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.

Professional Background

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 been actively researching the COVID-19 epidemic using my expertise in applied statistics and mathematical modeling, particularly the Susceptible-Infected-Recovered (SIR) models, commonly in use to forecast the COVID-19 epidemic. While working for HJF, I served as a senior advisor for a data analytics group supporting the White House OSTP and FEMA, and four analytics organizations within DoD working on Covid modeling and data analysis. To

date, I have published three papers^{1,2,3}, in peer-reviewed journals related to the epidemic and have two other articles currently in review. One of my published papers on COVID-19 is a review of appropriate use of models for forecasting. Issues with policy have been, in some part, due to the very issues discussed in this article. I have also been asked to act as reviewer for several publications of articles related to Covid research.

5. In November 2020, I testified for the County Commissioners and Judge of Colorado, Texas concerning a declaration challenging restrictions imposed by the Texas Governor. I extensively reviewed the evidence and data regarding the relatively low mortality and morbidity risk that SARS-CoV-2 infection poses to most people, particularly the young and healthy, as well as the evidence about the health impacts of policies involving restrictions, and the overall effectiveness of restrictions.

6. In October 2020, Harvard Professor Dr. Martin Kulldorff invited me to co-sign the Great Barrington Declaration he co-authored with Oxford Professor Dr. Sunetra Gupta and Stanford Professor Jay Bhattacharya. The Declaration was written from a global public health and humanitarian perspective, with special concerns about how the current COVID-19 strategies are forcing our children, the working class and the poor to carry the heaviest burden. I was joined in co-signing by over 40 highly regarded scientists analyzing the pandemic from a variety of perspectives.

7. The Declaration offers an alternative approach to the current COVID-19 strategies being implemented in jurisdictions across the United States and the world called Focused Protection. According to Focused Protection, the most compassionate approach to the COVID-19 pandemic is one that balances the risks and benefits of reaching herd immunity by allowing those who are at minimal risk of death and serious health outcomes to live their lives normally, while better protecting those who are at highest risk. Since October, the Declaration has been co-signed by at least 12,000 medical and public health scientists, and 35,000 medical practitioners. The Great Barrington Declaration is available at https://gbdeclaration.org/

Expert Opinions

Contrary to Good Public Health Practice, Restrictions Do Not Address the Key Risk Metrics, and Assume that COVID-19 Is Equally Dangerous to All Populations.

8. State restrictions reference case counts and percent positivity as metrics to decide whether to impose activity restrictions. These metrics, contrary to good public health practice, do

¹ Koehlmoos, T.P., Janvrin, M.L., Korona-Bailey, J., Madsen, C., and Sturdivant, R. (2020). COVID-19 Self-Reported Symptom Tracking Programs in the United States: Framework Synthesis. *Journal of Medical Internet Research* **22**(10):e23297. DOI: 10.2196/23297

² Thomas, D.M., Sturdivant, R., Dhurandhar, N.V., Debroy, S., and Clark, N. (2020). A primer on COVID-19 Mathematical Models. *Obesity* **28**(8), 1375-1377, doi:10.1002/oby.22881.

³ Ronca, S.E., Sturdivant, R.X., Barr,K.L., and Harris, D. (2021). SARS-CoV-2 Viability on 16 common indoor surface finish materials. *Health Environments Research & Design Journal*, 1-16, doi:10.1177/1937586721991535

not consider the level of mortality risk of the disease or distinguish between people who face high mortality risk should they become infected and people who face low mortality risk. Good public health practice requires that the fraction of the population that is vulnerable, and the level of that risk, be considered among the criteria for imposing activity restrictions. In the paragraphs that follow, I review evidence on the size of the mortality risk with respect to COVID-19 infection, including evidence that shows that the risk is not uniformly imposed on the population.

9. The best evidence on the infection fatality rate from SARS-CoV-2 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people within a population who have specific antibodies against SARS-CoV-2 in their bloodstream. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports, which miss infected people who are not identified by the public health authorities. Because they ignore unreported cases in the denominator, fatality rate estimates based on case reports are substantially biased upwards.

10. According to a meta-analysis⁴ by Dr. John Ioannidis of every seroprevalence study conducted with a supporting scientific paper (74 estimates from 61 studies and 51 different localities around the world), the median infection survival rate from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%. A more recent meta-analysis by scientists independent of Dr. Ioannidis' group, published in the National Bureau of Economic Research working paper series, reaches qualitatively similar conclusions⁵.

11. The mortality risks based on data now for COVID-19 are, for most age groups, very similar to those of the seasonal flu, typically around 0.1% overall, as pointed out by Dr. Anthony Fauci, Dr. H. Clifford Lane and Dr. Robert R. Redfield in a March New England Journal of Medicine article⁶, and much lower than for respiratory viruses such as SARS or MERS. For younger age groups, in particular, the rates are lower.

12. Very clearly, the mortality risk for those infected with SARS-CoV-2 is not the same for all patients. Older patients are at substantially higher risk of death if infected, while younger patients face a vanishingly small risk. In September 2020 the CDC updated its current best estimate of the infection fatality ratio—the ratio of deaths to the total number of people infected—for various age groups.⁷ The CDC estimates that the infection fatality ratio for people ages 0–19 years is .00003, meaning infected children have a 99.997% survivability rate. The CDC's best estimate of the infection fatality rate for people ages 20–49 years is .0002, meaning that young adults have

⁴ John P.A. Ioannidis, *The Infection Fatality Rate of COVID-19 Inferred from Seroprevalence Data*, Bulletin of the World Health Organization BLT.20.265892.

⁵ Andrew T. Levin, et al., Assessing the Age Specificity of Infection Fatality Rates for COVID-19: Meta-Analysis & Public Policy Implications (Aug. 14, 2020) MEDRXIV, https://bit.ly/3gpIoIV

⁶ Anthony S. Fauci, et al., *Covid-19 Navigating the Uncharted*, The New England Journal of Medicine, 382;13 (March 26, 2020), DOI: 10.1056/NEJMe2002387.

⁷ Coronavirus Disease 2019 (COVID-19), *COVID-19 Pandemic Planning Scenarios* (Sep. 10, 2020) CDC, <u>https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html</u>.

a 99.98% survivability rate. The CDC's best estimate of the infection fatality rate for people age 50–69 years is .005, meaning this age group has a 99.5% survivability rate. The CDC's best estimate of the infection fatality rate for people ages 70+ years is .054, meaning seniors have a 94.6% survivability rate.

13. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in the Lancet8) provides a detailed age break down of the infection survival rate in a preprint companion paper⁹: 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65.

14. Age is an important factor for COVID-19 deaths. The other is co-morbidities, or other existing and serious medical conditions. As of November 21, 2020, the CDC reported that 94% of deaths reported for COVID-19 included at least one comorbidity, with an average of 2.6 additional conditions noted.¹⁰ Some comorbidities listed are clearly deaths not due to Covid at all – for example over 8,000 due to "intentional and unintentional injury". The latter point has impacts about overall disease severity, suggesting it may be lower than estimated.¹¹ Regardless, it is clear that in addition to age, the other group at higher risk is those with underlying health issues.

15. Although COVID-19 affects various age groups and health conditions very differently, government restrictions assume that the disease affects everyone equally. This, too, is not justified by the scientific literature and represents poor public health practice. By assuming the disease affects everyone equally in its criteria for reopening, the State is forcing unnecessary restrictions on a large segment of the population that will needlessly devastate the lives of millions.

Public Health Principles Consider All Health Implications of Policies Rather than a Single Outcome

16. There is clear evidence that Plaintiffs and others have been and can be harmed from lockdowns and similar restrictions.

17. As numerous peer reviewed publications have demonstrated, and as the former FDA Commissioner has admitted, the lockdowns themselves are depriving people of life. They are literally causing people to die, including by suicide.¹² These deaths, sadly, are often in younger

⁸ Silvia Stringhini, et al., Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study (June 11, 2020) The Lancet, https://bit.ly/3l87S13

⁹ Francisco Perez-Saez, et al., *Serology-Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland,* (June 15, 2020) OSF PREPRINTS, https://osf.io/wdbpe

¹⁰ See <u>https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm</u> table 3.

¹¹ Karl Dierenbach, CDC data suggest lockdowns could kill as many people as COVID, November 4, 2020, The Federalist, https://thefederalist.com/2020/11/04/cdc-data-suggest-lockdowns-could-kill-as-many-people-as-covid/

¹² Dr. Mike deBoisblanc, the head of California's John Muir Medical Center's trauma team says his area has seen more death from lockdown suicides than from the pandemic itself. "We've never seen numbers like this, in such a short period of time...I mean, we've seen a year's worth of suicide attempts in the last four weeks", Dr. deBoisblanc said in May, only two months after the lockdown was initiated. *See <u>https://nypost.com/2020/05/24/california-city-has-seen-more-deaths-by-suicide-than-covid-19-doctor/.*</u>

individuals representing far more life years lost than the median age of COVID-19 deaths which is greater than 75 years of age in the United States.¹³ Former FDA Commissioner Scott Gottlieb stated on October 21, 2020: "I would suspect that a good portion of the deaths in that younger cohort were deaths due to despair, due to other reasons. We've seen a spike in overdoses, and I would suspect that a good portion of those excess deaths in that younger cohort were from drug overdoses and other deaths that were triggered by some of the implications of we've gone through to try to deal with COVID-19."¹⁴

18. One study acknowledges that "Medical and Public Health experts are not expert in this type [cost-benefit] of analysis" and argues that "cost and benefit should be measured in terms of human welfare in the form of length, quality, and wellbeing of lives, and 'to make no assessment is just to make policy in a vacuum."¹⁵ The author, Joffe, MD, FRCPC, "present[s] a cost-benefit analysis of the response to COVID-19 that finds lockdowns are far more harmful to public health than COVID-19 can be."¹⁶ The author finds that "on balance the lockdowns cost a minimum of 5X more WELLBY [wellbeing quality of life years los] than they save, and more realistically, cost 50-87X more. Importantly, this cost does not include the collateral damage discussed above [from disrupted healthcare services, disrupted education, famine, social unrest, violence, and suicide] nor the major effect of loneliness and unemployment on lifespan and disease."¹⁷ Dr. Joffe concludes, that "[w]e must open up society to save many more lives than we can by attempting to avoid every case (or even most cases) of COVID-19. It is past time to take an effortful pause, calibrate our response to the true risk, make rational cost-benefit analyses of the trade-offs, and end the lockdown groupthink."¹⁸

19. During the period from January to August, the average total number of deaths during the last three years in California has been 179,901 deaths. During this same period for 2020, the total deaths have been 201,007. This represents an excess mortality of 21,105 deaths. During this same period, however, there have only been 12,933 deaths attributed to (but not necessarily caused by) COVID-19. The remaining 8,172 deaths, and others across the country just like them, have been confirmed by the CDC's Director Redfield to be caused by lockdowns and restrictions like those instituted by many local leaders: "We're seeing, sadly, far greater suicides now than we are deaths from COVID. We're seeing far greater deaths from drug overdose, that we are above

¹⁶ Id.

¹⁷ Id.

¹³ See <u>https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Sex-Age-and-S/9bhg-hcku</u>.

¹⁴ <u>https://www.dailywire.com/news/new-cdc-numbers-show-lockdowns-deadly-toll-on-young-people.</u>

¹⁵ <u>https://www.preprints.org/manuscript/202010.0330/v1</u>.

¹⁸ *Id. Revolver News* conducted another study that analyzed the cost of lockdowns and that reached an alarming conclusion: "COVID-19 lockdowns are ten times more deadly than the actual COVID-19 virus in terms of years of life lost by American citizens."¹⁸ <u>https://www.revolver.news/2020/08/study-covid-19-lockdowns-deadlier-than-pandemic-itself/</u>. In its study, *Revolver* found that "an estimated 18.7 million life-years will be lost in the United States due to the COVID-19 lockdowns. Comparative data analysis between nations shows that the lockdowns in the United States likely had a minimal effect in saving life-years. Using two different comparison groups, we estimate that the COVID-19 lockdowns in the U.S. saved between a quarter to three quarters of a million life-years." *Id.*

excess, than we had as a background, than we are seeing deaths from COVID."¹⁹ A CDC report on excess deaths suggests over 90,000 excess deaths due to COVID lockdown policies as of October 3, 2020.²⁰

20. These deaths caused by government action in response to COVID-19 include people being afraid to go to the hospital for another condition for fear of catching the coronavirus, loss of health insurance after layoffs, inability to afford medications after pay cuts, or the skyrocketing rates of depression in America's adults, a condition that negatively impacts many aspects of health.²¹

21. "To assess mental health, substance use, and suicidal ideation during the pandemic, representative panel surveys were conducted among adults aged ≥ 18 years across the United States during June 24–30, 2020" by the CDC COVID-19 Response Team and others.²² The August 14, 2020 CDC Morbidity and Mortality Weekly Report titled "Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic" reported that in the midst of the lockdowns, "40% of U.S. adults reported struggling with mental health or substance use."²³ Further, the CDC reported that 11% of U.S. adults surveyed had seriously considered suicide in the previous 30 days before they completed the survey.²⁴

22. An October study titled "Well-being of Parents and Children During the COVID-19 Pandemic: A National Survey" published in Pediatrics indicated that three months of restrictions (March through May) had a similar impact on children as well as their parents: more than one in four U.S. parents (27%) reported a decline in their own mental health, and about one in seven (14%) perceived a corresponding decline in their children's behavioral health.²⁵

23. As acknowledged by the Assistant Secretary for Mental Health and Substance Use, Elinore F. McCance-Katz, M.D., Ph.D., and Michael Caputo, then assistant secretary for Public Affairs at the Department of Health and Human Services, lockdowns have resulted in: "calls to our Disaster Distress Helpline...[have] gone up 1,000 percent;" "throughout the country, you can see...calls to the Suicide Prevention Lifelines greatly increasing...we've seen an increase in the

²² <u>https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm?s_cid=mm6932a1_e&deliveryName=USCDC_921-DM35222</u>.

²³ Id.

¹⁹ <u>https://www.cnn.com/2020/07/14/health/us-coronavirus-tuesday/index.html.</u>

²⁰ Lauren M. Rossen, et al., Excess deaths associated with COVID-19, by age and race and ethnicity – United States, January 26 – October 3, 2020, October 23, 2020, CDC, https://www.cdc.gov/mmwr/volumes/69/wr/mm6942e2.htm?s cid=mm6942e2 w

²¹ In late September 2020, the New York Times analyzed COVID-19 and excess deaths and found that "[f]rom March 15 through Sept. 5, the most recent date with reliable death statistics, estimated excess deaths were about 42 percent higher than the official coronavirus fatality count." <u>https://www.nytimes.com/interactive/2020/05/05/us/coronavirus-death-toll-us.html</u>. It explained that this excess could, in part, be explained by the fact that "people have been scared to <u>seek care for ailments</u> that are typically survivable" and that "[d]rug deaths have also risen an average of <u>13</u> percent so far this year over last year." *Id*.

²⁴ https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm?s_cid=mm6932a1_e&deliveryName=USCDC_921-DM35222.

²⁵ <u>https://pediatrics.aappublications.org/content/146/4/e2020016824</u>.

proportion of emergency department visits that are due to suicide attempts;" "people reported...that they were new users of substances or increasing their use of substances;" deaths due to alcohol and drug use; people losing their jobs and their businesses; families losing their homes; people unable to access medical care; and increased domestic abuse. Dr. McCance-Katz described overbroad lockdowns best as the government having "used a sledgehammer when I think we needed a scalpel."²⁶

24. A study of overdose related cardiac arrests²⁷ shows that the number in 2020 is 53% higher than 2018-2019 averages and rose sharply in April to 123% above baseline. The authors conclude: "the fallout from the COVID-19 pandemic—perhaps especially social isolation—is sharply accelerating fatal overdose trends".

25. This is why the World Health Organization's Dr. David Nabarro recently stated:

"We in the World Health Organization do not advocate lockdowns as the *primary* means of control of this virus. The only time we believe a lockdown is justified is to buy you time to reorganize, regroup, rebalance your resources, protect your health workers who are exhausted, but by and large, we'd rather not do it. ... And so, we really do appeal to all world leaders: stop using lockdown as your primary control method. Develop better systems for doing it."²⁸

26. A recent review article which points out that paradoxically lockdown measures may increase risks from Covid-19 by compromising the immune system and physical and mental health of people.²⁹ The article also points out the disproportionate impacts on groups already facing inequalities.

Policies that Restrict and Remove Freedoms and Impact Overall Health and Well Being of Citizens must be Able to Demonstrate Potential for Significant Effectiveness Based on Science and Data

27. Data and science to support restrictions on freedom by the government, particularly those that deprive citizens of constitutionally guaranteed rights, should be extremely compelling. Epidemiological theory and best practices garnered over decades of research provide important

²⁶ <u>https://www.hhs.gov/podcasts/learning-curve/learning-curve-14-elinore-mccance-katz-assistant-secretary-of-substance-abuse-and-mental-health-services-administration.html?fbclid=IwAR0YOPSNPvjB0-5dkWGeCtM4gVPMHQ HT4zImyj7WNU0NBqhTE8UJkojq2VM.</u>

²⁷ Joseph Friedman, et al., Overdose-related cardiac arrests observed by emergency medical services during the US COVID-19 epidemic, December 3, 2020, JAMA Psychiatry, https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2773768

²⁸ https://www.youtube.com/watch?v=x8oH7cBxgwE&feature=youtu.be&t=915.

²⁹ Michaela C. Schippers, *For the greater good? The devastating ripple effects of the Covid-19 crisis*, September 29, 2020, Frontiers in Psychology, https://www.frontiersin.org/articles/10.3389/fpsyg.2020.577740/full

guidance in handling the pandemic, and strongly advise against many of the measures currently used. Studies of the data on measures employed by states and countries around the world suggest that they do not significantly alter the course or outcomes of the pandemic.

The Epidemic Science

28. A solid body of literature exists about epidemics such as Covid-19 which has informed planning documents for handling such an outbreak. The approaches differ from those used more than 50 years ago as scientist have better understanding of viruses, and data analysis has discovered important evidence about what works. Planning documents for pandemics in the US**30** as well as all major European countries³¹ reflect this literature which is well summarized in a paper by Donald Henderson, esteemed epidemiologist and leader of the effort to eradicate smallpox, and colleagues³². Specific interventions are discussed subsequently.

29. Quarantines. "The interest in quarantine reflects the views...when much less was known about the epidemiology...It is difficult to identify circumstances in the past half-century when large-scale quarantine has been effectively used in the control of any disease. The negative consequences of large-scale quarantine are so extreme...that this mitigation measure should be eliminated from serious consideration Voluntary home quarantine for individuals who are asymptomatic...to keep possibly contagious, but still asymptomatic, people out of circulation...raises significant practical and ethical issues".³³

30. Travel restrictions. "Travel restrictions, such as closing airports and screening travelers at borders, have historically been ineffective."³⁴ The article then cites the World Health Organization which notes: "screening and quarantining entering travelers at international borders did not substantially de- lay virus introduction in past pandemics . . . and will likely be even less effective in the modern era."³⁵

31. Social gatherings. "public events with an expected large attendance have sometimes been cancelled or postponed, the rationale being to decrease the number of contacts with those who might be contagious. There are, however, no certain indications that these actions have had any definitive effect on the severity or duration of an epidemic...this prohibition might include church services, athletic events, perhaps all meetings of more than 100 people...closing theaters, restaurants, malls, large stores, and bars. Implementing such measures would have seriously disruptive consequences for a community if extended through the 8-week period of an epidemic

³³ Id.

³⁴ Id.

³⁰ CDC, *The National Strategy for Pandemic Influenza*, November, 2009 with 2017 update https://www.cdc.gov/flu/pandemic-resources/national-strategy/index.html

³¹ European Centre for Disease Prevention and Control, *Influenza pandemic preparedness plans*, https://www.ecdc.europa.eu/en/seasonal-influenza/preparedness/influenza-pandemic-preparedness-plans

³² Thomas V. Inglesby, et al., Disease mitigation measures in the control of pandemic influenza, September 5, 2006, Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science 4:26, DOI: <u>10.1089/bsp.2006.4.366</u>

³⁵ World Health Organization Writing Group. *Nonpharmaceutical public health interventions for pandemic influenza, national and community measures*. 2006, Emerg Infect Dis; 12:88–94.

in a municipal area, let alone if it were to be extended through the nation's experience with a pandemic (perhaps 8 months)...a policy calling for communitywide cancellation of public events seems inadvisable."³⁶

32. Social distance. "It has been recommended that individuals maintain a distance of 3 feet or more during a pandemic...the efficacy of this measure is unknown...such a recommendation would greatly complicate normal daily tasks like grocery shopping, banking, and the like."³⁷

33. Masks and PPE. The science suggests use in certain settings, such as hospitals, and the N95 is recommended during a pandemic. Further, "studies have shown that the ordinary surgical mask does little to prevent inhalation of small droplets bearing influenza virus."³⁸

34. School closures. "In previous influenza epidemics, the impact of school closings on illness rates has been mixed...schools are often closed for 1–2 weeks early in...outbreaks of influenza primarily because of high absentee rates...this would seem reasonable on practical grounds. However, to close schools for longer periods is not only impracticable but carries the possibility of a serious adverse outcome."³⁹ The article is specifically considering previous epidemics, primarily influenza, which often were more severe for children. Covid-19 is different in that it holds little risk of serious outcomes for children.

35. A principal tenet of the Great Barrington Declaration (GBD) is that policies that apply to the entire population are actually likely to produce worse results when there is a clear age differential in terms of outcomes, as is the case for Covid-19. Epidemic theory, summarized by Dr. Ted Cohen and Dr. Marc Lipsitch, supports this position. The authors conclude: "for those pathogens that cause more severe disease among hosts of an older age, interventions that limit transmission can paradoxically increase the burden of disease in a population."⁴⁰

Covid Data and Science Confirms Existing and Previous Epidemic Theory

36. Analysis of data collected throughout the pandemic confirms the theory. A comprehensive study of 188 countries over the first 8 months of pandemic⁴¹ shows that the primary factors associated with Covid-19 mortality are impacted by factors inherent to the country – latitude and longitude, age distribution, stagnation in life expectancy and economy for example. Stringency measures, to include lockdowns, are not associated with the outcome. Others have

³⁸ Id.

³⁹ Id.

³⁶ Thomas V. Inglesby, et al., Disease mitigation measures in the control of pandemic influenza, September 5, 2006, Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science 4:26, DOI: <u>10.1089/bsp.2006.4.366</u>

³⁷ Id.

⁴⁰ Ted Cohen and Marc Lipsitch, *Too little of a good thing: A paradox of moderate infection control*, March 26, 2008, Epidemiology, DOI: 10.1097/EDE.0b013e31817734ba

⁴¹ Quentin De Larochelamber, et al., *Covid-19 mortality: a matter of vulnerability among nations facing limited margins of adaptation*, November 2020, Frontiers in Public Health, https://www.frontiersin.org/articles/10.3389/fpubh.2020.604339/full

found similar results in comparing the data across countries⁴² and states.⁴³ In addition to factors such as age and income, levels of obesity and other population factors were associated with the outcomes. However, "full lockdowns, and wide-spread testing were not associated with COVID-19 mortality per million people".⁴⁴

37. Much of the support cited for use of lockdowns and other non-pharmaceutical measures has been mathematical and statistical models. The models have been consistently wrong in their predictions and often misinterpreted or used incorrectly⁴⁵. One of the most often cited and utilized models is that of the Imperial College. However, the model and it's conclusions have been analyzed and disproven. An analysis⁴⁶, based on the data, suggests in fact that the imperial college model that best fits the actual data is one which shows no effect of lockdowns or NPI's. The paper concludes by pointing out the dangers of use of the models given their sensitivity to parameter estimates and that "claimed benefits of lockdown appear grossly exaggerated."

38. Data for individual countries and locations is overwhelming in demonstrating that mitigation measures and lockdowns are not effective. As an example, in September an article in Scientific American describes how the state of New Mexico "controlled" spread.⁴⁷ Just a few months later headlines described an alarming "surge" in cases and hospitalizations.⁴⁸ The story is easily repeated in other states and countries.

39. Perhaps the most extreme example of lockdown and mitigation measure ineffectiveness is found in Peru.⁴⁹ Unlike neighboring Brazil, heavily criticized for not taking strict measures, Peru locked down their country extremely early and with some of the harshest restriction in the world enforced by the military. They kept people in their homes, mandated both masks and

⁴⁶ Vincent Chin, et al., December 10, 2020, *Effects of non-pharmaceutical interventions on COVID-19: a tale of three models*, https://www.medrxiv.org/content/10.1101/2020.07.22.20160341v3

⁴² Bjørnskov, Christian, *Did Lockdown Work? An Economist's Cross-Country Comparison*, August 2, 2020. Available at SSRN: <u>https://ssrn.com/abstract=3665588</u> or <u>http://dx.doi.org/10.2139/ssrn.3665588</u>

⁴³ James L. Doti, *A model to explain statewide differences in Covid-19 death rates*, November 20, 2020, available at SSRN: https://ssrn.com/abstract=3731803 or http://dx.doi.org/10.2139/ssrn.3731803

⁴⁴ Rabail Chaudhry, et al. *A country level analysis measuring the impact of government actions, country preparedness and socioeconomic factors on COVID-19 mortality and related health outcomes*, July 2, 2020, EClinicalMedicine, <u>https://doi.org/10.1016/j.eclinm.2020.100464</u>

⁴⁵ Thomas, D.M., Sturdivant, R., Dhurandhar, N.V., Debroy, S., and Clark, N., 2020, *A primer on COVID-19 Mathematical Models*, Obesity 28(8), 1375-1377, doi:10.1002/oby.22881

⁴⁷ Christie Aschwanden, *How New Mexico controlled the spread of Covid-19*, September 15, 2020, Scientific American, https://www.scientificamerican.com/article/how-new-mexico-controlled-the-spread-of-covid-19/

⁴⁸ Jessica Garate, et al., *New Mexico health officials make dire predictions as Covid-19 cases surge*, November 5, 2020, KRQE https://www.krqe.com/health/coronavirus-new-mexico/new-mexico-health-officials-make-dire-predictions-as-covid-19-cases-surge/

⁴⁹ Jordan Schachtel, *The world's toughest lockdown has resulted in the world's highest COVID-19 death toll*, August 18, 2020, The Dossier, https://jordanschachtel.substack.com/p/the-worlds-toughest-lockdown-has

face shields, incorporated strict curfews and closed all but the most essential services. By August, Peru had among the highest per capita death rates with surges in cases greater than Brazil.

40. In addition to observed data, a randomized control trial (RCT) study of US Marine Recruits⁵⁰ examines effectiveness of mitigation measures. The study is published in a top journal, the New England Journal of Medicine, and is an extremely well designed and conducted study with very high compliance. The study group or more than 1800 participated in a two-week quarantine that included high quality cloth mask wearing, social distancing, isolation, and daily temperature and symptom checks. They lived on a closed college campus which they could not leave. They did not even have access to "personal electronics and other items that might contribute to surface transmission." At the end of the study, roughly 2% of recruits in the study group tested positive. Meanwhile, in a group of over 1,500 marines who did not quarantine and follow the protocols slightly fewer (1.7%) tested positive over the same period.

41. A common criticism of the GBD approach is that it allows increased spread that makes it more, not less, possible to protect the most vulnerable. The assumption is that lockdown and other mitigation measures actually do reduce overall spread. Further, a study in England⁵¹ examined the risks for adults living in households with children. Among over 2.5 million adults over the age of 65 – therefore at increased risk – they found no association with Covid-19 outcomes for any age group of children in the home. The study further found that while there was a slight increase in infections when there were children ages 11-18 for adults under age 65, there was no increase of death. For children aged under 11, there was actually a reduction in the risk of death for adults under age 65.

Example of Universal Mask Mandates

42. A specific example of a mitigation measure governments have consistently mandated, is the use of facemasks, touted as "science". Both data and science suggest such a mandate for widespread and universal use is not justified or effective.

43. When the CDC and public health officials suddenly shifted from the well-established scientific positions about the marginal effectiveness of masks there was little to no new evidence of effectiveness. At that time, the entire justification for the CDC guidelines rested on asymptomatic spread concerns. In the time since, new studies have even cast doubt on how much impact asymptomatic people play in transmission. A recent study⁵² involving contract tracing of over 3400 close contacts of 391 confirmed cases found only 0.3% attack rate among asymptomatic cases compared to 3.3% for those with mild symptoms (or 10 times less). The rate increases further as symptoms become severe to 5.6% and 6.2% for those with moderate or severe symptoms. A

⁵⁰ 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

⁵¹ Harriet Forbes, et al., Association between living with children and outcomes from COVID-19: an OpenSAFELY cohort study of 12 million adults in England, November 2, 2020, BMJ https://www.medrxiv.org/content/10.1101/2020.11.01.20222315v1

⁵² Lei Luo, et al., Contact settings and risk for transmission in 3410 close contacts of patients with COVID-19 in Guangzhou, China: a prospective cohort study, December 1, 2020, Annals of Internal Medicine, https://pubmed.ncbi.nlm.nih.gov/32790510/

remarkably large study53, testing over 10 million people, in Wuhan China found "there was no evidence of transmission from asymptomatic positive persons". They found 303 cases, all asymptomatic, and traced 1174 close contacts. This is also important in terms of who should quarantine; locking down asymptomatic people is not supported by these studies.

44. The ineffectiveness of masks was well known prior to 2020 as stated in a New England Journal of Medicine perspective from May 2020: "We know that wearing a mask outside health care facilities offers little, if any, protection from infection... In many cases, the desire for widespread masking is a reflexive reaction to anxiety over the pandemic."⁵⁴

45. The evidence prior to 2020 is captured in a review by the WHO. In 2019 they completed a systematic review of the scientific literature for all NPIs.⁵⁵ The thorough study found 10 studies, all randomized control trials (RCTs), of sufficient scientific quality for meta-analysis. They concluded that "there was no evidence that face masks are effective in reducing transmission of laboratory-confirmed influenza." They rated the quality of the evidence as "moderate" – this highest rating of available evidence for any of the 16 NPIs analyzed. Additional studies, particularly in the community settings, were suggested to increase the quality. Two such studies: The Marine Corps study mentioned previously and the "Danish Mask Study" significantly add to the quality of the literature, specifically in the community setting.

46. Support for mask effectiveness is largely based on laboratory studies. However, the evidence even in that setting is at best inconclusive. The problem is that cloth and surgical masks allow particles the size of Covid-19 through. A 2009 study of small particles involving 5 different surgical masks concludes for "included particles in the same size range of viruses confirms that surgical masks should not be used for respiratory protection."⁵⁶ A more recent study considered small particles and used human volunteers to test masks. The very best-case mask filtered 70% of particles with others filtering less than 50%.⁵⁷ Another study, done even before Covid, measured the filtering efficacy and the size of mask pores particularly, concluding very poor filtering made worse with wear time and washing of the masks.⁵⁸ The airborne nature of Covid-19 means that this performance is not effective when exposure is more than brief to the virus.⁵⁹ The studies cited

⁵⁷ Emily E. Sickbert-Bennett, et al., *Filtration efficiency of hospital face mask alternatives available for use during the COVID-19 pandemic*, August 11, 2020, JAMA Network, https://jamanetwork.com/article.aspx?doi=10.1001/jamainternmed.2020.4221

⁵⁸ Bhanu Bhakta Neupane, et al., June 2019, *Optical microscopic study of surface morphology and filtering efficiency of face masks*, DOI 10.7717/peerj.7142.

⁵⁹ John A. Lednicky, et al., *Viable SARS-CoV-2 in the air of a hospital room with COVID-19 patients, September 11, 2020*, Internatial Journal of Infectious Diseases, https://doi.org/10.1016/j.ijid.2020.09.025

⁵³ Shiyi Cao, et al., Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China, November 20, 2020, Nature Communications, https://www.nature.com/articles/s41467-020-19802-w

⁵⁴ Michael Klompas, et al., Universal masking in hospitals in the Covid-19 era, May 21, 2020, New England Journal of Medicine, https://www.nejm.org/doi/full/10.1056/NEJMp2006372.

⁵⁵ World Health Organization, 2019, Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza.

⁵⁶ Samy Rengasamy, et al., *Filtration performance of FDA-cleared surgical masks*, 2009, J Int Soc Respir Prot, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7357397/pdf/nihms-1604065.pdf

here involve surgical masks, likely better than most cloth masks worn by people.⁶⁰ Further, the time of wear and proper use is also likely better in the studies than when people wear masks for many hours.

47. Translating results from a lab setting to conclude similar rates of spread reduction requires evidence. A significant ability of masks to reduce spread in the entire population is not supported by data and science. Attempts to find data supporting this hypothesis have been particularly lacking in scientific rigor. A study of 1083 counties in the US which showed a decrease in hospitalizations after mask mandates had to be withdrawn as rates actually increased shortly after publication.⁶¹

48. Even if masks filter some percentage of particles, the number of such particles is far greater than needed to cause a serious infection.⁶² An infectious dose of COVID-19 is approximately 300 particles. The number of particles emitted in a single minute of speaking is greater than 700,000. Even a 50% reduction would have no impact on transmissibility.

49. The WHO, in 2020, changed recommendations about mask use quite suddenly in June or July. They published an "interim guidance" document⁶³ on December 1, 2020 to discuss their new guidelines. The first key point of this document states "a mask alone, even when it is used correctly, is insufficient to provide adequate protection or source control." Later they reiterate this point and add a mask "is insufficient to provide an adequate level of protection for an uninfected individual or prevent onward transmission from an infected individual (source control)." They remarkably then continue on to recommend use "despite the limited evidence of protective efficacy of mask wearing in community settings."

50. The WHO interim guidance suffers from some additional shortcomings. For example, they mention studies that "use country or region-level data" to support mask effectiveness but fail to point out that most of those reports have since been invalidated by surges in cases and that there are other studies such as those discussed subsequently that show no effect.

51. The CDC "scientific" support for mask use has been particularly troubling. Guidance prior to 2020 in pandemic planning documents was consistent with that of the WHO. Without any additional evidence the CDC recommended masks and have since attempted to produce support for this change in policy. None of their work would pass rigorous scientific peer review. A study involving counties in Kansas⁶⁴ suffers numerous flaws, most notably use of large counties for the

⁶⁰ Samy Rengasamy, et al., Simple respiratory protection – Evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles, October 7, 2010, Annals of Work Exposures and Health, https://academic.oup.com/annweh/article/54/7/789/202744.

⁶¹ Dhaval Adjodah, et al., *Decrease in Hospitalizations for Covid-19 after mask mandates in 1083 US counties*, WITHDRAWN October 21, 2020, medRx, https://www.medrxiv.org/content/10.1101/2020.10.21.20208728v2

⁶² Lisa M. Brosseau et al, November 19, 2020, Letter to the Editor: Facial Masking for COVID-19, New England Journal of Medicine, https://www.nejm.org/doi/full/10.1056/NEJMc2030886

⁶³ World Health Organization, December 1, 2020, Mask use in the context of COVID-19 Interim Guidance.

⁶⁴ Van Dyke, et al., *Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020*, https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e2.htm.

mask group and small counties for the non-mask, thus inflating the amount of change in virus spread due to lower denominators. Further, the study authors' carefully select the time frame; examining the same counties over a longer time frame removes the effect. A more extensive study is for mask mandates and their relationship to hospitalizations⁶⁵ using the time period March 1 – October 17, 2020 in very similar fashion to the retracted study mentioned previously. Despite the clear and dramatic increase in hospitalizations almost immediately after the study time period, which completely invalidates the study conclusions, the CDC did not retract the study and, in fact, published it in early February 2021.

52. Additional evidence from the CDC⁶⁶ includes primarily laboratory studies with flaws as noted previously. In one such study the authors note major "leakage jets" for cloth and surgical masks.⁶⁷ A second notes an issue of the mask actually breaking the larger droplets into smaller particles that they were unable to measure, which would essentially aerosolize the virus.⁶⁸

53. Additional evidence in the CDC scientific brief is based on simulations or models rather than actual data, or flawed observational studies some of which are basically anecdotal. None would rise to the WHO 2019 standard for evidence. Examples include a study in New York⁶⁹ which begins at a time well after the incidence of cases had already begun to fall. There is no discernable change to the case trend after mask use began. Another considers Arizona from January to August.⁷⁰ The study is another that should be retracted – not long after the study timeframe the incidence rates increased in both counties with and without mask use. The "hairdresser" study is included as evidence despite a host of flaws: all reports are purely anecdotal, there is no control group, and less than 50% of clients actually responded. Further, some reported getting sick just not testing for Covid.⁷¹

54. Perhaps the greatest evidence that mask use in the community is ineffective is provided by two guidance documents published by the CDC during the pandemic. The first was a notice

⁶⁵ Heeson Joo, et al., February 5, 2021, *Decline in COVID-19 hospitalization growth rates associated with statewide mask mandates – 10 states, March – October 2020*, MMWR / February 5, 2021 / Vol. 70

⁶⁶ CDC, November 20, 2020, *Scientific Brief: Community Use of Cloth Masks to Control the Spread of SARS-CoV-2*, https://www.cdc.gov/coronavirus/2019-ncov/more/masking-science-sars-cov2.html

⁶⁷ I.M.Viola et al., 2020, *Face coverings, aerosol dispersion and mitigation of virus transmission risk.* https://arxiv.org/abs/2005.10720external icon

⁶⁸ E.P. Fischer et al, 2020, *Low-cost measurement of face mask efficacy for filtering expelled droplets during speech*. https://www.ncbi.nlm.nih.gov/pubmed/32917603external icon

⁶⁹ W. Lyu et al, 2020, *Community use of face masks and COVID-19: evidence from a natural experiment of state mandates in the US.* https://www.ncbi.nlm.nih.gov/pubmed/32543923

⁷⁰ M.S. Gallaway et al, 2020, *Trends in COVID-19 incidence after implementation of mitigation measures – Arizona, January 22 – August 7, 2020.* https://www.ncbi.nlm.nih.gov/pubmed/33031366

⁷¹ M.J. Hendrix et al, May 2020, Absence of apparent transmission of SARS-CoV-2 from two stylists after exposure at a hair salon with a universal face covering policy – Springfield Misouri, https://www.ncbi.nlm.nih.gov/pubmed/32673300

about the use of masks for protection against wildfire smoke⁷² that is titled "Cloth masks will <u>not</u> protect you from wildfire smoke" and continues the masks "do not catch small, harmful particles in smoke that can harm your health." Covid particles are significantly smaller than smoke particles. The second was a recent study in support of wearing two masks⁷³. The study itself is scientifically flawed; a laboratory study using mannequins. The authors note the significant limitations and suggest the findings should not be interpreted as "being representative of the effectiveness of these masks when worn in real world settings." The study is at least a tacit admission that mask use has not been effective in reducing transmission of the virus.

55. A basic principle of scientific hypothesis testing of the effectiveness of interventions is that they should demonstrate clear and convincing evidence that they "work." Finding examples of success should not be difficult for an effective medical intervention. The opposite is clearly the case with community use of face masks – studies of effectiveness are extremely limited, and reduced increasingly to a very small group that are the exceptions rather than the rule. Proving that something "doesn't work" is statistically and scientifically difficult. However, the preponderance of evidence from the pandemic indicates no effect.

56. A growing body of data and literature published in 2020 supports what was available prior to Covid. A meta-analysis of 10 different studies since 1946 concludes "We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility."⁷⁴ Another examining 15 randomized trials concludes "Compared to no masks, there was no reduction of influenza-like illness cases or influenza for masks in the general population, nor in healthcare workers."⁷⁵ A third meta-analysis included both randomized trials and observational studies, a total of 31, and concluded "evidence is not

⁷² CDC, 2020, *Wildfire smoke and COVID-19*, https://www.cdc.gov/disasters/covid-19/wildfire_smoke_covid-19.html

⁷³ John T. Brooks, et al, February 19, 2021, *Maximizing fit for cloth and medical procedure masks to improve performance and reduce SARS-CoV-2 transmission and exposure, 2021.* https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm?s cid=mm7007e1 x

⁷⁴ 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

⁷⁵ T Jefferson, et al., *Physical interventions to interrupt or reduce the spread of respiratory viruses*, April 7, 2020, MedRxiv, https://www.medrxiv.org/content/10.1101/2020.03.30.20047217v2

sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19."⁷⁶

57. The European CDC, in similar fashion to the WHO December 2020 update, conducted an extensive review⁷⁷ of evidence regarding mask wear. As with the WHO review they found "limited evidence on the effectiveness…in the community" and yet continued to recommend use.

58. In 2020 two more randomized trials including a control group add to the quality of available evidence documented by the WHO. The first involved hospital workers with the group wearing cloth masks actually having a significantly higher rate of lab confirmed influenza-like illness than a group wearing no masks. The study also examined the penetration rates finding over 97% of particle penetration in cloth masks and 44% in medical masks.⁷⁸ A more recent study involves Covid-19 spread in Denmark. The study found a non-significant difference in the control and mask groups (2.1% compared to 1.8% positive) when high quality surgical masks were worn. The difference was even smaller when they considered participants who reported the highest compliance with mask use.⁷⁹

59. Numerous studies of data during the Covid pandemic confirm the known science prior to 2020. An extremely extensive Cochrane review of over 60 studies found that face mask use did not reduce case either in the general population or among health care workers.⁸⁰ A quasi-experimental study of European data⁸¹ similarly concludes "requiring facemasks or coverings in public was not associated with any independent additional impact." Despite pressure to retract for fear their article would be used to "support non-mask wearing" researchers from the University of Illinois stood by an article showing that the data does not support mask efficacy.⁸²

60. The evidence of mask use effectiveness is such that there are even studies that show a negative impact. The study by C. Raina MacIntyre et al mentioned previously was conducted pre-COVID but showed an actual increase in infection with cloth masks in a hospital setting. A more

⁸⁰ T. Jefferson, et al., November 20, 2020, *Do physical measures such as hand-washing or wearing masks stop or slow down the spread of respiratory viruses*, https://www.cochrane.org/CD006207/ARI_do-physical-measures-such-hand-washing-or-wearing-masks-stop-or-slow-down-spread-respiratory-viruses

⁸¹ Paul R. Hunter, et al, May 6, 2020, Impact of non-pharmaceutical interventions against COVID-19 in Europe: a quasi-experimental study, https://www.medrxiv.org/content/10.1101/2020.05.01.20088260v1.full.pdf

⁷⁶ Julii Brainard, et al., *Facemasks and similar barriers to prevent respiratory illness such as COVID19: A rapid systematic review*, April 1, 2020, MedRxiv, https://doi.org/10.1101/2020.04.01.20049528

⁷⁷ ECDC, February 15, 2021, Using face masks in the community: first update, https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-face-masks-community-first-update.pdf

⁷⁸ C Raina MacIntyre, et al., *A cluster randomized trial of cloth masks compared with medical masks in healthcare workers*, April 22, 2015, BMJ Open, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4420971/

⁷⁹ 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

⁸² Lisa M Brosseau and Margaret Sietsema, April 1, 2020, Commentary: Masks-for-all for COVID-19 not based on sound data, https://www.cidrap.umn.edu/news-perspective/2020/04/commentary-masks-all-covid-19-not-based-sound-data

recent review noted a similar conclusion.⁸³ Physical and chemical attributes of respiration through a mask may scientifically describe reasons for increases in infections.⁸⁴

61. Empirical evidence overwhelmingly confirms the scientific literature. While observational, the data should not be ignored. Mask effectiveness should not be hidden in what actually occurs. A comprehensive study⁸⁵ of all counties in the U.S. shows that the difference in Covid-19 outcomes in those with mandates is not only not different than those without mandates, but actually worse. As an example, comparing similar large counties in Florida there were 64 cases per 1,000 in mask mandate counties, and in those without only 40 per 1,000. The results are the same in almost every state where there were counties with and without mandates to compare.⁸⁶ Similar results were found looking more broadly: for example, at state level the numbers were 27 per 100,000 with mask mandates and only 17 for no mandates.

62. The evidence from states, counties and countries worldwide is remarkably consistent. Mask use, which reached very high levels well before the winter virus season, had no discernable impact on the virus outcomes when considering trends – in fact, cases increase dramatically often after or in spite of increased mask wear.^{87,88} Comparisons of the disease trajectory for like countries/counties consistently depict remarkably similar trajectories despite various level of mask mandates and usage.⁸⁹

63. The example of mask use is important for several reasons. First, there are potential consequences to extended mask use, both physiological and psychological.^{90,9192} Studies are just beginning to emerge of actual physical harms from mask wear. Other studies have found issues

⁸³ https://www.thieme-connect.com/products/ejournals/html/10.1055/a-1174-6591

⁸⁴ Colleen Huber, December 7, 2020, Proposed mechanisms by which masks increase risk of COVID-19, PDMJ, https://pdmj.org/papers/masks_false_safety_and_real_dangers_part4/

⁸⁵ Scott Morefield, December 21, 2020, New study shows mask mandates had zero effect in Florida or nationwide, https://townhall.com/columnists/scottmorefield/2020/12/21/new-study-shows-mask-mandates-had-zero-effect-in-florida-or-nationwide-but-the-l-n2581879

⁸⁶ Justin Hart, December 20, 2020, RationalGround.com analysis, https://twitter.com/justin_hart/status/1340725090514653184/photo/1

⁸⁷ Ian Miller, November 2020, More mask charts, https://rationalground.com/more-mask-charts/

⁸⁸ Ian Miller, December 2020, Post-Thanksgiving mask charts: still no evidence that masks work, https://rationalground.com/post-thanksgiving-mask-charts-still-no-evidence-that-masks-work/

⁸⁹ Ian Miller, November 2020, Mask charts, https://rationalground.com/mask-charts/

⁹⁰ Baruch Vainshelboim, *Facemasks in the Covid-19 era: a health hypothesis*, November 19, 2020, Medical Hypothesis, doi: https://doi.org/10.1016/j.mehy.2020.110411

⁹¹ Sven Fikenzer, et al., *Effects of surgical and FFP2/N95 facemasks on cardiopulmonary exercise capacity*, June 30, 2020, Clinical Research in Cardiology, https://doi.org/10.1007/s00392-020-01704-y

⁹² Russell Blaylock, May 11, 2020, *Face masks pose serious risks to the healthy*, Technocracy, https://www.technocracy.news/blaylock-face-masks-pose-serious-risks-to-the-healthy/

with oxygen saturation levels⁹³,⁹⁴ which impacts healthy immune systems.⁹⁵ This issue could actually lead to increase susceptibility to Covid and other viruses long term.⁹⁶ Other risks include foreign particles causing lung damage⁹⁷ and microbial infections⁹⁸.

64. Harms for mask wear for children is an increasing concern. While children are at very low risk of infection, and tend to spread the virus and a much lower rate, masks have also become common for school openings. One is a large study in Germany among over 25,000 children⁹⁹ and reports impairments such as headache in over 50%, fatigue (37%), difficulty concentrating (50%) and irritability (60%) among others. A second documents both the risks for children from Covid and a substantial number of harms from mask wear.¹⁰⁰

65. A second impact of mask mandates is removing the freedom to choose from individuals and without compelling scientific or data to support such a restriction. Other restrictions are often similarly unsupported. Such mandates are one size fits all, therefore ignoring clear situations where a mask is not needed – for example, for people with immunity. A third issue is that the mask debate itself proves a distraction from other policies and decisions that have had devastating consequences.¹⁰¹ Finally, mandates that are ineffective done in the name of "science" erode the public trust and potentially contribute to poor response when scientifically justified interventions are recommended by government agencies and health officials, such as a potentially

⁹³ A. Beder, et al, 2008, *Preliminary report on surgical mask induce deoxygenation during major surgery*, Neurocirugia, http://scielo.isciii.es/pdf/neuro/v19n2/3.pdf.

⁹⁴ Boris Borovoy, et al, September 13, 2020, *Hypoxia, hypercapnia and physiological effects*, PDMJ, https://pdmj.org/papers/masks_false_safety_and_real_dangers_part3/

⁹⁵ Dmitriy Lukashev, et al., 2006, *Cutting Eduge: Hypoxia-inducible factor 1alpha and its activation-inducible short isoform functions of CD4 and CD8 T lymphocytes*, The Journal of Immunology, https://www.jimmunol.org/content/177/8/4962

⁹⁶ Colleen Huber, July 6, 2020, Masks are neither effective nor safe: a summary of the science, Primary Doctor Medical Journal, https://pdmj.org/papers/masks_are_neither_effective_nor_safe/index.html

⁹⁷ Boris Borovoy, et al, September 13, 2020, *Friable mask particulate and lung vulnerabil*ity, PDMJ, https://pdmj.org/papers/masks_false_safety_and_real_dangers_part1/

⁹⁸ Boris Borovoy, et al, September 13, 2020, *Microbial challenges from masks*, PDMJ, https://pdmj.org/papers/masks_false_safety_and_real_dangers_part2/

⁹⁹ Silke Schwarz et al., January 2021, Corona children studies "Co-Ki": first results of a Germany-wide registry on mouth and nose covering (mask) in children, https://orcid.org/0000-0002-8199-8874

¹⁰⁰ Carla Peeters, September 9, 2020, *Rapid response: Psychosocial, biological, and immunological risks for children and pupils make long-term wearing of mouth masks difficult to maintain,* the BMJ https://www.bmj.com/content/370/bmj.m3021/rr-6

¹⁰¹ Tom Jefferson and Carl Heneghan, July 23, 2020, *Masking the lack of evidence with politics*, https://www.cebm.net/covid-19/masking-lack-of-evidence-with-politics/

effective and safe vaccine should one be developed. Public distrust of medical professions, and actual science/data increases with potentially detrimental impacts.¹⁰²

Policies that Restrict and Remove Freedoms must be Supported by Appropriate and Correct Data

66. Testing, generally involving the RT-PCR test for the SARS-CoV-2 virus is at the heart of many decisions regarding mandates imposed by government authorities. Criteria such as number of new daily cases, number of hospitalized and the percent positivity are often used and require analysis of results from these tests. The available scientific information regarding the accuracy of COVID-19 PCR tests, as conducted by clinical laboratories in the U.S., suggests that they are not sufficiently accurate regarding infectivity risk to warrant the central role they play in the criteria that government officials have adopted for restricting activity. There are two major problems that render these criteria scientifically unjustified.

67. First, neither the new daily cases number nor percent positivity number represent random samples of the population, but rather represent results from selected populations who have been referred, or have self-referred, for testing. The selection process for testing may occur because a physician has a clinical suspicion of COVID-19 disease, because a person came into contact with someone else who tested positive, or because a workplace requires employees to be tested regularly. The first two groups are typically more likely to have COVID-19-like symptoms and more likely to be positive than a randomly chosen population, while the third group is not a random subset of the population and includes many asymptomatic people as well as essential workers who are at higher risk of exposure to SARS-CoV-2. The percent positivity number is thus a biased estimate of the actual transmission risk of COVID-19 in the population. Without population representative sampling for testing, the number does not reflect the risk of transmission and thus is scientifically unjustified as a criterion for imposing restrictions on normal activities.

68. Second, the criteria do not account for the fact that the RT-PCR tests, as used in most laboratories around the US, likely register positive test results even for non-infectious viral fragments. Because the RT-PCR test is based on a very small sample of genetic material, the test amplifies the virus—if present—by a process of repeatedly doubling the concentration of viral genetic material.103 If the sample genetic material is doubled enough times, the test will detect the presence of the virus even when the viral load is very small. Thus, although a positive test result indicates that a person has come into contact with the genomic sequence or some other viral antigen at some point it time, the mere presence of the viral genome is not sufficient, on its own, to indicate

¹⁰² Joseph A Ladapo, *Masks are a distraction from the pandemic reality*, October, 28, 2020, The Wall Street Journal, https://www.wsj.com/articles/masks-are-a-distraction-from-the-pandemic-reality-11603927026

¹⁰³ T. Jefferson, et al., *Viral Cultures for COVID-19 Infectivity Assessment – A Systematic Review (Update 3)* (Sept. 3, 2020), MEDRXIV, https://www.medrxiv.org/content/10.1101/2020.08.04.20167932v3.full.pdf.

infectivity.104 In addition, viral genomic material can still be present—and thus detected if the sample is doubled enough times—weeks after an infected person has ceased to be infectious.105

69. The problem arises from the fact that the implementation of the RT-PCR test for COVID-19 requires that clinical laboratories decide in advance how many doublings of the genetic material they will require before deciding that a sample is negative for the presence of the virus. This threshold, known as the "cycle time" of the test, determines both the rate at which a positive test result will be returned when the original sample does not include viral concentrations in sufficient amount to be infectious (hereafter, the functional false positive rate), and the rate at which a negative test result will be returned when the original sample does include viral concentrations in sufficient amount to be infectious (hereafter, the functional false negative rate). A higher cycle time threshold—requiring more doublings before declaring a negative test result—increases the functional false positive rate of the RT-PCR test because even if a non-infectious viral load is present in the sample obtained from the patient, a large number of permitted doublings could amplify whatever is present such that the test result is positive.

70. A systematic review of the literature on cycle time thresholds for the SARS-CoV-2 RT-PCR tests (encompassing 25 different published studies on the topic) concludes that "A binary Yes/No approach to the interpretation RT-PCR unvalidated against viral culture will result in false positives with segregation of large numbers of people who are no longer infectious and hence not a threat to public health."106 The scientific literature thus establishes the importance of cycle time thresholds in interpreting RT-PCR SARS-CoV-2 results.107,108

71. This is important in the present context because RT-PCR tests are the basis of the case counts and percent positivity criteria used in many places. Both criteria are premised on a measurement that includes many people who are identified as SARS-CoV-2 positive but who pose little or no community transmission risk. When criteria do not make explicit the cycle time thresholds used by the laboratories analyzing the RT-PCR tests, the criteria are not scientifically justified in making decisions about policy.

72. Dr. Anthony Fauci spoke to this issue in July: "It's very frustrating for the patients as well as for the physicians...somebody comes in, and they repeat their PCR, and it's like 37 cycle threshold, but you almost never can culture virus from a 37 threshold cycle....so, I think if

¹⁰⁴ (*Id.*)

¹⁰⁵ (*Id*.)

¹⁰⁶ (*Id*.)

¹⁰⁷ Flora Marzia Liotti, et al., Assessment of SARS-CoV-2 RNA test results among patients who recovered from COVID-19 with prior negative results, November 12, 2020, JAMA Internal Medicine, doi:10.1001/jamainternmed.2020.7570

¹⁰⁸ Rita Jaafar, et al., *Correlation between 3790 qPCR positives samples and positive cell cultures including 1941* SARS-CoV-2 isolates, September 28, 2020, Clinical Infectious Diseases, ciaa1491, <u>https://doi.org/10.1093/cid/ciaa1491</u>

somebody does come in with 37, 38, even 36, you got to say, you know, it's just dead nucleotides, period."109 However, the guidelines in the US have largely remained unchanged.

73. In Europe, a group of over 20 scientists with incredible expertise in biology/virology and more, curated by the International Consortium of Scientists in Life Sciences (ICSLS) sent a letter110 to the editorial board of Eurosurveillance. They request retraction of a paper111 published in January 2020 describing the RT-PCR method to detect SARS-CoV2. In an attached review112, submitted to the journal for publication, they carefully and in detail describe "10 major scientific flaws" with "consequences for false positive results" in the original paper. Their analysis points out the importance of carefully interpreting PCR test results before automatically counting them as "cases".

74. The WHO, in December, finally published guidance113 for PCR use to address the problem noting "the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as positivity rate decreases, irrespective of the assay specificity." The guidance points out that a positive test should be interpreted by looking at the Ct (cycles) and also consideration of "clinical signs and symptoms" before a diagnosis of a Covid case.

75. In many places, dramatic increases in testing among asymptomatic people (schools, workplaces for example) has led to inflated estimates of case numbers and corresponding policy decisions that needlessly impact healthy and non-contagious people. In addition, this approach distorts the true level of disease and distracts from efforts to protect those that are actually at risk and most vulnerable.114 When disease prevalence in a location is low, there is a danger from this approach of "pseudo-epidemics", as previously observed in epidemics when PCR tests are used115,

¹⁰⁹ Daniel Payne, *In newly surfaced July interview, Fauci warns that widely used COVID tests may pick up 'dead' virus*, November 8, 2020, https://justthenews.com/politics-policy/coronavirus/newly-surfaced-video-july-fauci-tests-dead-virus

¹¹⁰ Pieter Borger, et al., *Retraction request letter to Eurosurveillance editorial board*, November 28, 2020, https://cormandrostenreview.com/retraction-request-letter-to-eurosurveillance-editorial-board/

¹¹¹ Victor M. Corman, et al., Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR, January 21, 2020, Eurosurveillance 25(8), <u>https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045</u>

¹¹² Pieter Borger, et al., *External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results*, November 27, 2020, https://cormandrostenreview.com/report/

¹¹³ WHO, December 14, 2020, *WHO information notice for IVD users*, https://www.who.int/news/item/14-12-2020-who-information-notice-for-ivd-users

¹¹⁴ Jay Bhattacharya and Martion Kulldorf, *The case against Covid tests for the young and healthy*, September 3, 2020, https://www.wsj.com/articles/the-case-against-covid-tests-for-the-young-and-healthy-11599151722

¹¹⁵ Marilynn Larkin, *Curbing false positives and pseudo-epidemics*, March, 2007, The Lancet, <u>https://doi.org/10.1016/S1473-3099(07)70044-0</u>

in locations where the epidemic has passed due to false positives.116,117 Among the consequences observed when false positives occur are people then missing other medical treatment, in addition to unnecessary quarantine and isolation.118

76. Related to testing is the ultimate reporting of not just cases, but hospitalizations and deaths due to Covid-19. Hospitalizations are often a metric cited when justifying mandates. As testing has expanded, most hospitals now test all patients regardless of diagnosis. Thus, many admitted patients with a positive test result are not hospitalized for Covid-19, but are included in the reports on Covid-19 hospitalization. As an example, a Miami-Dade county survey119 found that over half of those listed as Covid-19 hospitalizations, 471 of 898, were not admitted for Covid-19. Similar issues then arise when deaths are counted.120

77. Reporting of cases and deaths in many states are potentially inflated. As an example, in New York121 a "confirmed case" is a "positive test from a molecular test, such as a PCR test." Thus, the issues with PCR testing play a role in the counts of cases. A "confirmed death" is a "death within 60 days of a positive molecular test." Thus, again, PCR test issues play a role. Further, the death could be completely unrelated to Covid-19 using this definition.

August 2021 Update – Impact of New Variants

78. New variants of SAR-CoV2 are expected (Delta, Lambda, etc) as the virus seeks to live. The pandemic planning guidelines and response are unchanged – protect the vulnerable, care for the sick and allow and encourage others to live normal lives to avoid the devastating consequences outlined in this document. While new variants have different transmissibility and outcomes, the basic nature of the virus is the same in terms of effectiveness of NPIs such as mask wear. The virus is still spread via small airborne particles making masking, and many other behavior changes, ineffective as means to reduce spread in the population.

79. Data continues to show the lack of impact of masks in stopping an airborne virus. Countries praised for heavy mask wear (Japan, Iceland, Thailand, Czech Republic, Vietnam and many more) have since seen large outbreaks in keeping with locations with less mask use. Mask wear, among mitigation measures, is the most clearly ineffective based on months of observing

¹¹⁶ Association of American Physicians and Surgeons (AAPS), October 7, 2020, *Do we have a coronavirus pandemic or a PCR test pandemic*, https://aapsonline.org/covid-19-do-we-have-a-coronavirus-pandemic-or-a-pcr-test-pandemic/

¹¹⁷ Mike Yeadon, *The PCR false positive pseudo-epidemic*, December 1, 2020, https://lockdownsceptics.org/the-pcr-false-positive-pseudo-epidemic/

¹¹⁸ Brandon Healy et al., January 1, 2021, The impact of false positive COVID-19 results in an area of low prevalence, DOI: 10.7861/clinmed.2020-0839

¹¹⁹ Ben Conarck, *In Miami, a sign of widespread transmission: More non-COVID patients have the virus*, November 18, 2020, Miami Herald, https://www.miamiherald.com/news/coronavirus/article247234864.html.

¹²⁰ Jennifer Cabrera and Len Cabrera, *Death certificate review raises questions about official number of Covid-19 deaths*, October 30, 2020, Alachua Chronicle, https://alachuachronicle.com/death-certificate-review-raises-questions-about-official-number-of-covid-19-deaths/

¹²¹ NYC Health Covid-19: Data, December 13, 2020, https://www1.nyc.gov/site/doh/covid/covid-19-data.page.

the pandemic data. A few examples of analysis of the data recently published include a study based on a very large database in U.S. schools showing no difference in spread in schools with and without mask wear.¹²² Another study looked at all U.S. states and found no difference in case growth rates based on mask mandates.¹²³ Former President Biden Covid advisor Michael Osterholm recently admitted that cloth and surgical masks are ineffective, finally confirming what data and studies have shown both during and prior to the current pandemic.¹²⁴

80. Efforts to produce studies designed to justify mandates continue to use flawed models or statistical methods that overstate potential benefits. A NY Times article¹²⁵ offers an example. The authors cite a study of students in North Carolina to provide evidence of masks working based on relatively low cases and outbreaks in schools. However, the authors themselves point out that there were no schools in the study where masks were not worn to use as a comparison. As previously pointed out, there are numerous examples of schools without mask wear with similar outcomes. Such evidence has been available since June of 2020. In Sweden (and many other European countries) schools were in person, no masks, throughout the entire pandemic with no deaths among children and less risk for teachers than for other similar working adults.¹²⁶

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

Rooner Thurs

Rodney X. Sturdivant, Ph.D.

Date of Signature: August 11, 2021

Waco, Texas

¹²² Oster, E., et al., *COVID-19 Mitigation Practices and COVID-19 Rates in Schools: Report on Data from Florida, New York and Massachusetts*, May 21, 2021, BMJ, https://www.medrxiv.org/content/10.1101/2021.05.19.21257467v1

¹²³ Guerra, D. and Guerra, D., *Mask mandate and use efficacy in state-level COVID-19 containment*, MedRX, https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v2

¹²⁴ Courtney O'Brien, Former Biden COVID advisor says cloth masks ineffective, suggests Americans start wearing N-95 masks, https://www.foxnews.com/media/biden-covid-adviser-americans-need-to-wear-n95-masks

¹²⁵ Kanesha Zimmerman and Danny Benjamin Jr, August 10, 2021, *We studied one million students, universal masking works*, NY Times opion, https://www.nytimes.com/2021/08/10/opinion/covid-schools-masks.html

¹²⁶ Jonas F. Ludvigsson et al, February 18, 2021, Open schools, Covid-19, and child and teacher morbidity in Sweden, New England Journal of Medicine, https://www.nejm.org/doi/full/10.1056/NEJMc2026670.