SECTION: PIL

IN THE HON'BLE SUPREME COURT OF INDIA
(CIVIL ORGINAL WRIT JURISDICTION)
WRIT PETITION (CIVIL) NO. 607 OF 2021

IN THE MATTER OF

DR. JACOB PULIYEL .....PETITIONER

VERSUS

THE UNION OF INDIA & ORS. .....RESPONDENTS

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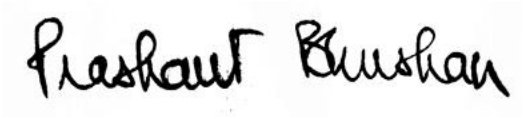

(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER
301, NEW LAWYERS CHAMVER
SUPREME COURT OF INDIA
NEW DELHI-110 001
CODE NO. 515

NEW DELHI
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REJOINDER NOTE OF ADVOCATE PRASHANT BHUSHAN TO THE COMPILATION FILED BY THE UOI AND STATE OF TAMIL NADU.

1. At the outset, it is submitted this note is not giving a point wise reply to the compilations. However the contents of the compilation are denied as irrelevant to the prayers of the petitioner that clinical trial data with respect to the vaccines being administered in India under emergency use authorization be made public and that vaccine mandates be struck down as unconstitutional. The UOI has attempted to mislead the court with overwhelming voluminous reports that are irrelevant to the present case. Every advisory with the word COVID or Pandemic cannot be used to support the UOI claims on vaccine mandates. The science is nuanced and the petitioner has made a scientific and legal claim against vaccine mandates, based on peer reviewed scientific studies that there is no public health rationale mandating the vaccines when the vaccinated are not clearly at higher risk of infection from the virus and of transmitting the disease than the vaccinated, and in addition

when serological surveys now show more than 80% of the population in India has had COVID and is sero-positive, with a stronger immune protection from having had the natural infection compared to the vaccinated. There is no evidence whatsoever presented by the UOI in its voluminous compilation to rebut any of the evidence that has been presented by the petitioner and infact, many of the papers support the petitioners claims. The UOI has therefore been misguided in the preparing of this compilation as will be evident from the rejoinder below.

Vaccine Mandates

2. The respondents counter at para 64 states that as per the Operational Guidelines document, Covid 19 vaccination is voluntary. The petitioner is grateful for the unequivocal stand of the respondents that COVID-19 vaccination is voluntary and not mandatory. This is consistent with the fundamental right to bodily integrity and right to self determine what is injected into one's body. This is also in keeping with the decision of Delhi High Court in the Measles Rubella case where the court held that vaccination cannot be made mandatory and that there needs to be information dissemination on the vaccines for informed consent. The stand of the government of India through the Ministry of Health and Family Welfare, clarifies that any mandates by States violate the rights of citizens.

3. However in a complete denial of its stand that COVID Vaccines are voluntary, the UOI has filed a series of advisories and guidelines in the present compilation to support a claim that

vaccines should be mandated. This is completely incongruous with the stand that the UOI has taken in its counter affidavit. Therefore, while the counter states that the vaccines are voluntary, however an effort has been made to find articles and advisories in this compilation to show that vaccines should be mandated.

4. A very important presentation was made in the United States Senate by Professor Aditi Bhargava, a professor at University of California San Francisco and a molecular biologist with 33 years of research experience. She makes a notable comparison between Covid vaccines and vaccines of a disease like Polio and small pox. She points out that RNA and DNA viruses are fundamentally different. Most DNA viruses mutate at a very slow rate. DNA virus infection or vaccination induces life-long immunity. After a natural infection or vaccination with DNA virus such as the chickenpox, no one needs to be vaccinated or develops the disease in their lifetime. In contrast, respiratory RNA viruses mutate frequently and do not induce life-long immunity as we have seen with SARS-CoV-2 or flu/common cold viruses. One can have influenza multiple times in their lives with or without vaccines. Flu has not been eradicated, nor is there any talk to eradicate it. There is no herd immunity of flu. There can be no vaccine induced herd immunity for COVID.

(The transcript of the presentation by Prof Bhargava before the US Senate on 2nd November 2021 is annexed as **Annexure RN 1 (Pages 29 to 30)**

5. The two WHO press releases (Pages 1-23 of the UOI compilation) on the outbreak of the COVID-19 pandemic and on the International Health Regulation Emergency Committee on Outbreak of Covid of March and January 2020 do not have relevance to COVID-19 vaccines.

6. Webpages of WHO, UNICEF, CDC and EMA recommending COVID vaccines to adults and children and EUL procedure and flow of approval for COVID 19 vaccines (Pages 23-143 of the UOI compilation) only support the petitioner's case against vaccine coercion and vaccine mandates. Various statements in these advisories caution about transmission of the virus despite vaccination and therefore the need for the vaccinated to be masked and protected by other means. In a recent reply (dated 04 Mar 2022) to an RTI query, the ICMR has categorically said "ICMR has not conducted any study to assess the transmission potential of SARS-Cov-2 in vaccinated vs unvaccinated individuals."
https://twitter.com/awakenindiamvmt/status/1503251127940558850 Thus there is no rationale for mandating vaccines if the vaccinated are at equal risk of infection and can transmit the virus. These advisories do not guarantee the safety or efficacy of the COVID Vaccines but caution that they seem safe for "most people". Mandates take in their sweep "all" people and therefore are clearly illegal and against scientific caution.

7. The claims in some of the articles and statements of the CDC in the United States, that vaccination can stop the pandemic are evidently and scientifically false. Highly vaccinated populations have had huge outbreaks as has been detailed in the petitioners written submissions: US/Europe Jan 2022 wave, Israel's Omicron wave even after boosters, Singapore's wave even after booster, ongoing huge surge in New Zealand, etc.The US CDC has been deriding immunity from natural infection for a long time, against known science and also against overwhelming evidence from various studies. But recently (Jan 2022) even they had to admit the truth that immunity from natural immunity is as good or better:

https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm#contribAff

"By early October, persons who survived a previous infection had lower case rates than persons who were vaccinated alone."

(A copy of the CDC paper dated 28th January 2022 is annexed as **Annexure RN 2 (Page 31 to 34).**

Additionally, we can readily observe in India know that immunity from natural infection is strong and long lasting, as densely populated slums like Dharavi did not even have a second wave (most people there were exposed in the first wave in 2020 itself).

8. The document "Safety of Covid-19 vaccines" (page-47 of Compilation) from European Medicine Agency is an implicit

admission by GoI of its lack of seriousness in similarly tracking vaccine safety in India. It is telling that GoI should give a print out of European agency's website and not a similar website from India.

9. The "Emergency Use Listing Procedure" of WHO (page 52-114 of the Compilation) is irrelevant to the current case. The "CONSIDERATIONS FOR EVALUATION OF COVID19 VACCINES" of WHO (page 115-143 of the Compilation) is also irrelevant to the current case. The Union of India is loading the court with irrelevant information.

10. The study by the CMC researchers (Page 144-150 of the Compilation) is with regard to theseeming protection offered by Covid-19 vaccines during the second wave. This is irrelevant to the current case for two reasons: (1) The publication does not talk about infection/transmission by vaccinated people, (2) It also does not consider protection offered by natural exposure, which most Indians have at this time.

11. The letter by the research scientists of the Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland in the Journal of American Medical Association. (page 151-153 of Compilation) supports the petitioner's case that immunity from natural infection is strong and long-lasting (and hence vaccine mandates are unscientific and illogical): *"Although evidence of natural immunity in unvaccinated healthy US adults up to 20 months after confirmed*

COVID-19 infection is encouraging, it is unclear how these antibody levels correlate with protection against future SARS-CoV-2 infections, particularly with emerging variants." The statement is cautious and such caution is common in scientific parlance, as everything in science is subject to possible new evidence. However the known science as well as data from India and around the world is that immunity from natural infection is strong and long lasting, as also affirmed by this publication. The State of Tamil Nadu for instance has filed several papers in compilation to show that immunity from vaccines wanes with time and therefore vaccines are ineffective in protecting against infection and transmission.

12. Study conducted by AIIMS, Delhi's research scientists in Diabetes & Metabolic Syndrome: Clinical Research & Reviews Journal. (page 154-158 of compilation) is irrelevant since its talks of protection offered by the vaccines during the second wave. This is irrelevant to the current case for two reasons: (1) The publication does not talk about infection/transmission by vaccinated people, (2) It also does not consider protection offered by natural exposure, which most Indians have at this time. In fact, the paper concludes that the vaccines lower the risk of hospitalization and severity of illness which the petitioner admits, but they not protect against infection and transmission and therefore cannot be mandated.

13. Study conducted by Israeli research scientists titling "Protection and waning of natural and hybrid COVID-19 immunity". (page

159-173 of compilation) - This publication supports the petitioner's case against vaccine mandates. (1) It affirms that protection offered by vaccine wanes with time (hence the huge waves in Israel, Singapore, etc despite high vaccination levels), (2) More importantly, it also affirms that protection offered by natural infection is stronger and longer-lasting; the publication talks about protection even a year after natural infection, whereas vaccine induced immunity wanes within 3-6 months. Figure-3 in page 173 shows this very clearly. Quote from page 164:

"Clear evidence of waning immunity is evident for all cohorts. The rate of confirmed infections for *Recovered individuals* for whom the time elapsed from infection was 4 to 6 months was 10.5 per 100,000 person days (95 CI: 8.8 to 12.4) increasing with time since recovery to 30.2 (95% CI: 28.5 to 32.0) at more than 12 months. For the *Vaccinated cohort*, the rates were 21.1 (95% CI: 20.0 to 22.4) when the time since vaccination was less than two months increasing with time since vaccination to 88.9 (95% CI: 88.3 to 89.6) at 6 to 8 months.

"Our results are in line with those of a study conducted by an Israeli HMO,7 that previously infected individuals with or without one vaccination dose have better protection than uninfected doubly-vaccinated individuals 3 to 8 months after the last immunity-conferring event. Our data on Covid-19 hospitalized patients with severe disease has too few cases for a definitive analysis but does not seem to support a recent report22 that suggests that vaccinated individuals were more

protected than previously infected individuals 3 to 6 months after the immunity-conferring event."

14. Observation study conducted by Tamil Nadu Policemen titling "COVID-19 vaccine effectiveness in preventing deaths among high-risk groups in Tamil Nadu, India." (page 174-176 of compilation) -The point made by this publication is supposedly protection offered by Covid-19 vaccines during the second wave in reducing hospitalization and deaths. This is irrelevant to the current case for two reasons: (1) The publication does not talk about infection/transmission by vaccinated people, (2) It also does not consider protection offered by natural exposure, which most Indians have at this time.

15. Study conducted by AIIMS Research Consortium AIIMS Journal Medical Association. (page 177-189 of compilation) This publication is a study of re-infection among health care workers during India's second wave. It misses two important aspects: (1) long-lasting protection after natural exposure to the virus, and (2) immunity against infection offered by Covid vaccines, wanes within a few months of vaccination (hence the recent surge of Omicron even among fully vaccinated, even boosted individuals). Considering these two aspects, there is no case for vaccine coercion or mandates.

16. Study conducted by AIIMS, Patna's research scientists and published in Epidemiology and Infection Journal, Cambridge and Study published in Diabetes and Metabolic Syndrome (page

190-198 of compilation) - This publication is a study of Covid infection and severity during India's second wave and discusses how vaccination lowers length of hospital stays and development of severe illness. It misses two important aspects: (1) long-lasting protection after natural exposure to the virus, and (2) immunity against infection offered by Covid vaccines, wanes within a few months of vaccination (hence the recent surge of Omicron even among fully vaccinated, even boosted individuals). Considering these two aspects, there is no case for vaccine coercion or mandates.

17. Study published in Diabetes & Metabolic Syndrome: Clinical Research & Reviews Journal. (page 199-200 of compilation) – The study shows that breakthrough infections are increasing and there is a high prevalence of breakthrough infections in the health care facility among vaccinated persons especially due the new variants.

18. Scientific Brief dated May 10, 2021 by World Health Organization on Covid-19 Natural Immunity. (page 201-204 of compilation) - This May 2021 WHO document supports the petitioner's case against vaccine mandates. It affirms long lasting protection after natural exposure. "Available scientific data suggests that in most people immune responses remain robust and protective against re-infection for at least 6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months)." Empirical

science prior to the pandemic as well as various studies have affirmed the long-lasting protection after natural exposure.

DISCLOSURE OF CLINICAL TRIAL DATA

19. Good Clinical Practices for Clinical Research in India - Central Drugs Standard Control Organization (page 205-292) – This is a document that provides for the ethics of good clinical research. The UOI is in breach of many of the principles of such good practice as has been highlighted by the petitioner in various affidavits. The cornerstone of clinical trials is informed consent. There can be no informed consent where there is no disclosure of clinical trial data or of institutional affiliations or conflict of interests, etc. There has been complete opacity with regard to the ingredients of the vaccines, the side effects and adverse events, on the ground that the information has been denied disclosure by the vaccine companies. Further as detailed in this documents for any clinical evaluation of a new drug or vaccine on children, the phase three trials in adults should have been complete and the results published and scrutinized by independent scientist especially when the disease for which the drug is being tried does not display a severity or serious risk to that vulnerable population such as children. Further, the document highlights the Helsinki declaration which is again clearly violated by the government in mandating these vaccines through coercion. “In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and

society." The Helsinki declaration require disclosure of clinical trial data (both positive and negative), free and informed consent, etc which has not been complied with by the UOI.

20. The UOI in their compilation have provided list of documents that govern the clinical trial procedure, the approvals thereof and minutes of the meetings which has facilitated the clinical trial procedure of COVID-19 vaccinations in India. These include the Good Clinical Practices, process under NTAGI and the minutes of the SEC meeting on approvals among other things. It is hereby submitted that the information provided thereof only report the procedure of clinical trials and not the segregated clinical trial data. The release of the clinical trial data the petitioner seeks is raw data with personal identification redacted which must be available to independent scientists to re-evaluate the results originally reported. The regulatory authorities must release data submitted to them for independent review. The trial subjects put themselves at risk for the clinical trial and thus, this data must be publicly available. The trial subjects have a right to have the data evaluated by the best scientists, not just the companies that are conducting these trials.

21. Recently a Federal Court in the US has ordered the FDA to release the data it relied on to license Pfizer's COVID-19 vaccine, imposing a dramatically accelerated schedule that should result in the release of all information within about eight months. The court held that the FOIA request is of paramount public importance.

(A copy of the Reuters report dated 7th January 2022 "Paramount importance: Judge orders FDA to hasten release of Pfizer vaccine docs" is annexed as **Annexure RN3 (Page 35 to 47).**

22. This data sought may be given in accordance with what other authorities internationally have done so far. The European Medical Agency since 2010 has a policy on access to "any document originated, received or held by the Agency."The policy made a wide range of regulatory documents potentially accessible to anyone who asks for them, including clinical study reports. Documents are released without charge, primarily in PDF format, and made available via a web-based download. https://www.ema.europa.eu/en/documents/other/policy-43-european-medicines-agency-policy-access-documents_en.pdf)

23. The segregated data that the petitioners seek is data segregated by risk groups say age, sex, pregnancy etcand data segregated by trial center(different groups in different centers may have different risks).

24. Additionally, to assuage all privacy concerns the petitioners reiterate that all clinical trial raw data not include personal identification and the same must be redacted so independent scientists can reevaluate results reported.

ADVERSE EVENT EVALUATION

25. The Respondent, in their Document compilation in the sub-section on Adverse Event Evaluation, provides a description of the adverse events database as compiled by the Respondent. The Petitioner submits that a repository of AEFI has to be as detailed as VAERS (Vaccine Adverse Events Reporting System in the US) andEudraVigilanceof European Medicines Agency. Individuals and doctors must be able to report suspected adverse events and the reporter must be given a unique identification number and the reports must be available open access. The forms must be easy to fill. Complicated details required by the AEFI committee must be filled in by contacting the reporter. Additionally, these must be widely advertised in the major newspapers (as reporting of adverse events was elaborated upon in the Measles-Rubella case of the Delhi High Court).The Drug Control Act requires active surveillance which should be one contact with new medicine recipient by the doctor/hospital between 1 to 2 weeks after being administered the Phase 4 trial drug (not passive surveillance which means recording only cases that come back to the dispensing hospital). If not practical in Phase 4 then they must each be provided a hand out about how to report adverse events to the AEFI committee as mentioned above. This is over and above the monthly newspaper announcement.The system at present allows only the District Immunization Officer and vaccinators to report. These risks censoring of reports.

26. AEFI data as of 26th Feb (Page 366 – 388 of compilation) - A quick calculation of this data presented by the government is revealing. Number of vaccine doses administered in India: 176 crores (approx). Number of adverse events reported: 76,814 (page 366). This comes to approximately 1 adverse event per 23,000 doses. The same vaccine Astrazeneca in Europe has caused 244,603 adverse events in 69 million doses (page-49), which translates to approximately 1 adverse event per 282 doses.This level of discrepancy (about a factor of 80 lesser compared to Europe) is absurd, and points to the utter callousness in AEFI collection by GoI.

27. In India the government does not regard an adverse event immediately after the vaccine as one related to the vaccine unless it is a recognized adverse effect of the vaccine. This is clear from the fact that of the many deaths reported after vaccination, the government has not recognized a single one of them as related to the vaccine because they do not regard death as a recognized adverse effect of the vaccine. This is another major problem with the adverse event reporting system in India. WHO has recently revised how AEFI are classified. Only reactions that have previously been acknowledged in epidemiological studies to be caused by the vaccine are classified as a vaccine product related reaction. Deaths observed during post-marketing surveillance are not considered as 'consistent with casual association with vaccine', if there was no statistically significant increase in deaths recorded during the small Phase 3

trials that preceded it. In the case of COVID vaccines the critical phase 3 trials were curtailed soon after they had begun.

(A copy of the paper titled, "Revised World Health Organisation assessment of adverse events following immunization – a critique" dated 17th May 2019 is annexed Annexure P18 of the Writ Petition)

Vaccination in Children

28. UNICEF on Vaccination for Children (page 684-690) –it must be submitted that UNICEF is not a scientific regulatory body but a child welfare agency. Therefore UNICEF can at best issue an advisory based on scientific evidence but UNICEF guidelines cannot be used as evidence in support of vaccine mandates. This document begins with a falsehood (page 685): "Widespread vaccination has been instrumental in helping curb the spread of coronavirus." A systematic analysis in a peer-reviewed publication has in fact found the exact opposite: "Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States", 30 Sep 2021, https://link.springer.com/article/10.1007/s10654-021-00808-7. The statement (page 685) "A COVID-19 vaccine can prevent your child from getting infected and spreading coronavirus" is patently false and misleading again as has been detailed by the petitioner. Even the ICMR (Indian Council of Medical Research) has clearly said the Covid-19 jabs are not preventive, but "disease modifying". https://timesofindia.indiatimes.com/videos/news/covid-

vaccines-are-disease-modifying-dont-prevent-infection-icmr/videoshow/88597995.cmsGiven the recent surge of third wave cases in fully jabbed people, claims of "prevention" by vaccination can be seen to be false even by laypersons.Furthermore, the very next statement (page 685) "If your child gets infected, a COVID-19 vaccine could prevent them frombecoming severely ill in subsequent exposure to COVID-19 infection" not only directly contradicts the previous statement claiming that the jabs prevent infection, it is also not backed by scientific studies. Since the risk of becoming severely ill from Covid is so low among children, we cannot possibly know from current trials as to whether this risk is further reduced (or enhanced) by the current jabs for children.Moreover, most Indian children have already been exposed to SARS-Cov-2 (and have recovered) even without our knowledge.The statement "Vaccination does not mean your children can stop following COVID-19 Appropriate Behaviour" (page 687) is an admission that vaccination does not prevent infection or transmission, contradicting the earlier claim."Vaccines also ensure that children do not become super-spreaders." (page 689) is false; it is contradicted by voluminous scientific research that those vaccinated can spread as much as those unvaccinated. For instance, consider the recent Jan 2022 publication in The Lancet journal of Infectious Diseases. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00768-4/fulltext, Jan 2022, "Transmissibility of SARS-CoV-2 among fully vaccinated individuals". It says "This study showed that the impact of vaccination on community

transmission of circulating variants of SARS-CoV-2 appeared to be not significantly different from the impact among unvaccinated people.", and "Indeed, there is growing evidence that peak viral titres in the upper airways of the lungs and culturable virus are similar in vaccinated and unvaccinated individuals."

"Children with other health conditions, such as obesity, diabetes, and asthma, might be at higher risk of serious illness with COVID-19 that can be avoided by taking the vaccine." (page 689) is a wishful claim unsupported by evidence. The covaxin trials involve just 175 children in the age-band 12-18 (https://clinicaltrials.gov/ct2/show/NCT04918797). The above health conditions are so rare in children that benefit of jab (or harm) cannot possibly be shown in such a trial.

29. WHO's statement on COVID-19 vaccination for children and adolescents (page 691-698 of compilation) - (1) The statement "The risk of myocarditis/pericarditis associated with SARS-CoV-2 infection is higher than the risk after vaccination" (page 694) is falsified by the following study in the context of children and adolescents.

https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full As Table-1, page-9 of the paper shows, the risk of myocarditis after vaccination is higher than myocarditis after Covid infection, for males under 40 years of age. Furthermore, since Covid19 vaccines do not really prevent infection, the real question is whether vaccination reduces risk of myocarditis overall (even after infection after vaccination). The WHO

statement does not answer this real question. Moreover, all of this is irrelevant for Indian children, since as the WHO document admits, after the second wave, "seropositivity in children 6-18 years was similar to that in older age groups", i.e. most Indian children are already exposed and recovered at this time. (2) The statement "the impact of vaccination on reducing transmission in the context of the more transmissible delta variant appears to be lower" (page 695) supports the petitioner's plea against vaccine mandates, and indeed also against jabs for children. Note that with Omicron and further waning of vaccine efficacy against infection, there is simply no case for jabbing children for the purported benefit of adults.

30. Pediatric COVID-19 Vaccination Operational Planning Guide (page 699-704 of compilation) - On 29 Oct 2021, the FDA (USA) approved the emergency use of Pfizer's mRNA jab for use in kids aged 5-11 (https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age). The approval was based on the claim of 90% efficacy in its trials. (https://www.fda.gov/media/153409/download). It must be mentioned that the mRNA vaccine is NOT the vaccine used in India However, on-field study in New York (publication preprint: https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full.pdf) has shown that just 7 weeks after vaccination, vaccine efficacy against infection is in the 18-65% range among 12-17y olds, and even negative efficacy among 5-11y old. Negative efficacy means that risk of infection is higher among

vaccinated compared to the unvaccinated. Therefore, claims of jabbing kids to reduce transmission are false and misleading. Such waning efficacy is the same as what has been observed among adults in other studies. India should learn from this poor experience and stop the jabs for kids, even more so as most Indian kids have already been exposed at this time.

31. Study published in medRxiv Journal (page 709-729 of compilation) This preprint claims "risk-benefit assessments revealed favorable results for vaccinating children and adolescents, especially those with underlying disease, alongside adults to prevent transmission, severe infection, negative outcomes, and new variants formation". But none of these are substantiated. (1) Claims of Covid19 vaccines preventing infection/transmission are negated by voluminous literature as already presented.

(2) Claims of vaccines preventing new variants formation is also falsified by careful studies. A recent study of SARS-Cov-2 variant evolution across continents says: "the occurrence and frequency of vaccine-resistant mutations correlate strongly with the vaccination rates in Europe and America". This is due to evolutionary pressure, and has led to Delta and Omicron infections in fully-jabbed individuals. https://pubs.acs.org/doi/10.1021/acs.jpclett.1c03380 (3) Among children, risk of severe Covid is so rare that in Pfizer's trials involving 2268 children, there was not a single instance of severe Covid: https://www.fda.gov/media/153409/download. Covaxin trials involve far less children: just 175 in the 12-18

age-group https://clinicaltrials.gov/ct2/show/NCT04918797. Such small trial sizes cannot possibly find any instance of severe Covid, leave alone show benefit of the jabs in reducing such instances.

32. Study published in The New England Journal of Medicine. (page 730-740) - (1) This study considers children and adolescents already hospitalized for Covid or some other reason. Such children are likely comorbid with other serious conditions. Such instances were extremely rare indeed: only 445 cases across 23 US states, over 4 months of the Delta wave. Therefore these study results emphatically do not make the case for mass vaccination of all (healthy) children.(2) It is telling that GoI should cite a study using BNT162b2 vaccine while justifying Covaxin for children! This clearly means that GoI has insufficient evidence/data to support use of Covaxin for children in India.(3) Furthermore, also to be considered is the fact that all-cause mortality among vaccinated children in the 15-19y age-group appears 3 times higher than the unvaccinated group, as per UK data: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland and analysis at https://tinyurl.com/uk1019dr . This is deeply concerning and needs investigation.

33. Study published in Emerging Infectious Diseases Journal of CDC (USA). (page 741-744) - (1) This study looks at vaccine efficacy against infection, among 12-15y olds in Israel, in Jul-

Aug 2021. This short period does not account for waning vaccine efficacy, which has been shown in the more recent New York study of children and adolescents: https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full.pdfhttps://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full.pdf Just 7 weeks after vaccination, vaccine efficacy against infection is in the 18-65% range among 12-17y olds, and even negative efficacy among 5-11y old. Negative efficacy means that risk of infection is higher among vaccinated compared to the unvaccinated. (2) This study also does not consider immunity already acquired through natural exposure, which is the case for most Indian children as of now.

34. Study published in medRxiv Journal on Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant. (page 745-753 of compilation) - This publication supports the petitioner's plea against childrens vaccination. Vaccine efficacy wanes with time. While 90% efficacy was claimed in late Oct 2021, at the time of FDA approval of Covid jabs for 5-11y olds, the same fell to even negative efficacy among 5-11y old after just 7 weeks.

35. Safety and efficacy of Covid Vaccination in children and adolescents published in Journal of Infection. (page 754-756 of compilation) - This cites several studies of vaccine efficacy against infection, among children. As stated above, this efficacy wanes with time. The higher all-cause mortality among

vaccinated UK children (detailed above) needs serious investigation.

36. Conclusion - (1) It is telling that GoI has not cited a single scientific reference for why unvaccinated people are "a danger to society" as is being made out in the various states' vaccine mandate diktats. (2) It is also telling that GoI has not cited a single scientific reference for why immunity from natural exposure (which most Indians have at this time) is insufficient or to counter the scientific claim that natural immunity is longer lasting and more robust than vaccine induced immunity. (3) Most of the cited vaccine data/studies are for vaccines other than Covaxin. It is telling that GoI should cite various studies on other vaccines, rather than Covaxin, which is what is used for children in India exclusively at this time. Why is there no proper data even after vaccinating lakhs of children over the last 2 months across India? (4) Why is the AEFI rate in India about 80 times less than in Europe, for the same vaccine? This reflects lack of seriousness in AEFI data collection on part of GoI and various states.

Rejoinder to Summary of Articles filed by the State of Tamil Nadu

37. The Articles that have been filed by the State of Tamil Nadu do not in any manner provide a scientific and public health rationale to support vaccine mandates. The articles (some of which are position papers by WHO or statements issued by

UNICEF, etc) at best are advisories that vaccines may prevent serious illness or death, which fact has been acknowledged by the petitioner. However they do not address the issue of the vaccinated getting infected and also transmitting the disease. That the vaccines do not protect from infection nor do they prevent the vaccinated from transmitting the diseases has been shown by the petitioner through various scientific studies published in reputed peer reviewed scientific journals. This has also become the basis for various countries (such as New Zealand, UK , etc) discarding any sort of vaccine mandates even for frontline health workers. That vaccines do not prevent infection or transmission for Covid-19 and are not effective in preventing against infection from the new variants, the clinical trials in relation to the vaccines have not been completed and the vaccines are only authorized for emergency use and further serious adverse events are being reported in India and globally from the Covid 19 vaccinations - forms the basis of the petitioners arguments that any mandates for these vaccines are not only against scientific caution, cannot be issued in public interest and are also against an individual's right to free and complete informed consent and the right to self determination.

38. **Article (Annexure 3)** on herd immunity. It is important to note that herd immunity can only be provided by a vaccine if it prevents person to person spread (which is not the case with the COVID vaccines). Contrary to what has been stated by the State of Tamil Nadu, the article does not claim that COVID vaccines

result in herd immunity . Therefore the article is used out of context by the State of Tamil Nadu.

Further it has been now established through serological surveys that more than 80% of the population in India has had the infection and is therefore sero-positive. Therefore the population has achieved herd immunity due to the immunity acquired from the natural infection.

39. **Annexure 4, Annexure 5** on higher rate of hospitalisation and deaths among unvaccinated in the studies – The petitioner has pointed out that the vaccines may reduce serious illness but this report does not provide any information or data on the vaccinated also transmitting the disease. Since the vaccinated are as likely to get infected and transmit the disease as the unvaccinated, and the vaccine at best protects them from serious illness, the unvaccinated do not pose any greater danger of spreading the infection than the vaccinated. Even if the vaccine reduces susceptibility to severe disease or death, without significantly reducing transmission, it is not a public health issue and every individual must be left free to determine the cost benefit of the risks to oneself due to Covid versus the risk of adverse events (short and long term, known and unknown). Furthermore, the studies cited by the TN govt are irrelevant in India at this time for two main reasons:

a) As serological surveys have shown, most Indians have immunity via natural exposure at this time, and such immunity is known (and also shown) to be much stronger than immunity induced by the current Covid vaccines.

b) The newest variant Omicron has been shown to be much milder than earlier variants, in various studies and is associated with reduced risks of hospitalisations.

40. **Annexure 6 –** on mutation of viruses – It is important to note that Healthline where this article is published is not peer reviewed scientific literature. The correct science regarding mutation of viruses is that during a pandemic, the vaccine puts pressure on viruses to mutate and evolve new vaccine resistant strains. The claims of the State of Tamil Nadu that the unvaccinated will lead to the rise of new strains of the virus is therefore a bald claim without any scientific backing. To the contrary the petitioner has relied on the advise of medical scientists, including doctors from AIIMS and those in the national expert committee on Covid who have warned against indiscriminate vaccination and that the vaccines themselves could be giving rise to the more infectious variants of COVID *(Written submissions compilation* ***Annexure 17***

41. **Annexure 7, Annexure 8, Annexure 10 –** The studies cited by the State of Tamil Nadu only support supports the claims of the petitioner that while vaccination may be effective in reducing the risk of hopistalisation and serious disease, it has waning protection against infection over time due to declining vaccine immunity and the emergence of the delta variant. Therefore the reliance on repeated booster doses as pointed out by these studies due to waning vaccine immunity. They suggest the need for boosters with another more expensive vaccine (Pfizer) which

is not even being used and available in India. Since these studies demonstrate that vaccine immunity wanes rapidly, the vaccines are not effective against mutant strains and therefore there is no rationale in mandating these vaccines.

42. ***Annexure 9*** **–** The study quoted by the State of Tamil Nadu concludes that vaccines are protective against COVID related disease in real world settings. However the case of the petitioner in not mandating vaccines relies on the transmission of the disease despite vaccination and not the ability of the vaccine to decrease severe illness.

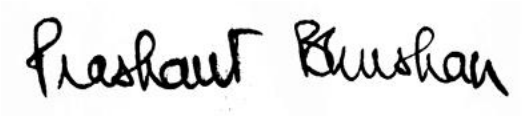
43. **Annexure 11 –** The study again supports the claims of the petitioner by concluding that two doses of the vaccine were associated with only short term protection which waned after 6 months. Therefore the need for booster vaccine doses.

44. **Annexure 12 –** Citing such a paper on the declining vaccination perceptions and attitudes among the public in the United States is a complete absurdity. This paper in fact suggests that trust in vaccinations has decreased in the United States due to the exposure of **t**he population to the correct and more scientific narrative through media platforms that is now emerging. The paper suggests that hesitancy is more among the Republicans in the United States but its relevance to India is difficult to understand.

Conclusion: The state of Tamil Nadu has not been able to counter any of the studies cited by the petitioner that natural

immunity acquired from COVID infection is more robust and long lasting that vaccine acquired immunity, that vaccines do not prevent infection and spread of the disease and they have not responded to any of the information provided by the petitioner on the serious short and potential long term side effects of the COVID vaccines, that make mandating such vaccines illegal and against scientific caution.

THROUGH:



(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER

NEW DELHI
DATED: 14.03.2022

November 2, 2021
Capitol Hill
Washington DC

Thank you for the invitation. My name is Aditi Bhargava. I am a Professor at UCSF and a molecular biologist with 33 years of research experience. The views expressed do not represent those of UCSF. We are here today to discuss whether it is ethical to mandate vaccines.

COVID-19 vaccines are often compared to polio vaccines. This is apples to oranges comparison because RNA and DNA viruses are fundamentally different. Most DNA viruses mutate at a very slow rate. DNA virus induces life-long immunity. After a natural infection with DNA virus such as the chickenpox, no one needs to be vaccinated or develops the disease in their lifetime.

In contrast, some respiratory RNA viruses mutate frequently and do not induce life-long immunity, as we have seen with SARS-CoV-2 or flu viruses. One can have influenza multiple times in their lives been vaccines or no vaccines. Flu has not been eradicated, nor is there any talk to eradicate it. There is no herd immunity for flu. It is simply not an achievable goal.

Safety issues with vaccines happen, despite best of intentions. There are no drugs without side effects. Unlike other drug trials, vaccine trials are a different as they are tested on a largely healthy population to prevent infection. For example, measles and rotavirus vaccines have been recalled due to safety concerns, despite stringent clinical trials and years of data. Rotavirus vaccine caused 1 death per 20,000 and that was 1 too many.

[Next slide please] Good vaccines are modeled to mimic natural infection and rely on one's own immune system to produce antibodies and provide protection. Natural immunity is the gold standard. CDC estimates that ~43% of the country is already infected with SARS-CoV-2 and thus naturally immune—and that was all before the more transmissible Delta variant took hold.

Living in a bubble or sterile conditions is counterproductive to everything we know about strengthening the immune system—it's Immunology 101. To downplay the beneficial and protective power of our immune systems goes against the founding principles of immunology; several studies about SARS-CoV-2 are validating that knowledge. There is no documented case of a naturally immune person getting reinfected with severe disease or hospitalized, despite the first case reported nearly 2 years ago. In sharp contrast, there are thousands of cases of severe COVID, hospitalization, and deaths in fully vaccinated people.

CDC now estimates 90% of Americans over the age of 16 have antibodies against SARS-CoV-2. But vaccine-induced antibodies are only a small fraction of immune responses. New studies from the British Health Ministry suggests that COVID vaccines might interfere with the ability of our immune system to produce antibodies against other parts of the virus, crucial aspect for developing cross protection. Thus, spike antibodies are incomplete and cherry-picked story. Vaccine-induced protection fell to 33-42% within 3 months- no different from the unvaccinated. Hence mandates to prevent spread by using spike antibody levels as a gold standard is gross misrepresentation of data.

[Next slide please] It should not have taken the Massachusetts breakthrough infections in the summer to discover that that fully vaccinated people are just as vulnerable to being infected and transmit SARS-CoV-2 as the unvaccinated. Had the trials been stringent, had Phase 2/3 stuck to the protocol of follow-ups, had the regulators enforced manufacturers to study prevention of infection in their clinical trials, this fiasco could have been avoided. Instead, manufacturers configured these trials to study the prevention of mild symptoms and used preclinical models, such as the rhesus monkeys, in whom the virus does not cause disease. If all we can do is to prevent symptoms and severe disease, we should be talking about drugs to treat COVID, not vaccines and mandates.

We lost the opportunity of discovering these major shortcomings by torpedoing the clinical trials when placebo groups were eliminated just 2 months after the 2nd dose. Instead, we are learning through trial and error on hundreds of millions of people. And we ***insist*** on eliminating a VERY important control group by these vaccine mandates. There is no scientific study or experimental design in which we can learn anything of value without a control group, certainly not about safety and efficacy.

Persistent high levels of antibodies often indicate pathology to the body's immune system. That is the basis of auto-immune diseases. Hence booster's long-term adverse events should be weighed seriously.

The notion that we are in an emergency, nearly 2 years after the pandemic and that should justify cutting corners or taking shortcuts, is simple wrong. Trust in scientific methods is at stake.

[Next slide please] Media Reports often state that "the Science is Clear." But scientific publications DO NOT claim that the science is clear. And as you have heard from various testimonies, real people suffered serious adverse events and perhaps life-long disability due to sloppy trials.

I will conclude by asking you, if the vaccines don't prevent infection and transmission, surely mandating person A to protect person B is pointless. But if the vaccines are effective in preventing infection, transmission, decreasing symptoms, hospitalization rates, and death—then what do the vaccinated FEAR?

Prashant Bhushan
(TRUE COPY)

ANNEXURE RN: 2

‘Paramount importance’: Judge orders FDA to hasten release of Pfizer vaccine docs

Jenna Greene | reuters.com | January 07, 2022

Jan 7 - Score one for transparency.

A federal judge in Texas on Thursday ordered the Food and Drug Administration to make public the data it relied on to license Pfizer’s COVID-19 vaccine, imposing a dramatically accelerated schedule that should result in the release of all information within about eight months.

That’s roughly 75 years and four months faster than the FDA said it could take to complete a Freedom of Information Act request by a group of doctors and scientists seeking an estimated 450,000 pages of material about the vaccine.

The court “concludes that this FOIA request is of paramount public importance,” wrote U.S. District Judge Mark Pittman in Fort Worth, who was appointed to the bench by former President Donald Trump in 2019.

The FDA didn’t dispute it had an obligation to make the information public but argued that its short-staffed FOIA office only had the bandwidth to review and release 500 pages a month.

While Pittman recognized “the ‘unduly burdensome’ challenges that this FOIA request may present to the FDA,” in his four-page order, he resoundingly rejected the agency’s suggested schedule.

Rather than producing 500 pages a month — the FDA's proposed timeline — he ordered the agency to turn over 55,000 a month. That means all the Pfizer vaccine data should be public by the end of the summer rather than, say, the year 2097.

Even if the FDA may not see it this way, I think Pittman did the agency — and the country — a big favor by expediting the document production.

I've been chronicling this fight since November and have heard from of readers who said they felt something was suspicious, even nefarious, in the FDA's proposed slo-mo timeline. Making the information public as soon as possible may help assuage the concerns of vaccine skeptics and convince them the product is safe.

Pittman in his order nodded to this as well, including a quote from the late senator John McCain, who said that excessive administrative secrecy "feeds conspiracy theories and reduces the public's confidence in the government."

Still, the FDA is likely to be hard-pressed to process 55,000 pages a month. The office that reviews FOIA requests has just 10 employees, according to a declaration filed with the court by Suzann Burk, who heads the FDA's Division of Disclosure and Oversight Management. Burk said it takes eight minutes a page for a worker "to perform a careful line-by-line, word-by-word review of all responsive records before producing them in response to a FOIA request."

At that rate, the 10 employees would have to work non-stop 24 hours a day, seven days a week to produce the 55,000 pages a month (and would still fall a bit short).

But as lawyers for the plaintiffs Public Health and Medical Professionals for Transparency pointed out in court papers, the FDA as of 2020 had 18,062 employees. Surely some can be dispatched to pitch in at the FOIA office.

Aaron Siri of Siri & Glimstad, who represents the plaintiffs, in an email said the decision "came down on the side of transparency and accountability."

His clients — a group that includes more than 200 doctors, scientists, professors and public health professionals, including some who have publicly questioned the efficacy of lockdown policies, mask mandates and the vaccine itself — have pledged to publish all the information they receive from the FDA on their website.

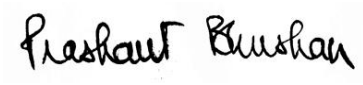
The Justice Department, which represented the FDA in the litigation, did not immediately respond to a request for comment on Thursday evening. Pfizer, not a party to the suit, also did not immediately respond to a request for comment.

Pittman in his order made clear that the FOIA request, even if burdensome, has to be a priority for the FDA.

Quoting from remarks made during the hearing before him on December 14, he wrote that "there may not be a 'more important issue at the Food and Drug Administration . . . than the pandemic, the Pfizer vaccine, getting

every American vaccinated," and assuring the public that the vaccine was not "'rush[ed] on behalf of the United States.'"

Source:
https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer-vaccine-docs-2022-01-07/



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ANNEXURE: RN3

COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May–November 2021

Tomás M. León, PhD; Vajeera Dorabawila, PhD; Lauren Nelson, MPH; Emily Lutterloh, MD; Ursula E. Bauer, PhD; Bryon Backenson, MPH; Mary T. Bassett, MD; Hannah Henry, MPH; Brooke Bregman, MPH; Claire M. Midgley, PhD; Jennifer F. Myers, MPH; Ian D. Plumb, MBBS; Heather E. Reese, PhD; Rui Zhao, MPH; Melissa Briggs-Hagen, MD; Dina Hoefer, PhD; James P. Watt, MD; Benjamin J. Silk, PhD; Seema Jain, MD; Eli S. Rosenberg, PhD | Centre for Disease Control and Prevention | January 28, 2022

Summary

What is already known about this topic?

Data are limited regarding the risks for SARS-CoV-2 infection and hospitalization after COVID-19 vaccination and previous infection.

What is added by this report?

During May–November 2021, case and hospitalization rates were highest among persons who were unvaccinated without a previous diagnosis. Before Delta became the predominant variant in June, case rates were higher among persons who survived a previous infection than persons who were vaccinated alone. By early October, persons who survived a previous infection had lower case rates than persons who were vaccinated alone.

What are the implications for public health practice?

Although the epidemiology of COVID-19 might change as new variants emerge, vaccination remains the safest strategy for averting future SARS-CoV-2 infections, hospitalizations, long-term sequelae, and death. Primary vaccination, additional doses, and booster doses are recommended for all eligible persons. Additional future recommendations for vaccine doses might be warranted as the virus and immunity levels change.

By November 30, 2021, approximately 130,781 COVID-19–associated deaths, one in six of all U.S. deaths from COVID-19, had occurred in California and New York.* COVID-19 vaccination protects against infection with SARS-CoV-2 (the virus that causes COVID-19), associated severe illness, and death (*1*,*2*); among those who survive, previous SARS-CoV-2 infection also confers protection against severe outcomes in the event of reinfection (*3*,*4*). The relative magnitude and duration of infection- and vaccine-derived protection, alone and together, can guide public health planning and epidemic forecasting. To examine the impact of primary COVID-19 vaccination and previous SARS-CoV-2 infection on COVID-19 incidence and hospitalization rates, statewide testing, surveillance, and COVID-19 immunization data from California and New York (which account for 18% of the U.S. population) were analyzed. Four cohorts of adults aged ≥18 years were considered: persons who were 1) unvaccinated with no previous laboratory-confirmed COVID-19 diagnosis, 2) vaccinated (14 days after completion of a primary COVID-19 vaccination series) with no previous

COVID-19 diagnosis, 3) unvaccinated with a previous COVID-19 diagnosis, and 4) vaccinated with a previous COVID-19 diagnosis. Age-adjusted hazard rates of incident laboratory-confirmed COVID-19 cases in both states were compared among cohorts, and in California, hospitalizations during May 30–November 20, 2021, were also compared. During the study period, COVID-19 incidence in both states was highest among unvaccinated persons without a previous COVID-19 diagnosis compared with that among the other three groups. During the week beginning May 30, 2021, compared with COVID-19 case rates among unvaccinated persons without a previous COVID-19 diagnosis, COVID-19 case rates were 19.9-fold (California) and 18.4-fold (New York) lower among vaccinated persons without a previous diagnosis; 7.2-fold (California) and 9.9-fold lower (New York) among unvaccinated persons with a previous COVID-19 diagnosis; and 9.6-fold (California) and 8.5-fold lower (New York) among vaccinated persons with a previous COVID-19 diagnosis. During the same period, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates in California followed a similar pattern. These relationships changed after the SARS-CoV-2 Delta variant became predominant (i.e., accounted for >50% of sequenced isolates) in late June and July. By the week beginning October 3, compared with COVID-19 cases rates among unvaccinated persons without a previous COVID-19 diagnosis, case rates among vaccinated persons without a previous COVID-19 diagnosis were 6.2-fold (California) and 4.5-fold (New York) lower; rates were substantially lower among both groups with previous COVID-19 diagnoses, including 29.0-fold (California) and 14.7-fold lower (New York) among

unvaccinated persons with a previous diagnosis, and 32.5-fold (California) and 19.8-fold lower (New York) among vaccinated persons with a previous diagnosis of COVID-19. During the same period, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates in California followed a similar pattern. These results demonstrate that vaccination protects against COVID-19 and related hospitalization, and that surviving a previous infection protects against a reinfection and related hospitalization. Importantly, infection-derived protection was higher after the Delta variant became predominant, a time when vaccine-induced immunity for many persons declined because of immune evasion and immunologic waning (*2*,*5*,*6*). Similar cohort data accounting for booster doses needs to be assessed, as new variants, including Omicron, circulate. Although the epidemiology of COVID-19 might change with the emergence of new variants, vaccination remains the safest strategy to prevent SARS-CoV-2 infections and associated complications; all eligible persons should be up to date with COVID-19 vaccination. Additional recommendations for vaccine doses might be warranted in the future as the virus and immunity levels change.

Four cohorts of persons aged ≥18 years were assembled via linkages of records from electronic laboratory reporting databases and state-specific immunization information systems.† Persons were classified based on whether they had had a laboratory-confirmed SARS-CoV-2 infection by March 1, 2021 (i.e., previous COVID-19 diagnosis)§; had received at least the primary COVID-19 vaccination series¶ by May 16, 2021; had a previous COVID-19 diagnosis and were fully vaccinated**; or had neither received a

previous COVID-19 diagnosis by March 1 nor received a first COVID-19 vaccine dose by the end of the analysis period. The size of the unvaccinated group without a previous diagnosis was derived by subtracting the observed groups from U.S. Census estimates.†† To maintain each defined cohort, persons who received a COVID-19 diagnosis during March 1–May 30, 2021, or who died before May 30, 2021, were excluded (to maintain eligibility for incident cases for all cohorts on May 30, 2021),§§ as were persons who received a first vaccine dose during May 30–November 20, 2021. During May 30–November 20, 2021, incident cases were defined using a positive nucleic acid amplification test (NAAT) result from the California COVID-19 Reporting System (CCRS) or a positive NAAT or antigen test result from the New York Electronic Clinical Laboratory Reporting System. In California, person-level hospitalization data from CCRS and supplementary hospitalization reports were used to identify COVID-19–associated hospitalizations. A lifetable method was used to calculate hazard rates (average daily cases during a 7-day interval or hospitalizations over a 14-day interval), hazard ratios, and 95% CIs for each cohort. Rates were age-adjusted to 2000 U.S. Census data using direct standardization.¶¶ Supplementary analyses stratified case rates by timing of previous diagnoses and primary series vaccine product. SAS (version 9.4; SAS Institute) and R (version 4.0.4; The R Foundation) were used to conduct all analyses. Institutional review boards (IRBs) in both states determined this surveillance activity to be necessary for public health work, and therefore, it did not require IRB review.

Approximately three quarters of adults from California (71.2%) and New York (72.2%) included in this analysis were vaccinated and did not have a

previous COVID-19 diagnosis; however, 18.0% of California residents and 18.4% of New York residents were unvaccinated with no previous COVID-19 diagnosis (Table 1). In both states, 4.5% of persons were vaccinated and had a previous COVID-19 diagnosis; 6.3% in California and 4.9% in New York were unvaccinated with a previous diagnosis. Among 1,108,600 incident COVID-19 cases in these cohorts (752,781 in California and 355,819 in New York), the median intervals from vaccination or previous COVID-19 diagnosis to incident diagnosis were slightly shorter in California (138–150 days) than in New York (162–171 days).

Before the Delta variant became predominant in each state's U.S. Department of Health and Human Services region (June 26 in Region 9 [California] and July 3 in Region 2 [New York]),*** the highest incidence was among unvaccinated persons without a previous COVID-19 diagnosis; during this time, case rates were relatively low among the three groups with either previous infection or vaccination and were lowest among vaccinated persons without a previous COVID-19 diagnosis (Supplementary Figure 1, https://stacks.cdc.gov/view/cdc/113253) (Supplementary Figure 2, https://stacks.cdc.gov/view/cdc/113253). During the week beginning May 30, 2021, compared with COVID-19 case rates among unvaccinated persons without a previous COVID-19 diagnosis, COVID-19 case rates were 19.9-fold (California) and 18.4-fold (New York) lower among vaccinated persons without a previous diagnosis; rates were 7.2-fold (California) and 9.9-fold (New York) lower among unvaccinated persons with a previous COVID-19 diagnosis and 9.6-fold (California) and 8.5-fold (New York) lower among vaccinated persons with a previous COVID-19 diagnosis (Table 2).

As the Delta variant prevalence increased to >95% (97% in Region 9 and 98% in Region 2 on August 1), rates increased more rapidly among the vaccinated group with no previous COVID-19 diagnosis than among both the vaccinated and unvaccinated groups with a previous COVID-19 diagnosis (Supplementary Figure 1, https://stacks.cdc.gov/view/cdc/113253) (Supplementary Figure 2, https://stacks.cdc.gov/view/cdc/113253). For example, during the week of October 3, compared with rates among unvaccinated persons without a previous COVID-19 diagnosis, rates among vaccinated persons without a previous diagnosis were 6.2-fold lower (95% CI = 6.0–6.4) in California and 4.5-fold lower (95% CI = 4.3–4.7) in New York (Table 2). Further, rates among unvaccinated persons with a previous COVID-19 diagnosis were 29-fold lower (95% CI = 25.0–33.1) than rates among unvaccinated persons without a previous COVID-19 diagnosis in California and 14.7-fold lower (95% CI = 12.6–16.9) in New York. Rates among vaccinated persons who had had COVID-19 were 32.5-fold lower (95% CI = 27.5–37.6) than rates among unvaccinated persons without a previous COVID-19 diagnosis in California and 19.8-fold lower (95% CI = 16.2–23.5) in New York. Rates among vaccinated persons without a previous COVID-19 diagnosis were consistently higher than rates among unvaccinated persons with a history of COVID-19 (3.1-fold higher [95% CI = 2.6–3.7] in California and 1.9-fold higher [95% CI = 1.5–2.3] in New York) and rates among vaccinated persons with a history of COVID-19 (3.6-fold higher [95% CI = 2.9–4.3] in California and 2.8-fold higher [95% CI = 2.1–3.4] in New York).

COVID-19 hospitalization rates in California were always highest among unvaccinated persons without a previous COVID-19 diagnosis (Table 2) (Figure). In the pre-Delta period during June 13–June 26, for example, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates were 27.7-fold lower (95% CI = 22.4–33.0) among vaccinated persons without a previous COVID-19 diagnosis, 6.0-fold lower (95% CI = 3.3–8.7) among unvaccinated persons with a previous COVID-19 diagnosis, and 7.1-fold lower (95% CI = 4.0–10.3) among vaccinated persons with a previous COVID-19 diagnosis. However, this pattern also shifted as the Delta variant became predominant. During October 3–16, compared with hospitalization rates among unvaccinated persons without a previous COVID-19 diagnosis, hospitalization rates were 19.8-fold lower (95% CI = 18.2–21.4) among vaccinated persons without a previous COVID-19 diagnosis, 55.3-fold lower (95% CI = 27.3–83.3) among unvaccinated persons with a previous COVID-19 diagnosis, and 57.5-fold lower (95% CI = 29.2–85.8) among vaccinated persons with a previous COVID-19 diagnosis.

Among the two cohorts with a previous COVID-19 diagnosis, no consistent incidence gradient by time since the previous diagnosis was observed (Supplementary Figure 3, https://stacks.cdc.gov/view/cdc/113253). When the vaccinated cohorts were stratified by the vaccine product received, among vaccinated persons without a previous COVID-19 diagnosis, the highest incidences were observed among persons receiving the Janssen (Johnson & Johnson), followed by Pfizer-BioNTech, then Moderna vaccines (Supplementary Figure 4, https://stacks.cdc.gov/view/cdc/113253). No

pattern by product was observed among vaccinated persons with a previous COVID-19 diagnosis.

Discussion

This analysis integrated laboratory testing, hospitalization surveillance, and immunization registry data in two large states during May–November 2021, before widespread circulation of the SARS-CoV-2 Omicron variant and before most persons had received additional or booster COVID-19 vaccine doses to protect against waning immunity. Rate estimates from the analysis describe different experiences stratified by COVID-19 vaccination status and previous COVID-19 diagnosis and during times when different SARS-CoV-2 variants predominated. Case rates were initially lowest among vaccinated persons without a previous COVID-19 diagnosis; however, after emergence of the Delta variant and over the course of time, incidence increased sharply in this group, but only slightly among both vaccinated and unvaccinated persons with previously diagnosed COVID-19 (*6*). Across the entire study period, persons with vaccine- and infection-derived immunity had much lower rates of hospitalization compared with those in unvaccinated persons. These results suggest that vaccination protects against COVID-19 and related hospitalization and that surviving a previous infection protects against a reinfection. Importantly, infection-derived protection was greater after the highly transmissible Delta variant became predominant, coinciding with early declining of vaccine-induced immunity in many persons (*5*). Similar data accounting for booster doses and as new variants, including Omicron, circulate will need to be assessed.

The understanding and epidemiology of COVID-19 has shifted substantially over time with the emergence and circulation of new SARS-CoV-2 variants, introduction of vaccines, and changing immunity as a result. Similar to the early period of this study, two previous U.S. studies found more protection from vaccination than from previous infection during periods before Delta predominance (*3*,*7*). As was observed in the present study after July, recent international studies have also demonstrated increased protection in persons with previous infection, with or without vaccination, relative to vaccination alone†††, §§§ (*4*). This might be due to differential stimulation of the immune response by either exposure type.¶¶¶ Whereas French and Israeli population-based studies noted waning protection from previous infection, this was not apparent in the results from this or other large U.K. and U.S. studies**** (*4*,*8*). Further studies are needed to establish duration of protection from previous infection by variant type, severity, and symptomatology, including for the Omicron variant.

The findings in this report are subject to at least seven limitations. First, analyses were not stratified by time since vaccine receipt, but only by time since previous diagnosis, although earlier studies have examined waning of vaccine-induced immunity (Supplementary Figure 3, https://stacks.cdc.gov/view/cdc/113253) (*2*). Second, persons with undiagnosed infection are misclassified as having no previous COVID-19 diagnosis; however, this misclassification likely results in a conservative bias (i.e., the magnitude of difference in rates would be even larger if misclassified persons were not included among unvaccinated persons without a previous COVID-19 diagnosis). California seroprevalence data

during this period indicate that the ratio of actual (presumptive) infections to diagnosed cases among adults was 2.6 (95% CI = 2.2–2.9).†††† Further, California only included NAAT results, whereas New York included both NAAT and antigen test results. However, antigen testing made up a smaller percentage of overall testing volume reported in California (7% of cases) compared with New York (25% of cases) during the study period. Neither state included self-tests, which are not easily reportable to public health. State-specific hazard ratios were generally comparable, although differences in rates among unvaccinated persons with a previous COVID-19 diagnosis were noteworthy. Third, potential exists for bias related to unmeasured confounding (e.g., behavioral or geographic differences in exposure risk) and uncertainty in the population size of the unvaccinated group without a previous COVID-19 diagnosis. Persons might be more or less likely to receive testing based on previous diagnosis or vaccination status; however, different trajectories between vaccinated persons with and without a previous COVID-19 diagnosis, and similar findings for cases and hospitalizations, suggest that these biases were minimal. Fourth, this analysis did not include information on the severity of initial infection and does not account for the full range of morbidity and mortality represented by the groups with previous infections. Fifth, this analysis did not ascertain receipt of additional or booster COVID-19 vaccine doses and was conducted before many persons were eligible or had received additional or booster vaccine doses, which have been shown to confer additional protection.§§§§ Sixth, some estimates lacked precision because of sample size limitations. Finally, this analysis was conducted before the emergence of the Omicron variant, for which vaccine or infection-

derived immunity might be diminished.¶¶¶¶ This study offers a surveillance data framework to help evaluate both infections in vaccinated persons and reinfections as new variants continue to emerge.

Vaccination protected against COVID-19 and related hospitalization, and surviving a previous infection protected against a reinfection and related hospitalization during periods of predominantly Alpha and Delta variant transmission, before the emergence of Omicron; evidence suggests decreased protection from both vaccine- and infection-induced immunity against Omicron infections, although additional protection with widespread receipt of booster COVID-19 vaccine doses is expected. Initial infection among unvaccinated persons increases risk for serious illness, hospitalization, long-term sequelae, and death; by November 30, 2021, approximately 130,781 residents of California and New York had died from COVID-19. Thus, vaccination remains the safest and primary strategy to prevent SARS-CoV-2 infections, associated complications, and onward transmission. Primary COVID-19 vaccination, additional doses, and booster doses are recommended by CDC's Advisory Committee on Immunization Practices to ensure that all eligible persons are up to date with COVID-19 vaccination, which provides the most robust protection against initial infection, severe illness, hospitalization, long-term sequelae, and death.***** Additional recommendations for vaccine doses might be warranted in the future as the virus and immunity levels change.

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Corresponding author: Tomás M. León, tomas.leon@cdph.ca.gov.

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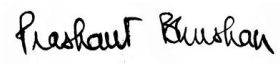

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