DECLARATION OF RODNEY X. STURDIVANT, PHD.

I, Rodney X. Sturdivant, Ph.D., pursuant to § 1-6-105, MCA, hereby declare, under penalty of perjury, the following to be true and correct:

1. I am a resident of San Antonio, Texas. I am 56 years old and am otherwise competent to render this declaration. I am mentally sound and competent to attest to the matters set forth herein. The matters set forth in this Declaration are based upon my own personal knowledge, unless otherwise stated. I have personal knowledge of the matters set forth below, and could and would testify competently to them if called upon to do so.

2. I am an Associate Professor of Statistics at Baylor University and director of the Baylor Statistical Collaboration Center. I have been on the Baylor faculty since July, 2020. Prior appointments and professional experiences include Research Biostatistician, Henry M. Jackson Foundation (HJF) supporting the Uniformed Services University of Health Sciences, Professor of Applied Statistics and Director of the M.S. in Applied Statistics and Analytics at Azusa Pacific University, Chair of Biostatistics and Clinical Associate Professor of Biostatistics in the College of Public Health at The Ohio State University and Professor of Applied Statistics and Academy Professor in the Department of Mathematical Sciences, West Point. I hold two M.S. degrees from Stanford, in Operations Research and Statistics, and a Ph.D. in biostatistics from the University of Massachusetts – Amherst. I have taught courses involving advanced statistical methods at four institutions, and worked on collaborative research with researchers in a wide variety of medical and public health settings.

3. My primary research area involves application of applied statistics, particularly in fields of medicine and public health. Between 1996 and 2020, I have published articles in peer-reviewed journals and presented results at national and international conferences, including top-ranked journals and conferences in statistics, public health, epidemiology, medicine, and health policy. My work has included studies of infectious diseases or outbreaks such as Leishmania, Anthrax, Bird Flu, HIV/AIDS and recently COVID-19. I co-authored a popular textbook, Applied Logistic Regression, 3rd Edition, which has over 60,000 citations. I have used the text to teach the subject in universities and in workshops for applied statisticians around the country.

4. I have completed a review of the document authored by Barnett, D. and Williams, E. titled “Face Masks as an Intervention to Reduce Aerosol and Droplet-based Transmission of Respiratory Infectious Disease: A Brief Assessment of the Science”. Below are my assessments based on statistical methods and accuracy.

General notes:

5. If there is no effect of an intervention (e.g. facemasks) statistical analysis will lead to a conclusion that there is an effect 5% of the time (using typical Type I error choice). This

is what has occurred, to some extent, as analysts attempt to demonstrate mask effectiveness. The overwhelming data shows no effect, but it is possible to find data that will show an effect. Several issues worsen the Type I error problem:

a. One, well known to statisticians, is that of publication bias: studies where an effect is found are more likely to be submitted and accepted.
b. Publication bias was greatly exacerbated during the pandemic; the number of observational studies, in particular, published rose dramatically (as much as 8-10 times as many published articles in 2020). Peer review was either dramatically reduced or even not done in the interest of getting information that was critical to "public health" out. The result is a plethora of very poor studies that have huge statistical flaws.
c. "Data snooping" is an additional issue that is prevalent. A hypothesis is formed: "masks work" and analysts search in data to find evidence supporting that conclusion. This is a very dangerous approach and statisticians warn against the temptation to do so. However, if one looks at data in various ways (differ time periods, subsets of the data, etc) it is always possible to find some part of the data that supports a given hypothesis.

6. The paper discusses "best scientific evidence" but, importantly, fails to note that even if a study is of a preferred type, it may be flawed. A poorly designed RCT is worse than a well-designed observational study. Meta-analysis, at the top of the "hierarchy", are increasingly popular and treated as always "good" since they consider more than one study. However, they are perhaps more dangerous if not done well. Too often, the studies "collected" for inclusion are not quality or complete and authors suggest the meta-analysis can make up for those deficiencies. Thus, the meta-analysis actually acts to hide flawed data as the original papers are merely referenced and rarely actually reviewed.

7. The paper noticeably fails to include the highest quality studies from all categories (RCT, meta-analysis, observational data). The papers not included are well known (i.e. WHO review[1], a quality May 2020 meta-analysis[2], the Danish mask study[3], the Marine Corps study[4] – see Sturdivant declaration for references and additional discussion). The omission of these studies is indicative of the author bias that calls into question the quality of the chosen studies.

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[1] World Health Organization, 2019, *Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza*.

[2] Jingyi Xiao, et al., *Nonpharmaceutical measures for pandemic influenza in nonhealthcare settings – personal protective and environmental measures*, May 2020, Emerging Infectious Diseases, https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article

[3] Henning Bundgaard, et al., *Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers A Randomized Controlled Trial*, November 18, 2020, Annals of Internal Medicine, https://www.acpjournals.org/doi/10.7326/M20-6817

[4] A.G. Letizia, et al., *SARS-CoV-2 transmission among Marine recruits during quarantine*, November 11, 2020, The New England Journal of Medicine, DOI: 10.1056/NEJMoa2029717

8. This "brief assessment" is a comprehensive compilation of some of the most flawed statistical studies that I have ever reviewed. The authors fail to include a host of quality studies. Instead, the studies included have major issues and, in particular, many are meta-analysis not only based on the poor studies (several such papers appearing in multiple meta-analysis cited) but often the meta-analysis itself has flaws.

Specific notes (not comprehensive) on studies about mask effectiveness

9. **Study 1**: Tabatabaeizadeh, S-A (2021). Perhaps the worst meta-analysis I have seen; only a total of 4 articles (clearly issues with selection of studies to include and hardly a sufficient number). All are studies with claims of nearly complete effectiveness of masks (e.g. RR estimates of 0.03, 0.04) and of extremely poor quality. Some examples of the issues:
    a. The Heinzerling et al. "study" is a CDC MMWR report that does not actually compare mask use to non-use. The study finds 3 cases among 121 exposed all with "unprotected exposure". There is no comparison group so the study cannot make claims about the effectiveness of mask use. In fact, the claimed risk ratio in the meta-analysis is not actually in the cited paper. The use of facemasks in the very limited data shows no significant result (not even close).
    b. Two of the other papers (Wang et al, 2020) are not clearly comparisons of mask use and no mask use; one certainly compares surgical to N-95 the other is less clear.
    c. The fourth study, (Doung-ngern et al 2021) out of Thailand, involves data collected retrospectively by telephone survey; a method prone to great bias. Further, subjects were identified for inclusion in the study if asymptomatic in March 2020 and cases defined as those with Covid in April. Selection of controls was through contact tracing. Such a study is open to numerous additional factors and biases and cannot be used for inference about the effectiveness of a treatment.

10. **Study 2: Li et al (2020).** A very poor meta-analysis utilizing only 6 papers. One is the Heinzerling et al. paper used in study 1. Only one of the 6 involves non health care workers and it showed no statistically significant effect of mask use.

11. **Study 3: Coclite et al (2020)**. This review includes a variety of different types of studies including 3 RCTs (RCTs that are also used in the WHO, 2019 review). It is unclear why the other available RCTs were not included but regardless the conclusion was similar to that of the WHO review – at best a small effect of mask use which is **not statistically significant**. The observational studies considered in this review led to a similar conclusion. The studies that showed an effect were either based on mathematical models or laboratory studies. As discussed in my declaration, both types of studies cannot be utilized to infer an effect in the general population. In fact, this review is interesting in showing that studies involving actual data do not reveal a significant effect

while model/lab studies sometime do. Given that the study does not support mask use, I do not discuss the individual studies here; some (particularly those involving mathematical models) I have reviewed previously and note that they suffer from poor assumptions.

12. **Study 4: Liang et al (2020)**. 21 studies were included and, in this case, more were actually RCTs (6); Again, other RCTs were available but not included. It is noteworthy that based on the RCTs alone masks would not have demonstrated an effect. There are significant flaws with the remaining studies included that lead to the conclusion of an effect.
    a. RCTs: in all 6 RCTs there **was not a significant effect** of mask use. Note that the meta-analysis authors use incorrect data from one RCT (Suess et al, 2012) that appears to suggest significance. However, the data is not the overall comparison of mask to no-mask group in the original paper. Rather, it is a sub-analysis of mask wear specifically 36 hours after symptom onset among those contracting influenza. The result is not generalizable to mask wear by health/asymptomatic individuals in the general population.
    b. An additional 5 of the observational studies show **no statistically significant effect;** many with at most a very small estimated difference in the groups or with extremely large confidence intervals reflecting the lack of precision of any estimates.
    c. One observational study (Wu et al,2004) is a poorly designed retrospective study in Beijing involving telephone interviews; data collected in this manner is subject to numerous biases. Another (Yin et al, 2004) obtained data via questionaires; likewise poor quality and subject to bias.
    d. Teleman et al (2004) and Wilder-Smith (2005) should not be included in the meta-analysis; they are based on the same data, and the "no mask" group is just those healthcare workers not using N95 meaning they could have used other masks. Data collection in this study is also extremely low quality; telephone interviews. Another (Wang et al,2020) similarly does not define a no mask group (discussed in Study 1). It is noteworthy that this extremely poor quality study is the only in the meta-analysis involving Covid-19.
    e. The Loeb et al (2004) study "no mask" group is actually those inconsistently wearing masks. Further the study is extremely small (only 9 in the control group) with a failure to control for many factors; for example, one nurse who inconsistently wore a mask also had by far the most shifts and therefore exposure. Data for the study is all based on interviews.
    f. Sung et al (2016) is a study in a single hospital involving patients with stem cell transplant. The study considers occurrence of respiratory illness in patients in two time periods (2003-2009 and 2010-2014) after a policy of surgical mask use for those in the hospital contacting them was implemented. The study is not generalizable and, further, there are numerous factors that could impact the results given the disparate time frames. It is a very poor quality study for inclusion in a meta-analysis.

g. Cheng et al (2010) is a very weak analysis based solely on symptoms (not confirmed disease) of 4 people in a hospital setting. The confidence interval is incredibly wide reflecting the lack of precision for the study.

13. **Study 5: Hopkins et al (2020)**. Does not provide any results about mask effectiveness.

14. **Study 6**: **Chu et al (2020)**. A meta-analysis based solely on observational studies (many of the same cited in other such studies or documents with significant flaws). The authors surprisingly do not find any RCTs and, in fact, intentionally seem to exclude them and opt for weaker studies. The analysis is flawed in many other ways. Attempts to garner a response from both the authors and the Lancet about the issues failed. Two examples with details of the issues are found online[5]; a brief summary of some of the problems:
    a. Some of the studies used were not published or peer reviewed.
    b. Includes 3 of the 4 papers with issues previously discussed in the study 1 analysis (Heinzerling et al and the two Wang et al. papers); also included are the very poorly designed Wu et al, 2004, Yin et al, 2004, Wilder-Smith, 2004, Loeb et al, 2004, and Teleman, 2004 studies used/discussed in the Study 4 meta-analysis.
    c. Results from several studies were actually incorrectly reported in the meta-analysis (e.g. as with study 1, the authors incorrectly report results for both Heinzerling and Wang papers).
    d. In many cases the results are not statistically significant in the original papers.
    e. Several of the studies actually do not have mask and no mask comparison groups.
    f. Many of the studies involve only N95 masks in hospital settings.

15. **Study 7: Karaivanov et al (2021)**. A study very low on the hierarchy of scientific evidence. Perhaps can be considered "cross sectional", although the fact that the paper is really based on a subsequent model makes the evidence weaker. This is a study from Canada based on data from the "first few weeks after mandate" – too soon to demonstrate effectiveness, particularly as the time period chosen was when cases were already receding. The authors use a series of "counter factuals" that claim an earlier mandate would have led to even more rapid reduction in spread. This latter is a model, not actual data. Essentially, the model assumes effectiveness and then computes the mask effect based on the results of that model. Further, it is limited in time period, very dangerous in the context of the Covid virus as at other times in the same locations spread increases despite mask wear.

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[5] Chu et al. (2020) reviews: 1) https://swprs.org/who-mask-study-seriously-flawed/
2) http://economicsfaq.com/retract-the-lancets-and-who-funded-published-study-on-mask-wearing-criticism-of-physical-distancing-face-masks-and-eye-protection-to-prevent-person-to-person-transmissi/

16. **Study 8: Pedersen et al (2021)**. This study consider "change points" in the virus spread in Italy and suggests correlation with various mitigation measures such as lockdowns and making masks available. The study is an example of the dangers of spurious correlation. There is no possible means of actually inferring mask efficacy from such as study. It is not even clear that the masks were used, as the metric was when they were freely distributed. The study authors note change points not correlated with mitigation measures and suggest they "may be explained" by regional measures. There are far too many factors not considered for this study to be useful or included as evidence about mitigation effectiveness.

17. **Study 9: Abboah-Offei et al (2021)**. This is a "rapid review" and no statistical analysis is presented. The authors just conclude mask use "could lower the risk" based on their own subjective opinion after summarizing some of the many studies they find. Many of the studies cited are the same as those discussed for other studies above with either no statistical significance, practical significance or with numerous flaws. The authors do not share any specific details about the results of the studies. The review is not useful as evidence for mask efficacy.

18. **Study 10: Grinshpun et al (2021)**. This is a lab study simply demonstrating a "reconfiguring" of the forward directed pattern of aerosol emissions from coughing or sneezing using a face mask. Since aerosols remain in the air for some time and can travel significant distances the study is of no relevance to universal mask year. At most, it suggests masks could help some in instances where a person coughs or sneezes when a person is directly in front of them.

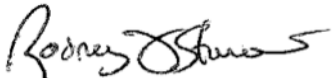
Specific notes (not comprehensive) on studies about masks for children and detrimental impacts of masking

19. The remainder of the document involves studies about the harms of masking. Studying harms is different than effectiveness. It is simply not enough to observe a lack of harm in a given setting if there are documented harms elsewhere. There are studies and data showing adverse impacts and as mask use in children continues more will be learned. In addition to possible physical impacts, psychological, social, and developmental concerns are increasingly documented. Such impacts require longer term study.

20. The section on children and mask includes two studies. Study 1 (Goh et al) involved children walking on a treadmill in an N-95 mask. The study is not comparable to mask use for many hours every day in schools. The second study was a pilot study involving only 24 children over a 3 day period with children walking for 3 minutes and then running for 3 minutes. Again, the study is hardly sufficient to make broader claims involving long term use.

21. The section on detrimental effects includes a single systematic review that concludes they did not collect enough data to quantify adverse effects. Such a conclusion does not stand as evidence that harmful effects do not exist and, again, there are studies suggesting such adverse impacts do occur.

I DECLARE UNDER PENALTY OF PERJURY AND UNDER THE LAWS OF THE STATE OF MONTANA THAT THE FOREGOING IS TRUE AND CORRECT.



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Rodney X. Sturdivant, Ph.D.

Date of Signature: September 30, 2021

Waco, Texas