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*Attorneys for Defendants*  
The Regents of the University of California and  
Michael V. Drake

SUPERIOR COURT OF THE STATE OF CALIFORNIA  
COUNTY OF ALAMEDA

CINDY KIEL, J.D., an Executive Associate  
Vice Chancellor at UC Davis, MCKENNA  
HENDRICKS, a UC Santa Barbara student,  
EDGAR DE GRACIA, a UCLA student, and  
LELAND VANDERPOEL, an employee at the  
Fresno satellite extension of the UCSF Medical  
Education Program, and FRANCES OLSEN,  
Professor of Law at UCLA,

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. HG20072843  
Unlimited Civil Jurisdiction

ASSIGNED FOR ALL PURPOSES TO:  
Hon. Richard L. Seabolt  
Department 521

**DECLARATION OF CARRIE L.  
BYINGTON, M.D., IN SUPPORT OF  
DEFENDANTS' OPPOSITION TO  
PLAINTIFFS' MOTION FOR  
PRELIMINARY INJUNCTION**

Date: October 14, 2020  
Time: 01:30 p.m.  
Dept.: 521  
Reservation No.: 2206283

Complaint filed: August 27, 2020  
Trial: None set

1 I, Carrie L. Byington, M.D., declare:

2 1. I provide this declaration in support of Defendants The Regents of the University  
3 of California and Michael V. Drake's ("Defendants") Opposition to Plaintiffs' Motion for  
4 Preliminary Injunction. I base this declaration on my expertise as outlined below and facts within  
5 my personal knowledge, to which I could and would testify competently if called upon to do so.

6 2. I am Executive Vice President, UC Health, and a Professor of Pediatric Infectious  
7 Diseases at the University of California, San Francisco. I am a medical doctor, specializing in  
8 pediatric infectious diseases. My research has focused on the clinical management and prevention  
9 of respiratory infection and the development of diagnostic technology for the recognition of  
10 pathogens with pandemic potential. I have worked on the prevention and control of infectious  
11 diseases in the United States and internationally. Among other experience, I have planned  
12 emergency infrastructure for universities, was responsible for protecting Team USA athletes and  
13 staff from Zika Virus during the 2016 Olympic Games in Brazil, and chaired the American  
14 Academy of Pediatrics Committee on Infectious Diseases during the Ebola and Zika outbreaks  
15 (2014-2018). I have authored numerous peer-reviewed articles and policy statements on the  
16 prevention and control of influenza in children in my capacity as member, vice chair, and chair of  
17 the American Academy of Pediatrics Committee on Infectious Diseases from 2007-2018.

18 **EDUCATION AND PROFESSIONAL BACKGROUND**

19 3. I received my B.S. in biology from Texas A&M University, *cum laude*, in 1985,  
20 and my M.D. from Baylor College of Medicine in 1989. I completed a pediatric residency at  
21 Baylor College of Medicine and I completed a fellowship in Pediatric Infectious Diseases at the  
22 University of California, San Francisco.

23 4. My research focus has been on respiratory pathogens and pandemics. My career in  
24 academic medicine has bridged clinical care and public health. Before I began my position at UC  
25 (2019), I was Senior Vice President for Health Sciences and Vice Chancellor for Health Services  
26 at Texas A&M University (2017-2019); Distinguished Service Professor at University of Utah  
27 (2015); Director and Principal Investigator, Utah Center for Clinical and Translational Science  
28 (2015-2016); Associate Vice President of Faculty and Academic Affairs at the University of Utah

1 Health Sciences Center (2013-2016); Co-Director and Principal Investigator at the Utah Center  
 2 for Clinical and Translational Science (2013-2016); Benning Presidential Professor of Pediatrics  
 3 at the University of Utah Health Sciences Center (2010-2016); Vice Chair (Oversight Research  
 4 Enterprise) of the Department of Pediatrics at the University of Utah Health Sciences Center  
 5 (2009-2013); Associate Director of the University of Utah Center for Clinical and Translational  
 6 Science (2008-2013); Associate Chair for Clinical Research of the Department of Pediatrics at the  
 7 University of Utah Health Sciences Center (2007-2009); Professor of Pediatrics, Division of  
 8 General Pediatrics and Division of Pediatric Infectious Diseases at the University of Utah Health  
 9 Sciences Center (2006-2016); Lowell Bennion Public Service Professor at the University of Utah  
 10 (2001-2002); Associate Professor, Division of General Pediatrics and Division of Pediatric  
 11 Infectious Diseases at the University of Utah Health Sciences Center (2000-2006); Assistant  
 12 Professor, Division of General Pediatrics and Division of Pediatric Infectious Diseases at the  
 13 University of Utah Health Sciences Center (1995-2000); Fellow in Pediatric Infectious Diseases,  
 14 University of California, San Francisco (1993-1995), and Assistant Professor for the Division of  
 15 Ambulatory Pediatrics at Baylor College of Medicine (1992-1993).

16 5. Attached as **Exhibit A** is a copy of my Curriculum Vitae.

17 **MY ROLE IN UC'S STRATEGY AND RESPONSE TO THE COVID-19 PANDEMIC TO**  
 18 **PROTECT STUDENTS, STAFF, AND FACULTY THROUGHOUT THE UC SYSTEM**

19 6. I joined UC in 2019 as Executive Vice President, UC Health, and a Professor of  
 20 Pediatric Infectious Diseases at the University of California, San Francisco.

21 7. Since January 1, 2020, I have been collaborating with UC leadership and its  
 22 campus hospital leaders regarding UC's emergency response to COVID-19. Our goal has been to  
 23 prioritize the health and safety of our students, staff, and faculty at UC and the patients in its  
 24 health system. I also currently serve on numerous COVID-19 advisory groups for the State of  
 25 California.

26 8. Beginning March 18, 2020, I have chaired a subcommittee of the UC Office of the  
 27 President (UCOP) Management Response Team (MRT) named the UC Health Coordinating  
 28 Committee (the UC-HCC) to advise on UC Health's response to the pandemic. The UC-HCC

1 members include representatives from the entire UC System and includes standing and ad hoc  
2 working groups established by UC Health to provide subject matter expertise in domains  
3 including clinical research, education, public health, infectious disease, laboratory medicine,  
4 critical care medicine, telehealth, pharmacy, and other disciplines, as well as ethical, legal, and  
5 social issues related to UC Health's response to the pandemic. Among other things, I, as Chair of  
6 the UC-HHC, have been offering UC Health leaders, the Council of UC Chancellors, the UC  
7 President, and the UC Board of Regents, my expert advice through the UC-HCC and the incident  
8 command structure at each UC Health location, collaborating with internal stakeholders, and  
9 coordinating with various federal and state public health officials, other health systems, and  
10 relevant professional organizations. A narrative of many of the activities related to the UC-HCC  
11 COVID-19 response is found in published guidance available at: [https://www.ucop.edu/uc-](https://www.ucop.edu/uc-health/reports-resources/uch-coordinating-committee-guidance/index.html)  
12 [health/reports-resources/uch-coordinating-committee-guidance/index.html](https://www.ucop.edu/uc-health/reports-resources/uch-coordinating-committee-guidance/index.html) and in my written  
13 updates to the UC Board of Regents available at: [https://www.ucop.edu/uc-](https://www.ucop.edu/uc-health/staff/bios/carrie_byington.html)  
14 [health/staff/bios/carrie\\_byington.html](https://www.ucop.edu/uc-health/staff/bios/carrie_byington.html)

15 9. The UC-HCC has smaller subsections dedicated to targeted efforts for UC to  
16 respond to COVID-19. There is a UC-HCC Executive Group, a Government Outreach branch and  
17 a Planning Team. Within the Planning Team, there are individuals with expertise in bioethics,  
18 clinical research, education, infectious diseases and infection prevention, laboratory medicine,  
19 public health, and telehealth. These groups work with existing UC systemwide groups to provide  
20 recommendations to UC for its response to COVID-19.

21 **COVID-19 IS A HIGHLY CONTAGIOUS SERIOUS ILLNESS THAT POSES GREAT**  
22 **RISKS TO HUMAN HEALTH AND IS NOT YET CONTROLLED BY VACCINE**

23 10. COVID-19 is a respiratory virus that easily infects humans. Infections may range  
24 from asymptomatic (no symptoms) to life-threatening. Patients typically present with acute  
25 respiratory signs and symptoms, which can escalate in some patients to respiratory failure and  
26 other serious, life-threatening complications with organ damage to the brain, heart and kidneys  
27 and blood clotting. The most common symptoms are fever, cough, and shortness of breath. Other  
28 identified symptoms include muscle aches, headaches, chest pain, diarrhea, coughing up blood,

1 sputum production, runny nose, nausea, vomiting, diarrhea, sore throat, confusion, lack of senses  
2 of taste and smell, and anorexia. Due to the respiratory impacts of the disease, individuals may  
3 require oxygen therapy, and in severe cases, patients may need to be intubated and receive  
4 mechanical ventilation or be placed on ECMO, a technique of providing prolonged cardiac and  
5 respiratory support to persons whose heart and lungs are unable to function properly. Individuals  
6 with renal failure may require dialysis.

7 11. People of every age have contracted COVID-19. Severe cases and deaths have  
8 been reported at every age. Geriatric patients are at the greatest risk of severe cases, long-term  
9 impairment, and death. Likewise, those with immunologic conditions and with other pre-existing  
10 conditions, such as hypertension, certain heart conditions, lung diseases (e.g., asthma, COPD),  
11 diabetes mellitus, obesity, and chronic kidney disease, are at high risk of a life-threatening  
12 COVID-19 illness. Pregnant women are also recognized as a group that may have more severe  
13 infection with COVID-19 resulting in hospitalization and need for intensive care.

14 12. COVID-19 is readily spread through respiratory transmission. Importantly,  
15 asymptomatic person to person transmission of COVID-19 is common. People may transmit the  
16 virus even when they exhibit no symptoms and may transmit in the days before symptoms appear.  
17 The viral loads are high in both asymptomatic and pre-symptomatic individuals. All people are  
18 susceptible to COVID-19, as it is a novel virus. Even now, over six months into the pandemic,  
19 ~90% of the US population remains susceptible to COVID-19 with similar proportions  
20 susceptible world-wide. See **Exhibit B** (Anand, S. Lancet Sept 25, 2020—Prevalence of SARS-  
21 CoV2 antibodies in a large nationwide sample of patients on dialysis in the USA: a cross-  
22 sectional study). All people are capable of getting COVID-19 because of the ease with which it  
23 spreads through person to person contact. The virus is spread through droplet transmission; that  
24 is, when an infected individual speaks, coughs, sneezes, and the like, they expel droplets that can  
25 transmit the virus to others in their proximity. There is growing evidence that COVID-19 is also  
26 aerosolized, such that tiny droplets containing the virus remain in the air and can be inhaled by  
27 others who come into contact with that air and that COVID-19 can be transmitted in that fashion.  
28 The virus is also known to be spread through the touching of contaminated surfaces, for example,

1 when an infected person touches a surface with a hand they have coughed into and then another  
2 person touches that same surface before it has been disinfected and then touches their face.

3 13. There is not yet any FDA-approved vaccine against COVID-19 that could be used  
4 to immunize the population against the virus. As a result, the only way to limit its spread is  
5 through non-pharmaceutical interventions such as self-isolation, physical distancing, frequent  
6 handwashing, mask or face covering wearing, and disinfecting surfaces. Self-isolation involves  
7 not physically interacting with those outside one's household. Social or physical distancing is  
8 maintaining at least six feet of distance between individuals, which can also be implemented  
9 within one's household. Each of these interventions is aimed at keeping infected individuals far  
10 enough apart from other individuals so that they do not transmit the virus. Similarly, wearing a  
11 mask or face covering is meant to prevent an infected individual from spreading droplets of the  
12 virus which could infect others. Frequent handwashing and regular disinfecting of surfaces can  
13 help curb spread via contaminated surfaces.

14 14. Transmission of COVID-19 can occur in any location where there is close  
15 proximity (less than six feet) between individuals. Activities that occur indoors are considered  
16 higher risk than those that occur outdoors. And because transmission of the virus can potentially  
17 occur via aerosols or environmental surfaces, there is also risk of spread of the virus at any  
18 location where multiple individuals have been present and have breathed or touched surfaces.  
19 Some individuals who are infected with the virus do not have any symptoms but can transmit the  
20 virus and/or are infectious before they develop any symptoms. This means that isolating only  
21 persons known to be infected or exhibiting symptoms of infection will not stop the spread of  
22 infection. Young people, including those in the college age group, may be less likely to exhibit  
23 symptoms than older individuals. Individuals aged 20 to 29 account for over 20% of cases in the  
24 US today and readily transmit infection to others, including older adults, who may have more  
25 serious disease. To prevent increasing the scope of the outbreak of COVID-19, we must assume  
26 that anyone could be infected and transmit infection to others.

27 15. Due to the lack of adequate testing, the time lag in getting results back from  
28 laboratories, lengthy incubation time, and varied start and end points of stay at home

1 requirements, we may never definitively determine the full effects of stay-at-home orders and  
2 physical distancing. But physical distancing has worked to slow the spread of respiratory viruses  
3 generally and in California and the United States during the current pandemic. There is evidence  
4 that cities and states that implemented stay-at-home orders and kept them in place until  
5 transmission was under control are experiencing reduced transmission. There is also evidence  
6 suggesting that the ending of stay-at-home orders and other mitigation measures is leading to  
7 increased transmission. However, transmission of the virus will continue through the population  
8 until there is widespread herd immunity developed either through natural infection or preferably  
9 through deployment of one or more safe and effective vaccines against SARS-CoV2.

10 16. Due to the ease of transmission, the high risk to certain segments of the  
11 population, and the fact that the virus will continue to surge unless and until wide-spread  
12 vaccination and/or herd immunity is achieved, individuals will need to continue to take steps to  
13 prevent infection.

14 **THE FLU IS ALSO A HIGHLY CONTAGIOUS SERIOUS ILLNESS THAT IS**  
15 **TRANSMITTED IN WAYS THAT ARE SIMILAR TO COVID-19, INCREASING THE**  
16 **NEED TO PREVENT AND MANAGE BOTH ILLNESSES SIMULTANEOUSLY**

17 17. Influenza (flu) is also a respiratory virus that easily infects humans. Like COVID-  
18 19, flu virus infections may range from asymptomatic (no symptoms) to life-threatening. Patients  
19 with the flu typically present with acute respiratory signs and symptoms, which can escalate in  
20 some patients to serious complications such as pneumonia and may be life-threatening. The most  
21 common symptoms are fever, cough, sore throat, runny or stuffy nose, muscle or body aches,  
22 headaches, and fatigue. Other possible serious complications triggered by the flu can include  
23 inflammation of the heart (myocarditis), brain (encephalitis) or muscle (myositis,  
24 rhabdomyolysis) tissues, and multi-organ failure (for example, respiratory and kidney failure).  
25 Flu virus infection of the respiratory tract can trigger an extreme inflammatory response in the  
26 body and can lead to sepsis like syndrome, the body's life-threatening response to infection. The  
27 flu also can make chronic medical problems such as asthma or chronic heart disease worse.

28 18. People of every age can and have contracted the flu each year, including severe

1 cases. Severe cases and deaths have been reported at every age. Geriatric patients are at the  
2 greatest risk of severe cases, long-term impairment, and death. Likewise, those with immunologic  
3 conditions are at high risk of a life-threatening case of the flu. Pregnant women are also  
4 recognized as a group that may have more severe infection with the flu resulting in hospitalization  
5 and need for intensive care. Although all children younger than five years old are considered at  
6 high risk for serious flu complications, the highest risk is for those younger than two years old,  
7 with the highest hospitalization and death rates among infants younger than six months old.

8 19. Although Influenza and COVID-19 are both contagious respiratory illnesses that  
9 can result in serious illness, including illness resulting in hospitalization or death, they are caused  
10 by different viruses. COVID-19 is caused by infection with a new coronavirus (SARS-CoV-2),  
11 and the flu is caused by infection with influenza viruses. Because some of the symptoms of the  
12 influenza virus and COVID-19 are similar, such as fever, cough, shortness of breath or trouble  
13 breathing, and fatigue, it may be hard to tell the difference between them based on symptoms  
14 alone, and testing is needed to help confirm a diagnosis.

15 20. Because influenza and COVID-19 have similar presenting signs and symptoms, all  
16 individuals with these signs and symptoms will require diagnostic testing for both viruses and  
17 will need to be placed in isolation for COVID-19 and influenza until test results are returned.  
18 Contacts of these individuals will need to be identified by COVID-19 contact tracers and be  
19 placed in quarantine. These actions add further strain to clinical and public health resources,  
20 particularly in college towns.

21 21. Flu vaccines have a good safety record. Hundreds of millions of Americans have  
22 safely received flu vaccines over the past 50 years, and there has been extensive research  
23 supporting the safety of flu vaccines. A flu vaccine is the first and best way to reduce one's  
24 chances of getting the flu and spreading it to others. The Centers for Disease Control and  
25 Prevention (CDC) and the American Academy of Pediatrics, and the Infectious Diseases Society  
26 of America recommend that everyone 6 months of age and older receive a flu vaccine every year.

27 22. Indoor spaces, including classrooms, dormitories, and dining and lecture halls are  
28 a prime area for increased transmission of the influenza virus and the COVID-19 virus, due to the



1 close proximity of a large number of individuals—students and faculty—in a limited space. This  
2 close proximity allows for the transmission of the virus via droplets and aerosols between various  
3 individuals. A classroom or lecture hall also has a large number of common surfaces that multiple  
4 people touch: the doors, seats and desks. While surface transmission is not the primary way that  
5 COVID-19 is spread, it remains the case that available evidence suggests the virus can be  
6 transmitted in that way.

7 23. Both the influenza virus and COVID-19 virus are readily spread through droplet  
8 and aerosol transmission, so in public spaces, particularly indoor spaces, the density and  
9 proximity of the number of people present are the critical factors in assessing likelihood of  
10 transmission. If a classroom or lecture hall has higher density of and proximity between  
11 individuals than another public space, then regardless of mitigation measures, the location is not  
12 safer in terms of transmission of influenza and COVID-19 than another public space that has  
13 lesser density and proximity. While efforts at environmental decontamination are important  
14 public health interventions, the most effective measure to curb transmission of the COVID-19  
15 virus is to reduce the density of exposure to other people, which necessarily occurs in classrooms  
16 and lecture halls, while the most effective measure to curb transmission of the influenza virus is  
17 an influenza vaccination.

18 **IN ORDER TO HELP COMBAT INFLUENZA AND COVID-19 RISKS AND PROTECT**  
19 **STUDENTS, STAFF, AND FACULTY THROUGHOUT THE UC SYSTEM, I HAVE**  
20 **ADVOCATED FOR AND SUPPORT THE PRESIDENT'S EXECUTIVE ORDER**

21 24. From the beginning of my meetings with the Council of UC Chancellors in  
22 January 2020, I discussed UC's strategic response to COVID-19 and we considered what more  
23 UC could do before COVID-19 arrived in the United States. In this context, we encouraged flu  
24 vaccination campaigns and different UC locations offered vaccine fairs to immunize as many  
25 people as possible in Spring 2020.

26 25. Once COVID-19 arrived in the United States, UC-HCC recommended that the UC  
27 campuses maintain reduced density of the populations on their campuses, which resulted in  
28 recommendations that most students leave campus and that faculty and staff work from home

1 whenever possible. We created guidance for personal protective equipment for essential  
2 employees including universal use of face coverings on campuses and masks in hospital or  
3 clinical settings.

4 26. Additional recommendations regarding travel, definition of exposure, testing and  
5 contact tracing, use of non-pharmaceutical interventions, and campus and hospital operations are  
6 outlined in the UC-HCC reports available at: [https://www.ucop.edu/uc-health/reports-](https://www.ucop.edu/uc-health/reports-resources/uch-coordinating-committee-guidance/index.html)  
7 [resources/uch-coordinating-committee-guidance/index.html](https://www.ucop.edu/uc-health/reports-resources/uch-coordinating-committee-guidance/index.html)

8 27. Beginning in April 2020, as we were preparing our return plans for the fall  
9 semester (or quarter), the idea of a mandatory flu vaccine became part of the conversation with  
10 each UC Chancellor and with UC Student Health. My role was to speak with then-President Janet  
11 Napolitano and the UC Chancellors about why the flu vaccine could protect students, faculty, and  
12 staff from illness and also protect the public health infrastructure and hospital capacity developed  
13 in response to the COVID-19 pandemic.

14 28. In May 2020, I helped author the recommendations of the UC HCC Testing and  
15 Tracing Task Force that included recommendation for universal influenza vaccination for UC  
16 students, faculty, and staff.

17 29. On or about July 31, 2020, the Executive Order setting forth the flu vaccine policy  
18 was issued. On September 29, 2020, the Executive Order was amended. A copy of the amended  
19 Executive Order is attached **Exhibit C**.

20 30. I was involved in developing the campus recommendations to address the threat of  
21 COVID-19 and support the science underlying the recommendation of influenza vaccine as an  
22 important additional protection for human beings during the pandemic, which is reflected in the  
23 original and amended Executive Order.

24 31. By way of background, there is clear evidence that the COVID-19 is not under  
25 control in California or in the United States generally. The U.S. has the highest number of  
26 COVID-19 cases in the world. The U.S. reported 303,792 cases in the 7 days ending on  
27 September 26, 2020 and in the same 7-day period, California was the state with the second  
28 highest number of cases, 24,209 after Texas. University of California students come from all

1 states across the U.S. and from many countries.

2 32. The CDC recommends that (1) because of the COVID-19 pandemic, reducing the  
3 spread of respiratory illnesses, like the flu, this fall and winter is more important than ever; and  
4 (2) individuals should get a flu vaccination by November 1 of this year. The California  
5 Department of Public Health similarly recommends the annual flu vaccination for everyone six  
6 months of age and older, and has stated that getting the flu vaccine will be more important than  
7 ever in the midst of the ongoing COVID-19 pandemic.

8 33. To address the importance of the flu vaccine, especially during the COVID-19  
9 pandemic, the CDC has announced it is taking steps to maximize flu vaccination by increasing  
10 availability of the vaccine, including purchasing an additional two million doses of pediatric flu  
11 vaccine and 9.3 million doses of adult flu vaccine, by emphasizing the importance of flu  
12 vaccination for the entire flu season, and by conducting targeted communication outreach to  
13 specific groups who are at higher risk for complications from flu.

14 34. In my capacity as an infectious diseases physician and Executive Vice President of  
15 UC Health, I have recommended that flu shots are essential this year. As stated in my July 24,  
16 2020 COVID-19 update for the Regents published days before the original Executive Order  
17 issued ([https://www.ucop.edu/uc-health/\\_files/regent-updates/7-24-20-regents-update.pdf](https://www.ucop.edu/uc-health/_files/regent-updates/7-24-20-regents-update.pdf)), I  
18 recommended that everyone six months of age or older receive the influenza vaccine by the end  
19 of October in order: (1) to reduce the overall burden of illness on primary care physicians and  
20 emergency rooms to reduce co-mingling of influenza patients with patients who may be  
21 symptomatic with COVID-19; (2) to reduce the use of hospital inpatient capacity so those  
22 resources can be focused on patients with other illnesses, especially COVID-19; and (3) to  
23 minimize the likelihood that someone contracts both the flu and COVID-19 at the same time.  
24 Individuals suffering from two viral infections may be more ill.

25 35. In August 2020, I worked with the UC student health centers through Dr. Brad  
26 Buchman to increase the number of influenza vaccine doses available for campuses. We  
27 requested an additional 23,000 influenza vaccines from the California Department of Public  
28 Health.

1           36.     Based on my training and experience, the flu vaccine is a safe and effective way to  
2 help reduce the combined health risks and burdens on health and medical care posed by the  
3 combination of the flu virus and the COVID-19 virus this year and will provide protection above  
4 and beyond non-pharmaceutical interventions including face coverings, masking, physical  
5 distancing, and hand-washing. Further, during a time when masking is required in many  
6 California counties where UC campuses are located, it is important to require the flu vaccine this  
7 year, without a masking alternative. In this unprecedented year, it would be dangerous and  
8 irresponsible to have a flu vaccine mandate undermined by a masking only option.

9           37.     The original and amended Executive Orders reflect a prudent step towards added  
10 measure of health protection for students, staff, faculty, and others in the UC community who are  
11 in close physical proximity to one another.

12           **PLAINTIFFS' DECLARANTS' OPINIONS ARE INCONSISTENT WITH MY**  
13           **PROFESSIONAL TRAINING AND EXPERIENCE, AND WIDELY ADOPTED PUBLIC**  
14           **HEALTH GUIDANCE**

15           38.     I have reviewed the submissions of Plaintiffs' declarants in this case and disagree  
16 with many of the opinions they have offered.

17           39.     For example, I disagree with the opinions offered by Plaintiffs' declarants  
18 suggesting that a lack of randomized trials of the flu vaccine means that it not safe or effective in  
19 combatting the flu or reducing the burden on health services, such as hospitalizations.

20           40.     It is important to keep in mind that the flu vaccine is formulated each year to  
21 address the virus strains anticipated in a given flu season, and the flu vaccine is administered to  
22 vulnerable populations, including children, who may be excluded in certain types of clinical  
23 trials. These facts, among others, mean that observational studies, case-control studies, and  
24 longitudinal cohort studies in addition to randomized clinical trials have been used to evaluate the  
25 safety and efficacy of the flu vaccine.

26           41.     It is also important to keep in mind that, according to the CDC, flu vaccination has  
27 long been accepted as a safe and effective way to prevent millions of illnesses and thousands of  
28 related doctor and hospital visits every year.

1           42.     The CDC conducts studies each year to determine how well the flu vaccine  
2 protects against flu illness. While vaccine effectiveness can vary, recent studies show that flu  
3 vaccination reduces the risk of flu illness by between 40% and 60% among the overall population  
4 during seasons when most circulating flu viruses are well-matched to the flu vaccine. As a result,  
5 the flu vaccine prevents millions of illnesses and flu-related doctor's visits, as well as  
6 hospitalizations each year. For example, according to the CDC, during the 2018-2019 flu season,  
7 flu vaccination prevented an estimated 4.4 million influenza illnesses, 2.3 million influenza-  
8 associated medical visits, 58,000 influenza-associated hospitalizations, and 3,500 influenza-  
9 associated deaths.

10           43.     While no vaccine is perfectly safe or without any risks, the flu vaccine has been  
11 used for decades and is widely adopted to address the public health risks posed by the flu.

12           44.     I also disagree with the suggestion of some of Plaintiffs' declarants that getting a  
13 flu vaccination may increase the risk of getting sick from COVID-19. There is no evidence that  
14 getting a flu vaccination increases an individual's risk of getting sick from the coronavirus that  
15 causes COVID-19.

16           45.     I am familiar with the study by Greg G. Wolff cited by some of Plaintiffs'  
17 declarants, entitled "Influenza vaccination and respiratory virus interference among Department  
18 of Defense personnel during the 2017-2018 influenza season", and published in January 2020.  
19 While this study reported an association between flu vaccination and risk of four commonly  
20 circulating seasonal coronaviruses, none was the one that causes COVID-19. In addition, Wolff  
21 himself later stated in a Letter to the Editor (attached as **Exhibit D**) that the results from his study  
22 should not be used to discourage the flu vaccine.

23           46.     I also note that the findings of the Wolff study related to seasonal coronaviruses  
24 were later found to be incorrect. The results from that initial study led researchers in Canada to  
25 look at their data to see if they could find similar results in their population. The results of the  
26 Canadian study, "Influenza Vaccine Does Not Increase the Risk of Coronavirus or Other  
27 Noninfluenza Respiratory Viruses: Retrospective Analysis From Canada, 2010-2011 to 2016-  
28 2017," Skworonski, et al., published in May 2020 (attached as **Exhibit E**), showed that flu

1 vaccination did not increase risk for these seasonal coronaviruses. Instead, the Canadian findings  
2 highlighted the protective benefits of flu vaccination. The Canadian researchers also identified a  
3 flaw in the methods of the Wolff study, noting that it violated the part of study design that  
4 compares vaccination rates among patients with and without flu. This flaw led to the incorrect  
5 association between flu vaccination and seasonal coronavirus risk. When these researchers  
6 reexamined data from the Wolff study using correct methods, they found that flu vaccination did  
7 not increase risk for infection with other respiratory viruses, including seasonal coronaviruses.

8 47. I also disagree with the suggestion of some of Plaintiffs' declarants that the flu  
9 season this year may be a mild one because countries in the Southern hemisphere, such as  
10 Australia, experienced a light flu season. While countries such as Australia may have  
11 implemented more uniform nationwide measures to prevent the spread of COVID-19, the United  
12 States has not. As a result, the experience of the flu season in countries like Australia is not  
13 necessarily representative of what to expect in the United States this flu season. The U.S.  
14 continues to see wide-spread circulation of COVID-19, indicating the conditions are also present  
15 for community spread of influenza. Given the ongoing community transmission of COVID-19  
16 and thus the predictable circulation of influenza, the better approach is to follow the guidance  
17 from the California Department of Public Health and the CDC, which both recommend that (1)  
18 because of the COVID-19 pandemic, reducing the spread of respiratory illnesses, like the flu, this  
19 fall and winter is more important than ever; and (2) individuals should get a flu vaccination as  
20 soon as possible this year.

21 48. I disagree with Professor Andrew Noymer's declaration, paragraph 6, that vaccine  
22 mismatch is much more likely during the 2020/2021 influenza season. The selection of influenza  
23 strains for inclusion in vaccines is done each year by the World Health Organization (WHO) and  
24 the US Food and Drug Administration (FDA) Vaccines and Related Biological Products  
25 Advisory Committee (VRBPAC) and is based on evaluation of circulation of influenza strains in  
26 both the Northern and Southern hemispheres. Strain selection is difficult each year and is subject  
27 to many challenges. Vaccine mismatch has occurred a number of times since the Global Influenza  
28 Surveillance Network was established in 1952. Influenza, though decreased, continued to

1 circulate in the Southern hemisphere and data were available to help inform strain selection.

2 There is no evidence that COVID-19 will increase the odds of influenza vaccine mismatch.

3 49. I disagree with Dr. Laszlo G. Boros's declaration, paragraph 11, asserting that  
4 there may be an increased risk of miscarriage for women who received immunization with H1N1  
5 antigens two years in a row. The flu vaccine is recommended for pregnant women to protect them  
6 from the flu and to protect their babies during the first six months of life when they are not  
7 eligible for vaccination. The CDC has published the following information (available at:  
8 [https://www.cdc.gov/flu/highrisk/qa\\_vacpregnant.htm](https://www.cdc.gov/flu/highrisk/qa_vacpregnant.htm)). One of the largest and strongest studies  
9 about flu vaccine and miscarriage was conducted in CDC's Vaccine Safety Datalink  
10 (VSD) project. That recently published study (attached as **Exhibit F**) covered three flu seasons  
11 (2012-13, 2013-14, 2014-15) looking for any increased risk for miscarriage among pregnant  
12 women who had received a flu vaccine during their pregnancy. The study found *no* increased risk  
13 for miscarriage after flu vaccination during pregnancy.

14 50. Finally, the Advisory Committee on Immunization Practices (ACIP), the American  
15 College of Obstetricians and Gynecologists (ACOG), and the CDC continue to recommend that  
16 pregnant women get a flu vaccine during any trimester of their pregnancy because flu poses a  
17 danger to pregnant women and a flu vaccine can prevent serious illness, including hospitalization,  
18 in pregnant women. The ACOG statement identifies influenza vaccine as "an essential element of  
19 pre-pregnancy, prenatal, and postpartum care because influenza can result in serious illness,  
20 including a higher chance of progressing to pneumonia, when it occurs during the antepartum or  
21 postpartum period".

22 I declare under penalty of perjury under the laws of the State of California that the  
23 foregoing is true and correct to the best of my knowledge.

24 Executed in Oakland, California, on this 29th day of September 2020.

25 *Carrie Byington*

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Carrie L. Byington, M.D.