SIRI & GLIMSTAD LLP
Aaron Siri (Pro Hac Vice filed)
Email: aaron@sirillp.com
Elizabeth A. Brehm (Pro Hac Vice granted)
Email: ebrehm@sirillp.com
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Telephone: 212-532-1091
Facsimile: 646-417-5967

Caroline Tucker (SBN 261377)
Email: ctucker@sirillp.com
700 S. Flower Street, Suite 1000
Los Angeles, CA 90017
Telephone 213-376-3739
Facsimile 646-417-5967

CHRIS WIEST ATTORNEY AT LAW, PLLC
Chris Wiest (Pro Hac Vice granted)
Email: chris@cwiestlaw.com
25 Town Center Blvd, STE 104
Crestview Hills, KY 41017
Telephone: 513-257-1895
Facsimile: 859-495-0803

Attorneys for Plaintiff
AARON KHERIATY, M.D.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

AARON KHERIATY, M.D., Plaintiff, v. THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, a Corporation, and MICHAEL V. DRAKE, in his official capacity as President of the UNIVERSITY OF CALIFORNIA, Defendants.	Case No.: 8:21-cv-01367 JVS (KESx) **DECLARATION OF PLAINTIFF, AARON KHERIATY, M.D IN SUPPORT OF PLAINTIFF'S REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFF'S PRELIMINARY INJUNCTION** Date: September 27, 2021 Time: 1:30 pm Place: Courtroom 10C Judge: Hon. James V. Selna

I, Aaron Kheriaty, M.D., declare as follows:

1. I have reviewed the Reply Declaration of the University of California Faculty in support of Plaintiff's motion for a preliminary injunction and concur with both its reasoning and conclusions.

Experience & Credentials

2. Regarding my expertise and qualifications to opine on matters related to the University's Covid vaccine mandate policy, the University claims that I am not qualified to serve as an expert witness because I am not an epidemiologist, immunologist, or infectious disease specialist.

3. All physicians have training in epidemiology, immunology, and infectious disease, and in fact, general medical expertise in other areas is also necessary for evaluating the UC's policy on mandatory vaccination (e.g., medical ethics, medico-legal issues, informed consent, pathophysiology of adverse events, e.g., myocarditis and anaphylaxis, medical conditions that may be contraindications to vaccination, etc.). The breadth of knowledge necessary is sufficiently wide that those who are too sub-specialized (e.g., a PhD in immunology) might lack requisite expertise to opine on other

relevant issues (e.g., side-effects of the vaccine). A breadth of medical knowledge is an asset in assessing a policy like this, not a liability.

4. Applying the UC's own excessively stringent standard for expertise to their own experts: their immunologist (Prof. Crotty) and their infectious disease specialist (Dr. Byington) should not opine, as they do throughout their declarations, on epidemiology because they are not epidemiologists. Likewise, and for the same reason, their epidemiologist (Prof. Reingold) should not opine on immunology or infectious disease. None of them should opine on vaccine adverse events like myocarditis because they are not cardiologists, or anaphylaxis because they are not emergency medicine specialists, and so forth. But applying this unreasonable standard to the defendants' experts would clearly be absurd, just as it is absurd when the defendants attempt to apply it to our experts—all of whom have broad and deep expertise applicable to Covid and to the policy in question.

5. Regarding my particular expertise, the University of California endorsed that I had sufficient expertise in the ethics of policies related to Covid, and specifically to Covid vaccines, to appoint me to a committee—the UC Office of the President Critical Care Bioethics Working Group— that drafted the following Covid policies: "Allocation of Scarce Critical Resources under Crisis Standards of Care" (i.e., Covid pandemic ventilator triage), "Allocation Guidelines for Remdesivir if Demand Outstrips Supply" (an antiviral medication for Covid), and finally, "Framework for Health Care Worker Vaccine Distribution Prioritization" for Covid vaccines.[1] So, for purposes of helping to develop and write the UC's Covid Vaccine Distribution policy, implemented across the

[1] Regarding this vaccine policy I attach a letter from Carrie Byington, EVC of UC Health (i.e., the head of all the UC hospitals) sent to all the UC Health Vice Chancellors and UC Health Chief Executive Officers, which included the vaccine prioritization policy that our workgroup had developed.

entire University, the UC Office of the President and the Executive Vice Chancellor of UC Health endorsed that I had sufficient expertise. But now, against all plausibility, the University is claiming that I lack sufficient expertise to opine on the University's Covid vaccine mandate policy. This is a clear contradiction and a manifestly desperate gambit.

6. Also relevant here, the California Department of Public Health (CDPH) valued my expertise on Covid-related policies, as did the the Orange County Department of Health—in the latter case, specifically my expertise on vaccine allocation. I have served as a consultant for the State of CA Health and Human Services Agency, Department of Public Health on state policies for "Allocation of Bamlanivimab during Covid pandemic" (a monoclonal antibody for Covid), and the California Covid Pandemic Crisis Care Guidelines[2] (i.e., Covid pandemic ventilator triage). I remain a member of the COVID-19 Vaccine Task Force for the County of Orange Healthcare Agency, which developed and implemented Orange County's Covid Vaccine Allocation Policies.

7. At my own hospital, the Chief Medical Officer appointed me to convene and direct our Covid pandemic triage team and train the triage officers on the UC triage policy I helped write. I have likewise served on the frontlines of caring for Covid patients from the beginning of the pandemic, treating Covid patients on our psychiatric consult service in the ER, hospital wards, and hospital ICU. As chair of the hospital ethics committee, I have had more anguishing conversations than I can count with families to explain to them that their loved one was irretrievably dying of Covid. I have witnessed the worst that this illness can do and have cared for the most severely ill and dying Covid patients throughout the pandemic.

8. I contracted the virus last year, and despite my efforts to self-isolate, passed

[2]https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/COVID-19/California%20SARS-CoV-2%20Crisis%20Care%20Guidelines%20-June%208%202020.pdf.

it onto my wife and five children. Living and breathing the Covid pandemic for a year, I eagerly awaited a safe and effective vaccine for those that were still not immune to this virus to help us fight the pandemic. While serving on the Orange County Covid Vaccine Task Force[3] I have advocated—both in the committee and publicly in the *Los Angeles Times*—that the elderly and sick be prioritized[4] for vaccination, and that the poor, disabled, and underserved be given ready access[5] to vaccines.

9. I have a breadth and depth of knowledge of the clinical, ethical,[6] psychological,[7] social, epidemiological, and institutional[8] realities of the Covid pandemic, Covid treatment regimens, and pandemic mitigation measures, including vaccines. In short, it would be difficult to find UC faculty members (or other academic physicians) with clinical, bioethical, and policy-related experience that would make them

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[3] https://occovid19.ochealthinfo.com/taskforce-members-and-constituencies-they-represent.

[4] https://www.latimes.com/california/story/2021-02-05/california-covid-19-vaccine-priority-decision.

[5] https://www.latimes.com/california/story/2021-03-16/californias-covid-19-vaccine-expansion-relies-on-honor-system-you-have-to-try-to-trust; https://covid19beinformed.com/index.php/2021/03/16/californias-covid-vaccine-expansion-relies-on-honor-system-los-angeles-times/.

[6] Kheriaty A, Bradley G, "University Vaccine Mandates Violate Medical Ethics," *Wall Street Journal*, 14 June 2021; Kheriaty A, et. al., Moral Guidance on Prioritizing Care During a Pandemic," *Public Discourse*, 5 April 2020; Kheriaty A, "The Impossible Ethics of Pandemic Triage," *The New Atlantis*, April 3, 2020.

https://www.thenewatlantis.com/publications/the-impossible-ethics-of-pandemic-triage.

[7] Kheriaty, A, "The Other Pandemic: The Lockdown Mental Health Crisis," *Public Discourse*, 4 October 2020. https://www.thepublicdiscourse.com/2020/10/71969/.

[8] Kheriaty A. "Battlefield Promotions: A call to action for medical students during Covid," The New Atlantis, March 18, 2020. https://www.thenewatlantis.com/publications/battlefield-promotions.

more qualified than I am to opine on the specific policy in question, and the implications of the policy for students and employees of the University.

Opinion

10. My central empirical claim is that natural immunity is at least equivalent to vaccine mediated immunity. Natural immunity is in fact superior to vaccine immunity, though this is not necessary for my argument. While the University has objected that this claim is merely an "unproven hypothesis" or "theory," this claim is supported by uncontroverted robust and undeniable evidence in its favor. In fact, the University's claim that this is merely a hypothesis does not withstand even a cursory review of the available evidence.

11. If we applied the defendant's standard of evidence to the defendant's own claims regarding the necessity of vaccinating Covid-recovered patients, the rationale for their policy would fail miserably, as I also demonstrate below. If my claim about natural immunity is merely an "unproven hypothesis," then their central claim about the need to vaccinate Covid-recovered individuals can only be characterized as whimsical fancy—so poor is the evidence in favor of it.

12. In addition to the studies on natural (infection-induced) immunity summarized in the declarations filed in support of my claim, Israeli researchers utilized a large population-based sample of over 62,000 fully vaccinated individuals and over 42,000 previously infected individuals.[9] They found that fully vaccinated individuals were 6 to 13 times more likely to get infected than unvaccinated people who were previously infected; the risk of developing symptomatic Covid was 27 times higher

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[9] Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon, medRxiv 2021.08.24.21262415; doi: https://doi.org/10.1101/2021.08.24.21262415; https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf.

among the vaccinated than the previously infected, and the risk of hospitalization was 8 times higher. The authors conclude: "This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [Pfizer] two-dose vaccine-induced immunity."

13. These findings were not surprising, remarkable, or out of the ordinary. Infection with the virus allows our body to form an immune response to many epitopes (parts on the surface) of the virus, whereas the vaccines expose us only to one epitope, the spike protein. This is consistent with what we know about basic immunology for most viruses. As the authors of this study put it, "The advantageous protection afforded by natural immunity that this analysis demonstrates could be explained by the more extensive immune response to the SARS-CoV-2 proteins than that generated by the anti-spike protein immune activation conferred by the vaccine."[10]

14. The findings in this study are consistent with an earlier study in the journal *Nature* that showed people who recover from Covid infection continue to develop increasing numbers and types of coronavirus-targeting antibodies for up to one year.[11] By contrast, fully vaccinated individuals stop seeing increases in the potency or breadth of the overall memory antibodies four months after their second dose (see below). The conclusions are also consistent with a Cleveland Clinic study that found zero reinfections in the 2579 previously infected (including 1359 previously infected but unvaccinated) participants over the five-month study period. The authors concluded:

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[10] Ibid.

[11] Wang, Z., Muecksch, F., Schaefer-Babajew, D. *et al.* Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection. *Nature* 595, 426–431 (2021). https://doi.org/10.1038/s41586-021-03696-9; https://www.nature.com/articles/s41586-021-03696-9.

"Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before."[12]

15. For purposes of my legal case, natural immunity need only be *equivalent* to vaccine-immunity. But the evidence strikingly demonstrates that natural immunity is *superior* to vaccine-induced immunity; indeed, the differences are enormous. As reported in the journal *Science* (widely acknowledged, along with *Nature*, as the most prestigious and influential scientific journal) in a commentary on the above-mentioned Israeli study: "The natural immune protection that develops after a SARS-CoV-2 infection offers considerably more of a shield against the Delta variant of the pandemic coronavirus than two doses of the Pfizer-BioNTech vaccine."[13] The article continues:

> "It's a textbook example of how natural immunity is really better than vaccination," says Charlotte Thålin, a physician and immunology researcher at Danderyd Hospital and the Karolinska Institute who studies the immune responses to SARS-CoV-2…. "The differences are huge," says Thålin."[14]

The Israeli study showed a risk of reinfection with natural immunity during the three-month study period of between 0.12% and 0.23%. Less than half of these reinfections were symptomatic, and less than 1 in 10,000 was hospitalized; there were no deaths among the handful of reinfected cases.[15] While reinfection after Covid recovery is a very remote possibility, the probability is vanishingly small (as close to zero as statistics get in medicine); much smaller than the probability of breakthrough infections among the

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[12] https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2

[13] https://www.science.org/content/article/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-vaccination-remains-vital.

[14] Ibid.

[15] https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf.

vaccinated.

16. A single dose of the Johnson & Johnson (J&J) vaccine is sufficient to be "fully vaccinated," according to the University's mandate policy. According to J&J's own Phase 3 clinical trial, submitted to the FDA for Emergency Use Authorization and published in the *New England Journal of Medicine*,[16] this vaccine provides protection against moderate to severe Covid at 67% efficacy at 14 days after vaccination and 66% efficacy at 28 days after vaccination. Since this initial clinical trial, no study and no scientist has suggested that the efficacy of the J&J vaccine might in fact be higher than 66-67%. (According to a recent CDC study, mentioned below, the efficacy of J&J is now 60%).

17. According to the UC policy, this level of immunity counts as "fully vaccinated." Comparing this to the vanishingly small risks of reinfection for Covid-recovered naturally immune individuals described above, I can only reiterate Prof Thålin's remark: "the differences are huge." The gap between the risks of reinfection in Covid-recovered and the risk of breakthrough infections in the fully vaccinated is enormous. For purposes of my argument, natural immunity need only be equivalent to vaccine immunity; in fact, it is clearly superior on every measure (infection, symptomatic infection, moderate to severe illness, hospitalization).

17. Once multiple studies on a topic have been published, a meta-analysis is useful for drawing robust conclusions from the research as a whole. A meta-analysis combines the data from many studies selected for methodological quality and re-analyzes their pooled data comprehensively. This has the advantage of overcoming some of the limitations or weaknesses of smaller individual studies (after all, every study has methodological limitations and potential weaknesses). A meta-analysis of natural

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[16] https://www.nejm.org/doi/full/10.1056/NEJMoa2101544.

immunity recently published on Sept 7 analyzed fifty-four studies from 18 countries, with a total of over 12 million Covid-recovered individuals followed up to 8 months after recovery from Covid. It found that prevalence of reinfection for Covid-recovered individuals was 0.2% after 6-8 months.[17]

18. What is more, whereas evidence is mounting that vaccine efficacy is waning with time and new variants, there is no evidence that natural immunity has waned at all during the 19 months of the pandemic, including against new variants. Furthermore, there is considerable evidence, described and documented in our expert declarations, that natural immunity is unlikely to wane in the future. By contrast, waning vaccine immunity has been shown in several studies, leading to interest and speculation regarding the possibility or advisability of boosters. The CDC published a recent study on September 10, 2021 analyzing percentages of total cases, hospitalizations, and deaths by vaccination status across 13 jurisdictions, including New York City, as the delta variant's U.S. prevalence soared from less than 1% to 90% of new cases.[18] In the earlier date range (April to June), fully vaccinated people accounted for 8% of new Covid deaths, 7% of hospitalizations and 5% of cases. These percentages dramatically increased during the later (June to July) study period, to 16% of new Covid deaths, 14% of new hospitalizations and 18% of new cases.

19 More recently, the Massachusetts Department of Public Health reported that

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[17] The prevalence of adaptive immunity to COVID-19 and reinfection after recovery – a comprehensive systematic review and meta-analysis of 12 011 447 individuals Tawanda Chivese, Joshua T. Matizanadzo, Omran A. H. Musa, George Hindy, Luis Furuya-Kanamori, Nazmul Islam, Rafal Al-Shebly, Rana Shalaby, Mohammad Habibullah, Talal Al-Marwani, Rizeq F Hourani, Ahmed D Nawaz, Mohammad Z Haider, Mohamed M. Emara, Farhan Cyprian, Suhail A. R. Doi medRxiv 2021.09.03.21263103; doi: https://doi.org/10.1101/2021.09.03.21263103; https://www.medrxiv.org/content/10.1101/2021.09.03.21263103v2.

[18] https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w

in the first week of September 2021, breakthrough infections in fully vaccinated individuals accounted for 40% of all new infections.[19] Another CDC study published Sept 10 found that the decline in vaccine efficacy against severe illness and hospitalization is more pronounced in the elderly: "[efficacy] was significantly lower among adults aged ≥75 years (76%) than among those aged 18–74 years (89%)." In this study, the efficacy of the J&J (Jansen) vaccine across all ages was 60%.[20] Another recent study conducted at the Mayo Clinic looked at the durability of vaccine efficacy over time: the findings revealed that the risk of breakthrough infection increased by 7-fold after four months and 10-fold after five months following vaccination, compared to efficacy at the time of full vaccination.[21] These findings confirm earlier data from Israel and Qatar showing waning efficacy against infection of the Pfizer mRNA vaccine after four months.[22]

20. These findings are, as I said above, established in the scientific literature beyond reasonable doubt. As Dr. Robert Malone, who played a central role in the development of mRNA vaccine technology, recently put it: "'Natural immunity needs to

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[19] https://www.nbcboston.com/news/local/heres-how-many-breakthrough-cases-have-been-reported-in-mass/2486308/?amp.

[20] https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7037e2-H.pdf.

[21] https://www.medrxiv.org/content/10.1101/2021.09.04.21263115v1 with commentary at https://www.news-medical.net/news/20210908/Immunity-induced-by-PfizerBioNTech-COVID-19-vaccine-declines-with-time-Mayo-Clinic-study-finds.aspx.

[22] Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar Hiam Chemaitelly, Patrick Tang, Mohammad R. Hasan, Sawsan AlMukdad, Hadi M. Yassine, Fatiha M. Benslimane, Hebah A. Al Khatib, Peter Coyle, Houssein H. Ayoub, Zaina Al Kanaani, Einas Al Kuwari, Andrew Jeremijenko, Anvar Hassan Kaleeckal, Ali Nizar Latif, Riyazuddin Mohammad Shaik, Hanan F. Abdul Rahim, Gheyath K. Nasrallah, Mohamed Ghaith Al Kuwari, Hamad Eid Al Romaihi, Adeel A. Butt, Mohamed H. Al-Thani, Abdullatif Al Khal, Roberto Bertollini, Laith J. Abu-Raddad; medRxiv 2021.08.25.21262584; doi: https://www.medrxiv.org/content/10.1101/2021.08.25.21262584v1.

be studied' is a ploy and a distraction. The data are clear, as is the logic. Protection afforded by natural immunity is far superior to genetic vaccination with a single antigen."[23]

22. The defendants mention "the known protective effect and safety of vaccination, including for people who have previously had COVID-19" (p. 7) as a basis for mandating vaccination for Covid-recovered individuals. But they cite no evidence for additional protective effects of vaccination in this population. Even if additional immunity is gained, however, by vaccinating those previously infected, that does not detract from my central claim: that unvaccinated Covid-recovered patients have equal (indeed, superior) immunity to those fully vaccinated. Furthermore, given the already extremely low risk of reinfection with infection-induced (natural) immunity, additional immunological benefits from vaccines are clinically negligible in this population.

23. The Israeli study described above actually did include an analysis of precisely this situation: giving a one-dose vaccine booster to those previously infected and comparing these individuals to unvaccinated previously infected individuals. The previously infected went from 99.74% immunity before vaccination to 99.86% after vaccination.[24] The differences here before and after vaccination are negligible and have no clinical relevance whatsoever. The same analysis for symptomatic Covid reinfections found no statistically significant differences.[25] When the efficacy of natural immunity is already extremely high, vaccination—or other interventions for that matter—cannot change it much. And vaccinations always involve some risk of adverse events, however

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[23] https://twitter.com/rwmalonemd/status/1436892582102061059?s=11.

[24] There were 37/14,029 positive PCR tests (reinfections) in unvaccinated + previously infected and 20/14,029 in vaccinated + previously infected.

[25] 23/14,029 in unvaccinated previously infected and 16/14,029 in vaccinated previously infected: vaccination brought immunity from 99.84% to 99.89% [OR=0.65, 96% CI 0.34-1.25], i.e., this was not statistically significant.

small. Such risks are warranted only where there are potentially meaningful clinical benefits.

24 Defendants make several straw-man arguments in their response, attributing to me claims that I do not hold and that I did not make in my complaint or declaration. It would be tedious to mention all of these, but to cite a few examples, defendants write, "Dr. Kheriaty's argument fails because it is based on the flawed assumption that vaccines serve no purpose because they do not prevent infection and transmission at all (p. 16)." On the contrary, I neither claim that vaccines serve no purpose nor claim that they do not prevent infection and transmission at all—claims which would be absurd. But such claims are unnecessary for my argument.

25. This, along with several other statements in this document, suggest I place little to no value on the Covid vaccines. But I hold no such opinion and have no need or desire to denigrate vaccine efficacy for purposes of my case. My claim is *not* that vaccines are ineffective or useless; my claim is simply that natural immunity is *just as* effective (in fact, more effective) than vaccine immunity. Furthermore, based on all the available evidence, natural immunity is also more durable and longer lasting than vaccine immunity. This claim in no way *devalues* the vaccines; it merely draws attention to the *value* of natural immunity. (This is also why the endless pages of expert witness testimony submitted by defendants' experts to establish the efficacy and safety of Covid vaccines are altogether beside the point.)

26. The defendants likewise mischaracterize and grossly exaggerate my claims for natural immunity, as when they write: "Dr. Kheriaty assumes that infection-induced immunity will confer perfect immunity, that he will not transmit SARS-CoV-2, and that everyone who has had COVID-19 will consistently have a high level of immunity, against all variants for all of their lives" (p. 16). Similarly, elsewhere in the document defendants mischaracterize me as claiming superiority of natural infection "under any circumstance and for all time" (p.6). But my complaint and declaration make no such claims: nowhere

do I make claim for natural immunity's "perfection" or durability that lasts "forever" or "for all time" and for "everyone" "under every circumstance."

27. Such all-or-nothing claims are not possible in medicine. But such exaggerated claims are also not necessary for my case, and I do not advance such exaggerated claims. As is clear from the previous section, natural immunity is not 100% perfect: there are an extremely small number of re-infections reported among Covid recovered individuals, with a vanishingly small number of hospitalizations and no reported deaths. That natural immunity is not perfect (alas, nothing in medicine or biology is perfect) does not detract in the least from my central claim, to reiterate: natural immunity is as good—in fact, better—than vaccine immunity for Covid.

28 Finally, the defendants make the disingenuous claim that prior infection and natural immunity may be difficult in practice to establish or document using the available lab tests. Consider, however, that the policy need not capture *every* case of Covid-recovered individuals at the University: some people who had mild cases or asymptomatic infections may not have known that they had Covid and may not have been tested. But the relevant point is that *many* have been tested and have documented confirmed prior cases, and evidence of prior infection is sufficient to establish natural immunity. All the studies on natural immunity—indeed, all the studies on Covid infections, hospitalizations, and deaths as a whole—utilize PCR testing or antibody testing to confirm cases of Covid infection. And in all the published studies, natural immunity was in fact measured by one of these positive lab tests showing prior infection. Of course, no lab test is 100% perfect: there may be a small number of false positives or false negatives included in all these numbers.

29. But if the defendants want to claim that, due to this small possibility, a positive PCR test or positive antibody test for Covid is insufficient to establish prior infection (and thus natural immunity, as documented in every published study on the topic), then they must apply the same stringent criteria of perfect certainty to *all the data*

they presented to the Court. But this would render all of their Covid data suspect. If these lab tests are insufficient for purposes of a policy that includes regard for natural immunity, then the defendants need to toss out *every statistic they cited in all their documents related to Covid hospitalizations, infections, and deaths*. Because authorized PCR tests and antibody tests were *precisely the measures utilized* to track all these numbers in the research studies. Either (1) all the statistics on Covid presented to the Court are insufficient and unreliable because (potentially) slightly imperfect, or (2) these lab tests are sufficiently accurate measures for both Covid statistics and the UC's vaccination policy. The defendants cannot have it both ways.

30. If the defendants persist in arguing, against all reasonable standards, that PCR tests or antibody tests for Covid are insufficient to definitively establish prior infection and natural immunity, there is yet another option for establishing natural immunity: the FDA recently authorized a T-cell test that establishes prior infection for Covid. It is well known that circulating antibodies wane over time, though as described in our expert witness report, this does not mean that immunity wanes over time (since durable immunity is maintained by memory B-cells and T-cells and not just circulating antibodies). So even after antibodies wane, this FDA authorized lab test—developed by biotech company Adaptive in collaboration with Microsoft, called the "T-Detect" COVID-19 test[26]—can still determine prior infection and natural immunity.[27] The University's claim that prior infection and natural immunity might be practically difficult to establish cannot render their irrational policy rational.

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[26] https://abcnews.go.com/Health/fda-authorizes-cell-test-game-changer-covid-19/story?id=76318248.

[27] While this test may not be covered yet by all insurance carriers, those subject to the mandate could pay out of pocket the $150 cost of the test. This would be useful if a person never received a PCR test, or if they tested for antibodies too early in the infection or too late after infection for these to be detected.

31. In sum, it is my opinion that prior infection and thus natural immunity can be established by readily available clinical tests or medical record documentation, and that natural (infection-induced) immunity for Covid is every bit as effective (indeed, considerably better) than vaccine immunity. To exclude this form of immunity from consideration, as the UC vaccine mandate does, is discriminatory and irrational.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct this 13 day of September 2021, at San Juan Capistrano, California.

Aaron Kheriaty M.D.

Exhibit A

UNIVERSITY OF CALIFORNIA

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UC Health
1111 Broadway, Suite 1400
Oakland, CA 94607
Phone: (510) 987-0147
http://www.ucop.edu

December 16, 2020

UC Health Vice Chancellors
UC Health Chief Executive Officers

RE: Framework for Health Care Worker Vaccine Distribution Prioritization

Per recent discussions with the UC Health Coordinating Committee systemwide Bioethics working group, please reference the attached framework regarding health care worker vaccine distribution prioritization.

Please share this information as needed.

Sincerely,

Carrie Byington

Carrie Byington, MD
Executive Vice President
UC Health
@carrie_byington

cc: UCOP Management Review Team

University of California Framework for
Health Care Worker Vaccine Distribution Prioritization
As of December 16, 2020

Purpose: Provide a framework by which the University of California campuses can implement a program of vaccine allocation prioritization for health care workers.

Framework: The UC Health Coordinating Committee Bioethics Working Group based the following recommendations on a combination of committee deliberations, the NASEM report, the CDC MMWR article, and the California Interim Guidelines.

Ethical Principles:
The NASEM report cites the following foundational principles upon which the UCOP recommendations are based.

- **Maximum benefit**, which requires that we "...reduce the risks of severe morbidity and mortality caused by transmission due to SARS-CoV-2 for those (a) most at risk of infection and serious outcomes, for example, those in congregate living arrangements with comorbid conditions; (b) in roles considered to be essential for societal functioning; and (c) most at risk of transmitting SARS-CoV-2 to others. Individuals in the roles considered to be essential for societal functioning include those whose absence from their societal roles or work puts others and the society at risk of loss of needed goods and services if they become infected (e.g., physicians, nurses, other health care providers, first responders, workers employed in the food supply system, transportation workers, teachers, etc.)"[1] The NASEM report also highlights additional sources that articulate the rationale for prioritizing health care workers: "By virtue of their instrumental value in the pandemic response, health care workers and others who maintain critical infrastructure should be prioritized."[4]
- **Equal concern**
  - "...directs attention to the equal with and value of every person, protecting each person from discrimination". [1]
  - Also "...requires allocation and distribution by criteria that are non-discriminatory in design and impact. It excludes rationing based solely on characteristics such as religion, race, ethnicity, national origin, disabilities, and others. The moral right to equal concern requires allocation of vaccine to proceed impartially according to fair criteria".[1]
- **Mitigation of health inequities** --
  - "...address the higher risks faced by such persons in work environments and living arrangements that pose higher risk of transmitting and acquiring infection and with a higher prevalence of health problems that make it more likely that they will suffer severe outcomes and even die from COVID-19".[1] Examples given are (a) older adults in congregate settings, and (b) people of color.

- "Fundamental health inequities in COVID-19 and in other health conditions are rooted in structural inequalities, racism, and residential segregation. Any vaccine allocation framework designed to reduce COVID-19 risk must explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and compounding health inequities. Mitigating those health inequities is, therefore, a moral imperative of an equitable vaccine allocation framework." [1]
- "The committee's allocation criteria do so in part by taking into account the "vulnerability" of (i) People at increased risk of infection because of social conditions, such as crowded workplaces and multigenerational homes; and (ii) People at increased risk of severe outcomes because of comorbid conditions associated with social factors, limited access to health care, etc." [1]
- "A further way to mitigate the effects of health inequities is to incorporate a metric of social disadvantage, such as the Centers for Disease Control and Prevention's (CDC's) Social Vulnerability Index (SVI), the Area Deprivation Index (ADI), or the COVID-19 Community Vulnerability Index (CCVI), into the prioritization of vaccine recipients by making it an additional consideration (Schmidt, 2020)." [3] The framework does this by treating equity as a "crosscutting consideration" [1,2] -- "in each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index." [1,2]

Ethical guidelines from the CDC's Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccines Working Group[2] were also reviewed, many of which were congruent with NASEM guidelines:

- **Maximize benefit and minimize harm**
- **Promote justice**
- **Mitigate health inequities**
- **Promote transparency**

Prioritization based upon risk categories:

The NASEM guidelines then offer "**risk-based criteria for operationalizing the foundational principles to achieve its goal**".[1] Individuals have **higher priority** to the extent that they are at greater…

- **Risk of acquiring infection**: Individuals have higher priority to the extent that they have a greater probability of being in settings where SARS-CoV-2 is circulating and of being exposed to a sufficient dose of the virus.

- **Risk of severe morbidity and mortality**: Individuals have higher priority to the extent that they have a greater probability of severe disease or death if they acquire infection.
- **Risk of negative societal impact**: Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill. ("Individuals in the roles considered to be essential for societal functioning include those whose absence from their societal roles or work puts others and the society at risk of loss of needed goods and services if they become infected (e.g., physicians, nurses, other health care providers, first responders, workers employed in the food supply system, transportation workers, teachers, etc.)."[1]
- **Risk of transmitting infection to others**: Individuals have higher priority to the extent that there is a higher probability of their transmitting the infection to others.

Defining "Health Care Worker/Health Care Personnel":

Prioritization of high-risk health care workers for phase "1a" vaccination allocation requires a clear definition of "Health Care Worker" or "Health Care Personnel" at high risk. Our definition is consistent with that developed by the CDC: *"Paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials and are unable to work from home."*[2] Further, we also remain consistent with the NASEM definition where it is applicable to our particular circumstances: "*Frontline health care workers (who are in hospitals, nursing homes, or providing home care) who either (1) work in situations where the risk of SARS-CoV-2 transmission is higher, or (2) are at an elevated risk of transmitting the infection to patients at higher risk of mortality and severe morbidity. ...These groups include not only clinicians (e.g., nurses, physicians, respiratory technicians, dentists and hygienists) but also other workers in health care settings who meet the Phase 1a risk criteria (e.g., nursing assistants, environmental services staff, assisted living facility staff, long-term care facility staff, group home staff, and home care givers). The health care settings employing these workers who are at increased risk of exposure to the virus may also include ambulatory and urgent care clinics; dialysis centers; blood, organ, and tissue donation facilities; and outpatient clinics."* [1]

Allocation based upon risk for vaccine side effects:

Fever, headache and fatigue have occurred in the population receiving the vaccine in clinical trials. It will be important given this reality that distribution to high risk HCWs in the same areas does not occur, but rather a staggered approach so that personnel are still available in these areas during vaccine rollout. *We recommend that no more than approximately 30% of HCW in a particular unit or subspecialty be vaccinated in the same week.*

Prioritization:

Our starting point for vaccine distribution first considers "Risk of Acquiring Infection" in order to uphold the principle of maximizing benefit as outlined by NASEM. Again we follow the criteria for high-risk HCWs developed by NASEM: "*Situations associated with higher risk of transmission include caring for COVID-19 patients, cleaning areas where COVID-19 patients are admitted, treated and housed, and performing procedures with higher risk of aerosolization such as endotracheal intubation, bronchoscopy, suctioning, turning the patient to the prone position, disconnecting the patient from the ventilator, invasive dental procedures and exams, invasive specimen collection, and cardiopulmonary resuscitation. Additional groups include individuals distributing or administering the vaccine—especially in areas of higher community transmission—such as pharmacists, plasma and blood donation workers, public health nurses and other public health and emergency preparedness workers.*" [1]

Areas of our health system campuses meeting the above criteria can then be prioritized based upon the potential groupings outlined below. Following this are **draft** schemes from UCI, UCSD, UCSF, and UCLA. These schemes are intended to be *examples only* as the Bioethics working group recognizes that there will be necessary adaptations of the framework based upon the unique properties of individual campuses.

Potential Groupings within Phase 1a:

- **Group 1: Highest Risk:** front line patient-facing clinical staff with close, prolonged, and repeated exposure to patients with COVID-19, or at increased risk of exposure due to prolonged close contact with patients of unknown COVID status. (Examples: clinical staff performing aerosol-generating procedures on untested patients; Respiratory Therapists, Personnel involved in testing for COVID, clinical staff frequently involved with resuscitation).

- **Group 2: High Risk:** front line patient-facing clinical staff treating patients with COVID-19 without prolonged and repeated close contact, or treating patients at high risk for complications, or treating large volumes of patients in-person with unclear COVID status. (Examples: clinical staff working on units with known COVID+ patients; clinical staff performing procedures on COVID-tested patients; high-volume clinical areas with many in-person visits).

- **Group 3: Moderate Risk:** front line patient-facing clinical and support staff who provide direct patient care with some risk of exposure, essential services to patient care.

- **Group 4: Other Risk:** front line clinical staff and support staff with some risk of exposure due to working in high-traffic areas, essential services to patient care. Other essential

administrative, leadership and education positions as well as groups of HCW in limited numbers such as Perfusionists.

Potential Group 1 scheme (UCI):

Priority A (0-X1 Vaccines)

HCWs (MDs/RNs) and support staff (e.g. Registration, Dedicated Ambassadors, etc.) in close (within 3-6 feet), prolonged and repeated contact with high-risk patients in high risk units.

- Emergency Department
- Dedicated Response Inpatient Units
  - Dedicated Clinical/Ancillary staff
    - ICUs
      - MICU/CVICU
      - SICU
      - Neuro ICU
    - Medical/Surgical Units
      - 3T
      - 4T
      - 5T
- SPPO
- Respiratory Therapy
- Occupational Health
- COVID-19 Testing Staff
- Specialty Physicians
  - ED
  - ID
  - Pulmonary
  - Anesthesiology
  - Trauma

- ICU
- Hospitalists
- OR

Potential Group 1 scheme (UCSD):

TIER 1: Highest Risk: front line patient-facing clinical staff with exposure to with patients COVID-19 or treating high risk patients for complications. Includes residents/fellows	
ACUTE CARE	**AMBULATORY**
1. ED/Trauma/STEMI/Stroke/L&D	1. Urgent Care (includes COVID-19 testing sites)
2. Respiratory Therapy	2. Express Care
3. Intensive Care Units and COVID Units	3. Primary care IM, FM, Geriatrics, pediatrics
4. Behavioral Health Units	4. Pulmonary
5. Onc / BMT / SOT Units	5. ENT
6. Anesthesia	6. Ophthalmology
7. Procedural Areas (IR, GI, Pulmonary, Cardiology)	7. Cancer Care
8. Acute Dialysis	8. Outpatient Lab
9. EVS / Security	9. Pulmonary function lab
10. Medical Surgical Units	10. Cardiac Function Lab
11. Surgery	11. Eating disorder
12. Pharmacists responding to code blues	12. Speech Therapy
13. PT/OT	13. PT/OT
14. Radiology technicians	
15. Lab/Phlebotomists	

Potential Group 2 scheme (UCSF):

Group 2: High Risk: *front line patient-facing clinical staff treating patients with COVID-19 without prolonged and repeated close contact, or treating patients at high risk for complications, or treating large volumes of patients in-person with unclear COVID status. (Examples: clinical staff working on units with known COVID+ patients; clinical staff performing procedures on COVID-tested patients; high-volume clinical areas with many in-person visits).*

Oncology, Bone Marrow Transplant and Solid Organ Transplant Unit Providers and Staff • *All APPS, faculty, students, fellows, residents and staff for the following units:* o *14L* o *12L* o *11L* o *9L* o **Pediatric units- need to add**	*Cancer Center*
Perioperative services • All staff • *Includes Departments of Anesthesia, Surgery, Urology, Neurosurgery, and Orthopedics- All APPs, faculty, rotating students, fellows, residents*	*Primary care* • *All APPs, faculty, rotating students, fellows, residents, and staff for the following clinics:* • *Department of General Internal Medicine* • *Family medicine* • *Geriatrics* • *Pediatrics* • *HIV*
Procedural Areas • *All APPs, faculty, rotating students, fellows, residents, and staff for the following procedural areas:* o *Interventional Radiology* o *Gastrointestinal* o *Pulmonary* o *Cardiology*	*Cardiac Function Lab, Pulmonary Function Test, Sleep Lab - All APPs, faculty, rotating students, fellows, residents, and staff*
Medical / Surgical and TCU Units (non-COVID) • *All APPs, faculty, rotating students, fellows, residents, and staff*	*Other Medical & Surgery Specialties* • *All APPs, faculty, rotating students, fellows, residents, and staff*
Langley Porter Psychiatric Inpatient Unit • *All APPs, faculty, rotating students, fellows, residents, and staff*	*Outpatient Lab* • *All staff*
Inpatient consulting specialties with direct patient contact with COVID+ patients • *All providers, APPs, faculty, rotating students, fellows, residents, and staff*	
Phlebotomists	
Environmental services / security / police / transporters / valet	
Food and nutrition services	
COVID symptom screening staff	
Patient care assistants (if not vaccinated as part of unit-based vaccination	
Physical Therapy/Occupational Therapy/Speech Language Pathology who have not been vaccinated per criteria above	
Radiology Technicians	

Potential Group 1 and 2 scheme (UCLA):

<table>
<tr><th colspan="2">Group 1: Highest Risk Group</th></tr>
<tr><td colspan="2">DEFINITION: Front line clinical staff who care for patients with COVID-19 in high risk settings or who care for symptomatic patients* of unknown COVID status

<u>Group 1 will be further sub-prioritized with the following definitions:</u>
GROUP 1A DEFINITION: Front line patient-facing clinical staff with close, prolonged, and repeated exposure to patients with COVID-19, or at increased risk of exposure due to prolonged close contact with symptomatic* patients of unknown COVID status
GROUP 1B DEFINITION: Front line patient-facing clinical staff treating patients with COVID-19 without prolonged and repeated close contact, or treating patients or treating large volumes of symptomatic patients* within unknown COVID status

*influenza-like illness (ILI) symptoms</td></tr>
<tr><td colspan="2">NOTE: The list of departments/areas below is not listed by priority within the highest risk group. Vaccine prioritization within the highest risk group will be determined by [x].</td></tr>
<tr><th>Acute Care</th><th>Ambulatory</th></tr>
<tr><td rowspan="2">COVID cohort unit nursing staff:
• RRMC (4ICU, 7ICU, 7E, 8W)
• SMMC (4CW ICU, 5MN, 4MN)</td><td>Immediate Care</td></tr>
<tr><td>COVID-19 Drive Thru Testing Sites</td></tr>
<tr><td>Emergency Departments</td><td>CTRC (staff working with COVID-19 or suspected COVID-19 patients)</td></tr>
<tr><td>Respiratory Therapy</td><td>Venice Family Care</td></tr>
<tr><td>Internal Medicine*</td><td>Physicians & Nurse Practitioners who provide patient care at area SNFs</td></tr>
<tr><td>Anesthesiology*</td><td>Primary Care (direct patient contact) (ILI patients)</td></tr>
<tr><td>Pulmonary*</td><td>Venice Family Care</td></tr>
<tr><td>Infectious Disease*</td><td>UCLA Health-employed hospitalists working at other institutions</td></tr>
<tr><td>Thoracic/ICU Nurse Practitioners</td><td>Study coordinators and investigators</td></tr>
<tr><td>Emergency Medicine* (including EM Operations)</td><td>ENT providers performing invasive procedures for patients with unknown COVID status</td></tr>
<tr><td>Clinical Microbiology Lab</td><td>Staff administering COVID-19 vaccines</td></tr>
<tr><td>Critical Care Transport</td><td>Head & Neck (providing care for patients with unknown COVID status)</td></tr>
<tr><td>ECMO/VAD Program</td><td>BSL-3 research staff actively working with live COVID-19 virus</td></tr>
<tr><td>Lift Team</td><td></td></tr>
<tr><td>Interventional Areas:
• Main Operating Room
• Radiology (CT/IR)</td><td></td></tr>
</table>

• PTU/PACU • MPU • TRU	
Surgery*	
Mobile Stroke Program	
Pediatrics: • Transport • Hospitalists • Critical Care • PICU	
RRMC 5FDU	
Labor & Delivery	
Perfusion	
NPH Residents/House Staff	
Psychiatry*	
PT/OT (inpatient)	
Security	
Interns/Residents	
Ambulance Transport	
Clinical Surveillance Team	
Rape Treatment Center	
Dialysis Nurses (inpatient)	
Environmental Services	
Head & Neck*	
Obstetrics	
Med/Surg Nurse Practitioners	
Resource Team (if caring for COVID patients)	

Additional prioritization considerations based upon other risk categories:

Further stratification and granularity may be necessary based upon limited supply of vaccine in the first several months of distribution. We propose the following additional considerations based upon this reality:

1. Vaccinate providers delivering the vaccine to others
2. Vaccinate up to 30% of one unit and move to another high-risk setting(s) for the rest of the week. Come *back* to that high-risk setting the following week for the next 30% of the HCWs and so forth.
3. *In the event of a protracted ability to obtain adequate inventory of vaccine our Bioethics working group recommends prioritizing further by factoring in an individual's age (addresses the principles of "risk of severe illness and mortality") and/or address or California Healthy Places Index (addresses the* "risk of societal impact" *and* "risk of transmitting infection to others").

a. Health systems can consider further groups by self-identifying HCW >65 years of age. Highest rates of hospitalizations and death from COVID-19 have been seen in the older population. Prioritization based upon age is another parameter that can be obtained through employee records.

b. Incorporating address/Area Deprivation Index/other social vulnerability markers takes into account the ethical principle of mitigating health inequities. Neighborhoods that are low-income, and have a large population of racial and ethnic minorities are been demonstrated to shoulder the most significant burden of COVID-19 infection, morbidity and mortality. Many of our campuses have modeled the precise location of the clustering of COVID-19 infection. Addresses can be obtained through employee records. If practical and feasible, Area Deprivation Index, or a similar metric, should be determined to further risk stratify.

Acceptance, Evaluation, and Monitoring of Vaccine Administration

Should we explicitly establish priorities within the broad category of 1A health care worker described above?

We recognize that the pandemic has placed a disproportionate burden on certain patients, particularly those over 65 and/or from socially-disadvantaged groups. Some localities in the US have decided to first vaccinate those health care workers from a high mortality risk category, such as starting with those greater than 65. Although we strongly and unanimously endorse the moral commitment to take account of health equity and mortality risk in pandemic control response, after much discussion and deliberation we decided to consider all health care workers as a single tier without further stratification by age and social vulnerability markers.

Our argument has three components:

- First, collecting and using information about additional COVID-19 risk factors, such as age, comorbidities, and zip codes/geocodes that might reveal certain social vulnerabilities, may have the counterproductive effect of harming those individuals identified. Privacy concerns may ensue. Data must be used with care; UC Human Resources has expressed concern about collection of such information.
- Second, based on the most recent information about vaccine availability, we believe that only a few weeks will separate the early waves of 1A health care workers offered vaccination, not many months. This consequently likely obviates the need for further risk stratification beyond just risk of exposure alone.
- Third, we believe that we can accomplish the goal of equity by careful monitoring of the success of the program. It will be critical to make certain that inequities do not develop between those who receive an early dose and those who do not, for example privileged professionals vs patient care assistants or environmental health workers. It will also be

critical for occupational health to continue monitoring the rate of occupation and non-occupational transmission among health care workers.

What is the role of monitoring?

Based on these considerations, we strongly recommend active monitoring of the success of our allocation scheme in meeting the goal of preventing Covid-19 transmission to health care workers and reducing the overall burden of disease. In collecting data about Covid-19 occurrence, we will use the demographic data mentioned above in a way that carefully protects the privacy of all workers. Doing this retrospectively will provide time to use these sensitive data with appropriate care.

Should vaccine hesitancy be considered?

A final consideration is vaccine hesitancy. Although it might be useful to survey health care workers about their intention to accept a vaccine if one is offered, to streamline administration of scarce vaccine, we decided that it would be preferable to offer the vaccine to all. Those who refuse initially because of concern about safety should be offered the opportunity to be vaccinated later, as data accumulates. It will be important to monitor the rates of vaccine acceptance and declination.

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