Children's Health Defense – California Chapter Sends Letter to All California Superintendents Regarding Medical Ethics, Emergency Use Products, Voluntary Testing & Vaccine Safety

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by **Children's Health Defense California Chapter**
January 29, 2021

A Letter to CA Superintendents

Today, Children's Health Defense – California Chapter sent a letter to 1,100 California Superintendents to let them know that Emergency Use Authorization products, like the RT-PCR test and COVID vaccines, cannot be mandated, as they are investigational and experimental. They must be voluntary. Further, according to both the CDC and WHO, if RT-PCR testing is offered voluntarily, it must only be offered to those with symptoms through their own doctor. This letter also contains science showing that children are not asymptomatic carriers of COVID, and that COVID vaccines have not been proven to prevent person-to-person transmission. Please share this letter, either using the article's link or the PDF (CDE Superintendent

Letter from Childrens Health Defense – California Chapter) with your own school district to educate them on medical ethics, the science, and the law.

Dear Superintendent,

Children's Health Defense is a global leader in science, law, public policy and medical ethics. I am the President of the California Chapter of Children's Health Defense, a 501(c)(3), and I write on behalf of our organization.

The purpose of this letter is to help you to understand the science, law and policy as summarized below and in the PDF enclosure. We welcome the opportunity to work with you to open safely, legally and ethically.

As the world learns to navigate COVID-19, opening schools safely is in everyone's best interest. We have learned some California public school districts, such as LAUSD, and the California Department of Education (CDE) intend to mandate frequent Reverse-Transcriptase Polymerase Chain Reaction (RT-PCR) testing[1] on students and, when *investigational* COVID-19 vaccines are available to children, intend to mandate students and employees be vaccinated before they can return to campus. We are also monitoring CDE efforts to set up testing and vaccination centers on campuses.

Protracted school closures have created an educational and mental health emergency among students, due to learning loss from remote learning and isolation from their peers, sports, cultural activities, jobs and other support systems. Teen suicides are at an all-time high.[2] One of many tragic losses, teenager Dylan Buckner had "depression worsen significantly after COVID hit," which led to his suicide. His father stated, "The family believes that had COVID not happened, or the country's response to COVID had been more effective, Dylan would still be alive today."[3] In contrast, we invite you to

learn more about how Alsea School Superintendent Marc Thielman opened schools in an Oregon county in Fall 2020 without incident.[4]

Mandating products approved for emergency use violates federal and state law since Emergency Use Authorization (EUA) means the products are *investigational and experimental.* Federal and state law is very clear that mandates are illegal for EUA products. Both the RT-PCR test and all COVID vaccines are not FDA-approved; they are available under an EUA.

The right to fully-informed consent has roots in the Nuremberg Code, which states the consent of the individual is "absolutely essential."[5] If an intervention causes greater harm, is ineffective for the stated aim, and illegal, as such you must re-evaluate implementing the proposed interventions as a condition for students to return to in-person learning.

Below we address the issues with your intended approach in four sections:

1. The law surrounding Emergency Use Authorizations (EUA), under which both the RT-PCR and COVID *investigational* vaccines are being used on the public;
2. Peer-reviewed science regarding
    1. (2a) The RT-PCR test, demonstrating that it is not a diagnostic tool and cannot determine if someone is sick or infectious, and;
    2. (2b) Emerging issues with the *investigational* COVID vaccine;
3. Creation of on-campus COVID testing and vaccination centers; and
4. **Your institution's real legal liability should you proceed with any plans to mandate investigational testing protocols or vaccines.**

Note that while vaccine manufacturers may be shielded from liability by 42 USC 300aa-11 and 42 USC 300aa-22, your institution is not protected.[6]

You are hereby officially on notice that if you illegally or irresponsibly mandate products on students or public school employees, we may have no recourse but to take legal action. As an example, Children's Health Defense has initiated a related suit in New York against the NYC Department of Education and Mayor de Blasio for arbitrary school closures and coerced PCR testing as a condition to in-person learning privileges.[7] (*Aviles, et al. V. de Blasio, et al. 20-CV-09829 (PGG)*)

(1) Emergency Use Authorizations (EUA): Illegal to Mandate Products Under EUA

PCR testing and COVID vaccines are not fully licensed products. They are EUA products,[8] which by their very nature are legally considered *investigational*. As these are experimental medical products, it is unlawful and unethical for schools to mandate either the RT-PCR test or any currently available COVID vaccine. Federal law confirms explicitly that an EUA product must be voluntary because the federal statute requires "the option to accept or refuse administration of the product."[9]

Mandating the RT-PCR and experimental COVID vaccines also violates California State law (CA Health & Safety Code § 24172).[10] Federal and State law on this matter rest on the first principle of the Nuremberg Code requiring that the human subject be "so situated as to be able to exercise **free power of choice without undue inducement or any element of force, fraud, deceit, duress or other forms of constraint or coercion**." This is a bright line that cannot be blurred.

Of note, specific laws such as the US Federal Regulations,

notably the National Research Act [Title II, Public Law 93-348],[11] Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research [45 CFR 46][12] and revisions of various regulations, rules, and laws ([21 CFR 50][13], [21 CFR 56][14], [45 CFR 46 Subpart D][15], [10 CFR 745][16], [45 CFR 46 Subpart B][17], [45 CFR 46 Subpart D][18]) specifically and permanently guarantee that all persons in the United States are entitled to exercise the right of informed consent to accept or to refuse to enroll in any medical experiment.

The CDC admits that it is illegal and unethical to mandate PCR testing in schools.[19] Moreover, the States, and therefore public schools, cannot mandate the PCR test or COVID vaccines because the FDA and courts have found the federal preemption doctrine prevents States, and therefore public schools, from going outside the bounds of the Emergency Use Authorization law.[20]

This was also confirmed again last year at a CDC Advisory Committee on Immunization Practices (ACIP) meeting in August 2020, where ACIP Executive Secretary Amanda Cohn, MD stated:

“I just wanted to add that, just wanted to remind everybody, that under an Emergency Use Authorization, an EUA, vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won’t be able to be mandated.”[21]

In conclusion, the law is clear that States, and therefore public schools, cannot mandate experimental products and are preempted from mandating an EUA product.[22] The soonest the Moderna and Pfizer/BioNTech experimental vaccines could be considered by FDA for full licensure (in adults only) is when the trials are expected to conclude, on October 27, 2022 and January 31, 2023, respectively.

(2) The Faults with RT-PCR Testing and Emerging Dangers of the COVID Vaccines

The FDA may someday grant full licensure to the RT-PCR test and some COVID vaccines. For now, these products are approved for investigational emergency use only, as described above, so the problems with the reliability of the test and vaccine efficacy and safety are not technically relevant to the illegality of mandates.

Since the FDA may grant full licensure at some point, which may make it legal to consider mandating them, we must also advise you of the medical and scientific issues that make school mandates dangerous to the health and safety of the educational community under any circumstances.

Below we detail (a) documented issues with the reliability of the PCR test; and (b) COVID vaccine science showing no disruption of person-to-person transmission, concerning safety data, and other issues regarding COVID vaccines and children.

(a) Issues with PCR Testing as a Condition for In-person Learning or Teaching

We understand that California Public Schools intend to mandate regular RT-PCR testing on children, with the penalty of withholding access to in-person education if testing is not completed. The CDC has declared mandatory PCR testing unethical and illegal.

The RT-PCR test does not confirm infectiousness. Food & Drug Administration (FDA) guidance states the RT-PCR test must only be used in the presence of symptoms. As such, the RT-PCR should never be used on healthy people, and should only be used in a clinical setting combined with an exam by a licensed medical professional.

On July 17, 2020 and updated on July 20, 2020, the CDC recommends a symptoms-based strategy for testing, meaning only

those with symptoms should consider being tested.[23]

The EUA for the Roche PCR test states "positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and *other* diagnostic information is necessary to determine patient infection status."[24]

The Roche EUA also states "positive results do not rule out bacterial infection or co-infection with other viruses." Any positive PCR test is unconfirmed if the patient is not also tested for flu, pertussis, tuberculosis, or many of the other 1400 human pathogens associated with symptoms similar to COVID-19. Skipping this standard differential diagnosis results in confirmation bias, attributing all symptoms like cough or a fever to COVID.

Since the RT-PCR test Cycle threshold (Ct) in the U.S. is set too high – at a Ct of 40 – it can amplify a low viral load and be erroneously conflated with infectiousness.[25] On January 21, 2021, the World Health Organization (WHO) further clarified that "careful interpretation of weak positive results is needed. The Ct needed to detect virus is inversely proportional to the patient's viral load. Where test results do not correspond with the clinical presentation, a new specimen should be taken and retested using the same or different nucleic acid test (NAT) technology."[26]

Dr. Anthony Fauci, Director of the National Institutes for Allergy and Infectious Diseases of the National Institutes of Health, acknowledged in July 2020 that a positive RT-PCR test above a 35 Ct is meaningless.

("[I]f you get a cycle threshold of 35 or more, …the chance of it being replication-competent are [sic] miniscule. And we have patients – and it's 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, but you almost never can culture virus for a 37 cycle threshold. So I think if someone does come in with 37-38, even 36, you got to say, 'You know, it's just dead nucleotides, period."[27]

In fact, 97% of PCR positives are *false positives* if the cycle threshold is higher than 35. A critical review of the seminal Corman-Drosten study which established PCR testing standards concluded:

"In case of virus detection, >35 cycles only detects signals which do not correlate with infectious virus as determined by isolation in cell culture; if someone is tested by PCR as positive when a threshold of 35 cycles or higher is used (as is the case in most laboratories in Europe & the US), the probability that said person is actually infected is less than 3%, the probability that said result is a false positive is 97%."[28]

If you only read one reference in this entire letter, it should be the above to the Corman-Drosten Review: www.cormandrostenreview.com. This paper describes in detail most of the shortcomings of the PCR test that is driving the fear of SARS CoV-2, the virus said to cause the symptoms called COVID-19.

Returning to the most egregious problem with the RT-PCR test, a scientific literature review study by Tom Jefferson MD found specific Ct values correlate with infectiousness or lack thereof, and suggests that a Ct of 35 is still too high: "The inability of PCR to distinguish between the shedding of live virus or of viral debris, means that it cannot measure a person's viral load (or quantity of virus present in a person's excreta." In the review, all tests with Ct >30 resulted in non-infectious specimen. Jefferson also stated "weak positives (those with high Ct) are unlikely to be infectious, as a whole live virus is the prime requirement for

transmission, not the fragments identified by PCR."[29]

The RT-PCR test being set at a Ct of 40 in the United States is indeed far too high and creates what has been termed a "casedemic," disrupting all of society but especially children's education and mental health. We do not think California public schools should be furthering this problem by requiring a test that the scientific community has found to be utterly unreliable.

Even if RT-PCR tests do gain full licensure someday, California schools must certify to the students, staff and family the following, before our education system is further disrupted by a test that delivers a majority of false positives and doesn't measure infectiousness:

1. Provide all students and staff with fully informed consent and advise them of their right to decline taking a test, and the right for asymptomatic students and teachers to be in the classroom. In other words, testing must be voluntary.
2. Refer symptomatic children and staff to their primary care physician for voluntary testing and treatment. Students and staff can return to in-person learning or work when they are symptom-free or have quarantined for the recommended 7 to 10 days.
3. The primary care physician must rule out – via antibody or PCR testing – the other human pathogens that can cause symptoms similar to COVID-19.
4. For any tests run on a student or staff member by the primary care physician, confirm the RT-PCR Cycle threshold is 28 or less, since that is the highest Ct with

proof of replication-competent virus.

5. Confirm with a DNA or RAT test that the presumptively 'positive' sample is positive and not just picking up dead RNA fragments or background noise by using Sanger sequencing on every potentially positive test, and then confirming any potential positives with a human cell culture to verify the existence of replication competent virus. If the sample is unable to be cultured, then the individual is not infectious.
6. Demand that the test report includes viral load information, and not just a binary reading.
7. Per the 1/21/21 WHO guidance, perform a second test if the first one is positive.
8. Do not rely on antigen tests which are also fraught with issues of false positives and false negatives.

Current CDC guidance on testing in school settings states:

If a school is implementing a testing strategy [i.e. testing healthy and sick, not based on symptoms,] testing should be offered on a voluntary basis. It is ***unethical and illegal*** *to test someone who does not want to be tested, including students whose parents or guardians do not want them to be tested.*[30]

Please also keep in mind that according to the CDC, schools should be the first to reopen and the last to close.[31]

Given the above, the best course of action for the CDE and Districts is to ensure that sick students stay home, as has been the policy for pre-COVID times. There are already many other *evidence-based* protocols in place to allow safe return

to in-person schooling, such as: hand washing, temperature-taking, suggesting sick students stay home until symptoms have resolved, classroom disinfection, and improved HVAC systems. Students should not be the victims of an experimental test, which will lead to a furthering of the Educational Emergency and even more social isolation that leads to mental health issues and suicide.

(b) Children are Not Asymptomatic Vectors; Science Shows COVID Vaccines are Risky

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.[32] Any intervention, especially one that is prophylactic, must cause fewer harms to the recipients than the infection. Since children have the lowest death rate from COVID infection, the cost-benefit of administering to children an investigational vaccine with emerging safety issues is especially difficult to justify. Therefore, it is clearly irrational to vaccinate children with a COVID vaccine to protect them from death.

Given these facts, an unfounded theory has emerged to use students as pawns who, if vaccinated, could somehow stop transmission to teachers and school staff. However, the data show: students are *not* asymptomatic carriers, they and teachers have *far lower* rates of COVID diagnosis than the general population, and the vaccine does not prevent person-to-person transmission.

Contrary to popular opinion, asymptomatic transmission is unfounded. Students are not disease reservoirs and are clearly not COVID vectors. The School Response COVID Dashboard shows that students and staff are among the least likely to be diagnosed with COVID. Compared to the positivity rate of 8.1% in the general California population in the most recently available data period (12/13/20), only 0.56% of California students tested positive for COVID, and the staff positivity

rate was only 1.46%, even though teachers are daily interacting with students. This proves it is a significant mistake to assume children are asymptomatic vectors.[33] In fact, in Germany, students are valued as the "brakes" to COVID transmission.[34]

A recent CDC-funded study in Wisconsin concluded no staff members were infected by children, and transmission rates were very low:

In a setting of widespread community SARS-CoV-2 transmission, few instances of in-school transmission were identified among students and staff members, with limited spread among children within their cohorts and no documented transmission to or from staff members. Only seven of 191 cases (3.7%) were linked to in-school transmission, and all seven were among children.[35]

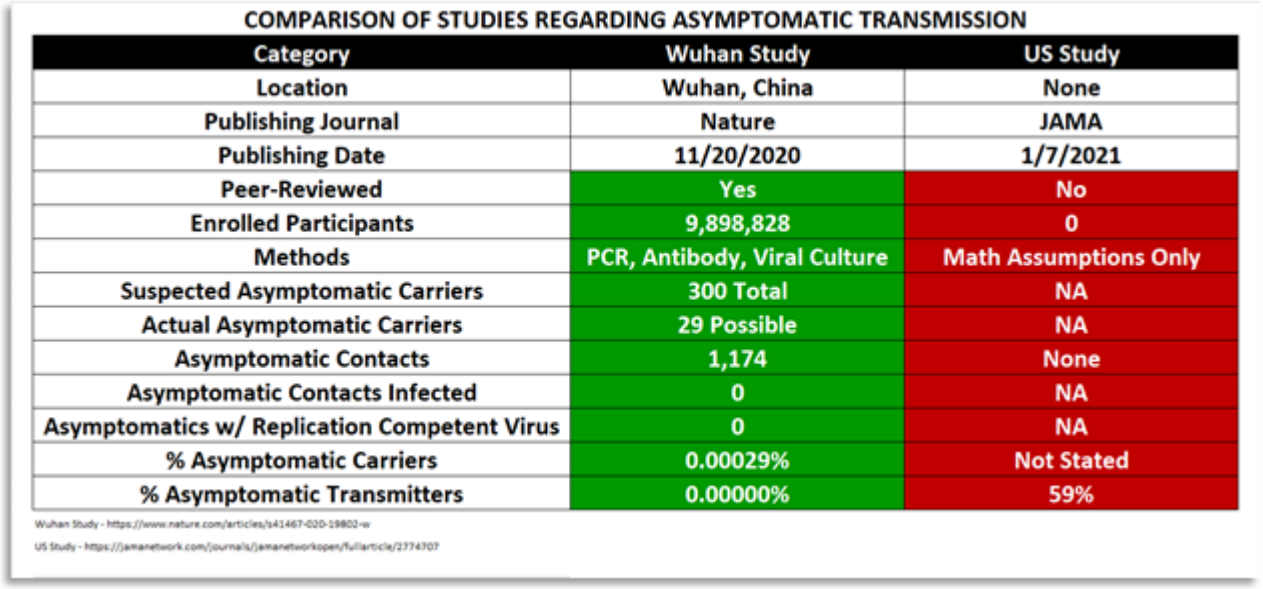
You may be surprised to learn that Sweden – the country that famously did not lock down – had an excellent outcome among children. "Despite Sweden's having kept schools and preschools open, we found a low incidence of severe Covid-19 among schoolchildren and children of preschool age during the SARS-CoV-2 pandemic. Among the 1.95 million children who were 1 to 16 years of age, 15 children had Covid-19, MIS-C, or both conditions and were admitted to an ICU, which is equal to 1 child in 130,000."[36]

A meta-analysis of 54 studies on transmission amongst almost 78,000 participants found that only 0.7% of cases attributed to "household transmission" could have spread from pre-symptomatic or asymptomatic carriers in the household.[37]

Additionally, a study among 10 million residents of Wuhan China demonstrated that *asymptomatic transmission was non-existent*.[38] Among 300 possible carriers, "virus cultures were negative for all asymptomatic positive and re-positive cases,

indicating no “viable virus” in positive cases detected in this study. All asymptomatic positive cases, re-positive cases and their close contacts were isolated for at least 2 weeks until the results of nucleic acid testing were negative. None of detected positive cases or their close contacts became symptomatic or newly confirmed with COVID-19 during the isolation period.”

In contrast, a widely-quoted CDC-endorsed study claiming 59% of cases were due to asymptomatic transmission enrolled no subjects and is merely a mathematical model.[39] To further clarify, here is a side-by-side comparison of the Wuhan study compared to the CDC study:



COMPARISON OF STUDIES REGARDING ASYMPTOMATIC TRANSMISSION

Category	Wuhan Study	US Study
Location	Wuhan, China	None
Publishing Journal	Nature	JAMA
Publishing Date	11/20/2020	1/7/2021
Peer-Reviewed	Yes	No
Enrolled Participants	9,898,828	0
Methods	PCR, Antibody, Viral Culture	Math Assumptions Only
Suspected Asymptomatic Carriers	300 Total	NA
Actual Asymptomatic Carriers	29 Possible	NA
Asymptomatic Contacts	1,174	None
Asymptomatic Contacts Infected	0	NA
Asymptomatics w/ Replication Competent Virus	0	NA
% Asymptomatic Carriers	0.00029%	Not Stated
% Asymptomatic Transmitters	0.00000%	59%

Wuhan Study - https://www.nature.com/articles/s41467-020-19802-w

US Study - https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774707

In a 2020 Health & Human Services press conference, Dr. Fauci stated “even 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.[40] The driver of outbreaks is always a symptomatic person. Even if there’s a rare asymptomatic person that might transmit, **an epidemic is not driven by asymptomatic carriers**.”

Given the statistically zero COVID death rate in children, the low rate of COVID positivity in children, and the lack of asymptomatic spread, there is absolutely no case for the

vaccination of children to protect them or others from COVID.

Should COVID vaccines become fully licensed in the future and still be (inexplicably) under consideration for schoolchildren and staff after reviewing the above, we explain below how the COVID investigational vaccines do not prevent person-to-person transmission and are fraught with mounting safety issues as reported in the media, in the V-Safe App (used post-vaccination by study participants,) and in the U.S. Vaccine Adverse Events Reporting System (VAERS.) Most significantly, the investigational vaccines have not been tested in children.

Since the COVID vaccines do not prevent person-to-person transmission, it is irresponsible to think this medical product could somehow protect adults by vaccinating children. Dr. Anthony Fauci admitted in October the goal of COVID vaccines is to provide personal protection only, not to prevent death, or person-to-person transmission. Fauci said he and his colleagues would "settle for … the primary endpoint to prevent clinically recognizable disease."[41] Moderna Chief Medical Officer Tal Zaks stated "our trial will not demonstrate prevention of transmission, because … you have to swab people twice a week for very long periods, and that becomes operationally untenable," citing the need for a five-to-ten times longer trial length and even higher costs.[42]

Through January 15, 2021, 181 U.S. deaths[43] have been reported after COVID vaccination to the Vaccine Adverse Event Reporting System (VAERS.)[44] There are almost 8,000 total COVID vaccine reactions reported to VAERS so far, including 764 reports for serious adverse events.[45] A CDC-funded study at Harvard Pilgrim concluded that "fewer than 1% of vaccine adverse events are reported" to VAERS, a passive reporting system.[46] Therefore, it is reasonable to multiply any reported events by 100 to approximate the actual number of deaths and adverse events after any vaccination. In fact, the COVID

vaccine serious injury rate, based on the December Advisory Committee on Immunization Practices meeting covering the first five days of COVID vaccination is 2.8%.[47] Note that all approved COVID vaccines require two doses, so these data are mostly based on one dose. In the trials, the second dose was much more reactogenic, so we expect the serious injury rate to be much higher after the second dose.

In addition to these government-documented safety issues, hundreds of catastrophic injuries – like life-threatening anaphylaxis and a bizarre shaking syndrome – and deaths have been reported in the media and on social media.[48] Most recently baseball great Hank Aaron died 18 days after receiving the first of two experimental COVID vaccines.[49] These vaccines use brand new mRNA technology with known complications – and we can certainly anticipate many more unforeseen complications.[50]

In fact, today there are about two dozen vaccines in use in the United States and another 66 have been withdrawn, most for safety issues, such as LymeRix, RotaShield and DTP.[51] These fully licensed vaccines were judged as safe with government approval. This shows a vaccine withdrawal rate of 73%. If three-quarters of fully licensed vaccines are withdrawn, the probability of a warp speed experimental vaccine being withdrawn is far higher.

We urge you not to put schoolchildren in harm's way with an untested new technology in a quixotic attempt to prevent them from being asymptomatic vectors. COVID vaccines are more like a high-risk prophylactic drug that might only benefit the recipient, not anyone around them. There is no place for medical mandates, especially not for interventions that only provide personal protection. That is an individual choice. As mentioned above, manufacturers enjoy full liability protection when people are injured or killed by vaccines. The school district does not.

(3) On-Campus COVID Testing and Vaccination Sites

The CDE and some public school districts in California are contemplating or attempting to create COVID testing sites on school campuses. For all the reasons stated above, there should be no such sites established on any California public school campuses or school properties. While voluntary community or school testing might initially seem benign, these sites could easily be converted into vaccination centers for students, staff and the public. Again, because of the experimental nature of the vaccine, this too would be highly inappropriate.

(4) School District and California Department of Education Legal Liability

In summary, mandating EUA products is illegal. Mandates do not allow for informed consent, which is spelled out clearly in California Health and Safety Code (CA Health & Saf Code § 24172).[52] Relying on the RT-PCR or any other investigational testing product will lead to over-diagnosis and avoidable harms to many students and staff, including a discriminatory system where those who test negative can move freely while those who do not wish to be tested or those who test positive – even falsely positive – are denied their rights to an education and to work.

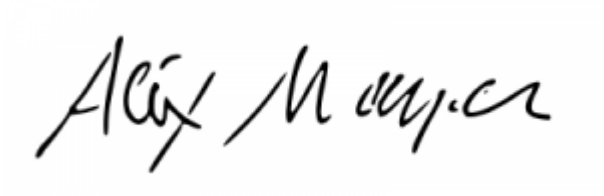
Those who are forced to learn remotely do not have equal access. Remote learning disadvantages the poor: some may not have a fast internet connection, and students may not have a quiet room with a computer to learn away from family distractions and household/neighborhood noise. Administering to students and staff a vaccine with known safety issues is reckless and will cause injury and death for which school districts and the CDE will be liable.

Being in the unenviable position of defending an illegal program in a Court of Law would certainly prove to be a distraction from your important work.

It is our sincere hope that your district would never seriously consider such mandates.

We respect your position and fully appreciate your duty to educate children safely. Children's Health Defense – California Chapter will follow up with you to ensure you understand both the law and science. We aim to help you make the right decisions for the children of California. Please contact us at ca.team@childrenshealthdefense.org or 415-496-5301 should you need more information or if you would like scientific and legal help to operate lawfully and ethically.

Sincerely,



Alix Mayer, MBA
President & Board Director, Children's Health Defense – California Chapter
Board Director, Children's Health Defense

Cc: Ray L. Flores II, Attorney at Law

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[1] Usually conducted via nasal swab.
[2] https://www.nytimes.com/2021/01/24/us/politics/student-suicides-nevada-coronavirus.html?referringSource=articleShare&fbclid=IwAR1SFUKTqmfiJB1F3_lEv_Xf3YAh9sUamm2_giT3cu6T9jARY6sbIlmP20M
[3] https://www.nbcchicago.com/news/local/suburban-football-star-dies-in-apparent-suicide-family-says-covid-worsened-depression/2411545/
[4] https://www.instagram.com/tv/CKUYGZGn4O8/?igshid=9xmjnp23bd8

[5] https://en.wikipedia.org/wiki/Nuremberg_Code
[6] https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section300aa-22&num=0&edition=prelim
[7] https://childrenshealthdefense.org/defender/chd-sues-nyc-dept-of-education/?fbclid=IwAR3edlSvDa2QMqNAoCO5pSj4am0OPz9o-V9SMGkkTrdPoZJ-iFBD1lQmtOI
[8] (Decl. Varma ecf 19 P.43.)
[9] ” 21 USCS § 360bbb-3 (“Authorization for medical products for use in emergencies”).
[10] http://leginfo.legislature.cahttp://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=24172.&lawCode=HSC.gov/faces/codes_displaySection.xhtml?sectionNum=24172.&lawCode=HSC
[11] https://www.govinfo.gov/content/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf#page=5
[12] https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML
[13]https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.1
[14] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=56
[15] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html
[16] https://www.govinfo.gov/app/details/CFR-2011-title10-vol4/CFR-2011-title10-vol4-part745
[17] https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.b
[18] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/special-protections-for-children/index.html
[19] https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-testing.html
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities
[21] US Centers for Disease Control (September 2020), *August*

2020 ACIP Meeting – COVID-19 vaccine supply & next steps. https://www.cdc.gov/vaccines/videos/low-res/acipaug2020/Covid-19Supply-NextSteps_3_LowRes.mp4 (@1:14:40)

[22] See e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 570-71 (2001)

[23] https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html and https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

[24] https://diagnostics.roche.com/us/en/products/params/cobas-sars-cov-2-test.html

[25] https://www.fda.gov/media/134922/download

[26] https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05?fbclid=IwAR2FnuSklIn9qtxve9EEEK9ht5WVw-QzWyeRUJJ203q0II4YBJecbJRylrA

[27] TWiV 641: COVID-19, *Video interview with Dr. Anthony Fauci*, This Week in Virology, 4:22-5:10 (Jul. 16, 2020), at https://www.youtube.com/watch?v=a_Vy6fgaBPE

[28] www.cormandrostenreview.com

[29] https://www.medrxiv.org/content/10.1101/2020.08.04.20167932v4

[30] https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-testing.html

[31] https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e1.htm?s_cid=mm7003e1_w

[32] https://www.cdc.gov/coronavirus/2019-ncov/community/schoolschildcare/k-12-testing.html

[33] https://statsiq.co1.qualtrics.com/public-dashboard/v0/dashboard/5f78e5d4de521a001036f78e#/dashboard/5f78e5d4de521a001036f78e?pageId=Page_c0595a5e-9e70-4df2-ab0c-14860e84d36a

[34] https://www.usnews.com/news/world/articles/2020-07-13/german-study-shows-low-coronavirus-infection-rate-in-schools and https://theweek.com/speedreads-amp/925304/german-researchers-argue-children-may-act-brake-coronavirus-infections

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