Dear _____:

I am writing to object to _____ (hereinafter "Company") COVID- 19 vaccine policies.

This Company has elected to either outright mandate that all employees be forced to receive one of the three investigational treatments for COVID-19 (Unapproved Therapies) as a condition of employment, or otherwise coerce employees into taking one of the Unapproved Therapies by offering the discriminatory alternatives of forced masking, segregation, and/or weekly PCR testing. Please be advised that all of these medical interventions (Unapproved Therapies, masks, and PCR tests) are authorized under emergency use authorization (EUA) only and therefore cannot be mandated or forced through duress and coercion.

Notwithstanding the EUA status of the Unapproved Therapies, none of the Unapproved Therapies have been tested for, and thus there is no data to support, their ability to stop or even slow the transmission of COVID-19, and certainly none of the current variants that are allegedly the dominant virus infecting Americans. Therefore, these policies are unreasonable on their face because the stated purpose of the measures cannot be accomplished through the policy. In addition, due to emerging evidence of tens of thousands of "breakthrough" cases (aka vaccine failure) and the failure of your policy to acknowledge the natural immunity of those previously infected with SARS-CoV-2 (which would at least serve to verify that those individuals are immune), your mandates lack even a rational scientific basis for imposing them besides being unlawful under both our federal and California Constitutions.

You are also hereby put on notice that a number of individuals, both within California and nationally, have already suffered severe adverse effects as a direct and proximate result of complying with coercive vaccine policies or just a culture of coercion that exists at work even without an official policy. This amounts to a hostile work environment. This tragic trend is likely to continue, given the evidence of harm from these experimental products,[1] and the acknowledgement from both the vaccine manufacturers and the public health authorities of such potential adverse effects.[2] Unless you terminate your coercive COVID-19 policies immediately, your company may soon be liable for damages, long-lasting poor health outcomes, and even the

[1] *See, e.g.,* https://www.authorea.com/users/414448/articles/522499-sars-cov-2-mass-vaccination-urgent-questions-on-vaccine-safety-that-demand-answers-from-international-health-agencies-regulatory-authorities-governments-and-vaccine-developers (important summary of emerging vaccine safety concerns by noted medical professionals); https://drive.google.com/file/d/1pH0Y3jvHtgaEwcDR9QGTB2f90IaPbcRW/view (Dr. Tess Lawrie summary of emerging adverse effects of vaccines).

[2] *See e.g.,* https://www.fda.gov/media/144637/download (myocarditis and pericarditis); https://cdn.pfizer.com/pfizercom/2021-07/BLA_Acceptance_Media_Statement_FINAL.pdf (myocarditis and pericarditis and other known and still unknown adverse effects); https://thevaccinereaction.org/2021/07/fda-adds-warning-about-rare-reaction-to-jj-covid-19-vaccine (Guillain-Barré syndrome);https://www.medscape.com/viewarticle/953901?src=mkm_covid_update_210629_MSCPEDIT&uac=298618HK&impID=3475853&faf=1#vp_1 (thrombosis and thrombocytopenia after mRNA); https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine (adding myocarditis warning).

loss of life. The drug manufacturers enjoy immunity from any harm from their products, but your Company does not.

EUAs and the Lack of Safety Data

The EUA applications for the Unapproved Therapies were based on data which supports that these products *may* reduce certain symptoms of COVID-19 for some individuals, but the FDA's EUA authorizations made clear that there is no evidence the Unapproved Therapies can prevent recipients from becoming infected with and transmitting the virus. As the FDA explains, at the time of the EUA approval, the data was "not available to make a determination about how long the vaccine will provide protection, **nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 [*i.e.*, the virus that causes COVID-19] from person to person**."[3] The FDA makes clear much is unknown about the **safety** of these products, including:

- No understanding of"[a]dverse reactions that are very uncommon,"
- No understanding of adverse reactions "that require longer follow-up to be detected," and
- No understanding, and no test to rule out, whether the vaccines will cause "[v]accine-enhanced disease," which is known to be very deadly in animal trials and typically does not show up as an acute symptom, but rather a longer term problem.[4]

As a result, the authorization letters for each Unapproved Therapy expressly provide that the vaccines are each "an investigational vaccine **not licensed** for any indication" and require that "**[a]ll promotional material relating to the COVID-19 Vaccine clearly and conspicuously ... state that this product has not been approved or licensed by the FDA**, but has been authorized for emergency use by FDA."[5]

Additional Safety and Liability Considerations in Mandating or Coercing EUA Vaccines

As stated above, there is no evidence to indicate that any of the current Unapproved Therapies prevent infection or transmission of SARS-CoV-2 and any policies mandating or coercing their use to prevent infection or spread lack scientific support. There is also evidence indicating that these experimental products are in fact causing significant adverse effects for an increasing number of individuals.[6] Medical professionals around the world have been

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[3] FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine" available at https://www.fda.gov/news-events/press-announcements/fda-takes-additional- action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (emphasis added).

[4] *Id.*

[5] *See* https://www.fda.gov/media/144416/download, https://www.fda.gov/media/144673/download at 9, and https://www.fda.gov/media/146303/download.

[6] *See, e.g.,* https://www.authorea.com/users/414448/articles/522499-sars-cov-2-mass-vaccination-urgent-questions-on-vaccine-safety-that-demand-answers-from-international-health-agencies-regulatory-authorities-governments-and-vaccine-developers (important summary of emerging vaccine safety concerns by noted medical professionals); https://drive.google.com/file/d/1pH0Y3jvHtgaEwcDR9QGTB2f90IaPbcRW/view (Dr. Tess Lawrie summary of emerging adverse effects associated with CV-19 vaccines). *See also* Dr. Byram W. Bridle, COVID-19

documenting and are continuing to note rising cases of myocarditis, thrombocytopenia, thrombosis, various fertility issues, and a host of other serious neurological dysfunctions following vaccination.[7]

Your Company's policy is also failing to take into consideration that a significant portion of your employee population is likely to have already had SARS-CoV-2 and have recovered.[8] Even putting aside the more robust natural immunity conferred by having been previously infected, which already suggests a lack of rational scientific basis for your over-inclusive policy, there have been concerns raised by medical professionals that vaccinating those already recovered can actually lead to serious injury or death, such as by causing antigen specific tissue inflammation in any tissues harboring viral antigens.[9] Failing to take into account the natural immunity of your employees, which data shows confers a high level of lasting immunity, in fashioning this policy could prove to be detrimental liability-wise when these cases are brought to court because this simple step could avoid massive potential injury and there is no logical reason not to undertake it.

EUA Products are Experimental by Definition

Until medical products or devices are approved for use by being licensed by the FDA for that particular use, the efficacy and safety of the products is still in question and under investigation. To be licensed, the FDA must find that a medical product is "safe for use and … effective in use.".[10] Until licensed, a medical product remains investigational, even after issuance of an EUA. The EUA can only state that the product MAY be safe and effective. "The issuance of an EUA is different than an FDA approval (licensure) of a vaccine. A vaccine available under emergency use authorization is still considered investigational."[11] And as the FDA explains, "an investigational drug can also be called an experimental drug" because these two terms are synonymous.[12] For example, the EUA fact sheet for an intravenous drug to treat H1N1 granted EUA by the FDA explains that it is "an experimental drug."[13] Similarly, after an EUA was

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[7] *Id.*

[8] According to CDPH's own data, roughly 85.9% of Californians have antibodies for the virus that causes SARS-CoV-2. See https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Sero-prevalence-COVID-19-Data-aspx.

[9] *See* https://noorchashm.medium.com/a-letter-of-warning-to-fda-and-pfizer-on-the-immunological-danger-of-covid -19-vaccination-in-the-7d17d037982.

[10] 21 U.S.C. § 355(b)(1)(A)(i) (an application for licensure requires "full reports of investigations which have been made to show that such drug is safe for use and whether such drug is effective in use").

[11] https://www.niaid.nih.gov/diseases-conditions/covid-19-vaccine-faq

[12] Until a medical product's Investigational New Drug Application is approved by the FDA, and hence licensed, it is considered experimental. https://www.fda.gov/media/138490/download ("an investigational drug can also be called an experimental drug"); https://www.northwell.edu/coronavirus-covid-19/vaccine/frequently-asked-questions ("Vaccines that receive EUA are considered experimental until the FDA formally approves it.").

[13] https://web.archive.org/web/20100222172129/http:/www.cdc.gov/h1n1flu/eua/pdf/patient_fact_sheet_peramivir_IV_23Oct2009.pdf. Peer review studies found that using the term "experimental" in reference to an EUA medical product reduced their uptake and hence advised against informing the public that these products are still "experimental." *See*, *e.g.*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7893369/ ("A 2010 survey examining the acceptance of peramivir, approved as an EUA, found that use of the term 'experimental' on the fact sheet decreased willingness across the board. … FDA and the sponsor must … avoid language that stimulates negative responses

granted for the COVID-19 vaccine co-developed by the National Institutes of Health ("**NIH**") and Moderna, it was described by the NIH as an "[e]xperimental coronavirus vaccine."[14]

This Company Cannot Coerce Individuals to Use Experimental Products

Legal precedent dating back to the end of the second World War establishes that it is not legal to coerce an individual to accept an unlicensed, and hence experimental, medical product. The reasons for this are obvious. No one should be forced to endure an experimental medical procedure or treatment against their will. Doing that to a person is morally wrong. An individual must voluntarily agree, free from any undue influence, to accept the product. This principle was first codified in America long-ago.[15] It was then incorporated into the United States Code, the Code of Federal Regulations, and guidance from federal health agencies. *See e.g.*, 21 U.S.C. § 360bbb-0a (Even for patients with a life-threatening condition, an unlicensed medical product cannot be coerced, rather Congress required obtaining the patient's "written informed consent.") 42 U.S.C. § 9501 (Same for mental health patients);[16] 45 C.F.R. § 46.116 (For an unlicensed medical product, the "Basic elements of informed consent" include that "participation is voluntary," "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled" and that consent be obtained without "coercion or undue influence.");[17]

Section 564 of the Federal Food, Drug, and Cosmetic Act (the "**Act**") provides that the Secretary of HHS is to "ensure that individuals to whom the product is administered are informed" of "the option to accept or refuse administration of the product." (*Id.*) S.C. 360bbb-3][18]. Each Fact Sheet for Healthcare Providers for the three COVID-19 vaccines state that: "The recipient or their caregiver **has the option to accept or refuse** [the] COVID-19 Vaccine." All of the fact sheets provide the required information in sequence, including telling potential recipients: "It is your choice to receive or not receive the [] COVID-19 Vaccine." These

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(i.e., experimental)."); https://pubmed.ncbi.nlm.nih.gov/25882123/ ("In late 2009, peramivir was granted an EUA" and its "CDC fact sheet" stated it is an "experimental drug" but the study found that "the use of the term experimental, while necessary and accurate, presented real impediments for willingness" to take the EUA product.).

[14] [7] https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective.

[15] "The Nuremberg Code is the most important document in the history of the ethics of medical research. The Code was formulated 50 years ago, in August 1947 … by American judges … It served as a blueprint for today's principles that ensure the rights of subjects in medical research [which includes unlicensed medical products]." https://www.nejm.org/doi/full/10.1056/NEJM199711133372006. See also https://history.nih.gov/display/history/Nuremberg+Code, 313 BMJ 1448 (1996) ("The voluntary consent of the human subject is absolutely essential [for unlicensed medical interventions]. This means that the person … [is] able to exercise free power of choice, without the intervention of any element of … coercion.").

[16] *See also* 38 U.S.C. § 7331 (Same for veterans); 42 U.S.C § 300ff-61 ("in testing for HIV/AIDS, the applicant will test an individual only after the individual confirms that the decision of the individual with respect to undergoing such testing is voluntarily made").

[17] *See also* 21 C.F.R § 50.20 (sets forth conditions for obtaining informed consent for use of an unlicensed medical product and reiterating that consent should be free from "coercion or undue influence")

[18] FDA's *Emergency Use Authorization of Medical Products and Related Authorities – Guidance for Industry and Other Stakeholders* available at https://www.fda.gov/media/97321/download (emphasis added).

standards show that the recipient is to give **informed consent to the procedure that cannot be coerced**. The FDA *Information Sheet: Informed Consent* says: "Coercion occurs when an overt threat of harm [such as expulsion from school or employment] is intentionally presented by one person to another in order to obtain compliance."[19]

Coercive Vaccine Policies Violate the Act, EUA, Public Policy, and the Nuremberg Code

This Company is deliberately taking away each employee's statutorily guaranteed right to decide whether to accept or refuse administration of the Unapproved Therapies and/or products. It is doing so openly, without any regard for the personal and autonomous right of each individual to choose whether they want to receive or use an unapproved and unlicensed medical product. The Company is effectively forcing each employee to choose between facing either termination or expulsion from work, receiving an experimental medical treatment to which they do not consent, or submitting to discriminatory and illegal requirements of forced masking, segregation, and invasive testing using other EUA products to which they do not voluntarily consent. This policy contains layers of illegality and liability creating directives.

The right to informed medical consent is considered a fundamental, overriding principle of medical ethics and international law, first laid down by United States government in the Nuremberg Code. It says: "The voluntary consent of the human subject is absolutely essential. This means that the person...[is] able to exercise free power of choice, without the intervention of any element of...coercion."[20].

This Company cannot lawfully navigate around the prohibition against mandating an EUA vaccine by offering the punitive alternatives of forced masking, segregation, and/or weekly or periodic testing for those exercising their right to decline the experimental vaccine. **Masks and COVID-19 testing products are also only authorized under EUA, and thus also require informed consent and the right to refuse.** There is also evidence showing both the ineffectiveness of masks and/or harmful effects of prolonged mask usage,[21] and the dubious ability of COVID-19 PCR-based testing products to accurately diagnose infectious viral loads.[22] This evidence indicates that your "alternatives" to experimental vaccines could also be both harmful to your employees' health, as well as scientifically meaningless as tools to prevent transmission.

Employer Policies are a Veiled Campaign of Discrimination and Coercion

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[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent#coercion

[20] The Nuremberg Code (1947), 313 BMJ 1448 (1996)

[21] A review of 44 studies revealed a "statistically significant correlation in the quantitative analysis between the negative side effects of blood-oxygen depletion and fatigue in mask wearers. *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8072811/

[22] *See, e.g.,* https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html; *see also* World Health Organization, https://apps.who.int/iris/rest/bitstreams/1352897/retrieve ("Widespread screening of asymptomatic individuals is not a currently recommended strategy due to the significant costs associated with it and the lack of data on its operational effectiveness.").

Evidence of tens of thousands of fully vaccinated persons experiencing "breakthrough" cases of COVID-19, and the CDC's unscientific decision to stop monitoring/counting most breakthrough cases, makes any mandate distinguishing between vaccinated individuals and unvaccinated individuals scientifically unsupportable.[23] If fully vaccinated individuals are also contracting and spreading COVID-19, the discrimination against unvaccinated individuals appears to be little more than an unlawful attempt to coerce uptake of an investigational product. By creating a two-tiered system of employment, whereby persons vaccinated with COVID-19 EUA products can participate in work life unburdened by forced masking or PCR testing, while those who have either already naturally recovered from the virus and/or who are showing no signs of illness must engage in safety theatre meant to shame, ostracize, and coerce vaccine uptake, your Company is engaging in discriminatory actions that violate various state and federal laws. These laws include Constitutional protections regarding equal protection, the right to privacy, the right to education, the right to freedom of association, as well as the bioethical principles noted above.

Reverse Course to Avoid Exposure to Massive Potential Liability

The potential harm to employees from this coercive policy is very real. One recent tragic example in California is the case of Maddie Johnson, an undergraduate pre-med student at Chapman University in Orange, California. She took the injection believing that it was safe and effective as advertised by the media and her university. Her life has been forever altered and her budding medical career is now on hold, possibly indefinitely. Her mother has been documenting her daughter's severe reaction to the vaccine on social media.[24]

It is inconceivable, in light of terrible tragedies like this and the potential harm to your employees, that your Company would choose to voluntarily take on the responsibility for forcing this on your staff. Not one governmental agency is requesting this, you and your Company are making this decision alone. The legal liability for you and your institution could be immense.

Because of these reports of actual and potential serious adverse effects caused by the experimental vaccines, you are hereby put on notice that your school could very well soon be liable for damages, poor health outcomes, and even the loss of life due to your coercive COVID-19 policies. While manufacturers and vaccine administrators are protected by the PREP Act, employers creating coercive policies are not.[25]

A balancing test must be done here by those in charge, and a thoughtful response to perceived threats to health and safety must be implemented. Rushed, coercive, potentially harmful, discriminatory and illegal actions are not the answer. If the Company is legitimately

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[23] *See e.g.,* https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm; https://news.yahoo.com/how-many-covid-hospitalizations-double-vaccinated-171607939.html; https://www.msn.com/en-gb/health/medical/nearly-30-of-those-dying-with-delta-variant-of-covid-are-double-vaccinated/ar-AAL1RQE

[24] https://www.gofundme.com/f/help-madeline-johnson-recover-from-a-vax-injury?utm_campaign=p_cp+share-sheet&utm_medium=copy_link_all&utm_source=customer; https://www.instagram.com/marah_johnson//

[25] Congressional Research Service. The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures. Updated Mar. 19, 2021. https://crsreports.congress.gov/product/pdf/LSB/LSB10443

concerned about its vulnerable population at work, then those individuals should be offered an injection and be outfitted with, and trained to use, and n95 mask to protect themselves. This is a method to protect those who the Company aims to protect without harming, coercing, and illegally violating the rights of others. I enjoy my work and I enjoy this Company. It is my hope that those charged with managing it don't destroy its reputation and existence through these illegal policies.

For the foregoing reasons, I urgently request that your Company immediately withdraw its unlawful and unethical COVID-19 mandates and/or coercive policies. Forcing or coercing experimental products on individuals who do not want to take them not only violates federal law and critically important medical ethical principles, but it removes all trust in the public health authorities attempting to violate such critically important and long-established safeguards, rules, and ethical principles, as well as any trust in any employers willing to go along with such violations at the expense of their employees.

Also enclosed herewith is a Request for More Information so that I may make an informed choice whether or not to take the experimental injections and/or use any other EUA products the Company is purportedly requiring for me to continue my employment. Thank you for your anticipated response.

Date:

Very truly yours,

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