

Date:

To Whom It May Concern:

I am sending you this notice, on behalf of Daniel Fidalgo. My findings raise significant concerns, both medically and legally, of the current mask policy in place. Masks are ineffective for the purpose claimed by the mandate, potentially harmful, and only authorized for use by an EUA.

**Masks are ineffective and in many ways they harm.**

It's a myth that masks prevent viruses from spreading. The overall evidence is clear: Standard cloth and surgical masks offer next to no protection against virus-sized particles or small aerosols.

1The size of a virus particle is much too small to be stopped by a surgical mask, cloth or bandana.

A single virion of SARS-CoV-2 is about 60-140 nanometers or 0.1 microns.<sup>2</sup> The pore size in a surgical mask is 200-1000x that size. Consider that the CDC website states, "surgical masks do not catch all harmful particles in smoke." And that the size of smoke particles in a wildfire are ~0.5 microns which is 5x the size of the SARS-CoV-2 virus! Wearing a mask to prevent catching SARS-CoV-2, or similarly sized influenza, is like throwing sand at a chain-link fence: it doesn't work. There has been one large randomized controlled trial that specifically examined whether masks protect their wearers from the coronavirus. This study found mask wearing "did not reduce, at conventional levels of statistical significance, the incidence of Sars-Cov-2-infection."<sup>3</sup>

Consider also, that the existence of more particles does not mean more virus. Research shows less virus does not mean less illness. Dr. Kevin Fennelly, a pulmonologist at the National Heart, Lung and Blood Institute debunked the view that larger droplets are responsible for viral transmission. Fennelly wrote:

"current infection control policies are based on the premise that most respiratory infections are transmitted by large respiratory droplets- i.e., larger than 5 [microns] – produced by coughing and sneezing, ...Unfortunately, that premise is wrong."<sup>4</sup>

Fennelly referenced a 1953 paper on anthrax that showed a single bacterial spore of about one micron was significantly more lethal than larger clumps of spores.<sup>5</sup> Exposure to one virus particle is theoretically enough to cause infection and subsequent disease. This is not an alarming thought - it simply means what it has always meant, that our immune system protects us continually all our life.<sup>6</sup>

There have been hundreds of mask studies related to influenza transmission done over several decades. It is a well-established fact that masks do not stop viruses. "Part of that evidence shows that cloth facemasks actually increase influenza-linked illness."<sup>7</sup> Bacteria are 50x larger than virus particles.<sup>8</sup> As such, virus particles can enter through the mask pores, yet bacteria remain trapped inside of the mask, resulting in the mask-wearer continually exposed to the bacteria.

Related to the 1918-1919 influenza pandemic, there was almost universal agreement among

experts, that deaths were virtually never caused by the influenza virus itself but resulted directly from severe secondary pneumonia caused by well-known bacterial “pneumopathogens” that colonized the upper respiratory tract.<sup>9</sup> Dr. Fauci and his National Institute of Health studied pandemics and epidemics and concluded, “the vast majority of influenza deaths resulted from secondary bacterial pneumonia.”<sup>10</sup>

All parties mandating the use of facemasks are not only willfully ignoring established science but are engaging in what amounts to a whole school clinical experimental trial. This conclusion is reached by the fact that facemask use and COVID-19 incidence are being reported in scientific opinion pieces promoted by the CDC and others.<sup>11</sup> The fact **is after reviewing ALL of the studies worldwide, the CDC found “no reduction in viral transmission with the use of face masks.”<sup>12</sup>**

Additionally, Children have been repeatedly shown not to be drivers of this contagion. It is well accepted that children have a statistically zero chance of dying from COVID. The CDC shows the K-12 mortality rate from or with COVID is .00003.<sup>13</sup> Any intervention, especially one that is prophylactic, must cause fewer harms to the recipient than the infection. Since children have the lowest death rate from COVID infection, the cost-benefit of requiring children to wear an investigational face-covering with emerging safety issues is especially difficult to justify. Anthony Fauci was very clear that asymptomatic transmission was not a threat. He stated, “in all the history of respiratory-borne viruses of any type, asymptomatic transmission has never been the driver of outbreaks. The driver of outbreaks is always a symptomatic person.”<sup>14</sup>

Wearing respirators come(s) with a host of physiological and psychological burdens. These can interfere with task performances and reduce work efficiency. These burdens can even be severe enough to cause life-threatening conditions if not ameliorated.<sup>15</sup> Fifteen years ago, National Taiwan University Hospital concluded that the use of N-95 masks in healthcare workers caused them to experience hypoxemia, a low level of oxygen in the blood, and hypercapnia, an elevation in the blood's carbon dioxide levels.<sup>16</sup> Studies of simple surgical masks found significant reductions in blood oxygen as well. In one particular study, researchers measured blood oxygenation before and after surgeries in 53 surgeons. Researchers found the mask reduced the blood oxygen levels significantly, and the longer the duration of wearing the mask, the greater the drop in blood oxygen levels.<sup>17</sup>

Moreover, people with cancer, will be at a further risk from hypoxia, as cancer cells grow best in a bodily environment that is low in oxygen. Low oxygen also promotes systemic inflammation which, in turn, promotes “the growth, invasion and spread of cancers.”<sup>18</sup> Repeated episodes of low oxygen, known as intermittent hypoxia, also “causes atherosclerosis” and hence increases “all cardiovascular events” such as heart attacks, as well as adverse cerebral events like stroke.<sup>19</sup>

Furthermore, the mandatory mouth mask in schools is a major threat to a child’s development. It ignores the essential needs of a growing child. The well-being of children and young people is

highly dependent on the emotional connection with others. Masks create a threatening and unsafe environment, where emotional connection becomes difficult.<sup>20</sup>

**Informed consent is required for investigational medical therapies.**

Regardless of the lack of safety and efficacy behind the decision to require a child to wear a mask, it is illegal to mandate EUA approved investigational medical therapies without informed consent. Mask use for viral transmission prevention is authorized for Emergency Use only.<sup>21</sup> Emergency Use Authorization by the FDA, means “the products are investigational and experimental” only.<sup>22</sup> The statute granting the FDA the power to authorize a medical product of emergency use requires that the person being administered the unapproved product be advised of his or her right to refuse administration of the product.<sup>23</sup> This statute further recognizes the well-settled doctrine that medical experiments, or “clinical research,” may not be performed on human subjects without the express, informed consent of the individual receiving treatment.<sup>24</sup>

The right to avoid the imposition of human experimentation is fundamental, rooted in the Nuremberg Code of 1947, has been ratified by the 1964 Declaration of Helsinki, and further codified in the United States Code of Federal Regulations. In addition to the United States regarding itself as bound by these provisions, these principles were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research.<sup>25</sup> Add State info here if possible. The law is very clear; It is unlawful to conduct medical research (even in the case of emergency), unless steps taken to ... secure informed consent of all participants.<sup>26</sup>

Furthermore, by requiring children to wear a mask, you are promoting the idea that the mask can prevent or treat a disease, which is an illegal deceptive practice. It is unlawful to advertise that a product or service can prevent...disease unless you possess competent and reliable scientific evidence... substantiating that the claims are true.<sup>27</sup>

The FDA EUA for surgical and/or cloth masks explicitly states, “the labeling must not state or imply... that the [mask] is intended for antimicrobial or antiviral protection or related, or for use such as infection prevention or reduction.”<sup>28</sup> As you can see from the image below, masks do not claim to keep out viruses.

**Illegally mandating an investigational medical therapy generates liability.**

There are no efficacy standards on child-sized masks and respirators under OSHA, but there are proven microbial challenges as well as breathing difficulties that are created and exacerbated by masking children.

Requiring children to wear a mask sets the stage for contracting any infection, including COVID19, and making the consequences of that infection much graver. In essence, a mask may very well put children at an increased risk of infection, and if so, having a far worse outcome.<sup>29</sup>

The fact that mask wearing presents a severe risk of harm to the wearer should – standing alone – not be required for children, particularly given that these children are not ill and have done nothing wrong that would warrant an infringement of their constitutional rights and bodily autonomy. Promoting use of a non-FDA approved, Emergency Use Authorized mask, is unwarranted and illegal. This mandate is in direct conflict with Section 360bbb-3€(1)(A)(ii)(I-III), which requires the wearer to be informed of the option to refuse the wearing of such “device.” Misrepresenting the use of a mask as being intended for antimicrobial or antiviral protection, and/or misrepresenting masks for use as infection prevention or reduction is a deceptive practice under the FTC. It is clear, there is no waiver of liability under deceptive practices, even under a state of emergency. As such, forcing children to wear masks, or similarly forcing use any other non-FDA approved medical product without the child’s (or the child’s parental) consent, is illegal and immoral.

This letter serves as official notice that **YOUR CHILDS NAME** does not consent to being forced to wear a mask. **YOUR CHILDS NAME** advocates will not fail to take the maximum action permissible under the law against your organization, and against you personally. Accordingly, I urge you to comply with Federal and State law, and advise children they have a right to refuse or wear a mask as a measure to prevent or reduce infection from COVID-19. Any other course of action is contrary to the law. I am willing to testify as to the veracity of the contents in this document. Please confirm no further pressure will be exerted upon **YOUR CHILDS NAME** to follow this illegal mask mandate, and that **YOUR CHILDS NAME** will not face any retaliatory disciplinary action.

Sincerely,

Your name

1 <https://www.jamanetwork.com/article.aspx?doi=10.1001/jamainternmed.2020.4221>

2 Berenson, A (November 24, 2020). Unreported Truths about Covid-19 and Lockdowns: Part 3: Masks 3  
3 <https://www.acpjournals.org/doi/10.7326/M20-6817>

4 [https://www.thelancet.com/journals.lanres/article/PIIS2213-2600\(20\)30323-4/fulltext](https://www.thelancet.com/journals.lanres/article/PIIS2213-2600(20)30323-4/fulltext)

5 [https://www.thelancet.com/journals.lanres/article/PIIS2213-2600\(20\)30323-4/fulltext](https://www.thelancet.com/journals.lanres/article/PIIS2213-2600(20)30323-4/fulltext)

6 <https://www.sciencedaily.com/releases/2009/03/090313150254.htm>

7 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4420971/>

8 <https://www.merriam-webster.com/words-at-play/virus-vs-bacteria-difference>

9 The pathology and bacteriology of pneumonia following influenza. Chapter IV, Epidemic respiratory disease. The pneumonias and other infections of the respiratory tract accompanying influenza and measles, 1921 St, LouisCV Mosby (p. 107-281)

10 <https://academic.oup.com/jid/article/198/7/962/2192118>

11 <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>

12 Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures, Jingyi Xiao<sup>1</sup>, Eunice Y. C. Shiu<sup>1</sup>, Huizhi Gao, Jessica Y. Wong, Min W. Fong, Sukhyun Ryu, and Benjamin J. Cowling (Volume 26, Number 5, May of 2020).

13 <https://www.cdc.gov/coronavirus/2019-ncov/community/schoolschildcare/k-12-testing.html>

14 <https://www.youtube.com/watch?v=X1orSO094u0Y>

15 Arthur Johnson, Journal of Biological Engineering (2016).

16 The Physiological Impact of N95 Masks on Medical Staff, National Taiwan University Hospital (June 2005).

17 Bader A et al. Preliminary report on surgical mask induced deoxygenation during major surgery. Neurocirugia 2008;19:12-126..

18 Aggarwal BB. Nuclear factor-kappaB: The enemy within. Cancer Cell 2004;6:203-208, and Blaylock RL. Immunoexcitatory mechanisms in glioma proliferation, invasion and occasional metastasis. Surg Neurol Inter 2013;4:15.

19 Savransky V et al. Chronic intermittent hypoxia induces atherosclerosis. Am J Resp Crit Care Med 2007;175:1290-1297.

20 <https://www.world-today-news.com/70-doctors-in-open-letter-to-ben-weyts-abolish-mandatory-mouth-mask-atschool-belgium/>

21 <https://www.fda.gov/media/137121/download>

22 <https://ca.childrenshealthdefense.org/wp-content/uploads/CDE-Superintendent-Letter0from-Childrens-HealthDefense-California-Chapter.pdf>

23 21 U.S.C. § 360bbb-3 (The FD&C Act)

24 21 U.S.C. § 360bbb-3(e)(1)(A) (“Section 360bbb-3”)

25 C.F.R. § 50.20

26 <http://www.invertedalchemy.com/2020/12/belief-is-not-medical-counter-measure.html> , 21 C.F.R. § 50.23, 21 C.F.R. §50.20 21 C.F.R. § 50.24

27 FTC Act, 15 U.S. Code § 41

28 <https://www.fda.gov/media/137121/download>

29 Russell Blaylock, Id. (quoting Shehade H et al. Cutting edge: Hypoxia-Inducible Factor-1 negatively regulates Th1 function. J Immunol 2015;195:1372-1376. See also: Westendorf AM et al. Hypoxia enhances immunosuppression by inhibiting CD4+ effector T cell function and promoting Treg activity. Cell Physiol Biochem 2017;41:1271-84. See further: Sceneay J et al. Hypoxia-driven immunosuppression contributes to the premetastatic niche. Oncoimmunology 2013;2:1 e22355.