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CLERK

**IN THE CIRCUIT COURT OF JEFFERSON COUNTY, ALABAMA**

**DUSTIN VANN,**

**Plaintiff**

**SHELLY WHITLOCK SMITH**

**Plaintiff**

**v.**

**HOMEWOOD BOARD OF EDUCATION**

**Defendant**

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CASE NO. CV- 202100161  
BIRMINGHAM DIVISION

**VERIFIED APPLICATION FOR TEMPORARY RESTRAINING ORDER AND  
PRELIMINARY INJUNCTION**

**INTRODUCTION**

Plaintiffs, Dustin Vann and Shelly Whitlock Smith submit this verified application requesting this Honorable Court grant a Temporary Restraining Order and a Preliminary Injunction. Plaintiffs move under Rule 65, of the Alabama Rules of Civil Procedure, for a preliminary injunction against Defendants enjoining the Homewood School Board from implementing its communicated policy regarding medical countermeasures including masks wherein the students' right to attend school on school property is contingent upon the compliance with the policy requirements as articulated. And further, to enjoin the Homewood School Board from any further acts infringing upon the health freedoms of students consistent with their contractual right to attend public school. Plaintiffs request an exemption from posting of a Bond as the act sought to be enjoined is completely discretionary resulting from a mere recommendation from the Alabama Department of Public Health. In support of the above, the Plaintiffs state the following:

**SUMMARY OF FACTS**

1. The rule for granting a Temporary Restraining Order or Preliminary Injunction is:

"A Preliminary Injunction may issue only when the party seeking the injunction demonstrates (1) that without the injunction the party would suffer irreparable injury; (2) that the party has no adequate remedy at law; (3) that the party has at least a reasonable chance of success on the merits; and that the hardship imposed on the party opposing the preliminary injunction by the injunction would not unreasonably outweigh the benefit accruing to the party seeking the injunction."

2. The Homewood Board of Education has communicated to the residents of the City of Homewood a policy which includes medical countermeasures, including masks, social distancing, and quarantine.

3. Most importantly, the policy makes the Homewood students' attendance at school contingent upon compliance with the medical countermeasures. Plaintiff, Shelly Whitlock Vann, has been irreparably harmed by the Board's unwillingness to halt the policy and is holding her son Jackson out of school until the mandate ceases. Justin Vann will be irreparably harmed by the policy as his children are being unjustly psychologically challenged and forced to deal with matters of political medical tyranny while in elementary school.

4. The policy is to take effect in conjunction with the start of school Wednesday August, 11, 2021.

5. The powers of a City Board of Education are specifically addressed in "**Code of Alabama Section 16-11-9, Powers generally:** "The city board of education is hereby vested with all the powers necessary or proper for the administration and management of the free public schools within such city and adjacent territory to the city which has been annexed as a part of the school district which includes a city having a city board of education."

6. The Homewood Board of Education has interpreted the above referenced provision of the Alabama Code to mean that the Board has the power to implement a policy which mandates compliance by children as a contingency of accessing public school education on campus. The Homewood Board of Education has made its medical countermeasure policy relying on the Alabama Department of Public Health's recommendations without due diligence as to the validity of the Alabama Department of Public Health's analysis of Department of Health and Human Services (DHHS) data. The idea of using fear to manipulate the public is not new, and is a strategy frequently deployed in public health. In June 2020, three American public health professionals, concerned about the psychological effects of the continued use of fear-based appeals to the public in order to motivate compliance with extreme COVID-19 countermeasures, authored a piece for the journal *Health Education and Behavior* calling for an end to the fear-mongering. In doing so, they acknowledged that fear has become an accepted public health strategy, and that it is being deployed aggressively in the United States in response to COVID-19: "... behavior change can result by increasing people's perceived severity and perceived susceptibility of a health issue through heightened risk appraisal coupled by raising their self-efficacy and response-efficacy about a behavioral solution. In this model, fear is used as the trigger to increase.

7. There has been one large randomized controlled trial that specifically examined whether masks (one of the proposed countermeasures) 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>

8. 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.<sup>1</sup> The 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>

9. 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.

10. The United States Government provides guidance in 21 C.F.R. Section 50.24 et seq., Illegal Clinical Trial, to States, municipalities, and businesses relative to the legal requirements for the promulgation of medical countermeasures during a public health emergency stating a “belief” that face masks limit the spread of SARS CoV2. To date, not a single study has confirmed that a mask prevented the transmission of, or the infection by SARS CoV-2.

11. **21 U.S.C. § 360bbb-3(b)(1)(C): There is No Emergency** On February 4, 2020, the Department of Health and Human Services (“DHHS”) Secretary declared, pursuant to § 360bbb-3(b)(1)(C), that SARS-CoV-2 created a “public health emergency.” This initial emergency declaration has been renewed repeatedly and remains in force today. The emergency declaration is the necessary legal predicate for the utilization of PCR Testing.

12. PCR Testing has been utilized by DHHS to define “CASES” of the disease, COVID-19, pursuant to an Emergency Use Authorization,

13. The actual number of COVID-19 “cases” is far lower than the reported number. DHHS authorized the emergency use of the polymerase chain reaction (“PCR”) test as a diagnostic tool for COVID-19, with disastrous consequences. The PCR tests are themselves experimental products, authorized by the FDA under separate EUAs. PCR test manufacturers use disclaimers like this in their product manuals: “[t]he FDA has not determined that the test is safe or effective for the detection of SARS-Co-V-2.” Manufacturer inserts furnished with PCR test products include disclaimers stating that the PCR tests should NOT be used to diagnose COVID-19. **This is consistent with the warning issued by the Nobel Prize winning inventor of the PCR test that such tests are not**

**appropriate for diagnosing disease. (EMPHASIS)**

14. The emergency declaration and its multiple renewals are illegal, since in fact there is no underlying emergency. Assuming the accuracy of Defendants' COVID-19 death data, SARS-CoV-2 has an overall survivability rate of 99.8% globally, which increases to 99.97% for persons under the age of 70, on a par with the seasonal flu. However, Defendants' data is deliberately inflated. On March 24, 2020, DHHS changed the rules applicable to coroners and others responsible for producing death certificates and making "cause of death" determinations — **exclusively for COVID-19**. The rule change states: "COVID-19 should be reported on the death certificate for all decedents where the disease caused *or is assumed to have caused or contributed* to death." In fact, DHHS statistics show that 95% of deaths classed as "COVID-19 deaths" involve an average of four additional co-morbidities. The CDC knew "...the rules for coding and selection of the underlying cause of death are expected to result in COVID-19 being the underlying cause more often than not."

15. It is imperative to emphasize that **MASKS HAVE NOT BEEN AUTHORIZED FOR EMERGENCY USE UNDER AN EUA GRANTED BY THE FOOD AND DRUG ADMINISTRATION!!!!**

16. The source of reasoning by the Board for the implementation of the proposed policy is specifically communicated to the citizens of Homewood in the correspondence to "Homewood Families":

"The Alabama Department of Health (ADPH) released the public school toolkit today with information regarding contact tracing, quarantine, facial coverings, and other school operations for next year..... We are in dynamic times and our leadership remains dynamic as well.....According to ADPH 's toolkit, if students are wearing facial coverings in the classroom and are distanced by three feet or more, asymptomatic students do not have to quarantine if they are exposed to Covid 19..... In order to keep our students and teachers in the classrooms, facial coverings will be required inside school buildings. Facial coverings inside our schools will significantly reduce the number of students who are required to quarantine....We understand that the debate regarding facial coverings is very divisive. Last year, our health leaders mandated facial coverings state-wide to ensure the safety of all of our families, not just in schools but throughout Alabama. Although a similar mandate is not currently in place, the strong "*recommendation*" from our state health leaders along with our rising Covid-19 cases in Alabama shows that we all must work together to do our best to keep our faculty, staff and students in school. By reinstating indoor facial coverings, we are hopeful this will give our schools the best opportunity to have more regular school activities this year and allow for in person learning to take place in a safe environment."

17. The Board's reference above, "...Last year, our health leaders mandated facial coverings statewide ....." is a misrepresentation of fact.

18. Any mandate from the Governor or the Alabama Department of Public Health must be derived from specific statutory authority.

19. The Code of Alabama specifically outlines the required prerequisites to the implementation of any state government policy.

20. The initial requirement is a declaration of emergency by the Governor based upon a verifiable Emergency.

21. It is important for this Honorable Court to carefully correlate the provisions of the Code of Alabama with the provisions of the United States Code of Federal Regulations.

22. The Alabama Code requires "specifically articulated statutory authority" for the State of Alabama to act in a defined "Emergency".

23. The State of Alabama, through the Alabama Department of Health, has released "recommendations" regarding medical countermeasures including masks.

24. In the interpretation of the Applicants herein, The State of Alabama has not issued mandates because it (a) has no specifically defined authority to do so, (b) the State Health leaders are fully aware that no verifiable disease has been proven to exist given the facts regarding PCR Testing, and/or (c) State officials understand that any mandate regarding medical countermeasures not authorized by a specific Emergency Use Authorization would be a crime under 21 C.F.R. Section 50.24 et seq., Illegal Clinical Trial, to States, municipalities, and businesses relative to the legal requirements for the promulgation of medical countermeasures during a public health emergency.

25. To bring the above referenced legal analysis into perspective, the Homewood Board of Education has interpreted their administrative powers to include the implementation of medical countermeasures (masks) and require compliance for Homewood students to access public school, a right the student's enjoy as residents of Homewood.

26. It is important to emphasize the magnitude of the damage being caused by the Emergency Use Authorization regarding the PCR tests. Why? Because health officials must consider the science.

27. The way in which the PCR tests are administered guaranties an unacceptably high number of false positive results. Cycle Threshold Value ("CT value") is essentially the number of

times that a sample (usually from a nasal swab) is magnified or amplified before a fragment of viral RNA is detected. The CT Value is exponential, and so a 40-cycle threshold means that the sample is magnified around a trillion times. The higher the CT Value, the less likely the detected fragment of viral RNA is intact, alive and infectious.<sup>5</sup>

28. Virtually all scientists, including Dr. Anthony Fauci, agree that any PCR test run at a CT value of 35-cycles or greater is useless. Dr. Fauci has stated (emphasis below added):

*What is now evolving into a bit of a standard is that if you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule... We have patients, and it is very frustrating for the patients as well as for the physicians... somebody comes in and they repeat their PCR and it's like 37 cycle threshold... you can almost never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, you gotta say, you know, it's dead nucleotides, period. In other words, it is not a COVID-19 infection.*<sup>6</sup>

A study funded by the French government showed that even at 35-cycles, the false positivity rate is as high as 97%. Despite this, a majority of the PCR tests for COVID-19 deployed under EUAs in the United States are run at 35-45 cycles in accordance with manufacturer instructions. Under the EUAs issued by the FDA, there is no flexibility to depart from the manufacturer's instructions and change the way in which the test is administered or interpreted.

29. Further, the U.S. Department of Health and Human Services and their counterparts in state governments (like Alabama) have used the specter of "asymptomatic spread" — the notion that fundamentally healthy people could cause COVID-19 in others — to justify the purported emergency. But there is *no credible scientific evidence* that demonstrates that the phenomenon of "asymptomatic spread" is real. On the contrary, on June 7, 2020, Dr. Maria Von Kerkhov, head of the WHO's Emerging Diseases and Zoonosis Unit, told a press conference that from the known research, asymptomatic spread was "very rare." "From the data we have, it still seems to be rare that an asymptomatic person actually transmits onward to a secondary individual." She added for emphasis: "it's very rare." Researchers from Southern Medical University in Guangzhou, China, published a study in August 2020 concluding that asymptomatic transmission of COVID-19 is *almost non-existent*. "Asymptomatic cases were least likely to infect their close contacts," the researchers found. A more recent study involving nearly 10 million residents of Wuhan, China found that there were no — zero — positive COVID-19 tests amongst 1,174 *close contacts* of asymptomatic cases, *indicating the complete absence of asymptomatic transmission*.

30. On September 9, 2020, Dr. Fauci was forced to admit in an official press conference: “[E]ven if there is some asymptomatic transmission, 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, even if there is a rare asymptomatic person that might transmit, an epidemic is not driven by asymptomatic carriers.”

31. Once an emergency has been declared and while it remains in force, the DHHS Secretary can issue and maintain EUAs “only if” (emphasis added) certain criteria are met. One of these is in fact (not simply perceived, projected or declared) “a serious or life threatening disease or condition.” For the reasons set forth above, SARS-CoV-2 and COVID-19 do not constitute a “serious or life threatening disease or condition” within the meaning of the statute.

32. For over a year now, the DHHS and state-level public health authorities have told the American public that SARS-CoV-2 can be spread by people who have none of the symptoms of COVID-19, therefore Americans must mask themselves, and submit to innumerable lockdowns and restrictions, even though they are not manifestly sick.

33. The theory of asymptomatic transmission — used as the justification for the lockdown and masking of the healthy — was based *solely* upon mathematical modeling. This theory had no actual study participants, and no peer review. The authors made the unfounded assumption that asymptomatic persons were “75% as infectious” as symptomatic persons. But in the real world, healthy false positives turned out to be merely healthy, and were never shown to be “asymptomatic” carriers of anything. Studies have shown that PCR test-positive asymptomatic individuals do not induce clinical COVID-19 disease, not even in a family member with whom they share a home and extended proximity. An enormous study of nearly ten million people in Wuhan, China showed that asymptomatic individuals testing positive for COVID-19 **never** infected others. Asymptomatic individuals do not spread COVID-19 and do not need to be masked, distanced, quarantined or vaccinated.

34. Let’s address the issue of potential irreparable harm to the students of the Homewood Schools. The Homewood Board of Education has made its medical countermeasure policy relying on the Alabama Department of Public Health’s recommendations without due diligence as to the validity of its analysis of DHHS data. The idea of using fear to manipulate the public is not new, and is a strategy frequently deployed in public health. In June 2020, three American public health professionals, concerned about the psychological effects of the continued use of fear-based appeals to the public in order to motivate compliance with extreme COVID-19 countermeasures, authored a piece for the journal *Health Education and Behavior* calling for an end to the fear-mongering. In doing so, they

acknowledged that fear has become an accepted public health strategy, and that it is being deployed aggressively in the United States in response to COVID-19:

**“... behavior change can result by increasing people’s perceived severity and perceived susceptibility of a health issue through heightened risk appraisal coupled by raising their self-efficacy and response-efficacy about a behavioral solution. In this model, fear is used as the trigger to increase**

35. 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 face masks **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.

36. 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.**

37. 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>

38. Wearing respirators comes 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>

39. 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>

40. 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.

41. 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>

42. 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> T

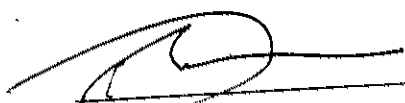
43. The law is very clear; It is unlawful to conduct medical research (even in the case of emergency), unless steps taken to ... secure informed consent of all participants.<sup>26</sup>

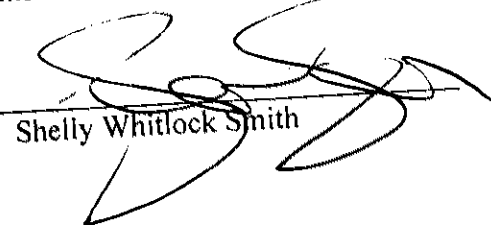
44. Furthermore, by requiring children to wear a mask, you are promoting the idea that the mask can prevent or treat a disease, which is an illegal deceptive practice. It is unlawful to advertise that a product or service can prevent...disease unless you possess competent and reliable scientific evidence...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

### **PRAYER FOR RELIEF**

WHEREFORE, PREMISE CONSIDERED, Applicants request this Honorable Court enter a Temporary Restraining Order. Federal, State and local action across the country is being predicated on data that is both incorrect and was promulgated and presented in an illegal manner. As such, we are requesting emergency injunctive relief in the form of a Temporary Restraining Order. Specifically, we humbly request that the Court issue the following relief on an emergency and then permanent basis and include an exemption a Bond as the proposed acts of the Board are completely discretionary:

1. Enjoin the Homewood School Board from implementing its communicated policy regarding medical countermeasures including masks wherein the students' right to attend school on school property is contingent upon the compliance with the policy requirements as articulated.
2. Enjoin the Homewood School Board from any further acts infringing upon the health freedoms of students consistent with the students' contractual right to attend public school.

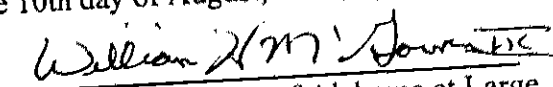
  
Justin Vann

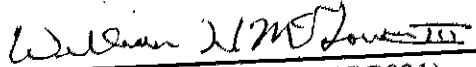
  
Shelly Whitlock Smith

STATE OF ALABAMA )

COUNTY OF JEFFERSON )

Sworn to and subscribed before me, William H. McGowen III, a Notary Public for the State of Alabama at Large, on this the 10th day of August, 2021, by Justin Vann and Shelly Whitlock Smith.

  
Notary Public, State of Alabama at Large  
My commission expires May 21, 2025

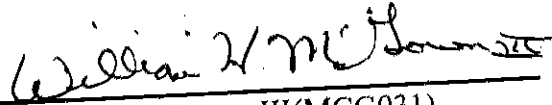


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### CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of August, I filed the foregoing with the Clerk of Court in Jefferson County and served by Special Process Server this Verified Application to the following:

Homewood Board of Education  
450 Dale Avenue  
Homewood, Alabama 35209



William H. McGowen III(MCG031)

- <sup>1</sup> <https://www.jamanetwork.com/article.aspx?doi=10.1001/jamainternmed.2020.4221>
- <sup>2</sup> Berenson, A (November 24, 2020). Unreported Truths about Covid-19 and Lockdowns: Part 3: Masks
- <sup>3</sup> <https://www.acpjournals.org/doi/10.7326/M20-6817>
- <sup>4</sup> [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)
- <sup>5</sup> [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)
- <sup>6</sup> <https://www.sciencedaily.com/releases/2009/03/090313150254.htm>
- <sup>7</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4420971/>
- <sup>8</sup> <https://www.merriam-webster.com/words-at-play/virus-vs-bacteria-difference>
- <sup>9</sup> 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. Louis CV Mosby (p. 107-281)
- <sup>10</sup> <https://academic.oup.com/jid/article/198/7/962/2192118>
- <sup>11</sup> <https://www.odc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>
- <sup>12</sup> 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).
- <sup>13</sup> <https://www.cdc.gov/coronavirus/2019-ncov/community/schoolschildcare/k-12-testing.html>
- <sup>14</sup> <https://www.youtube.com/watch?v=X1orSO094uY>
- <sup>15</sup> Arthur Johnson, Journal of Biological Engineering (2016).
- <sup>16</sup> The Physiological Impact of N95 Masks on Medical Staff, National Taiwan University Hospital (June 2005).
- <sup>17</sup> Bader A et al. Preliminary report on surgical mask induced deoxygenation during major surgery. Neurocirugia 2008;19:12-126..
- <sup>18</sup> 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.
- <sup>19</sup> Savransky V et al. Chronic intermittent hypoxia induces atherosclerosis. Am J Resp Crit Care Med 2007;175:1290-1297.
- <sup>20</sup> <https://www.world-today-news.com/70-doctors-in-open-letter-to-ben-weyts-abolish-mandatory-mouth-mask-at-school-belgium/>
- <sup>21</sup> <https://www.fda.gov/media/137121/download>
- <sup>22</sup> <https://ca.childrehealthdefense.org/wp-content/uploads/CDE-Superintendent-LetterFrom-Childrens-HealthDefense-California-Chapter.pdf>
- <sup>23</sup> 21 U.S.C. § 360bbb-3 (The FD&C Act)
- <sup>24</sup> 21 U.S.C. § 360bbb-3(e)(1)(A) ("Section 360bbb-3")
- <sup>25</sup> C.F.R. § 50.20
- <sup>26</sup> <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
- <sup>27</sup> FTC Act, 15 U.S. Code § 41
- <sup>28</sup> <https://www.fda.gov/media/137121/download>
- <sup>29</sup> 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 p22355.