March 26, 2021

Dear Supervisor,

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 on this urgent matter regarding your County’s COVID-19 programs. We are a non-profit organization concerned with medical science, law, public policy, medical ethics and now more than ever, impingements on our personal freedoms from both the public and private sectors. One way we are doing this is by taking steps to protect the health of children by ensuring all medical interventions, such as vaccines and COVID-19 testing, are ethical, necessary, voluntary, and only offered with fully informed consent. Over many years, our non-profit has identified the environmental and iatrogenic causes of chronic illness in children, has brought corporate offenders to justice, and has enacted safeguards to prevent future transgressions.

As you may recall, we copied you on a Notice of Liability which we sent to all school districts in California, regarding the legal and ethical need to make COVID testing and vaccines voluntary as they are only authorized for use under federal Emergency Use Authorization (EUA) and are thus illegal to mandate under Federal and CA state law.¹

Our letter dated January 29, 2020² served as a Notice of Liability regarding schools and school districts’ plans to impose illegal mandates of certain EUA products on students and employees. A number of districts contacted us after receiving that letter, including large urban districts such as the San Jose Public School District, to inform us they have elected to follow the law and science, rather than risk being sued. We applaud these districts’ decisions.

However, a number of other school districts, as well as public agencies, counties, cities, and private entities across the state and nation, continue to roll out plainly illegal and dangerous mandates imposed on employees, customers, students, constituents and others. We are rapidly descending into a society in which blatantly criminal and legally-suspect actions are being imposed on us to simply participate in many normal aspects of life. Your County has possibly been operating in violation of multiple sections of federal and state law, as are most entities that do public business.


The EUA Statute authorizes the Secretary of the U.S. Department of Health and Human Services (HHS) to declare a health emergency and authorize the use of drugs, treatments, or other products that may be beneficial but have not yet been demonstrated to be safe or effective and are thus only available for use under the EUA. The federal COVID EUA was declared by HHS Secretary Azar on April 1, 2020 and includes numerous authorizations for a wide range of products, none of which are fully approved, and all of which may be offered only on a voluntary — not a mandatory — basis.

The large clinical trials for the EUA mRNA injectables and recombinant vaccines in the U.S. will not conclude until late 2022 and early 2023. Full licensure may be considered after the trial results are in, and after government agencies such as FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) and CDC’s Advisory Committee on Immunization Practices (ACIP) have reviewed safety and efficacy data from the trials and experimental usage on the population.

There are substantial known and unknown risks associated with using any EUA product, including in the context of COVID. EUA products are, by definition, experimental and investigational; anyone administering or receiving an EUA product is participating in a medical experiment. That is precisely why EUA products cannot be mandated.

Among the key product types authorized for COVID-related EUAs are:

a. devices, systems and procedures that may detect the possible presence of some viral material in a person (i.e., “tests” or “RT-PCR tests” or “antigen tests” or “antibody tests”);

b. wearable devices that may have some effect on reducing transmission (i.e., “masks” or “Personal Protective Equipment (PPE)”); and

c. two different manufacturers’ mRNA injectable drug treatments delivered via two consecutive shots (i.e., “vaccines”).

d. one manufacturer’s recombinant single-shot vaccine.

For these — or any other EUA products — to be distributed and used, disclosure documents published by the FDA for each product must be provided at the time of distribution to all potential users, detailing the potentially significant risks and benefits associated with use of that specific product.

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5 J&J: https://clinicaltrials.gov/ct2/show/NCT04505722?id=NCT04436276+OR+NCT04400838+OR+NCT04324606+OR+NCT04536051+OR+NCT04444674+OR+NCT04505722+OR+NCT04509947+OR+NCT04535453+OR+NCT04283461+OR+NCT04537208&draw=2&rank=5&load=cart

6 Moderna: https://clinicaltrials.gov/ct2/show/NCT04283461?id=NCT04436276+OR+NCT04400838+OR+NCT04324606+OR+NCT04536051+OR+NCT04444674+OR+NCT04505722+OR+NCT04509947+OR+NCT04535453+OR+NCT04283461+OR+NCT04537208&draw=2&rank=10&load=cart

Additionally, extensive protocols are required by federal law for assessing the effectiveness and safety of EUA products, while also protecting users’ medical health, privacy and other guaranteed rights.

Emergency Use Authorization (EUA) Law

Mandating employees, students or others to use products that have been approved only conditionally for emergency use violates federal and state law. Federal and state law are clear: mandates are illegal for EUA products. The prohibition on EUA mandates has been upheld in court. The RT-PCR test, COVID vaccines, and certain face coverings are not FDA-approved; they are available only under an EUA.

The EUA statute explicitly states that administration of all EUA products must "ensure that individuals to whom the product is administered are informed … of the option to accept or refuse administration of the product." 21 U.S.C. Sec. 360bbb-3(e)

Federal and state law on this rests 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. The consent of the individual is "absolutely essential."

In the letter we sent to schools, we officially put them on notice that if they illegally or irresponsibly mandate products on students or employees, we may take legal action. Children’s Health Defense has initiated a suit in New York against the NYC Department of Education and Mayor de Blasio for coerced PCR testing as a condition to in-person learning privileges. (Aviles, et al. V. de Blasio, et al. 20-CV-09829 (PGG))

A number of additional federal regulations, notably the National Research Act [Title II, Public Law 93-348], Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research [45 CFR 46] and revisions of various other regulations, rules, and laws ([21 CFR 50])
CFR 56\[^{18}\], [45 CFR 46 Subpart D]\[^{19}\], [10 CFR 745]\[^{20}\], [45 CFR 46 Subpart B]\[^{21}\], [45 CFR 46 Subpart D]\[^{22}\]}, 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 correctly stated it is illegal and unethical to mandate EUA testing or vaccination in schools.\[^{23}\] 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.\[^{24}\] 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."\[^{25}\]

In conclusion, the law is clear that states, and therefore public schools, cannot mandate experimental products and are preempted from mandating any EUA products.\[^{26}\]

De Novo Authorization for Marketing Purposes

The BioFire Respiratory Panel test is the first RT-PCR test to lose EUA status, instead receiving a “De Novo” marketing approval from the FDA on March 17, 2021.\[^{27}\] It specifically states the BioFire test should be used in “individuals suspected of respiratory tract infections, including COVID-19.” The BioFire panel tests for SARS CoV-2, the virus said to cause the symptoms named COVID-19, and about twenty other infections, so if used on healthy people, the likelihood is very high that someone’s biological sample could match part of the DNA of one of the many infections, leading to false positives.\[^{28}\] On the other hand, in an ill patient with respiratory symptoms, it could help a physician rule in or out many causes of illness, including SARS CoV-2 virus, four other coronaviruses, influenza, and pertussis (whooping cough).

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\[^{21}\] https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&ptid=20180719&n=pt45.1.46&r=PART&ty=HTML#sp45.1.46.b
\[^{23}\] https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-testing.html
\[^{26}\] See e.g., *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 570-71 (2001)
\[^{27}\] https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf
\[^{28}\] Ibid.
The De Novo marketing authorization goes on to state it is to be used:

“**during the acute phase of infection.** The detection and identification of specific viral and bacterial nucleic acids **from individuals exhibiting signs and/or symptoms of respiratory infection** is indicative of the presence of the identified microorganism and aids in the diagnosis of respiratory infection if used in conjunction with other clinical and epidemiological information. **The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.**”[29] [emphases added]

The BioFire De Novo authorization does not specifically include screening of healthy individuals, as it is most accurate during the acute phase of infection, when interpreted by a licensed healthcare practitioner who has examined the patient. FDA De Novo designation means the product can be marketed before complete efficacy and safety testing are completed, as a product that is “adequate to provide reasonable assurance of safety and effectiveness, and the probable benefits of the device outweigh the probable risks.”[30] It has not received full licensure from the FDA.

As County Supervisors, it is your duty and responsibility to compel the California Department of Education to get in line with CDC School Guidance and follow EUA testing law and De Novo testing authorization guidance and law, for all the reasons stated above.

**Mandatory Health Checks and Testing in Schools: Illegal and Against CDC School Guidance**

California Public Schools are setting up illegal infrastructure around mandatory use of EUA test products. California schools intend to mandate regular RT-PCR or antigen testing on children, with the penalty of withholding access to in-person education if testing is not completed. Los Angeles County Public School District is implementing the Daily Pass app, which:

“generates a unique QR code for each student and staff member that authorizes entry to a specific Los Angeles Unified location for that day only, as long as the individual receives a negative test result for COVID, shows no symptoms and has a temperature under 100 degrees. Upon an individual’s arrival to a campus, their QR code is scanned by a Los Angeles Unified school site leader who takes the individual’s temperature.”[31]

Only a licensed health care practitioner should interpret a test after examining the patient. According to the CDC flowchart for schools, if a student appears to have symptoms at school, she should be referred to her own healthcare provider to consider testing for any possible infectious illness.[32]

CDC guidance on testing in school settings, as of December 4, 2020, states:

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29 ibid
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.\(^{33}\)

California School Guidance issued on March 20, 2020 states schools may consider surveillance testing every two weeks or screening testing once or twice a week, depending on which tier they are in.\(^{34}\) Currently most counties are in the red tier so California School Guidance recommends testing those with symptoms, and asymptomatics every two weeks.\(^{35}\) DailyPass implies there may be more frequent testing, which we hope is not the case.

Please note that both the December 4, 2020 CDC School Guidance for COVID and California School Guidance for COVID updated on March 20, 2021\(^{36}\) go against FDA’s Umbrella EUA for COVID molecular tests (RT-PCR) which states they are only to be used “for … respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.”\(^{37}\) In other words, an individual’s doctor must suspect COVID-19, and the patient must have symptoms or have been exposed. The EUA is specifically not issued to screen healthy, asymptomatic individuals.

We have also just learned via a Zoom call with district parents that LAUSD plans to put students six feet apart in plexiglass booths with headphones to watch their teachers on Zoom. A teacher will be at home while another adult will monitor the children in class. CDC School Operational Strategy Guidance for Schools\(^{38}\) updated on March 19\(^{th}\) clearly states the standard is three feet, not six feet, and removed the recommendation for physical barriers. This should help schools fit more students into classrooms and allow more enjoyment of outdoor space.

While we applaud getting children back in school, we question how this restrictive environment will help reverse learning loss. It appears more like factory babysitting. It also sends a message to children that they are dangerous to adults, at a time when their mental health is extremely fragile due to extended lockdowns and isolation. It appears that Teachers Unions are exerting power in ways that do not benefit children, and schools are doing the minimum to receive large sums from the $1.9 Trillion Stimulus Bill to open minimally by a certain date.\(^{39}\)\(^{40}\) We urge you as County Supervisors to intervene in any schools or districts where overly restrictive environments are being created for our schoolchildren.

**EEOC Guidance: Anti-Discrimination Laws Apply**

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\(^{33}\) [https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-testing.html](https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-testing.html)


\(^{35}\) Ibid.

\(^{36}\) [https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID19-K12-Schools-InPerson-Instruction.aspx#K-12%20School%20Testing](https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID19-K12-Schools-InPerson-Instruction.aspx#K-12%20School%20Testing)

\(^{37}\) [https://www.fda.gov/media/136598/download](https://www.fda.gov/media/136598/download)


\(^{40}\) [https://www.voiceofsandiego.org/topics/education/local-school-districts-suddenly-have-unprecedented-cash/](https://www.voiceofsandiego.org/topics/education/local-school-districts-suddenly-have-unprecedented-cash/)
Regarding current testing and vaccine mandates for teachers, school staff and any business or entity operating in your county, the Equal Employment Opportunity Commission (EEOC) issued updated pandemic guidance on December 16, 2020.\(^{41}\) This guidance makes clear that all workplace anti-discrimination laws continue to apply during the time of COVID, including:

- the Americans with Disabilities Act (ADA),
- the Rehabilitation Act (including the requirement for reasonable accommodations and non-discrimination based on disability as well as strict rules about employer-mandated or employer-led medical examinations and inquiries),
- Title VII of the Civil Rights Act (which prohibits discrimination based on race, color, national origin, religion, and sex, including pregnancy),
- the Age Discrimination in Employment Act (which prohibits discrimination based on age, 40 or older),
- the Genetic Information Nondiscrimination Act, and
- other federal, state and local laws that may provide employees with additional protections.

As the National Law Review Journal reported in an article last month, the “EEOC guidance […] includes a variety of cautionary instructions for employers, including, for example, potential restrictions on disability-related questions and recognized protections that must be afforded to employees seeking exemption from vaccination [or other] requirements due to medical conditions or sincerely held religious beliefs.”\(^{42}\)

However, the EEOC guidance also provides information that is in direct conflict with the plain language of the EUA authorizing statute. The EEOC guidance suggests that employers may have the authority to mandate these EUA products on their employees. That is absolutely false. Again, both federal and state law are explicit: it is illegal to mandate any EUA products. Period.

Regardless, even employers considering adopting voluntary programs to distribute EUA products to employees must proceed very carefully. Sections A, D, G and K of the EEOC guidance lay out in some detail the procedures that all employers must follow with respect to setting up programs to distribute EUA products for use by employees.\(^{43}\)

First, for any program, employers would have to implement appropriate procedures to process disability and religious accommodation requests; this is an extensive process that, if mishandled, can easily expose employers to liability. Second, given that both the investigational vaccines and PCR tests are only available under EUA, requirements related to full disclosure, informed consent and accommodations associated with mandates for these not fully approved products can be even more onerous on employers than for fully approved products. Risks associated with EUA products are also generally much more significant than for fully approved products.


\(^{43}\) Id.
Nevertheless, some small but significant percentage of employers are rolling out or have already implemented illegal employee mandate programs. Many of these employers are already being sued. Beyond the legal liability exposure, employers who choose to mandate experimental, controversial and demonstrably risky products will face pushback in the court of public opinion and likely suffer losses due to impacts on employee and customer morale and commitment. Employer vaccine mandates in particular present a number of serious ethical, medical, economic and legal risks. Class action lawsuits brought by members of racial minorities are the most vulnerable to harm and the type of plaintiff class that employers likely do not want to defend against.

It is always permissible for employers to offer vaccines or other experimental products to employees on a voluntary basis, provided employees’ decision to answer questions is entirely voluntary regarding pre-screening, disability, or intent to get a COVID test or shot. Any such questions must not violate HIPPA laws, as well. Voluntary programs are far safer and more cost-effective for employers and provide the means to address workplace safety and operational concerns without the significant risks associated with mandatory programs — particularly mandates of products only available under an EUA. Of particular importance, even voluntary programs must follow EUA law regarding providing “informed consent” to anyone deciding whether or not to use or receive an EUA product like the RT-PCR test or a COVID shot, including:

That the Secretary has authorized the emergency use of the product;…the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and …OF THE OPTION TO ACCEPT OR REFUSE ADMINISTRATION OF THE PRODUCT [emphasis added,] of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks. [21 USC Sec 360bbb-3][44]

De Facto Mandates are Also Illegal

De facto mandates to get around the law are also illegal. A “voluntary” COVID shot or test is a de facto mandate if an organization or institution:

- Does not give information on the EUA mRNA injectables and recombinant vaccines or EUA test being voluntary - either by omission or commission;
- Does not fully inform potential recipients of the known and potential risks of the EUA mRNA injectables and recombinant vaccines or EUA test;
- Threatens to fire an employee if she does not submit to an EUA mRNA injectable, EUA recombinant vaccine or EUA test;
- Encourages and allows peer pressure, bullying or discrimination from community members – such as in schools or at organizations or companies - to get an EUA mRNA injectable, EUA recombinant vaccine or EUA test;

• Forces frequent EUA testing on those who cannot or do not want an EUA mRNA injectable or EUA recombinant vaccine;
• Does not keep EUA vaccine status or EUA test results confidential, violating HIPPA and FERPA;
• Coerces students and staff into taking EUA mRNA injectables, recombinant vaccines or tests by threatening to remove campus privileges, like dining hall, dorms, and in-person classroom learning;
• Falsely imprisons a student or employee in a home, dorm, hotel, other building, or even confines her to a geographic area, under duress of losing employment or privileges -- such as on-site or cafeteria privileges -- for refusing an EUA mRNA injectable, recombinant vaccine or test;
• Imposes punitive measures for those who do not want an EUA mRNA injectable, recombinant vaccine, or EUA test, like masking, distancing, privileges, or separated learning, eating or working;
• Issues a reward or special community privilege to those who get an EUA mRNA injectable, recombinant vaccine or test, like the DailyPass app, a sticker, arm band, QR code, or an app dictating where someone can enter, creating a discriminatory environment for those who do not don the “reward” or show the pass;

If an EUA mRNA injectable, recombinant vaccine or test were to become fully licensed someday, any discrimination or double standards applied to those who refuse or cannot have the products would create disclosure of private medical information to that person’s community. This is a de facto violation of HIPPA laws and, in the public school setting, FERPA law.

Since the vast majority of your county’s constituents are unlikely to know that the EUA COVID mRNA injectables, recombinant vaccines and EUA tests are not fully approved and their use is therefore voluntary, you, as a County Supervisor, should consider surveying your constituents to take their pulse on the issue. Since students are especially vulnerable to peer pressure and are less able to resist coercion and duress, you should consider instructing schools to survey students and staff. Children’s Health Defense – California Chapter recommends a heavily-funded communications plan to correct the current widespread and dangerous misunderstandings about the real law and science.

We recommend issuing weekly electronic surveys until 90% or more of your constituents (including K-12 students, their parents, and teachers) understand the following about EUA COVID shots and tests:

• They are voluntary, by law;
• Potential recipients must be advised of all known and potential risks;
• There shall be no peer pressure, bullying, discrimination, incentives, duress or coercion based on testing or vaccine status;
• They understand specific cases, situations and actions so they can easily recognize peer pressure, bullying, discrimination, incentives, duress or coercion.

Children’s Health Defense – California Chapter is happy to assist you in designing appropriate communications and a questionnaire to correct and assess EUA knowledge in your county.
This may be the first time you have become acquainted with EUA law. It is fair to say that we have all experienced something of a crash course in many new things this last year. We need to do a much better job of working together to ensure that we use and apply the best and most accurate information — grounded in both law and science — as we re-open safely and fully and seek to rebuild and restore our collective educational opportunities, health, mental health, social lives and economic viability.

**Urgent to Open Your County Safely & Re-gain Control of Your County**

Your county must take a systems approach to re-opening the entire county, without illegal mandates for EUA products. Children’s Health Defense – California Chapter joins the chorus of voices urging you to regain full control of your County so that you may once again act with county self-determinism.

The law may leave you feeling as though there are no legal avenues to open your county. That is not the case. A broader county-focused approach, based on the most up-to-date science, will create the context and public support for your schools to open safely and within the law.

The urgency is apparent to all. It’s time for all parents to get back to work and for children to return to school. The responses of the last year have created the largest learning loss ever experienced by children. Further, these measures — allegedly taken to protect peoples’ health — have resulted in externalities such as suicide, homicide, drug abuse, domestic abuse, mental health issues and deaths that together have come at a much bigger cost to our society than the deaths attributed to COVID.

A suggested course-correction to open your county and support fully functioning schools might be to take the reins back from your County employees: the County Public Health Officers. Like a medical diagnosis, the root cause of illness must be identified to get a correct diagnosis, followed by the correct treatment so the patient can fully heal. Four contributing factors led to the root cause of the COVID management crisis: Abdication of Duties, Presumption of Expertise, Experts & Expertise Over the Constitution, and Misinterpretation of Public Health Data. Once the root causes of the COVID management crisis are identified, the solution – or “prescription” for recovery - will be obvious.

**Abdication of Duties:** County Supervisors across California have effectively abdicated their legal responsibilities over major decisions and actions to unelected public health officials hired by the county board, severely impacting every adult, child and entity in the county. Public health officials have no economic qualifications and, in many instances, actually possess shockingly minimal relevant public health experience for navigating the present circumstances.

**Presumption of Expertise:** One factor that allowed the massive economic, educational and social destruction is the presumption that public health officers possess an uncanny command of all aspects of medical data. They were then deputized as the chief county economists to enact a lockdown economy that arbitrarily divided businesses and employees into two classes: essential and non-essential. It only worked due to medical illiteracy in most of the population. It is as absurd as a layperson meeting a brain surgeon at a party and asking if the brain surgeon can operate on his foot and file his taxes. The brain surgeon would demur, and admit she is neither a foot specialist nor an accountant.
**Experts and Expertise Over the Constitution:** Another factor is our collective surrender of common sense to all things complicated, from high tech to biotech, necessitating the need for “experts” whose “expertise” must not be questioned, as a way to shut down citizen participation, democratic principles and circumvent the Constitution. The Constitution was written to help us ethically and legally navigate difficult times like this.

**Misinterpretation of Public Health Data:** As you know, it is the legal responsibility of elected supervisors, not unelected public health officers, to make decisions for the County. We will follow up to help you better understand this data.

Children’s Health Defense – California Chapter urges you to immediately *take action* to:

- Bring your operations fully back onto solid legal footing.
- Implement responses that actually help the vulnerable without harming everyone else.
- Allow businesses and schools to function normally.
- Base all public health and economic decisions on fully transparent, legitimate, peer-reviewed data; a comprehensive evidentiary record; regular notice and comment; and the rule of law.

Unlike current lockdown measures, doing so will restore your local economy, your county’s tax base, children’s education and opportunities, and begin to heal the physical and mental health damage inflicted by lockdowns.

We are happy to assist you in this important work, and are standing by should you need any clarification. Please email us at: ca.team@childrenshealthdefense.org or call us at: 415-496-5301. Expect a second letter with referenced peer-reviewed scientific data, to help you re-gain control and to legally align all operations with the most current evidence. We are at-the-ready to advise you on a quick and safe re-opening.

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
Cc: All California K-12 Schools
Cc: County Boards of Education