

PANDA KNOWLEDGE FACTORY NPC
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COMMENTS ON THE PROPOSED REGULATIONS RELATING TO THE SURVEILLANCE AND CONTROL OF NOTIFIABLE MEDICAL CONDITIONS: AMENDMENT (the "Proposed Regulations")

1 INTRODUCTION

- 1.1 PANDA KNOWLEDGE FACTORY NPC ("**PANDA**") is a non-profit company. PANDA is operated by a multidisciplinary group of various experts, seeking to inform appropriate policies both nationally and internationally surrounding the COVID-19 outbreak (the "**Outbreak**"), including with including with data and analytics across a broad spectrum of disciplines. PANDA is recognised internationally as one of the preeminent independent sources of analysis in relation to the Outbreak.
- 1.2 PANDA, as an organisation, is committed to protecting the public from misinformed policies, regulations and laws which are implemented against the Outbreak, and which policies, regulations and laws are premised on incorrect information or no scientific support at all. PANDA aims at ensuring that the measures taken to combat, eradicate or lessen the effects of the Outbreak do not cause more harm than good. PANDA is further committed to taking appropriate action when individuals' rights are violated by irrational and unscientific policies, regulations and laws.
- 1.3 By way of summarising our comments below, the Proposed Regulations are not grounded in science, and are unnecessary, illegal and disproportionate to the risks society faces.

OPEN SCIENCE. HUMAN AGENCY.

Directors Nick Hudson, Ian McGorian, Peter Castleden

2 SCIENTIFIC MYTHS BEHIND THE REGULATIONS

The regulations are based on a number of myths regarding SARS-CoV-2 (the “**Virus**”) and COVID-19. This renders the Proposed Regulations irrational and the limitations they impose on Constitutional rights unreasonable and unjustifiable in an open and democratic society.

Myth 1 - COVID-19 Presents an Unprecedented Risk to Public Health

- 2.1 COVID-19 is endemic and recent experience with the latest variants show that the Virus has attenuated (as viruses do) such that it no longer presents more of a danger than any number of endemic viruses that society has lived with for centuries.
- 2.2 More than 99% of people who are infected with the Virus survive. In 2019, 58,000 people died of tuberculosis in South Africa.¹ Tuberculosis is an airborne respiratory virus for which there is a vaccine. The Minister has never seen fit to implement masking, social distancing or facilitated mandatory vaccination to combat tuberculosis.
- 2.3 According to a study by Stanford University published by the World Health Organisation,² the mean infection fatality rate (“**IFR**”) for COVID-19 is 0.15%. IFR is a calculation of the percentage of people who are infected with a virus and die. It is the standard measure of the risk that a disease poses. The recovery rate of people who tested positive for the Virus is over 99%³ in most countries that have been materially affected by the Virus. The survival rate is set out in the table below, which is again

¹ <https://tbfacts.org/tb-statistics-south-africa/#:~:text=TB%20continues%20to%20be%20the,that%2036%2C000%20were%20HIV%20positive.>

² https://www.who.int/bulletin/online_first/BLT.20.265892.pdf

³ <https://www.collective-evolution.com/2020/11/28/covid-19-has-a-99-95-survival-rate-for-people-under-70-stanford-professor-of-medicine/>

derived from the work of Stanford University and published in Medrxiv, a respected scientific journal.⁴

AGE	INFECTION FATALITY RATE	INFECTION SURVIVAL RATE
20-29	0.01%	99.99%
30-39	0.03%	99.97%
40-49	0.08%	99.92%
50-59	0.30%	99.70%

2.4 The IFR for seasonal influenza (flu) is between 0.1% and 0.2%.⁵ As has been stated from the onset of the Virus, the IFR for flu is therefore roughly the same as for COVID-19. The suggestion that the Proposed Regulations are required, consequently has no basis in logic or science. Moreover, the Minister has plainly failed to comply with Regulation 14(5).

2.5 A large-scale study by Public Health England of 300,000 confirmed cases of the Delta variant of the Virus showed that the under 50 unvaccinated age group had a hospitalisation rate of 0.48% (1443 / 300,000) and a 0.016% chance of dying (48/300,000).⁶ 84% of the South African population is under 50.

4 <https://www.medrxiv.org/content/10.1101/2021.07.08.21260210v1>

5 To calculate the IFR, divide deaths by symptomatic illnesses in Table 1 of the following paper - <https://www.cdc.gov/flu/about/burden/past-seasons.html?web=1&wdLOR=c0E4693DF-08ED-4B39-B0B2-0439964D0DEF>.

6 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1009243/Technical_Briefing_20.pdf

- 2.6 The actual risk that COVID-19 poses to society has evidently not been taken into account in the drafting of the Regulations. The Minister appears to be under the influence of individuals who insist on overstating the risk the Virus poses to South Africans.

Myth 2 – Masks Work

- 2.7 There is no scientific data supporting the idea that a homemade mask can contain the spread of an airborne virus. Sars-CoV-2 mainly spreads via minute aerosols that can remain suspended for days in the air. The virus passes easily through cloth masks, as well as surgical masks, given that the diameter of Sars-CoV-2 is ~0.1 microns⁷ and the diameter of the mask pore is ~ 13-585 microns⁸ for surgical masks and ~ 80-500 microns⁹ for cloth masks. There is extremely limited scientific data supporting the idea that a face mask can contain the spread of an aerosolised virus and this data is restricted to the use of well-fitting surgical masks (N95 masks) in specific settings and while following extensive protocols. These conditions are certainly not met in the case of mask use in the general public.

- 2.8 Masks have been shown to be ineffective against the spread of SARS-CoV-2. A list of studies in this regard is updated by PANDA.¹⁰ We have selected just some of the studies below (all emphasis ours):

- 2.8.1 In the most comprehensive study into the effects of mask-wearing on transmission of the Virus titled, "Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers"¹¹, Bundgaard et al found that, "Infection with SARS-CoV-2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The

7 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7224694/#:~:text=SARS%2DCoV%2D2%20is%20an,they%20do%20more%20than%20that.>

8 <https://www.porometer.com/PDFS/AN-CharacterisationofFacemasks.pdf>

9 <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC6599448/>

10 <https://www.pandata.org/infobank-masks/>

11 <https://www.acpjournals.org/doi/10.7326/M20-6817>

between-group difference was -0.3 percentage point (95% CI, -1.2 to 0.4 percentage point; P = 0.38) (odds ratio, 0.82 [CI, 0.54 to 1.23]; P = 0.33). Multiple imputation accounting for loss to follow-up yielded similar results ... the recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use.” In other words, even surgical masks did not have a material impact on infection with the Virus.

2.8.2 In “Physical interventions to interrupt or reduce the spread of respiratory viruses”,¹² Jefferson et al found in relation to influenza that, “There is low certainty evidence from nine trials (3507 participants) that **wearing a mask may make little or no difference to the outcome** of influenza-like illness (ILI) compared to not wearing a mask (risk ratio (RR) 0.99, 95% confidence interval (CI) 0.82 to 1.18. There is moderate certainty evidence that wearing a mask probably **makes little or no difference** to the outcome of laboratory-confirmed influenza compared to not wearing a mask (RR 0.91, 95% CI 0.66 to 1.26; 6 trials; 3005 participants)...the pooled results of randomised trials **did not show a clear reduction in respiratory viral infection with the use of medical/surgical masks** during seasonal influenza.”

2.8.3 In a policy review commissioned by the US Centers for Disease Control and Prevention relating to influenza titled “Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures”,¹³ Xiao et al. found that, “Evidence from 14 randomized controlled trials of these measures **did not support a substantial effect on transmission of laboratory-confirmed influenza** ... none of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group ... the overall reduction in ILI or laboratory-

12 <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006207.pub5/full>

13 https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article

confirmed influenza cases in the face mask group was not significant in either studies.”

- 2.8.4 In a systematic review titled, “The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence”¹⁴ Bin-Reza et al found that, “**None of the studies established a conclusive relationship between mask/respirator use and protection against influenza infection.** Some evidence suggests that mask use is best undertaken as part of a package of personal protection, especially hand hygiene.”
- 2.8.5 In their paper titled, “The Impact of Community Masking on COVID-19: A Cluster-Randomized Trial in Bangladesh”,¹⁵ Abaluck et al noted that the efficacy of cloth masks led to somewhere between an 11 percent increase to a 21 percent decrease in infections meaning that cloth masks have either no or limited efficacy.
- 2.8.6 In their paper titled, “Evidence for Community Cloth Face Masking to Limit the Spread of SARS-CoV-2: A Critical Review”,¹⁶ Liu et al found that, “The available clinical evidence of facemask efficacy is of low quality and the best available clinical evidence has mostly **failed to show efficacy**, with fourteen of sixteen identified randomized controlled trials comparing face masks to no mask controls failing to find statistically significant benefit in the intent-to-treat populations.”
- 2.8.7 In a paper titled, “Masks-for-all for COVID-19 not based on sound data”,¹⁷ Brosseau et al, found that, “[W]e continue to conclude that cloth masks and face coverings are likely to **have limited impact** on lowering COVID-19 transmission, because they have **minimal ability**

14 <https://pubmed.ncbi.nlm.nih.gov/22188875/>

15 https://www.poverty-action.org/sites/default/files/publications/Mask_RCT___Symptomatic_Seropositivity_083121.pdf

16 <https://www.cato.org/sites/cato.org/files/2021-11/working-paper-64.pdf>

17 <https://www.cidrap.umn.edu/news-perspective/2020/04/commentary-masks-all-covid-19-not-based-sound-data>

to prevent the emission of small particles, offer limited personal protection with respect to small particle inhalation, and should not be recommended as a replacement for physical distancing or reducing time in enclosed spaces with many potentially infectious people.”

- 2.8.8 Weber et al noted, in their paper titled, “Aerosol penetration and leakage characteristics of masks used in the health care industry”,¹⁸ that, “We conclude that the protection provided by surgical masks may be **insufficient in environments containing potentially hazardous sub-micrometer-sized aerosols.**”
- 2.8.9 In his survey of peer-reviewed scientific studies titled, “Does Universal Mask Wearing Decrease or Increase the Spread of COVID-19?”,¹⁹ Leo Goldstein noted that, “A survey of peer-reviewed studies shows that universal mask wearing (as opposed to wearing masks in specific settings) **does not decrease the transmission** of respiratory viruses from people wearing masks to people who are not wearing masks.”
- 2.8.10 In an article titled, “Masking: A Careful Review of the Evidence”,²⁰ Alexander noted that, “In fact, it is not unreasonable at this time to conclude that surgical and cloth masks, used as they currently are, **have absolutely no impact on controlling the transmission of Covid-19 virus**, and current evidence implies that face masks can be actually harmful.”
- 2.8.11 Reporting on the outcomes of a study, Hunter et al noted in “Impact of non-pharmaceutical interventions against COVID-19 in Europe: a

18 <https://pubmed.ncbi.nlm.nih.gov/8239046/>

19 <https://wattsupwiththat.com/2020/07/25/does-universal-mask-wearing-decrease-or-increase-the-spread-of-covid-19/>

20 <https://www.aier.org/article/masking-a-careful-review-of-the-evidence/>

quasi-experimental study,²¹ that, "Face masks in public **was not associated with reduced incidence.**"

- 2.8.12 In, "The surgical mask is a bad fit for risk reduction,"²² Neilson noted that, "As recently as 2010, the US National Academy of Sciences declared that, in the community setting, "**face masks are not designed or certified to protect the wearer from exposure to respiratory hazards.**" "**A number of studies have shown the inefficacy of the surgical mask** in household settings to prevent transmission of the influenza virus."
- 2.8.13 Swiss Policy Research produced a paper in 2021 titled, "Are Face Masks Effective? The Evidence,"²³ which found that, "Most studies **found little to no evidence for the effectiveness of face masks** in the general population, neither as personal protective equipment nor as a source control."
- 2.8.14 In their paper titled, "Mask mandate and use efficacy in state-level COVID-19 containment,"²⁴ Guerra and Guerra found that, "Mask mandates and **use are not associated with slower state-level COVID-19 spread** during COVID-19 growth surges."
- 2.8.15 In an article titled, "CDC Study finds overwhelming majority of people getting coronavirus wore masks,"²⁵ Boyd reports on a US Centers for Disease Control and Prevention study and notes that, "A Centers for Disease Control report released in September shows that masks and face coverings **are not effective in preventing the**

21 <https://www.medrxiv.org/content/10.1101/2020.05.01.20088260v1.full.pdf>

22 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4868614/>

23 <https://swprs.org/face-masks-evidence/>

24 <https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v1>

25 <https://thefederalist.com/2020/10/12/cdc-study-finds-overwhelming-majority-of-people-getting-coronavirus-wore-masks/>

spread of COVID-19, even for those people who consistently wear them.”

2.8.16 In a German language paper translated as “Mouth-nose protection in public: No evidence of effectiveness,”²⁶ Kappstein notes that, the use of masks in public spaces is questionable simply because of the lack of scientific data. If one also considers the necessary precautions, **masks must even be considered a risk of infection in public spaces** according to the rules known from hospitals ... If masks are worn by the population, the risk of infection is potentially increased, regardless of whether they are medical masks or whether they are so-called community masks designed in any way. If one considers the precautionary measures that the RKI as well as the international health authorities have pronounced, all authorities would even have to inform the population that masks should not be worn in public spaces at all. Because no matter whether it is a duty for all citizens or voluntarily borne by the citizens who want it for whatever reason, it remains a fact that **masks can do more harm than good in public.**”

2.9 Masks mandates have not reduced the impact of Covid-19 in South Africa or in any other country anywhere in the world.

2.9.1 Guerra and Guerra noted in their paper titled, “Mask mandate and use efficacy for COVID-19 containment in US States,”²⁷ “Calculated total COVID-19 case growth and mask use for the continental United States with data from the Centers for Disease Control and Prevention and Institute for Health Metrics and Evaluation. We estimated post-mask mandate case growth in non-mandate states using median issuance dates of neighbouring states with mandates...did not observe association between mask mandates or use and reduced COVID-19 spread in US states.” The following graph

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

27 <https://www.medrxiv.org/content/10.1101/2021.05.18.21257385v2>

is contained in this paper illustrating that masks made no difference to Virus spread in the United States.

Figure 1 Mask States vs No Mask States



Data from December 1, 2020 through March 2, 2021 (7-Day Moving Average)

Sources: CDC.gov, covidtracking.com, First Trust Advisors

2.9.2

In an article titled, "[These 12 Graphs Show Mask Mandates Do Nothing To Stop COVID](https://thefederalist.com/2020/10/29/these-12-graphs-show-mask-mandates-do-nothing-to-stop-covid/)",²⁸ Weiss writes that, "Masks can work well when they're fully sealed, properly fitted, changed often, and have a filter designed for virus-sized particles. This represents none of the common masks available on the consumer market, making universal masking much more of a confidence trick than a medical solution ... **Our universal use of unscientific face coverings is therefore closer to medieval superstition than it is to science**, but many powerful institutions have too much political capital invested in the mask narrative at this point, so the dogma is perpetuated. The narrative says that if cases go down it's because masks succeeded. It says that if cases go up it's because masks succeeded in preventing more cases. The narrative simply assumes rather than proves that masks work, despite overwhelming scientific evidence to the contrary."

²⁸ <https://thefederalist.com/2020/10/29/these-12-graphs-show-mask-mandates-do-nothing-to-stop-covid/>

2.9.3 In an article titled, "Comprehensive analysis of 50 states shows greater spread with mask mandates,"²⁹ Horowitz writes, "How long do our politicians get to ignore the results?" "The results: **When comparing states with mandates vs. those without, or periods of times within a state with a mandate vs. without, there is absolutely no evidence the mask mandate worked** to slow the spread one iota. In total, in the states that had a mandate in effect, there were 9,605,256 confirmed COVID cases over 5,907 total days, an average of 27 cases per 100,000 per day. When states did not have a state-wide order (which includes the states that never had them and the period of time masking states did not have the mandate in place) there were 5,781,716 cases over 5,772 total days, averaging 17 cases per 100,000 people per day."

2.10 Masks are not innocuous. There is a significant body of evidence, based on data going back many years, that masks can cause harm, especially in children.

2.10.1 In a paper titled, "Exercise with facemask: Are we handling a devil's sword?- A physiological hypothesis,"³⁰ Chandrasekaran found that, "Exercising with facemasks may reduce available Oxygen and increase air trapping preventing substantial carbon dioxide exchange. The hypercapnic hypoxia may potentially increase acidic environment, cardiac overload, anaerobic metabolism and renal overload, which may substantially aggravate the underlying pathology of established chronic diseases. Further contrary to the earlier thought, **no evidence exists to claim the facemasks during exercise offer additional protection from the droplet transfer of the virus.**"

2.10.2 In a paper reviewing randomised control trials titled, "A cluster randomised trial of cloth masks compared with medical masks in

29 <https://www.conservativereview.com/horowitz-comprehensive-analysis-of-50-states-shows-greater-spread-with-mask-mandates-2649589520.html>

30 <https://pubmed.ncbi.nlm.nih.gov/32590322/>

healthcare workers”,³¹ MacIntyre found that, “[T]he results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may **result in increased risk of infection**” **“This study is the first RCT of cloth masks, and the results caution against the use of cloth masks.** This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection. Further research is needed to inform the widespread use of cloth masks globally.

2.10.3 In a New York Post article, titled, “US mask guidance for kids is the strictest across the world”,³² Stanford Professor Jay Bhattacharya is quoted as saying, “Kids need to see faces.” “We have this idea that this disease is so bad that we must adopt any means necessary to stop it from spreading. It’s not that masks in schools have no costs. They actually do have substantial costs.”

2.10.4 In a Wall Street Journal Article titled, “The Case Against Masks for Children”,³³ paediatric pulmonologists Makary and Meissner report that, “Do masks reduce Covid transmission in children? Believe it or not, we could find only a single retrospective study on the question, and its results were inconclusive. Yet two weeks ago the Centers for Disease Control and Prevention sternly decreed that 56 million U.S. children and adolescents, vaccinated or not, should cover their faces regardless of the prevalence of infection in their community. Authorities in many places took the cue to impose mandates in schools and elsewhere, on the theory that masks can’t do any harm. That isn’t true. Some children are fine wearing a mask, but others struggle. Those who have myopia can have difficulty seeing because the mask fogs their glasses. (This has long been a problem for medical students in the operating room.) **Masks can cause severe acne and other skin problems.** The discomfort of a mask **distracts**

31 <https://pubmed.ncbi.nlm.nih.gov/25903751/>

32 <https://nypost.com/2021/10/02/us-mask-guidance-for-kids-is-the-strictest-across-the-world/>

33 <https://www.wsj.com/articles/masks-children-parenting-schools-mandates-covid-19-coronavirus-pandemic-biden-administration-cdc-11628432716>

some children from learning. By increasing airway resistance during exhalation, masks **can lead to increased levels of carbon dioxide in the blood.** And masks can be **vectors for pathogens** if they become moist or are used for too long.”

- 2.10.5 In their paper titled, “Corona children studies: Co-Ki: First results of a German-wide registry on mouth and nose covering (mask) in children”,³⁴ Schwarz et al note, “The average wearing time of the mask was 270 minutes per day. Impairments caused by wearing the mask were reported by 68% of the parents. These included irritability (60%), headache (53%), difficulty concentrating (50%), less happiness (49%), reluctance to go to school/kindergarten (44%), malaise (42%) impaired learning (38%) and drowsiness or fatigue (37%).”
- 2.10.6 In a paper titled, “Masks, false safety and real dangers. Part 2: Microbial challenges from masks”,³⁵ Borovoy et al noted that, “Laboratory testing of used masks from 20 train commuters revealed that 11 of the 20 masks tested contained over 100,000 bacterial colonies. Molds and yeasts were also found. Three of the masks contained more than one million bacterial colonies ... The outside surfaces of surgical masks were found to have high levels of the following microbes, even in hospitals, more concentrated on the outside of masks than in the environment. Staphylococcus species (57%) and Pseudomonas spp (38%) were predominant among bacteria, and Penicillium spp (39%) and Aspergillus spp. (31%) were the predominant fungi.”
- 2.10.7 In an Open Letter to All Belgian Authorities and All Belgian Media,³⁶ Belgian doctors and health professionals reported that, “Wearing a mask is not without side effects. Oxygen deficiency (headache,

34 <https://www.researchsquare.com/article/rs-124394/v3>

35 <https://childrenshealthdefense.org/wp-content/uploads/Masks-false-safety-and-real-dangers-Part-2-Microbial-challenges-from-masks.pdf>

36 <https://www.aier.org/article/open-letter-from-medical-doctors-and-health-professionals-to-all-belgian-authorities-and-all-belgian-media/>

nausea, fatigue, loss of concentration) occurs fairly quickly, an effect similar to altitude sickness. Every day we now see patients complaining of headaches, sinus problems, respiratory problems and hyperventilation due to wearing masks. In addition, the accumulated CO₂ leads to a toxic acidification of the organism which affects our immunity. Some experts even warn of an **increased transmission of the virus in case of inappropriate use of the mask.**"

- 2.10.8 In a paper titled, "Is a Mask That Covers the Mouth and Nose Free from Undesirable Side Effects in Everyday Use and Free of Potential Hazards?",³⁷ Kisielinski et al noted that, "The literature revealed relevant adverse effects of masks in numerous disciplines. In this paper, we refer to the psychological and physical deterioration as well as multiple symptoms described because of their consistent, recurrent and uniform presentation from different disciplines as a Mask-Induced Exhaustion Syndrome (MIES). **Extended mask-wearing by the general population could lead to relevant effects and consequences in many medical fields.**"

Myth 3 – Social Distancing Works

- 2.11 There is no basis in science for social distancing and therefore no rational basis for the enforcement of minimum distances in the Regulations. In an analysis titled, "Two metres or one: what is the evidence for physical distancing in covid-19?",³⁸ Jones et al conclude that, "Rules that stipulate a single specific physical distance (1 or 2 metres) between individuals to reduce transmission of SARS-CoV-2, the virus causing covid-19, are based on an outdated, dichotomous notion of respiratory droplet size."

37 <https://www.mdpi.com/1660-4601/18/8/4344>

38 <https://www.bmj.com/content/370/bmj.m3223>

Myth 4 - PCR Tests are Accurate

2.12 The 'real-time reverse transcription polymerase chain reaction test' ("**PCR test**") does not detect the Virus itself, but detects the presence of genetic material of the Virus called RNA. It does this by amplifying any RNA which is present in the sample. The cycle threshold (ct) is the number of times the specimen needs to be amplified in order to be able to detect whether or not virus RNA is present. At high cycle thresholds, the test can detect fragments of the RNA. These fragments of the Virus, as opposed to complete strands, are not infectious. The test can even detect pieces of the Virus that are left over from a previous infection weeks before. The PCR test confirms the presence of the Virus in the sample. It is not capable of diagnosing the COVID-19 disease. The presence of Virus in the sample does not mean that the person is currently infected with competent Virus rather than effectively dead strands of Virus. It does not confirm that the person tested is in fact sick. Consequently, a person who tests positive may not have COVID-19.

2.13 No medical test is 100% accurate. A 'false positive' means that the results say you have a particular condition, but you actually do not, whereas a 'false negative' tells you that you do not have a condition but you actually do. The errors in the rt-PCR tests used for SARS-CoV-2 testing are largely a result of human involvement in the testing process and vary from place to place. Research in the UK showed that the rate of false positives is between 0.8% and 4%.³⁹ This means that in the UK, the PCR test is at least 96% accurate. Although it sounds like a high number, given the policy decisions being made on the basis of the test results, this can still lead to alarming consequences for a very large number of people. Researchers in the United States⁴⁰ say that "evidence from external quality assessments and real-world data indicate a high enough false positive rate to make positive results highly unreliable over a broad range of scenarios." Rates of false-positive results also vary depending on the cycle threshold used.

39 [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30453-7/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30453-7/fulltext)

40 <https://www.medrxiv.org/content/10.1101/2020.04.26.20080911v4>

- 2.14 PCR tests often remain positive for up to 3 months⁴¹ after testing and could therefore result in travellers being trapped in the country, incurring extra costs and hurting our own economy and tourism. Additionally, the status of PCR tests and RT_PCR testing kits has been withdrawn by both the FDA and the CDC Research⁴² has shown them to be very unreliable⁴³ indicators of infection especially at high cycle thresholds (e.g., 97% of positive tests are false at Ct of 35). A German study⁴⁴ titled, "The performance of the SARS-CoV-2 RT-PCR test as a tool for detecting SARS-CoV-2 infection in the population" by Stang et al re-analysed PCR tests of 162,457 people and concluded that, "In light of our findings that more than half of individuals with positive PCR test results are unlikely to have been infectious, RT-PCR test positivity should not be taken as an accurate measure of infectious SARS-CoV-2 incidence. Our results confirm the findings of others that the routine use of 'positive' RT-PCR test results as the gold standard for assessing and controlling infectiousness fails to reflect the fact 'that **50-75% of the time an individual is PCR positive, they are likely to be post-infectious.**'"
- 2.15 A court in Portugal recently determined⁴⁵ that the PCR test "is unable to determine, beyond reasonable doubt, that a positive result corresponds, in fact, to the infection of a person by the SARS-CoV-2 virus." The Court quoted from a paper⁴⁶ published in The Lancet by Surkova et al which states that, "Any diagnostic test result should be interpreted in the context of the pretest probability of disease. For COVID 19, the pretest probability assessment includes symptoms, previous medical history of COVID-19 or presence of antibodies, any potential exposure to COVID-19, and likelihood of an alternative diagnosis. When low pretest probability exists, positive results should be interpreted with caution and a second specimen tested for confirmation." "Prolonged viral RNA shedding, which is known to last for weeks after recovery, can be a potential reason

41 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7532802/>

42 https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

43 <https://academic.oup.com/cid/article/72/11/e921/5912603>

44 [https://www.journalofinfection.com/article/S0163-4453\(21\)00265-6/fulltext](https://www.journalofinfection.com/article/S0163-4453(21)00265-6/fulltext)

45 <https://www.theportugalnews.com/news/2020-11-27/covid-pcr-test-reliability-doubtful-portugal-judges/56962>

46 [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30453-7/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30453-7/fulltext)

for positive swab tests in those previously exposed to SARS-CoV-2. However, importantly, no data suggests that detection of low levels of viral RNA by RT-PCR equates with infectivity unless infectious virus particles have been confirmed with laboratory culture based methods.” “To summarise, false-positive COVID-19 swab test results might be increasingly likely in the current epidemiological climate in the UK, with substantial consequences at the personal, health system, and societal levels (panel).” The Court went on to say that, “Thus, with so many scientific doubts, expressed by experts in the field, which are the ones that matter here, as to the reliability of such tests, ignoring the parameters of their performance and there being no diagnosis made by a doctor, in the sense of existence of infection and risk, it would never be possible for this court to determine that C ... had the SARS-CoV-2 virus, nor that A., B ... and D ... had high risk exposure.”

Myth 5 - Unvaccinated People are a Risk to Others

There is no valid scientific basis for the discrimination against unvaccinated people found in the Proposed Regulations.

2.16 Effect of the Vaccines On Transmission

Vaccination with a "COVID-19 Vaccine" (the "**Vaccines**") does not prevent transmission of the Virus and there is therefore no reason why different measures should be applied to vaccinated and unvaccinated people in public places.

The prevention of infection and transmission were not endpoints in the scientific trials and the observational studies conducted since the vaccines were released show that the viral loads of vaccinated and unvaccinated people are the same, that vaccinated people transmit the virus and that there has been no reduction in transmission in countries that have high vaccination rates.⁴⁷

47 <https://link.springer.com/article/10.1007/s10654-021-00808-7>

Several studies document large numbers of breakthrough cases⁴⁸ (infections in vaccinated individuals), reflecting the waning efficacy of the Covid-19 vaccines over a few months⁴⁹. In fact, the Delta SARS-CoV-2 variant produces similar viral loads in the vaccinated and unvaccinated population⁵⁰. Early data on the Omicron variant suggests that it is even more adept at escaping vaccine protection against infection⁵¹. It is also becoming apparent that the break-through infections post vaccination have triggered immune escape variants. Specific references to the scientific literature are set out below.

- 2.16.1 Acharya et al. found “no significant difference in cycle threshold values between vaccinated and unvaccinated, asymptomatic and symptomatic groups infected with SARS-CoV-2 Delta.”⁵²
- 2.16.2 Dr Herman Edeling’s study found that, “One has read, and previously made publicly available, copies of numerous scientific articles that have found that the Covid-19 “vaccines” are not effective at prevention of infection or transmission of the SARS- CoV-2 virus. Examples of such scientific articles can be found at the Edeling Medico-Legal Consultancy Trust, where each document bearing the prefix “NE” provides scientific evidence that the Covid-19 “vaccines” are not effective.” “An abundance of scientific evidence finds that

48 <https://www.medrxiv.org/content/10.1101/2021.12.22.21268021v1>,
<https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7031e2-H.pdf>,

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733,
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100822#html_fulltext,
<https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.30.2100636>

49 <https://www.medrxiv.org/content/10.1101/2021.08.18.21262237v1>,
<https://www.science.org/doi/10.1126/science.abm0620>, <https://pubmed.ncbi.nlm.nih.gov/34737312/>,
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3949410,

<https://www.medrxiv.org/content/10.1101/2021.12.10.21267590v1.full.pdf>

50 [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00648-4/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext),
<https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm>,

<https://www.ndm.ox.ac.uk/files/coronavirus/covid-19-infection-survey/finalfinalcombinedve20210816.pdf>,
<https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v6>

51 <https://www.imperial.ac.uk/news/232698/omicron-largely-evades-immunity-from-past/>,
<https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v3.full.pdf>,

<https://www.medrxiv.org/content/10.1101/2021.12.30.21268565v1>

52 <https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2>

the Covid-19 “vaccines” are not effective at preventing infection by or transmission of the SARS-CoV-2 virus.”⁵³

2.16.3 Riemersma et al. found, “no difference in viral loads when comparing unvaccinated individuals to those who have vaccine “breakthrough” infections. Furthermore, individuals with vaccine breakthrough infections frequently test positive with viral loads consistent with the ability to shed infectious viruses.” Results indicate that “if vaccinated individuals become infected with the delta variant, they may be sources of SARS-CoV-2 transmission to others.” They reported “low Ct values (<25) in 212 of 310 fully vaccinated (68%) and 246 of 389 (63%) unvaccinated individuals. Testing a subset of these low-Ct samples revealed infectious SARS-CoV-2 in 15 of 17 specimens (88%) from unvaccinated individuals and 37 of 39 (95%) from vaccinated people.”⁵⁴

2.16.4 Riemersma et al. reported that vaccinated individuals who get infected with the Delta variant can transmit SARS-CoV-2 to others. They found an elevated viral load in the unvaccinated and vaccinated symptomatic persons (68% and 69% respectively, 158/232 and 156/225). Moreover, in the asymptomatic persons, they uncovered elevated viral loads (29% and 82% respectively) in the unvaccinated and the vaccinated respectively. This suggests that the vaccinated can be infected, harbor, cultivate, and transmit the virus readily and unknowingly.⁵⁵

2.16.5 Chau et al. looked at transmission of SARS-CoV-2 Delta variant among vaccinated healthcare workers in Vietnams. Of 69 healthcare workers that tested positive for SARS-CoV-2, 62 participated in the clinical study, all of whom recovered. For 23 of them, complete-genome sequences were obtained, and all belonged to the Delta variant. “Viral loads of breakthrough Delta variant infection cases were 251 times higher than those of cases

53 <https://emlct.com/index.php/covid-19-documents/>

54 <https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v1>

55 <https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v2>

infected with old strains detected between March-April 2020". In other words, the viral load in vaccinated individuals was found to be significantly higher than in unvaccinated individuals.⁵⁶

- 2.16.6 In Barnstable, Massachusetts, Brown et al found that among 469 cases of COVID-19, 74% were fully vaccinated, and that "the vaccinated had on average more virus in their nose than the unvaccinated who were infected."⁵⁷
- 2.16.7 Subramanian reported that, "at the country-level, there appears to be no discernible relationship between percentage of population fully vaccinated and new COVID-19 cases." When comparing 2,947 counties in the United States, there was no clear discernible relationship between vaccination and a reduction in cases.⁵⁸
- 2.16.8 Reporting on a nosocomial hospital outbreak in Finland, Hetemäli et al. observed that "both symptomatic and asymptomatic infections were found among vaccinated health care workers, and secondary transmission occurred from those with symptomatic infections despite use of personal protective equipment."⁵⁹
- 2.16.9 In a hospital outbreak investigation in Israel, Shitrit et al. observed "high transmissibility of the SARS-CoV-2 Delta variant among twice vaccinated and masked individuals."⁶⁰
- 2.16.10 Singanayagam et. al found that, "[F]ully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in

56 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

57 <https://pubmed.ncbi.nlm.nih.gov/34351882/>

58 <https://link.springer.com/article/10.1007/s10654-021-00808-7>

59 <https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.30.2100636>

60 https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100822#html_fulltext

household settings, including to fully vaccinated contacts. Host-virus interactions early in infection may shape the entire viral trajectory." They found that (in 602 community contacts (identified via the UK contract-tracing system) of 471 UK COVID-19 index cases were recruited to the Assessment of Transmission and Contagiousness of COVID-19 in Contacts cohort study and contributed 8145 upper respiratory tract samples from daily sampling for up to 20 days) "vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts."⁶¹

2.16.11 A very recent study published by the CDC reported that a majority (53%) of patients who were hospitalized with Covid-19-like illnesses were already fully vaccinated with two-dose RNA shots. Table 1 reveals that among the 20,101 immunocompromised adults hospitalized with Covid-19, 10,564 (53%) were fully-vaccinated with the Pfizer or Moderna vaccine (Vaccination was defined as having received exactly 2 doses of an mRNA-based COVID-19 vaccine ≥ 14 days before the hospitalization index date, which was the date of respiratory specimen collection associated with the most recent positive or negative SARS-CoV-2 test result before the hospitalization or the hospitalization date if testing only occurred after the admission). This highlights the ongoing challenges faced with Delta breakthrough when vaccinated.⁶²

2.16.12 Salvatore et al. examined the transmission potential of vaccinated and unvaccinated persons infected with the SARS-CoV-2 Delta variant in a federal prison, July-August 2021. They found a total of 978 specimens were provided by 95 participants, "of whom 78 (82%) were fully vaccinated and 17 (18%) were not fully vaccinated ... **clinicians and public health practitioners should consider**

61 [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(21\)00648-4/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext)

62 https://www.cdc.gov/mmwr/volumes/70/wr/mm7044e3.htm#T1_down

vaccinated persons who become infected with SARS-CoV-2 to be no less infectious than unvaccinated persons.”⁶³

2.16.13

Di Fusco et al. conducted an evaluation of COVID-19 vaccine breakthrough infections among immunocompromised patients fully vaccinated with BNT162b2. “COVID-19 vaccine breakthrough infections were examined in fully vaccinated (≥ 14 days after 2nd dose) IC individuals (IC cohort), 12 mutually exclusive IC condition groups, and a non-IC cohort.” They found that “of 1,277,747 individuals ≥ 16 years of age who received 2 BNT162b2 doses, 225,796 (17.7%) were identified as IC (median age: 58 years; 56.3% female). The most prevalent IC conditions were solid malignancy (32.0%), kidney disease (19.5%), and rheumatologic/inflammatory conditions (16.7%). Among the fully vaccinated IC and non-IC cohorts, a total of 978 breakthrough infections were observed during the study period; 124 (12.7%) resulted in hospitalization and 2 (0.2%) were inpatient deaths. IC individuals accounted for 38.2% (N = 374) of all breakthrough infections, 59.7% (N = 74) of all hospitalizations, and 100% (N = 2) of inpatient deaths. The proportion with breakthrough infections was 3 times higher in the IC cohort compared to the non-IC cohort (N = 374 [0.18%] vs. N = 604 [0.06%]; unadjusted incidence rates were 0.89 and 0.34 per 100 person-years, respectively.”⁶⁴

2.16.14

Mallapaty (NATURE) reported that the protective effect of being vaccinated if you already had infection is “relatively small, and dwindles alarmingly at three months after the receipt of the second shot.” Mallapaty further adds what we have been warning the public health community which is that persons infected with Delta have about the same levels of viral genetic materials in their noses “regardless of whether they’d previously been vaccinated, suggesting that vaccinated and unvaccinated people might be equally infectious.” Mallapaty reported on testing data from 139,164 close contacts of 95,716 people infected with SARS-CoV-2 between January and August 2021 in the United Kingdom, and at a time when the Alpha and Delta variants were competing for dominance.

63 <https://www.medrxiv.org/content/10.1101/2021.11.12.21265796v1>

64 <https://www.tandfonline.com/doi/full/10.1080/13696998.2021.2002063>

The finding was that “although the vaccines did offer some protection against infection and onward transmission, Delta dampened that effect. A person who was fully vaccinated and then had a ‘breakthrough’ Delta infection was almost twice as likely to pass on the virus as someone who was infected with Alpha. And that was on top of the higher risk of having a breakthrough infection caused by Delta than one caused by Alpha.”⁶⁵

- 2.16.15 Wilhelm et al. reported on reduced neutralization of SARS-CoV-2 omicron variant by vaccine sera and monoclonal antibodies. “in vitro findings using authentic SARS-CoV-2 variants indicate that in contrast to the currently circulating Delta variant, the neutralization efficacy of vaccine-elicited sera against Omicron was severely reduced highlighting T-cell mediated immunity as essential barrier to prevent severe COVID-19.”⁶⁶
- 2.16.16 CDC reported on the details for 43 cases of COVID-19 attributed to the Omicron variant. They found that “34 (79%) occurred in persons who completed the primary series of an FDA-authorized or approved COVID-19 vaccine ≥ 14 days before symptom onset or receipt of a positive SARS-CoV-2 test result.”⁶⁷
- 2.16.17 Dejnirattisai et al. presented live neutralisation titres against SARS-CoV-2 Omicron variant, and examined it relative to neutralisation against the Victoria, Beta and Delta variants. They reported a significant drop in “neutralisation titres in recipients of both AZD1222 and BNT16b2 primary courses, with evidence of some recipients failing to neutralise at all.”⁶⁸

65 <https://www.nature.com/articles/d41586-021-02689-y>

66 <https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v1>

67 https://www.cdc.gov/mmwr/volumes/70/wr/mm7050e1.htm?s_cid=mm7050e1_w#contribAff

68 <https://www.medrxiv.org/content/10.1101/2021.12.10.21267534v1>

- 2.16.18 Cele et al. assessed whether Omicron variant escapes antibody neutralization “elicited by the Pfizer BNT162b2 mRNA vaccine in people who were vaccinated only or vaccinated and previously infected.” They reported that Omicron variant “still required the ACE2 receptor to infect but had extensive escape of Pfizer elicited neutralization.”⁶⁹
- 2.16.19 UK reporting showed that boosters protect against symptomatic COVID-19 caused by Omicron for about 10 weeks; the UK Health Security Agency reported protection against symptomatic COVID-19 caused by the variant dropped from 70% to 45% following a Pfizer booster for those initially vaccinated with the shot developed by Pfizer with BioNTech. Specifically reporting by the UK Health Security Agency showed “Among those who received an AstraZeneca primary course, vaccine effectiveness was around 60% 2 to 4 weeks after either a Pfizer or Moderna booster, then dropped to 35% with a Pfizer booster and 45% with a Moderna booster by 10 weeks after the booster. Among those who received a Pfizer primary course, vaccine effectiveness was around 70% after a Pfizer booster, dropping to 45% after 10-plus weeks and stayed around 70 to 75% after a Moderna booster up to 9 weeks after booster.”⁷⁰
- 2.16.20 Buchan et al. used a test-negative design to assess vaccine effectiveness against OMICRON or DELTA variants (regardless of symptoms or severity) during November 22 and December 19, 2021. They found that receipt of 2 doses of COVID-19 vaccines was not protective against Omicron. Vaccine effectiveness against Omicron was 37% (95%CI, 19-50%) ≥ 7 days after receiving an mRNA vaccine for the third dose.”⁷¹

69 <https://www.medrxiv.org/content/10.1101/2021.12.08.21267417v2>

70 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043680/technical-briefing-33.pdf

71 <https://www.medrxiv.org/content/10.1101/2021.12.30.21268565v1>

2.16.21 Public Health Scotland COVID-19 & Winter Statistical Report (Publication date: 19 January 2022) provided startling data on page 38 (case rates), page 44 (hospitalization), and page 50 (deaths), showing that the vaccination has failed Delta but critically, is failing omicron. It shows across the multiple weeks of study that across each dose (1 vs 2 vs 3 booster inoculations) that **the overwhelming majority of infections occur in vaccinated as opposed to unvaccinated individuals**, with the proportion of those who have received a 2nd dose being alarmingly elevated. Age-standardized rates of acute hospital admissions are stunningly elevated after 2nd inoculation (over the unvaccinated) during January 2022.⁷²

2.16.22 Regev-Yochay et al. in Israel looked at (publication date March 16th 2022) the immunogenicity and safety of a fourth dose (4th) of either BNT162b2 (Pfizer-BioNTech) or mRNA-1273 (Moderna) administered 4 months after the third dose in a series of three BNT162b2 doses. This was an open-label, nonrandomized clinical study. Researchers reported that most of the infected participants were potentially infectious, with relatively high viral loads (nucleocapsid gene cycle threshold, ≤ 25). Researchers 'observed low vaccine efficacy against infections in health care workers, as well as relatively high viral loads suggesting that those who were infected were infectious. Thus, a fourth vaccination of healthy young health care workers may have only marginal benefits'.⁷³

2.17 **Effect of the Vaccines On Susceptibility to Infection**

There are studies that suggest that the vaccinated are in fact more susceptible to infection and therefore present more of a risk in public spaces than unvaccinated people.

2.17.1 In a study from Qatar, Chemaitelly et al. reported vaccine efficacy (Pfizer) against severe and fatal disease, with efficacy in the 85-95%

72 https://publichealthscotland.scot/media/11223/22-01-19-covid19-winter_publication_report.pdf

73 <https://www.nejm.org/doi/full/10.1056/NEJMc2202542>

range at least until 24 weeks after the second dose. As a contrast, the efficacy against infection waned down to around 30% at 15-19 weeks after the second dose.⁷⁴

2.17.2 In the UK COVID-19 vaccine Surveillance Report for week #42, it was noted that there is “waning of the N antibody response over time” and “that N antibody levels appear to be lower in individuals who acquire infection following 2 doses of vaccination.” The same report (Table 2, page 13), shows that in the older age groups above 30, the double vaccinated persons have greater infection risk than the unvaccinated.⁷⁵

2.17.3 The UK’s COVID-19 vaccine surveillance report Week 3, 20 January 2022, raises very serious concern as to the failure of the vaccines against Delta (which is now being replaced by Omicron as the dominant variant) and Omicron. Greater case numbers are observed for those who have received the 2nd and 3rd doses, with persons who have had the 3rd dose (booster) at far greater risk of infection (positive PCR result) than the unvaccinated (30 years of age and above).⁷⁶

2.17.4 In the recent UK Public Health surveillance reports Week 9, Week 8, as well as week 7 (UK COVID-19 vaccine surveillance report Week 7 17 February 2022), week 6 (COVID-19 vaccine surveillance report Week 6 10 February 2022) and week 5 for 2022 (COVID-19 vaccine surveillance report Week 5 3 February 2022) as well as the reports accumulated for 2021 since vaccine roll-out, we see that the vaccinated are at higher risk of infection and especially for age groups above 18 years old, as well as hospitalization and even death. This is particularly marked for those who have received two

74 <https://www.medrxiv.org/content/10.1101/2021.08.25.21262584v1.full.pdf>

75

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf

76

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1049160/Vaccine-surveillance-report-week-3-2022.pdf

vaccinations. There is increased risk of death for those who are triple vaccinated, especially as age increases. The same pattern emerges in the Scottish data.⁷⁷

2.18 **Waning of the Vaccine Effect**

The efficacy of the vaccines may have been exaggerated by the manufacturers. Several studies show that efficacy wanes quickly, turning into negative effectiveness in the face of a new variant after as little as a few weeks. It is impractical in the extreme to expect to be able to vaccinate all South Africans every 3 months. The vast majority of South Africans remain unvaccinated months after the vaccines were made available and the appetite for "boosters" is small. Regulations that rely on the efficacy of vaccines (unproven as that is) are quite simply irrational and impractical.

- 2.18.1 In a paper titled, "Covid-19 vaccines and treatments: we must have raw data, now", Doshi et al noted that: "In the pages of The BMJ a decade ago, in the middle of a different pandemic, it came to light that governments around the world had spent billions stockpiling antivirals for influenza that had not been shown to reduce the risk of complications, hospital admissions, or death. The majority of trials that underpinned regulatory approval and government stockpiling of oseltamivir (Tamiflu) were sponsored by the manufacturer; most were unpublished, those that were published were ghost written by writers paid by the manufacturer, the people listed as principal authors lacked access to the raw data, and academics who requested access to the data for independent analysis were denied.

77

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1058464/Vaccine-surveillance-report-week-9.pdf,

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057599/Vaccine_surveillance_report_-_week-8.pdf,

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1055620/Vaccine_surveillance_report_-_week_7.pdf,

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1054071/vaccine-surveillance-report-week-6.pdf,

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1052353/Vaccine_surveillance_report_-_week_5.pdf

The Tamiflu saga heralded a decade of unprecedented attention to the importance of sharing clinical trial data. Public battles for drug company data, transparency campaigns with thousands of signatures, strengthened journal data sharing requirements, explicit commitments from companies to share data, new data access website portals, and landmark transparency policies from medicines regulators all promised a new era in data transparency. Progress was made, but clearly not enough. **The errors of the last pandemic are being repeated.** Memories are short. Today, despite the global rollout of covid-19 vaccines and treatments, the anonymised participant level data underlying the trials for these new products remain inaccessible to doctors, researchers, and the public—and are likely to remain that way for years to come. This is morally indefensible for all trials, but especially for those involving major public health interventions."⁷⁸

2.18.2 In a paper titled, "The ONS data provide no reliable evidence that the vaccine reduces all-cause mortality" Neil et al note that, "By Occam's razor we believe the most likely explanations are systemic miscategorisation of deaths between the different categories of unvaccinated and vaccinated; delayed or non-reporting of vaccinations; systemic underestimation of the proportion of unvaccinated; and/or incorrect population selection for Covid deaths."⁷⁹

2.18.3 In an article titled "Waning Immunity after the BNT162b2 Vaccine in Israel", published in the New England Journal of Medicine, Goldberg et al. reported that "immunity against the delta variant of SARS-CoV-2 waned in all age groups a few months after receipt of the second dose of vaccine."⁸⁰

78 <https://www.bmj.com/content/376/bmj.o102>

79 https://www.researchgate.net/publication/356756711_Latest_statistics_on_England_mortality_data_suggest_systematic_mis-categorisation_of_vaccine_status_and_uncertain_effectiveness_of_Covid-19_vaccination

80 <https://www.nejm.org/doi/full/10.1056/NEJMoa2114228>

- 2.18.4 In an article titled, “The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission, Eyre et al. reported that “while vaccination still lowers the risk of infection, similar viral loads in vaccinated and unvaccinated individuals infected with Delta question how much vaccination prevents onward transmission... transmission reductions declined over time since second vaccination, for Delta reaching similar levels to unvaccinated individuals by 12 weeks for ChAdOx1 and attenuating substantially for BNT162b2. Protection from vaccination in contacts also declined in the 3 months after second vaccination...vaccination reduces transmission of Delta, but by less than the Alpha variant.”⁸¹
- 2.18.5 In a paper published in Nature titled, “Viral loads of Delta-variant SARS-CoV-2 infections after vaccination and booster with BN 162b2”, Levine-Tiefenbrun reported the viral load reduction effectiveness declines with time after vaccination, “significantly decreasing at 3 months after vaccination and effectively vanishing after about 6 months.”⁸²
- 2.18.6 In their paper titled, “Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort study”, Hansen et al demonstrated negative vaccine effectiveness in vaccinated individuals when exposed to Omicron after just 3 months from the injection. This means that **vaccinated individuals are more likely to catch the virus and spread it.**⁸³

81 <https://www.medrxiv.org/content/10.1101/2021.09.28.21264260v1>

82 https://www.nature.com/articles/s41591-021-01575-4#auth-Matan-Levine_Tiefenbrun

83 <https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v3.full.pdf>

Table Estimated vaccine effectiveness for BNT162b2 and mRNA-1273 against infection with the SARS-CoV-2 Omicron and Delta variants during November 20 – December 12, 2021, Denmark.

Time since vaccine protection	Pfizer – BNT162b2				Moderna - mRNA-1273			
	Omicron		Delta		Omicron		Delta	
	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)	Cases	VE, % (95% CI)
1-30 days	14	55.2 (23.5; 73.7)	171	86.7 (84.6; 88.6)	4	36.7 (-69.9; 76.4)	29	88.2 (83.1; 91.8)
31-60 days	32	16.1 (-20.8; 41.7)	454	80.9 (79.0; 82.6)	8	30.0 (-41.3; 65.4)	116	81.5 (77.7; 84.6)
61-90 days	145	9.8 (-10.0; 26.1)	3,177	72.8 (71.7; 73.8)	48	4.2 (-30.8; 29.8)	1,037	72.2 (70.4; 74.0)
91-150 days	2,851	<u>-76.5 (-95.3;-59.5)</u>	34,947	53.8 (52.9; 54.6)	393	<u>-39.3 (-61.6;-20.0)</u>	3,459	65.0 (63.6; 66.3)
1-30 days after booster vaccination protection	29	54.6 (30.4; 70.4)	453	81.2 (79.2; 82.9)	-	-	5	82.8 (58.8; 92.9)

CI = confidence intervals; VE = vaccine effectiveness. VE estimates adjusted for 10-year age groups, sex and region (five geographical regions). Vaccine protection was assumed 14 days post 2nd dose. Insufficient data to estimate mRNA-1273 booster VE against Omicron.

Myth 6 - The Vaccines are Perfectly Safe

There is overwhelming evidence for both short and long-term harmful effects of the Vaccines. There is a lack of transparency and accountability from both the pharmaceutical industry, Government and medical committees who have authorised rollouts.

2.18.7

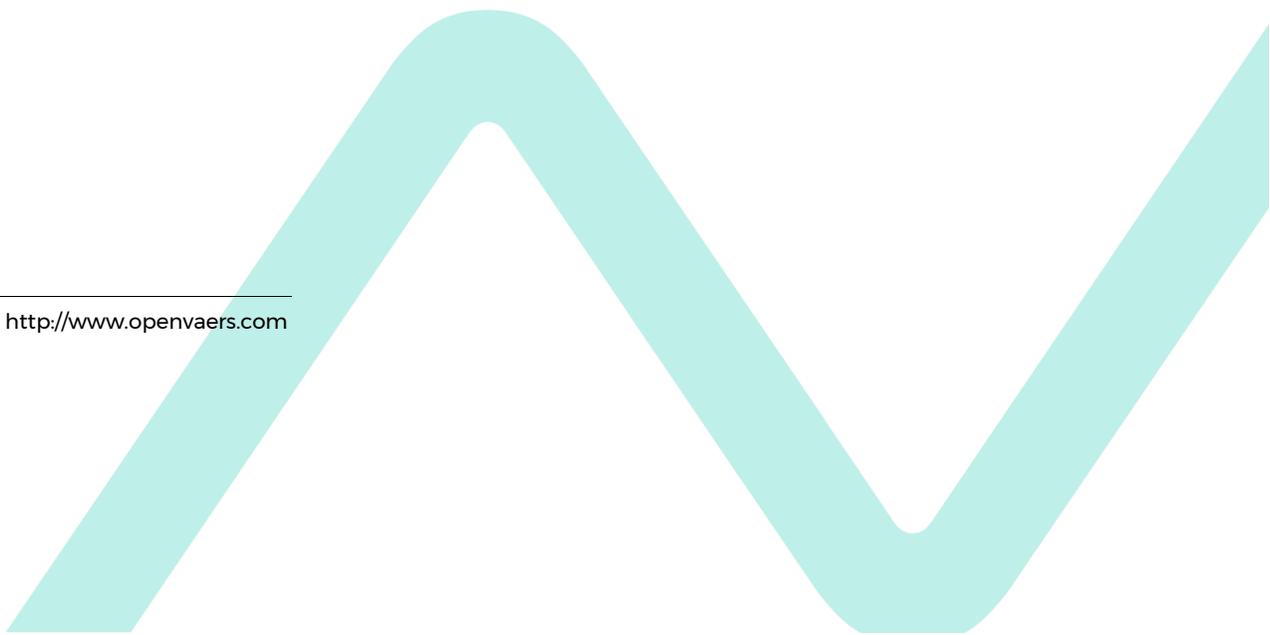
A paper⁸⁴ by Schauer et al titled "Persistent Cardiac MRI Findings in a Cohort of Adolescents with post COVID-19 mRNA Vaccine Myopericarditis" found that, "In a cohort of adolescents with COVID-19 mRNA vaccine-related myopericarditis, a large portion have persistent LGE abnormalities, raising concerns for potential longer-term effects. Despite these persistent abnormalities, all patients had rapid clinical improvement and normalization of echocardiographic measures of systolic function. For patients with short acute illness, no dysfunction demonstrated by echocardiogram at presentation and resolution of symptoms at follow-up, return to sports was guided by normalization of CMR alone. In patients with persistent CMR abnormalities we performed exercise stress testing prior to sports clearance per myocarditis recommendations. We plan to repeat CMR at 1 year post-vaccine for our cohort to assess for resolution or continued CMR changes. The CDC notes that even though the absolute risk for myopericarditis following mRNA COVID-19 vaccine is small, the **relative risk is higher for particular**

84 [https://www.jpeds.com/article/S0022-3476\(22\)00282-7/fulltext](https://www.jpeds.com/article/S0022-3476(22)00282-7/fulltext)

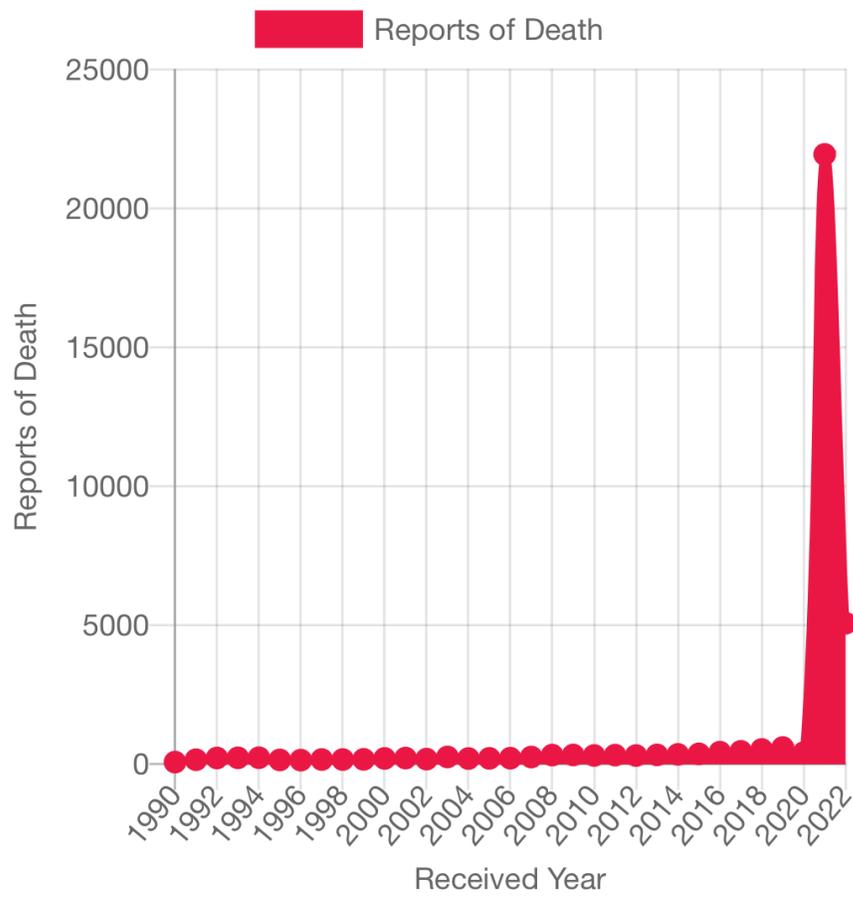
groups, including males 12-39 years of age. Further follow up assessment and larger multicenter studies are needed to determine the ultimate clinical significance of persistent CMR abnormalities in patients with post COVID-19 vaccine myopericarditis.”

2.18.8

Vaccine adverse events reporting systems are early warning systems designed to identify potential problems with the safety of vaccines. These systems, the world over, have been indicating problems with the Vaccines. As at 5 April 2022, the vaccine adverse events reporting system maintained by the US Government had received over 1.2 million reports of adverse events following vaccination, including more than 26,000 deaths. Such reports are made under strict guidelines issued by the US government and as such, the argument that they are manipulated is easily refutable. The graph below shows all reports in relation to all vaccines over the history of the US reporting system and the increase in reports with the introduction of the Vaccines is evident. As noted, the purpose of these systems is to function as an early warning system. Clearly a signal has been generated by this system and there can be no argument that these Vaccines are generating signals consistent with other vaccines.⁸⁵

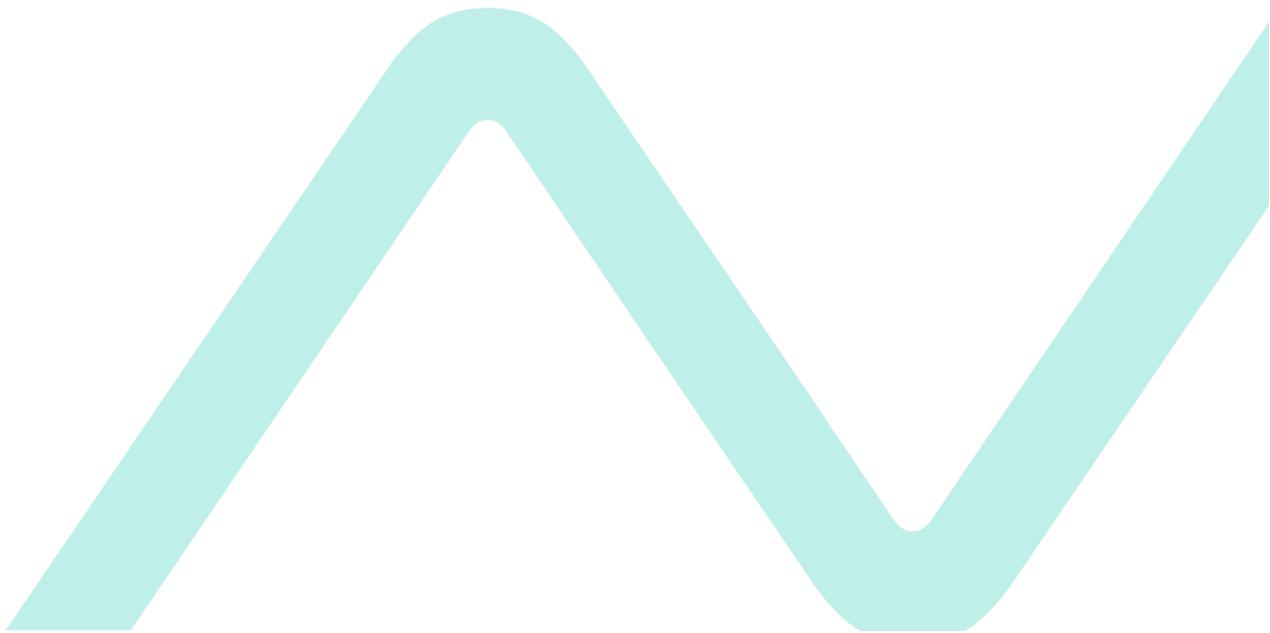


All Deaths Reported to VAERS by Year

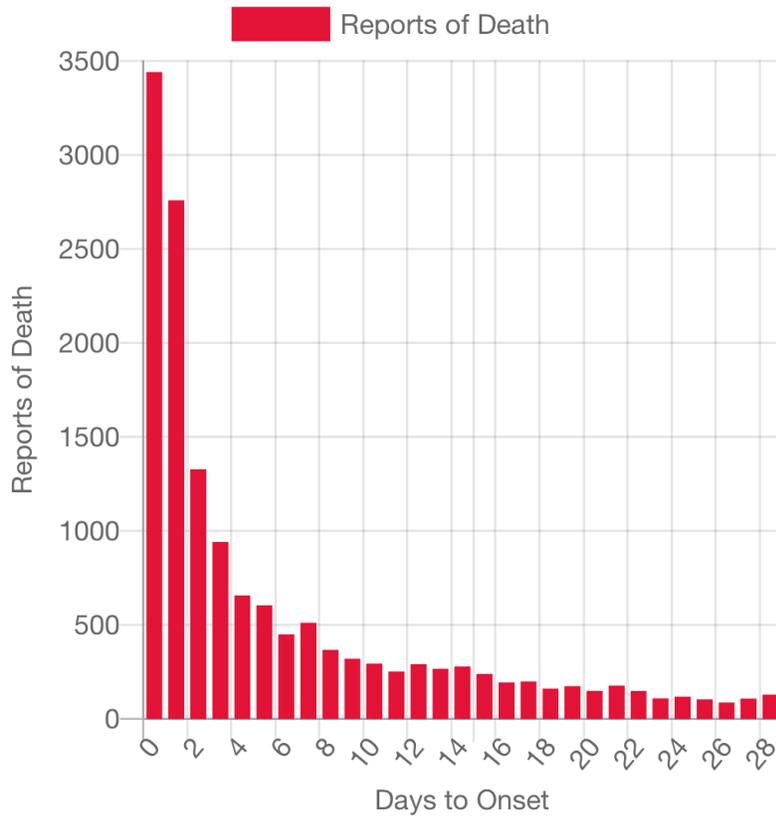


2.18.9

It is also noteworthy that most of the deaths reported to the US system occur within 48 hours of vaccination.



VAERS COVID Vaccine Reports of Deaths by Days to Onset-All Ages



2.18.10 A volunteer group in South Africa has established an adverse event reporting system which, as at 9 March 2022, had recorded 738 cases with 72 deaths, which is 9% of total post vaccination adverse events reports.⁸⁶

2.18.11 Multiple studies have recommended further investigation into the adverse effects of the Vaccines and the novel technological approach they implement. These include:

2.18.11.1 A paper by Molina-Rios et al, titled "Systemic lupus erythematosus & antiphospholipid syndrome after Covid Vaccination", in which it was noted that: "After a few days, she

86 <https://savaers.co.za/>

presented a massive pericardial effusion with cardiac tamponade that required surgical management."⁸⁷

- 2.18.11.2 A paper by Saraiva et al titled, "Varicella zoster virus reactivation following Covid Vaccination" which found that "... our work calls for more effective vigilance of COVID-19 vaccines side effects."⁸⁸
- 2.18.11.3 A paper by Moslemi et al titled, "Herpes simplex encephalitis (inflammation of the brain) following Covid Vaccination", which found that this side effect "requires immediate medical attention and can lead to devastating consequences if left undiagnosed and untreated."⁸⁹
- 2.18.11.4 A paper by Maroufi et al titled, "Longitudinally extensive transverse myelitis (inflammation of the spinal cord) after Covid Vaccination" which found that "... it may be reasonable to consider anti-NMDAR encephalitis upon encountering progressive neurological symptoms following vaccination."
- 2.18.11.5 A case report on 4 cases of myocarditis (3 men, 1 woman, 16 to 47 years old) after Covid Vaccination by Nunn et al that concluded, "... we recommend further investigation into the adverse effects of the new mRNA vaccine technology, which may be used for most vaccines in the future."⁹⁰
- 2.18.11.6 A paper by Munasinghe et al titled, "Reactivation of varicella-zoster virus after Covid Vaccination" which found that, "The incidence of different cutaneous manifestations following vaccination, including the reactivation of herpes is on the rise ..."⁹¹

87 <https://academic.oup.com/mrcr/advance-article/doi/10.1093/mrcr/rxac018/6542744?login=false>

88 <https://academic.oup.com/fampra/advance-article/doi/10.1093/fampra/cmab014/6542257?login=false>

89 <https://bmcinfectdis.biomedcentral.com/articles/10.1186/s12879-022-07186-9#additional-information>

90 <https://www.frontiersin.org/articles/10.3389/fmed.2022.836620/full>

91 <https://journals.sagepub.com/doi/10.1177/2050313X221077737>

- 2.18.11.7 An article titled, "Acute kidney rejection after Covid Vaccination" which found, in relation to a 25-year-old woman with a kidney transplant, " ... it is worth considering monitoring graft function after vaccination against COVID-19 ..."92
- 2.18.11.8 A case report titled, "Effusive–constrictive pericarditis after Covid Vaccination93" by Conte et al, that found, "a strong temporal relation between the second dose of BNT162b2 vaccine and symptoms occurrence".94

Myth 7 – There is no Natural Immunity

The Proposed Regulations take no account of natural immunity which is at high levels in South Africa, with estimates consistently pointing to around 80% of the population having been infected. Studies show that natural immunity against coronavirus is robust, long-lasting, and effective, even in the case of viral mutations. Natural immunity protects against severe illness, which vaccines do not and is therefore more relevant to controlling the spread of the virus than vaccination. It is therefore irrational not to take it into account.

- 2.18.12 Eyran, 2020 examined "The longitudinal kinetics of antibodies in COVID-19 recovered patients over 14 months", and found "a significantly faster decay in naïve vaccinees compared to recovered patients suggesting that the serological memory following natural infection is more robust compared to vaccination. Our data highlights the differences between serological memory induced by natural infection vs. vaccination."95
- 2.18.13 A paper titled, "One-year sustained cellular and humoral immunities of COVID-19 convalescents", by Jie Zhang et al showed that in

92 <https://www.nature.com/articles/s41541-022-00445-5>

93 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8874812/>

94 a strong temporal relation between the second dose of BNT162b2 vaccine and symptoms occurrence

95 <https://www.medrxiv.org/content/10.1101/2021.09.16.21263693v1>

COVID-19 convalescents from 6 months to 12 months after disease onset the percentages of convalescents with positive SARS-CoV-2-specific T-cell responses (at least one of the SARS-CoV-2 antigen S1, S2, M and N protein) were 71/76 (93%) and 67/73 (92%) at 6m and 12m, respectively. Furthermore, both antibody and T-cell memory levels of the convalescents were positively associated with their disease severity.”⁹⁶

- 2.18.14 In a paper titled, “Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections”, Sivan Gazit et al concluded that, “Our analysis demonstrates that SARS-CoV-2-naïve **vaccinees had a 13.06-fold increased risk for breakthrough infection with the Delta variant compared to those previously infected**, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant for a symptomatic disease as well.... This analysis demonstrated that natural immunity affords longer lasting and stronger protection against infection, symptomatic disease and hospitalization due to the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity.”⁹⁷
- 2.18.15 In “Necessity of COVID-19 vaccination in previously infected individuals”, Nabin K. Shrestha et al found that “Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before.”⁹⁸
- 2.18.16 Discrete Immune Response Signature to SARS-CoV-2 mRNA Vaccination Versus Infection, by Ellie Ivanova, Joseph Devlin, et al. found that, “While both infection and vaccination induced robust innate and adaptive immune responses, our analysis revealed

96 https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab884/6381561#YWChCytQ_Hc.twitter

97 <https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full>

98 <https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v2>

significant qualitative differences between the two types of immune challenges. In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was largely absent in vaccine recipients.”

2.18.17 In “Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells”, Kristen W. Cohen et al noted that, “Ending the COVID-19 pandemic will require long-lived immunity to SARS-CoV-2. We evaluated 254 COVID-19 patients longitudinally from early infection and for eight months thereafter and found a predominant broad-based immune memory response. SARS-CoV-2 spike binding and neutralizing antibodies exhibited a bi-phasic decay with an extended half-life of >200 days suggesting the generation of longer-lived plasma cells. In addition, there was a sustained IgG+ memory B cell response, which bodes well for a rapid antibody response upon virus re-exposure.”⁹⁹

2.18.18 In “Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees”, Kojima et al found, “no difference in the infection incidence between vaccinated individuals and individuals with previous infection.”¹⁰⁰

2.18.19 In “Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection”, Jennifer M. Dan et al “analysed multiple compartments of circulating immune memory to SARS-CoV-2 in 254 samples from 188 COVID-19 cases, including 43 samples at ≥ 6 months post-infection. IgG to the Spike protein was relatively stable over 6+ months.”¹⁰¹

99 <https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v1>

100 <https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2>

101 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7919858/>

- 2.18.20 Persistence of neutralizing antibodies a year after SARS-CoV-2 infection, by Anu Haveri et al “assessed the persistence of serum antibodies following wild-type SARS-CoV-2 infection six and twelve months after diagnosis in 367 individuals of whom 13% had severe disease requiring hospitalization. We determined the SARS-CoV-2 spike (S-IgG) and nucleoprotein IgG concentrations and the proportion of subjects with neutralizing antibodies (NAb).”
- 2.18.21 In “Quantifying the risk of SARS-CoV-2 reinfection over time”, Eamon O Murchu et al found that, “naturally acquired SARS-CoV-2 immunity does not wane for at least 10 months post-infection.”¹⁰²
- 2.18.22 In “SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy”, Abu-Raddad et al noted that “Reinfection is rare in the young and international population of Qatar. Natural infection appears to elicit strong protection against reinfection with an efficacy ~95% for at least seven months.”¹⁰³
- 2.18.23 In “Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel”, Yair Goldberg et al found that “the overall estimated level of protection from prior SARS-CoV-2 infection for documented infection is 94.8% (CI:[94.4, 95.1]); hospitalization 94.1% (CI:[91.9, 95.7]); and severe illness 96.4% (CI:[92.5, 98.3]). Our **results question the need to vaccinate previously-infected individuals.**”¹⁰⁴
- 2.18.24 Immune Memory in Mild COVID-19 Patients and Unexposed Donors Reveals Persistent T Cell Responses After SARS-CoV-2 Infection, by Asgar Ansari et al “found detectable immune memory in mild COVID-19 patients several months after recovery in the crucial arms of protective adaptive immunity.” “This study provides the evidence

102 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8209951/pdf/RMV-9999-e2260.pdf>

103 [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(21\)00141-3/fulltext#%20](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00141-3/fulltext#%20)

104 <https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1>

of both high magnitude pre-existing and persistent immune memory in Indian population.”

- 2.18.25 In “Highly functional virus-specific cellular immune response in asymptomatic SARS-CoV-2 infection”, Nina Le Bert et al found that “asymptomatic SARS-CoV-2-infected individuals are not characterized by weak antiviral immunity; on the contrary, they mount a highly functional virus-specific cellular immune response.”¹⁰⁵
- 2.18.26 In a paper titled, “SARS-CoV-2 re-infection risk in Austria”, Stefan Pilz et al confirmed that “**Protection against SARS-CoV-2 after natural infection is comparable with the highest available estimates on vaccine efficacies.**”¹⁰⁶
- 2.18.27 In “Anti-spike antibody response to natural SARS-CoV-2 infection in the general population”, Jia Wei et al noted that, “We estimated antibody levels associated with protection against reinfection likely last 1.5-2 years on average, with levels associated with protection from severe infection present for several years. These estimates could inform planning for vaccination booster strategies.”¹⁰⁷
- 2.18.28 In “SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN)”, Victoria Jane Hall et al found that, “A previous history of SARS-CoV-2 infection was associated with an 84% lower risk of infection, with median protective effect observed 7 months following primary infection. This time period is the minimum probable effect because seroconversions were not included. This study shows that previous

105 <https://rupress.org/jem/article/218/5/e20202617/211835/Highly-functional-virus-specific-cellular-immune>

106 <https://pubmed.ncbi.nlm.nih.gov/33583018/>

107 <https://www.medrxiv.org/content/10.1101/2021.07.02.21259897v1>

infection with SARS-CoV-2 induces effective immunity to future infections in most individuals.”¹⁰⁸

- 2.18.29 In “SARS-CoV-2 Natural Antibody Response Persists for at Least 12 Months in a Nationwide Study From the Faroe Islands”, Maria Skaalum Petersen et al showed that, “Although the protective role of antibodies is currently unknown, our results show that SARS-CoV-2 antibodies persisted at least 12 months after symptom onset and maybe even longer, indicating that COVID-19-convalescent individuals may be protected from reinfection.”¹⁰⁹
- 2.18.30 In “Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar”, Roberto Bertollini et al found that, “Of 9180 individuals with no record of vaccination but with a record of prior infection at least 90 days before the PCR test (group 3), 7,694 could be matched to individuals with no record of vaccination or prior infection (group 2), among whom PCR positivity was 1.01% (95% CI, 0.80%-1.26%) and 3.81% (95% CI, 3.39%-4.26%), respectively. The relative risk for PCR positivity was 0.22 (95% CI, 0.17-0.28) for vaccinated individuals and 0.26 (95% CI, 0.21-0.34) for individuals with prior infection compared with no record of vaccination or prior infection.”¹¹⁰
- 2.18.31 In “Longitudinal observation of antibody responses for 14 months after SARS-CoV-2 infection”, Puya Dehghani-Mobaraki et al noted, “In Conclusion, our study findings are consistent with recent studies reporting antibody persistency suggesting that induced SARS-CoV-2 immunity through natural infection, might be very efficacious against re-infection (>90%) and could persist for more than six months. Our study followed up patients up to 14 months

108 [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00675-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00675-9/fulltext)

109 <https://academic.oup.com/ofid/article/8/8/ofab378/6322055>

110 <https://jamanetwork.com/journals/jama/article-abstract/2781112>

demonstrating the presence of anti-S-RBD IgG in 96.8% of recovered COVID-19 subjects."¹¹¹

The imposition of restrictions on individuals and on venues based on vaccination status is reliant on the myth that the vaccines make public spaces safer. The vaccines in fact offer no protection against transmission and therefore do not make spaces inhabited by vaccinated people any safer than those inhabited by unvaccinated individuals. The safest spaces are those inhabited by recovered individuals.

3 THE PROPOSED REGULATIONS ARE ULTRA VIRES

- 3.1 Regulations like these, that fundamentally alter the fabric of society and affect virtually every aspect of human life, cannot be passed without proper input from all of those affected by the Proposed Regulations. As a minimum, Parliament should vote on key aspects of the Proposed Regulations and preferably there should be a referendum so that all affected individuals can express their views.
- 3.2 The Minister relies on his powers under Section 90(1)(j),(k) and (w) of the National Health Act (the "**Act**"). These Sections of the Act empower the Minister to make regulations regarding "communicable diseases", "notifiable medical conditions" and "any other matter which it is necessary or expedient to prescribe in order to implement or administer this Act". The seemingly infinite reach of these regulations is cause for alarm.
- 3.3 The Proposed Regulations evidently seek to give effect to one of the objects of the Act which is to respect, promote and fulfil the rights of the people of South Africa to an environment that is not harmful to their health or well-being. This cannot be an absolute right. The human environment can never be rendered entirely safe, nor can other human rights be obliterated in the pursuit of a perfectly safe world. The right to

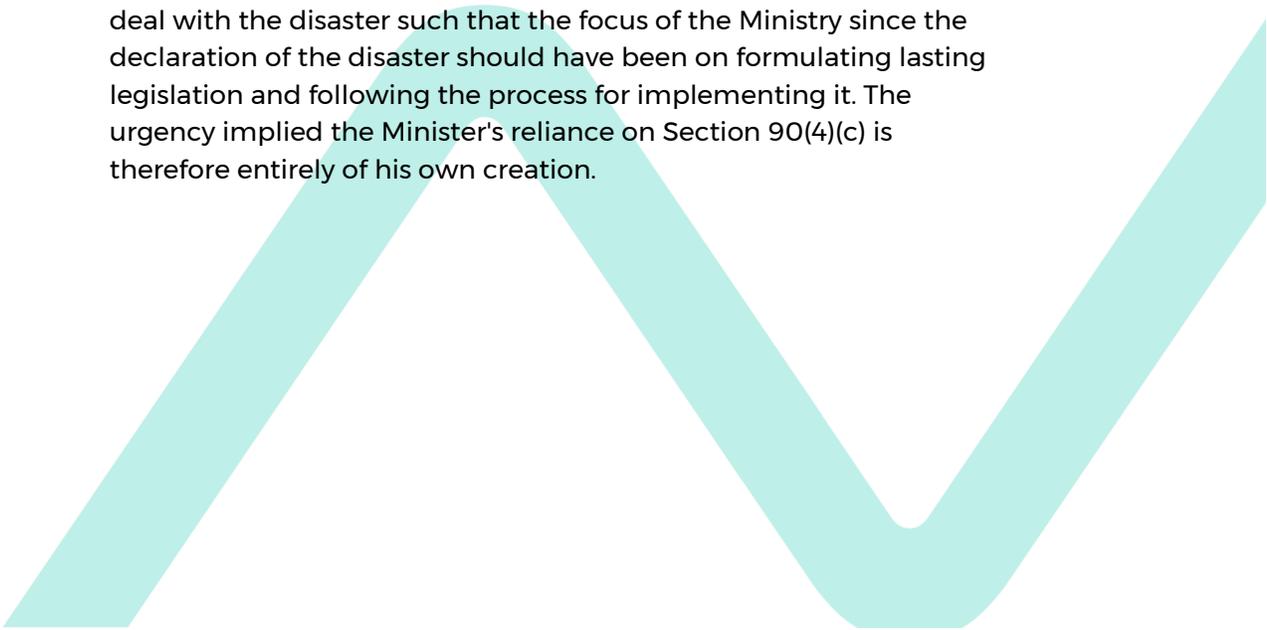
¹¹¹ <https://www.sciencedirect.com/science/article/pii/S1521661621001510>

an environment that is not harmful to health must be pursued alongside other rights, including more fundamental rights such as the rights to equality, dignity, life, association and bodily integrity.

- 3.4 The Universal Declaration on Bioethics and Human Rights (UNESCO 2005) states that the rights of the individual should be balanced against those of society in general. Article 3 thereof entitled “Human dignity and Human rights”, in subsection (2), states that the “interests and welfare of the individual shall have priority over the sole interests of science or society”. The Bioethics Declaration is also consistent with the Constitution, which provides for limitations on rights only to the extent that these are reasonable and justifiable in an open democratic society based on human dignity, equality and freedom.
- 3.5 When the minutiae of our lives are regulated under the auspices of creating a safe environment, it is no longer a matter of health, but a much broader matter that requires parliamentary approval in addition to consistency with the Constitution. The Proposed Regulations, like the regulations under the Disaster Management Act regulate virtually every aspect of life. The control of movement, gatherings, worship, work, access to public spaces and services – these are not matters that any single Minister has the power to regulate. As such, the Proposed Regulations are ultra vires.

4 THE PROPOSED REGULATIONS INFRINGE SECTION 90(4) OF THE ACT

- 4.1 Section 90(4)(a) of the Act requires that any regulations proposed to be made under the National Health Act must be published for comment at least three months before the date contemplated for their commencement. The Minister, however, relies on Section 90(4)(c) which provides that the Minister may, if circumstances necessitate the immediate publication of a regulation, publish that regulation without such consultation.

- 4.1.1 The Minister has not provided any argument or evidence for the apparent contention that circumstances necessitate the shortened comment period. No such reason is evident.
- 4.1.2 The limited time which has been allowed for comment, clearly also breaches The Promotion of Administrative Justice Act 3 of 2000 ("PAJA"). In particular, no reasonable opportunity has been afforded to the public to make informed representations. S 3(3) of PAJA envisages that people will be able to obtain legal representation or to present and dispute information in person. There has been no provision made for this.
- 4.1.3 The Proposed Regulations do not relate exclusively to Covid-19. Many of the notifiable medical conditions ("**NMCs**") in respect of which the Proposed Regulations apply have been with us for decades and centuries. There is no obvious reason why the ordinary process for passing regulations designed to address these NMCs cannot be considered in accordance with the usual prescribed periods.
- 4.1.4 No new legislation is required. Between the existing health regulations and the Disaster Management Act, government is able to adequately respond to pandemics.
- 4.1.5 The Minister has had more than two years to publish draft regulations for comment since a national state of disaster was declared in relation to Covid-19, in March 2020. Indeed, a state of disaster can only be declared if existing legislation is inadequate to deal with the disaster such that the focus of the Ministry since the declaration of the disaster should have been on formulating lasting legislation and following the process for implementing it. The urgency implied the Minister's reliance on Section 90(4)(c) is therefore entirely of his own creation.
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- 4.1.6 The powers that the Minister has under the Disaster Management Act are unaffected by the Proposed Regulations. The Minister has relied upon the Disaster Management Act Regulations for more than 2 years to deal with Covid-19. If the threat posed by Covid-19 should once again reach disaster levels, the Minister of Cooperative Governance has the power at any time to declare a new disaster and has all of the regulations passed under the current state of disaster as a template for controlling Covid-19 outbreaks. As such, the fact that the state of disaster is ending is not a reason to shorten the comment period.
- 4.2 There is no valid argument for the application of Section 90(4)(c) in these circumstances and the failure to comply with Section 90(4) renders the Proposed Regulations invalid.

5 THE PROPOSED REGULATIONS ARE INCONSISTENT WITH EXISTING REGULATIONS

- 5.1 Regulation 2 of the existing Regulations under the Act (the "**Regulations**") requires that in implementing the regulations, the provisions of the Constitution must be taken into account as well as full respect for the dignity, confidentiality, human rights and fundamental freedoms of persons. There is no evidence that the Minister has taken any of these rights into account. The Proposed Regulations contain draconian limitations on rights that are unprecedented in the history of our democracy. Limitations on Constitutional rights that were presented to the public and justified on the basis of a state of disaster are now being made permanent in a situation where the risk from the disease has attenuated such that it no longer represents a disaster (if it ever did). The effect of these Proposed Regulations is to normalise draconian limitations on rights. Rather than seeking to limit rights as little as possible, the Proposed Regulations emphasise the elimination of an endemic disease at any cost to rights. For decades under our constitution the NMCs listed in Annexure A (the "**Listed NMCs**") have not required such draconian limitations of rights. Open and democratic societies do not limit constitutional rights in order to control measles (for example). The limitations on rights implied by the Proposed Regulations are plainly

not reasonable or justifiable in an open and democratic society and therefore unconstitutional. Covid-19 is no more dangerous than any number of endemic viruses that have never required such draconian limitations on rights as are contained in the Proposed Regulations. In addition, “The vast majority of South Africans now have immunity, meaning Covid-19 in 2022 is likely to have a similar death rate to seasonal influenza (10,000-11,000 deaths a year) in the pre-Covid-19 era, as opposed to the 290,000 Covid-19 related excess deaths over the past 22 months of the pandemic, and much lower than the projected 58,000 annual TB-related deaths”, according to health experts Francois Venter, Mare Mendelson, Jeremy Nel, Lucille Blumberg, Zameer Brey and Shabir A Madhi. As such, even in the context of Covid-19, the Proposed Regulations are unconstitutional.

- 5.2 Regulation 14(5) of the existing Regulations provides that in the context of implementing medical examination, prophylaxis, counselling, treatment, isolation or quarantine measures, the need, nature and extent of the intervention must be assessed, based on the nature of the public health risk and the particular circumstances of the individual. There is no evidence that the Minister has complied with Regulation 14(5) when introducing the Proposed Regulations. COVID-19 is endemic and recent experience with the latest variants show that the Virus has attenuated (as viruses do) such that it no longer presents more of a danger than any number of endemic viruses that society has lived with for centuries. As noted in paragraph 2.2, more than 99% of people who are infected with the Virus survive. Regulation 14(5) is an excessive measure given the risk it evidently seeks to address.
- 5.3 Regulation 15(1) provides that mandatory prophylaxis or treatment can only be determined on a case-by-case basis. “Case” is defined as a person diagnosed with a notifiable medical condition either as a clinical case (a patient who presents with clinical signs and symptoms) or a laboratory confirmed case (a patient with a notifiable medical condition diagnosed through an approved laboratory diagnostic method). Curiously, the Proposed Regulations are based on the pre-February 2022 regulations under the Disaster Management Act (the “**DMA**”). The regulations under the DMA (the “**DMA Regulations**”) were amended to take into account centuries of epidemic management that had been ignored in the DMA Regulations to date. Over centuries of medical practice, a case

constituted a sick individual who presented a series of established clinical criteria, confirmed – if deemed necessary – by a laboratory test (hence the term “laboratory **confirmed** case”. As noted below, the PCR test that has traditionally been used to diagnose COVID-19 is not capable of diagnosing a person who has COVID-19. The February version of the DMA Regulations required that in addition to a positive test, a person also needed to be symptomatic for certain of the DMA Regulations to apply. Reverting to diagnosis purely by test result is unscientific.

- 5.4 Regulation 15(2) requires an order of the High Court to compel treatment and Regulation 15(5) requires specific requirements to be met before mandatory prophylaxis may be administered. This Regulation conflicts with Article 6(1) of The Universal Declaration on Bioethics and Human Rights (UNESCO 2005) Article 6(1), which provides that:

“Any preventative, diagnostic and medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent, where appropriate should be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.”

- 5.5 Regulation 18(1) provides that information concerning a case, contact or a carrier of an NMC is confidential and no person may disclose the information except for the purposes of public health surveillance, investigations and interventions or with a court order. The Proposed Regulations are inconsistent with Regulation 18(1) including in that they require disclosure of information regarding infections with NMCs that are prohibited by Regulation 18(1).

6 PROPOSED REGULATION 2

- 6.1 Amongst other things, Proposed Regulation 2 permits an "Environmental Health Practitioner" to search premises without a warrant, demand the

production of documents, make copies of documents and question people.

- 6.2 This Regulation seeks to create a form of Police with vast powers that has not been vetted by Parliament.
- 6.3 There is no valid reason why an Environmental Health Practitioner should have wider powers than a Police officer and not be subject to the same restrictions on search as any other law enforcement officer.
- 6.4 The Proposed Regulation requires accommodation establishments to obtain details from guests, including their residential addresses and cellular phone numbers. This means that all accommodation establishments will be required to collect this information. This is a major invasion of privacy and it is not clear that the establishments have the right to collect or process this information under POPIA.
- 6.5 Proposed Regulation 2(11) references the national state of disaster and states that the information that the Department obtains will only be de-identified at the end of a state of disaster. The implication is either that the whole of Regulation 2 only applies during a state of disaster or that the de-identification of information under this Proposed Regulation only applies after a state of disaster and not during ordinary conditions.

7 PROPOSED REGULATION 15A

Proposed Regulation 15A is effectively the old regulation 6 under the DMA Regulations prior to the February 2022 amendment. The February amendment inserted the requirement that the individual not only test positive, but also be symptomatic which, as noted above, aligns the regulations with centuries of medical practice. Without making this amendment to the Proposed Regulations, the latter are irrational and unscientific as well as incompatible with Regulation 15(1).

8 PROPOSED REGULATION 16A

- 8.1 Proposed Regulation 16A effectively results in masks being mandated forever in perpetuity in all indoor spaces, for all indoor religious services, on all forms of public transport. The Proposed Regulation provides that masking applies in respect of all NMCs listed in Annexure A that may be spread by droplet or aerosol. This list includes measles, any respiratory disease caused by a novel respiratory pathogen including flu, leprosy, tuberculosis, rubella and smallpox. These are endemic diseases that have been in circulation for centuries despite effective vaccines and for which there is no evidence that masks work.
- 8.2 The Proposed Regulations apply the same measures to combating NMCs that spread via droplets and aerosol. This is inappropriate. Droplets are much larger than aerosols. As noted in paragraph 2, aerosols are able to pass through much smaller spaces in mask fabrics, they travel much larger distances and hang in the air for much longer. There is no scientific basis for applying masks, especially homemade masks, to combat these diseases.
- 8.3 Proposed Regulation 16A is irrational and will not contribute in any way to achieving the objects of the Act.

9 REGULATION 16B

- 9.1 Almost all of the NMC's listed in Annexure A are capable of spreading beyond South Africa's borders. It is not clear who must make the declaration of a public health emergency of international concern and this needs to be clarified to ensure that South Africa retains its sovereignty. We note a troubling trend towards deferring to the World Health Organisation ("**WHO**") on matters that go beyond public health. The WHO is not an elected body.

- 9.2 The Regulation effectively imprisons any person who does not have a document described, vaguely, as "the full vaccination certificate" or "a negative PCR test results of not more than 72 hours". These people may not leave South Africa. This not only applies to South African citizens.
- 9.3 It is not clear that all of the NMCs can be tested for with PCR tests, but in principle the testing rules apply to all NMCs. Some of the NMCs cannot be vaccinated against but the vaccination rules appear to apply to them.
- 9.4 As noted in paragraph 2, PCR tests are not capable of diagnosing COVID-19, they are not particularly accurate and ethically are not a substitute for an actual diagnosis by a medical practitioner. As such, tests alone, notably PCR tests cannot rationally form the basis for any regulation or any limitation of Constitutional rights.
- 9.5 People who have symptoms for listed NMCs can be subjected to medical examination and testing and can be placed under mandatory isolation. The official symptoms for these NMCs are not listed and we know that even a runny nose can be considered a symptom of flu or COVID-19. If this Proposed Regulation is read as being confined to people exiting South Africa, it still means that individuals will be randomly subjected to testing and can be forced into isolation. In relation to isolation, the Proposed Regulations state that a person may be permitted to self-isolate at their residence, which makes it clear that isolation may be required in government isolation camps. This is a serious limitation of fundamental Constitutional rights that is unreasonable and unjustifiable given the inaccuracy of the testing regime and the fact that COVID-19 and many of the other NMCs do not pose a risk that is commensurate with these measures. Self-isolation also presumes that the individual will have access to a separate well-ventilated bedroom with a bathroom and toilet, which is unrealistic.
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10 REGULATION 16C

- 10.1 This regulation only applies during the "Covid-19 pandemic", but it does not only apply to infection with SARS-CoV2 or Covid-19. It applies to any NMC. Consequently, a person who arrives in South Africa with measles or flu can be forced into isolation.
- 10.2 No one may enter South Africa unless they have "the full vaccination certificate" or "a negative test result of not more than 72 hours." PCR tests are not sensitive enough to ensure that someone who tests negative 72 hours before travelling won't be carrying the virus and able to transmit it on arrival. The vaccinated are not required to submit a test but they can still transmit the virus. PCR tests often remain positive for weeks and even months after testing and could therefore result in travellers being trapped in the country, incurring extra costs and hurting our own economy and tourism. Additionally, the status of PCR tests and RT_PCR testing kits has been withdrawn by both the FDA and the CDC. Research has shown them to be unreliable indicators of infection.¹¹²
- 10.3 The restrictions on entering South Africa apply to everyone, including South African citizens. Every person entering South Africa must be screened – apparently for all of the NMCs. They may be placed under mandatory quarantine in a government camp although they may be permitted to self-quarantine at a place currently unspecified. This is plainly unconstitutional, particularly since the PCR Tests are inconclusive in respect of determining whether the person in question poses a risk to society.
- 10.4 If, during mandatory screening, a person is found to have been exposed to any person with a listed NMC, whether or not they have symptoms, they must be subjected to a medical exam which may include testing.

¹¹² https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

- 10.5 Because screening takes place on arrival and mandatory quarantine is only ordered thereafter, the effect of Proposed Regulation 16(4) is that everyone coming to South Africa should apply in advance for self-quarantine in case they are required to quarantine on arrival. This will place a massive burden on the Director-General: Health. It would also be recommended for every person to submit the sworn statement referenced in Regulation 16(7) in case they are subjected to quarantining. This is also not realistic.
- 10.6 Regulation 16(9) provides that all unvaccinated travellers will be offered vaccinations. In principle, this covers all NMCs and will result in border posts becoming major medical facilities, which is impractical and irrational, particularly in relation to COVID-19 given that the vaccine does not render the vaccinated person or any space they occupy, safer.

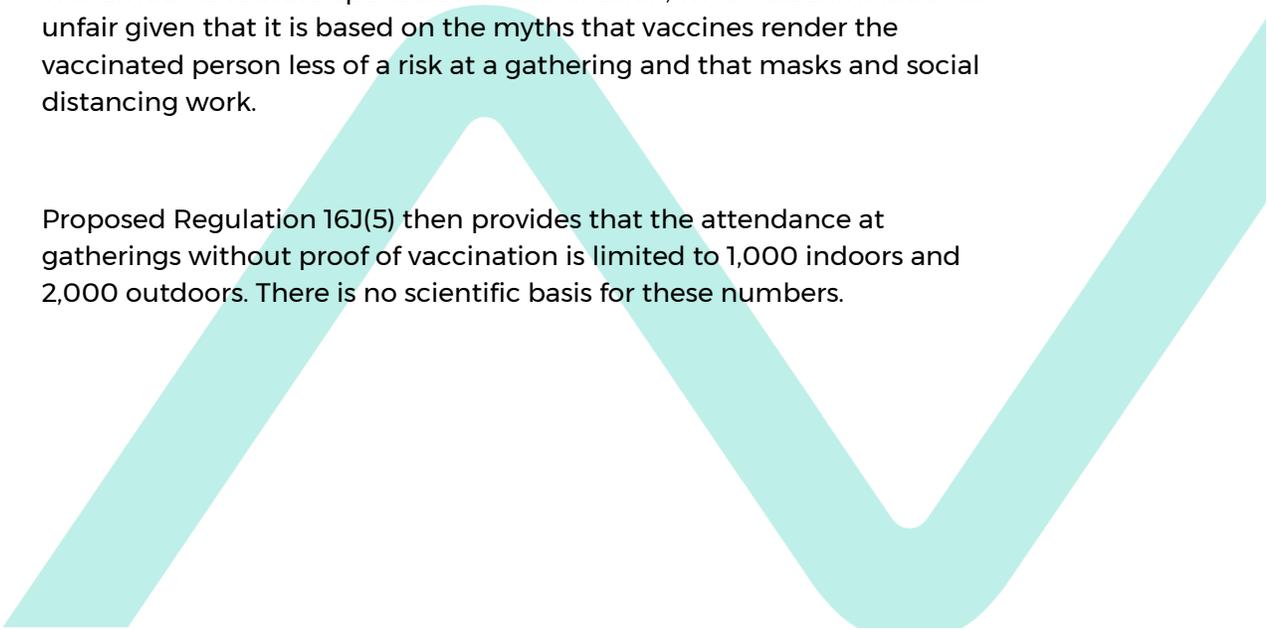
11 REGULATION 16F

Local air travellers must also be subjected to screening and may be subjected to medical examination. This is irrational and disproportionate to the risk that the bulk of the NMCs pose.

12 REGULATION 16I

- 12.1 Masks will be required at all funerals whether indoors or outdoors for so long as there is an epidemic or pandemic in relation to any of the listed NMCs. In practice, this means that masks will forever be required at funerals.
- 12.2 Masks will be required for the duration of the Covid-19 epidemic (ill-defined as that is) and irrespective of how mild the disease becomes.
- 12.3 As noted in paragraph 2, there is no scientific basis for masking to control NMC spread.

13 REGULATION 16J

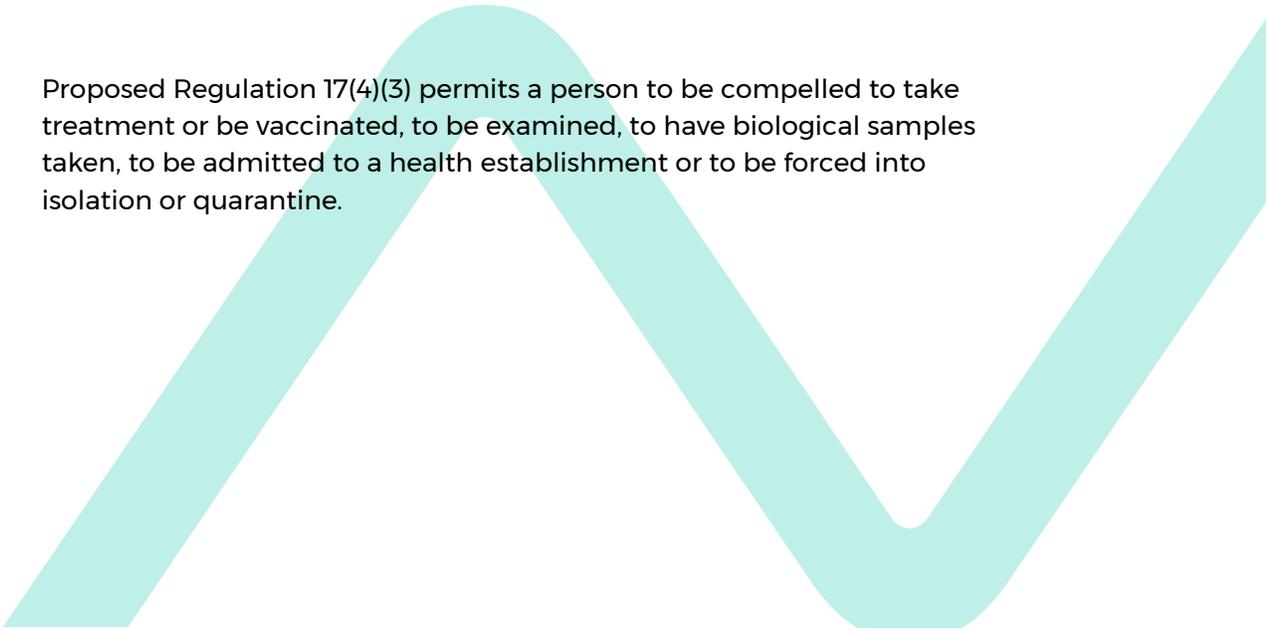
- 13.1 As noted in paragraph 2, there is no basis in science for the requirement to maintain a distance of 1m from other people.
- 13.2 There are many references to scientific evidence in this Proposed Regulation, but no clarity on what "scientific evidence" means. During the Covid-19 outbreak, many statements have been made (notably by the Ministry of Health) as to what the scientific evidence suggests that were unreferenced and that subsequently proved to be untrue. This wording is unworkable.
- 13.3 The drafting of Regulation 16J(4) is particularly bad, but it seems to provide that during the Covid-19 pandemic, indoor and outdoor gatherings are restricted to 50% of the venue capacity and:
- 13.3.1 attendees produce a vaccine certificate;
 - 13.3.2 there is social distancing of at least 1m (no dancing); and
 - 13.3.3 masks must be worn at outdoor events.
- 13.4 This amounts to state-sponsored discrimination, which discrimination is unfair given that it is based on the myths that vaccines render the vaccinated person less of a risk at a gathering and that masks and social distancing work.
- 13.5 Proposed Regulation 16J(5) then provides that the attendance at gatherings without proof of vaccination is limited to 1,000 indoors and 2,000 outdoors. There is no scientific basis for these numbers.
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- 13.6 It would appear though that this Proposed Regulation does not apply during the Covid-19 pandemic but only after the pandemic has ended. It is not clear what proof of vaccination applies for the other NMCs and it appears that in perpetuity organisers will need to check for a variety of vaccines or limit gatherings to 1,000 indoors or 2,000 outdoors.
- 13.7 This regulation infringes freedom of association. It effectively prevents any public protest by unvaccinated individuals (however that is defined). It also allows the Minister to arbitrarily limit any gatherings since certain of the listed NMCs cannot be vaccinated against. It is therefore plainly unconstitutional.

14 PROPOSED REGULATION 75 - VACCINATION

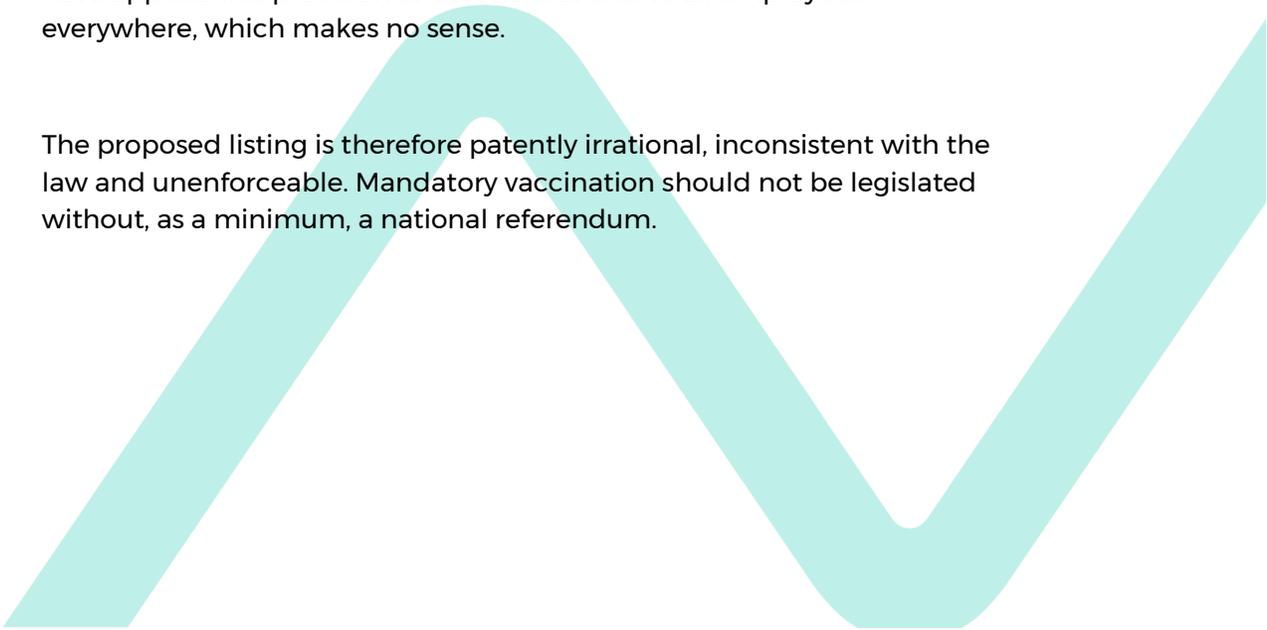
- 14.1 As noted in paragraph 2, the Vaccines do not prevent infection or transmission and do not therefore make public spaces safer. The requirement that persons entering South Africa be vaccinated is therefore irrational and since it applies to South African citizens, it is also plainly unconstitutional.
- 14.2 As noted in paragraph 2, PCR tests are unfit for purpose and Regulation 75 is so vague in relation to testing that it is unworkable. Moreover, the cession of sovereignty to the WHO is inappropriate and unconstitutional.

15 REGULATION 17

- 15.1 Proposed Regulation 17(4)(3) permits a person to be compelled to take treatment or be vaccinated, to be examined, to have biological samples taken, to be admitted to a health establishment or to be forced into isolation or quarantine.
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- 15.2 This Proposed Regulation clearly infringes the Constitutionally entrenched rights to equality (section 9), human dignity (section 10), life (section 11), freedom and security of the person (section 12 and particularly subsection 2 (b) the right to security in and control over their body, privacy (section 14) and freedom of religion, belief and opinion (section 15). There is no basis for the limitation of these rights given that the risk posed by COVID-19 is not proportionate to the response and the limitations are therefore unreasonable and unjustifiable in an open and democratic society.
- 15.3 The Proposed Regulation makes no reference to the use of traditional cultural medicines as prophylactic treatment and so therefore denies the use of medicines used by a large proportion of South African citizens. Not only allopathic medicines are effective, so are traditional and complementary medicines. It is hubris to believe that only allopathic medicines are effective and to prescribe only those.

16 ADDITIONAL COMMENTS

- 16.1 The Proposed Regulations purport to list the Virus as a Hazardous Biological Agent ("**HBA**"). By doing so, employers are being given wide powers to force their employees to be vaccinated against an expiring virus and one which does not originate at the place of employment.
- 16.2 Section 43 of the OHS Act was intended to protect workers in businesses where hazardous biological agents are produced, processed, handled, used, stored and transported. Instead, the Proposed Regulations now have applied this provision to coronavirus and to all employees everywhere, which makes no sense.
- 16.3 The proposed listing is therefore patently irrational, inconsistent with the law and unenforceable. Mandatory vaccination should not be legislated without, as a minimum, a national referendum.
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17 CONCLUDING REMARKS

The Minister does not have the power to implement the Proposed Regulations. They are ultra vires. The Proposed Regulations are not based on science but on myths including that masks and social distancing reduce transmission and that the COVID-19 Vaccines make the vaccinated and the spaces they occupy safer. As such, the Proposed Regulations are manifestly irrational and will be void if they are passed. The impact of the Proposed Regulations is not benign. They entail limitations on businesses that have a direct impact on lives and livelihoods. They entail limitations on Constitutional rights that result in unfair discrimination and the inability to enjoy hard-won liberties. The safety and efficacy of the Vaccines is questionable. These impacts are not proportionate to the risks that many of the NMCs, and certainly COVID-19, pose.

The Proposed Regulations are unnecessary. Other countries that did not implement lockdowns and have not mandated Vaccines and other interventions have proven that COVID-19 can be effectively managed through traditional measures applied to other diseases - giving the public accurate information and allowing them to take their own health decisions.

