication report in <u>Nature</u> (Medicine), Leung et al. examined the importance of respiratory droplets as well as aerosol routes of spread with a specific focus on coronaviruses, influenza viruses, and rhinoviruses. They measured the quantity of respiratory virus in exhaled breath of participants with acute respiratory infections (ARIs) and determined the possible efficacy of surgical face masks to prevent respiratory virus transmission.

As part of the study, they screened 3,363 persons in two study phases, eventually enrolling 246 participants with ARI who provided exhaled breath samples, with 122 (50%) of the participants being randomized to either not wearing a face mask during the first exhaled breath collection or randomized to wearing a face mask (n=124 (50%)). Seasonal human coronaviruses, influenza viruses and rhinoviruses within exhaled breath and coughs of children as well as adults with ARI were identified. In this study, it was found that surgical face masks can significantly reduce detection of influenza virus RNA in respiratory droplets and coronavirus RNA in aerosols, and with a trend toward reduced detection of coronavirus RNA in respiratory droplets. Their results suggest that surgical masks can potentially reduce the release of influenza virus particles into the environment in respiratory droplets, but not in aerosols. And it must be emphasized that this study relied on people who had symptomatic disease, something vastly different from the issues under consideration here.

Perhaps one of the most seminal and rigorous studies (along with <u>the Danish study published in</u> <u>the Annals of Internal Medicine</u>) emerged from a United States Marine Corps study performed in an isolated location; Parris Island. As reported in a recent <u>NEJM publication</u> (CHARM study), researchers studied SARS-CoV-2 transmission among Marine recruits during quarantine. Marine recruits at Parris Island (n=1,848 of 3,143 eligible recruits) who volunteered underwent a 2-week quarantine at home that was followed by a 2nd 2-week quarantine in a closed college campus setting.

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More specifically, of the 1,801 recruits who tested negative with PCR at study enrollment, 24 (1.3%) tested positive on day 7. On day 14, a total of 11 of 1,760 (0.6%) of the previously PCR-test negative participants tested positive; none of these participants were seropositive on day 0. As such, 35 participants who had had negative PCR test results within the first 2 days post arrival at the campus then became positive during the strict supervised quarantine. Of the 51 total participants who had at least one positive PCR test, 22 had positive tests on more than 1 day. Phylogenetic analysis was conducted whereby 6 independent monophyletic transmission clusters (independent viral strains) indicative of local transmission were uncovered during the supervised quarantine. The majority of clusters principally included members of the same platoon, and numerous infected recruits had an infected roommate.

The <u>authors reported</u> that about 2% who had earlier negative tests for SARS-CoV-2 at the beginning of strict supervised quarantine (we ask the reader to think; *military grade supervision*), and less than 2% of recruits who had unknown prior status, tested positive by day 14. Positive volunteers were mainly asymptomatic and transmission clusters occurred within platoons. The predominant finding was that despite the very strict and enforced quarantine (including 2 full weeks of supervised confinement and then forced social distancing and masking protocols), the rate of transmission was not reduced and in fact seemed to be higher than expected! Hence, we point out that not only was masking ineffective in preventing the spread of disease, but even *made things* worse. Despite quarantines, social distancing, and masking, in this cohort of mainly young male recruits, roughly 2% still went on to become infected and tested positive for SARS-CoV-2. Sharing of rooms and platoon membership were reported risk factors for viral transmission.

As with the Danish investigation this study of Marine recruits who were kept under stringent military level supervision raises serious questions about the utility of quarantines, as it appears that not only do masks appear to be ineffective in preventing communal disease spread but also that quarantines do not work even when supervised for 2 weeks in a closed college. As we have <u>stated elsewhere</u>, it seems that quarantines are ineffective and that would also seem to include enforced social distancing! At the risk of repeating ourselves, all this is to say that in this

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mask in reducing contamination varied with the mask's shape, the materials of which the masks were made, and the way the masks were worn. Importantly, it was shown that wearing a mask did not reduce incidents of contamination in the theatre. In fact, results suggested the opposite in that wearing no mask correlated with the greatest reductions in contamination (also associated with performing the operations under conditions of silence... no speaking by the staff during any of the procedures).

A publication in Annals of Internal Medicine by Bae et al. "<u>Effectiveness of Surgical and Cotton</u> <u>Masks in Blocking SARS-CoV-2</u>" was retracted on a request by the ACP journal. We are thus unable to comment on the findings.

Based on the foregoing evidence cited above, we find no conclusive evidence to support the use of masks for Covid-19 (except N-95 type masks in a hospital setting and when appropriately fitted and utilized). In fact, masking appears to carry substantial risks to the user. And we reiterate that our conclusions are not based on the absence of evidence for ineffectiveness alone, but actual evidence of ineffectiveness.

And we reiterate that our conclusions are not based on the absence of evidence for ineffectiveness alone, but actual evidence of ineffectiveness.

Possibly the one study that could only be construed as pseudo-science, is based on a recent MMWR by the <u>CDC</u> on the use of double masks, this even after Dr. Anthony Fauci backtracked and said there is <u>no evidence that this is effective</u>. This is why this study was left for last in our review. Along comes the CDC with a study on maximizing fit for cloth and medical procedure masks by placing a cloth mask over a surgical mask and knotting the ear loops of a medical procedure mask and then tucking in and flattening the extra material close to the face. A pliable elastomeric head form was used to simulate a person under various conditions e.g. coughing etc. CDC reported that "the unknotted medical procedure mask alone blocked 42.0% of the particles from a simulated cough (standard deviation [SD] = 6.70), and the cloth mask alone blocked 44.3%

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impede breathing or obstruct peripheral vision for some wearers, and knotting and tucking can change the shape of the mask such that it no longer covers fully both the nose and the mouth of persons with larger faces". We are then left to ask, what was the purpose of this publication if it cannot be generalized to real-world settings and may impact breathing? Incidentally, in the <u>SARS-</u> <u>CoV-2 Transmission among Marine Recruits during Quarantine (CHARM) study</u> on Parris Island, the military recruits used double-layered masks and findings were that masks and social distancing did not stop spread of COVID infection.

What about possible harms from wearing masks?

But what about harms from mask use? The information that is accumulating involves mask wearers within a Covid-19 environment and raises many concerns especially regarding <u>psychological damage</u> and especially <u>to infants</u> and children, with potential catastrophic impacts on the <u>cognitive development of children</u>. This is even more critical in relation to children with special needs or who are on the autism spectrum who need to be able to recognize <u>facial expressions</u> as part of their ongoing development. The accumulating evidence also suggests that prolonged mask use in children or adults can cause <u>harms</u>:

i) difficulty with breathing

ii) <u>inhalation of toxic substances</u> such as microplastics and chlorine compounds located in the masks (these are potentially serious risks)

iii) <u>CO₂ intoxication</u>

- iv) sudden cardiac arrest seen in children
- v) a <u>reduction in blood oxygenation (hypoxia)</u> or an elevation in blood CO2 (hypercapnia)

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x) anxiety and sleep problems, benavioral disorders and tear of contamination in children

xi) <u>deoxygenation during surgery</u>

xii) potentially life-threatening damage to the lungs (e.g. <u>Stanford engineers</u> report that masks can make it much more difficult to breathe, estimating that N95 masks as an example, reduce oxygen intake from 5% to 20% and if worn for a prolonged period)

xiii) as reported by <u>Koops</u>, facial skin infections, nose/throat and sinus infections, a change in breathing patterns.

Predominant finding?

The predominant conclusion is that face masks have a very important role in places such as hospitals, but there exists very little evidence of <u>widespread benefit for members of the public</u> (adults or children) as well as evidence that masking is truly an ineffectual way to manage pandemic-related spread of viral disease. As <u>Kolstoe stated</u>, it has become less about the science and <u>more about politics</u> and a symbol of <u>solidarity</u>.

Our view is that masks as they are worn now, and the masks that are in use, offer zero protection. They can be viewed as ineffective while others consider them as being <u>better than nothing</u> but without evidence to support that view. Masks are not sealed properly to the face and do not effectively stop virion penetration. We state emphatically that public health policy, or any policy for that matter, must be undergirded by sound data and evidence. As we have said, the reality is that widespread use of masks is not supported by science and in fact just the opposite. This mask hysteria is driving unnecessary fear in the population and must end. Those who deliver statements relentlessly on the use of masks are doing so without the luxury of any credible evidence to support those views. They speak on assumption or speculation and this is not science! However, it is important to understand that as we await definitive research, given the situation and the desire to prevent spread to higher-risk persons (e.g. elderly), when

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It is very sensible that one would use a face mask when visiting an elderly person who is highrisk or even if the setting is controlled such as a healthcare setting in a nursing home. This makes complete sense (even though again, we know that evidence does not support this notion)! It is reasonable to be cautious, even in the light of limited or nonexistent evidence (especially strong peer-review evidence) of effectiveness and the increasing information suggesting that there's now evidence of harms related to mask (over)use. Situation-by-situation decisions can be made that depend on the risk at hand. The full context must be considered but if you are adequately socially distanced, there is no reason to wear a mask. There is no evidence for this. Though we would also contend that one should wear a mask if that is what is expected but adhere to meticulous hand hygiene and socially isolate if ill.

<u>Danish reporting of a higher-quality mask study</u> on Covid and masks that was actually rejected or sidelined by top journals including *Lancet*, *New England Journal of Medicine*, and the American Association's JAMA is alarming if true and suggests a pattern of politicization of research and of the medical community, journal editors and the peer-reviewers. We look forward to its future publication.

Conclusion

In closing, perhaps <u>Yinon Weiss, who is a U.S. military veteran</u>, and who holds a degree in bioengineering from U.C. Berkeley, captures our current face mask calamity by reminding us how masks constrain our return to a more normal life. As outlandish as this might seem could this be the aim of those using the pandemic for the purpose of advancing various political ideologies? Masking drives fear in the population and a perennial sense of 'illness' that is crippling. As stated eloquently by <u>Weiss</u>, "Our universal use of unscientific face coverings is therefore closer to medieval superstition than it is to science, but many powerful institutions have too much political capital invested in the mask narrative at this point, so the dogma is perpetuated."

Our paper sought to examine the complete and most updated mask-related scientific evidence, along with anecdotal data and reports. Our current belief remains that asymptomatic individuals

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and a gown. A mask alone will not prevent health care workers with early Covid-19 from contaminating their hands and spreading the virus to patients and colleagues. Focusing on universal masking alone may, paradoxically, lead to more transmission of Covid-19 if it diverts attention from implementing more fundamental infection-control measures."

In sum, when we look at the science, there is emerging and troubling evidence of harms from mask use in the absence of any benefits. This is also related to things as mundane as simple incorrect use of masking, as well as the development of complacency that emerges due to mask use and thus the relaxation of other mitigation steps, as well as mask contamination.

We also cannot discount the possible harms on our immune systems and general health from such constant and prolonged use of masks, given we have never done this before. We are in uncharted territory and especially so with the possible implications for our children. Their immune systems are still being developed and we are forcing lockdowns, school closures, and masking on a developing child and we have no prior experience on the subsequent outcomes pertaining to children's development, health, and well-being.

Most discomforting is that those government bureaucrats in charge and particularly the 'medical experts' continue to fail to admit they were exceptionally incorrect with regard to most of what they have stated in terms of pandemic policies and response related to the Covid pandemic. They have harmed the very societies they are supposed to help protect. They have failed to look at the evidence or follow it, and continue to operate in an arbitrary nonscientific, nonevidence informed manner. They 'attack,' with the assistance of the mass media, those of us who question their policies and actions despite the disastrous outcomes of those public health policies. Indeed, we are often blamed for the failures (called 'deniers' or 'heretics') and crushing harms of all of their policies when it has actually been their specious, illogical, and unsound actions and recommendations that <u>deserve public outcry</u>.

Suggested points to consider

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e.g. elderly or if you are in a health care setting e.g. hospital or nursing home, long-term care facility, assisted-living facility, care home etc. This will also limit the spread of bacteria etc. to high-risk persons but again it must be stressed that this pertains most specifically to those visitors who have active symptomatic disease as opposed to those who are entirely asymptomatic

iv.) Children are at very low risk of acquiring SARS-CoVC-2 virus, or getting severely ill from infection; they are at also very low risk of spreading to other children, or to adults, and their teachers etc. Children should not be masked under any condition and only in instances when they are high-risk (immunocompromised), have contributory medical conditions.

v) Children must be allowed to interface with their natural environments (environments in general) so that their immune systems remain constantly taxed and 'tuned up' and is optimal for immune system development as well as their cognitive development, particularly in children with special needs such as autism

vi) People who are "post-convalescent" Covid should not wear masks. People with Covid-19, if they must be in the presence of others, should wear masks, although only minorly helpful at best.

vii) We implore that all government leaders and so-called medical experts include riskbenefit analyses each and any time they seek to advocate for or implement societal policies. We must have evidence of the benefits as well as harms and examine the trade-offs and most importantly, consider the implications to the public. If the policy is destructive, you end it!

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