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

FILING INDEX

S. NO.	PARTICULARS	COPIES	C. FEE
1.	REJOINDER AFFIDAVIT ON BEHALF OF THE PETITIONER TO THE COUNTER AFFIDAVIT FILED BY RESPONDENT NO. 1 & 2.	1	**20/-**
2.	ANNEXURE R1 TO ANNEXURE R11	1	**NIL**

(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER
301, NEW LAWYERS CHAMBER
SUPREME COURT OF INDIA
NEW DELHI-110 001
CODE NO. 515
E-Mail: prashantbhush@gmail.com
Mobile No.: 9811164068

NEW DELHI
DATED: 10.12.2021

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

PAPER-BOOK

(FOR INDEX KINDLY SEE INSIDE)

(REJOINDER AFFIDAVIT ON BEHALF OF THE PETITIONER)

COUNSEL FOR THE PETITIONER: **PRASHANT BHUSHAN**

INDEX

7.	**Annexure-R6:** A copy of the Business Standard article dated 29th July 2021 titled, "Madhya Pradesh has highest Covid-19 antibodies, Sero Survey data shows" and available at https:// www.business-standard.com/article /news-ani/ conduct-sero-surveys-to-generate-district-level-data-centre-to-states-uts-121072801503_1.html	41-42
8.	**Annexure-R7:** A copy of the report in the British Medical Journal titled "Evidence is insufficient to back mandatory NHS staff vaccination, says House of Lords committee", dated 3rd December 2021	43-45
9.	**Annexure-R8:** A copy of the Order dated 3rd December 2021 in N Re: MCP No. 165, Occupational Safety and Health Administration Rule on Covid-19 Vaccine And Testing, 86 Fed. Reg. 61402 No. 21-7000	46-49
10.	**Annexure-R9:** A copy of the report in the dailytelegraph dated 5th December 2021 titled, "Pfizer document concedes that there is a large increase in types of adverse event reaction to its vaccine	50-61
11.	**Annexure-R10:** A copy of the report in the British Medical Journal dated 2nd November 2021	62-69
12.	**Annexure-R11:** A copy of the RTI request (RTI Ref. No. MOHFW/R/E/21/04550) dated 19.07.2021, the Reply of the aforementioned RTI by the Central Drugs Standard Control Organisation (Register No. CDSCO/R/T/21 /00650) dated 03.09.2021, RTI Appeal (Registration number CDSCO/A/E/21/ 00120) and the final reply dated 29.11.2021	70-74

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

REJOINDER AFFIDAVIT ON BEHALF OF THE PETITIONER TO THE COUNTER AFFIDAVIT FILED BY RESPONDENT NO. 1 AND RESPONDENT NO. 2

I, Dr. Jacob Puliyel, S/o Late Mr. P M Mammen, r/o 6A, 7 Raj Narayan Marg, Delhi – 110054, do hereby solemnly affirm and state on oath as under:

1. That I am the Petitioner in the aforementioned writ petition and being familiar with the facts and circumstances of the case, I am competent and authorized to swear this Affidavit.

2. That I have read and understood the contents of the counter affidavit under reply. At the outset, it is submitted that the Petitioner is not giving a Para wise reply and therefore, the contents of the counter affidavit are denied except what is specifically admitted herein below.

3. That the Petitioner is filing the rejoinder affidavit to the counter affidavit filed by Respondents, wherein it has been expressly

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

stated that the respondents have perused relevant records and material with respect to the subject matter of the petition, which includes not only the Writ Petition but also the additional affidavits on behalf of the Petitioner. It may be stated at the outset that the contentions in the counter affidavit are vague and generalized with no bearing on the prayers that the petitioner seeks mainly, 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.

Mandating the use of vaccines

4. 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 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.

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

5. Through earlier affidavits the petitioner has brought on record some important aspects for the consideration of this Hon'ble

Court, mainly regarding the scientific evidence that has emerged regarding natural immunity which is long lasting and robust as compared to vaccine immunity, that vaccines do not prevent infection or transmission for Covid-19 and are not effective in preventing against infection from the new variants, that the clinical trials in relation to the vaccines have not been completed and the vaccines are only authorized for emergency use and further that serious adverse events are being reported in India and globally from the Covid 19 vaccinations. In light of this, any mandates for these vaccines are not only against scientific caution, cannot be in issued in public interest and are also against an individual's right to free and complete informed consent and the right to self determination.

6. Further, for any vaccine to be recommended universally in public interest, the public health rationale underlying such a policy must be based essentially on efficacy and safety of vaccination and transmission of the disease. However as detailed in earlier affidavits, various scientific studies have now emerged that provide evidence that vaccinated people not just transmit the virus as much as unvaccinated but also that breakthrough infections and hospitalizations are now rampant across various countries in vaccinated populations. The vaccination is therefore not preventing against disease nor its transmission and therefore no public interest purpose is served by mandating the vaccine. The State in mandating such vaccines has clearly exceeded the wide margin of appreciation to be granted by the court since relevant medical literature and studies do not signify either

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

efficacy of the vaccines in preventing or transmitting the disease. It is only claimed vaguely that the severity of the disease may be ameliorated in some instances. Such mandates are arbitrary and discriminatory and therefore an unconstitutional infringement of a citizens fundamental rights. Various High Court such as Meghalaya and Guwahati High Courts have noted these scientific developments and have struck down the mandates as unconstitutional.

Serological Surveys indicate a large number of people already have antibodies to COVID-19

7. An Indian Express article dated 26th July 2021 and titled "2 of 3 Indians have Covid-19 antibodies: ICMR serosurvey findings explained" reports that two-thirds of the general population above the age of 6 years had COVID-19 antibodies and that more than half of the children were sero-positive:

> "..Two-third of Indians above the age of 6 had SARS-CoV-2 antibodies, show findings of the fourth nationwide serological survey conducted by the Indian Council of Medical Research (ICMR) in June-July...
>
> ..The survey findings shows that more than half of the children (6 -17 years) were seropositive. It means they have been exposed to Covid-19 in the past months. The sero-prevalence among children was 57.2 per cent in the age group 6-9 years and 61.6 per cent in the age group 10-17 years..."

(A copy of the Indian Express article dated 26th July 2021 and titled "2 of 3 Indians have Covid-19 antibodies: ICMR serosurvey findings explained" has been annexed as **Annexure R1 (Page 28 to 30)**

8. A news report in the Indian Express dated 8th October 2021 reports that:

> "Tamil Nadu has witnessed an increase in the overall sero-prevalence among the people at 70 per cent, suggest the findings of a latest round of serosurvey by the state government.
>
> The Directorate of Public Health and Preventive Medicine on Thursday released the report of the 'state wide cross sectional Sero Survey', conducted in July-August across 827 clusters covering 24,586 samples."

(A copy of the Indian Express article dated 8th October 2021 titled, "Serosurvey finds 70 per cent in Tamil Nadu have anti-bodies against Covid-19" and available at https://indianexpress.com/article/cities/chennai/serosurvey-finds-70-per-cent-in-tn-have-anti-bodies-against-covid-19-7559335/ is Annexed as **Annexure R2 (Page 31 to 32)**

9. A news report titled "Delhi: 97% people have Covid -19 antibodies, shows sero survey" in the Indian Express Times reported that:

> "Delhi has a seropositivity of 97 per cent for Covid-19 antibodies, the sixth serological survey conducted in the city has revealed, Delhi Health Minister Satyendar Jain said

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

> Thursday. Every district has a seropositivity of above 95 per cent, he said.
>
> ...
>
> In children below the age of 18, the sero prevalence is 88 per cent, while it is 97 per cent to 98 per cent in adults."

(A copy of the Indian Express report dated 28th October 2021 titled "Delhi: 97% people have Covid -19 antibodies, shows sero survey", and available at https://indianexpress.com/article/cities/delhi/people-in-delhi-have-covid-19-antibodies-shows-sero-survey-7595390/ is Annexed as **Annexure R3 (Page 33 to 35)**

10. A news Report in the Hindu dated 25th September 2020 reported that:

> "One in every five persons in Puducherry district was infected with COVID-19 by August-end, the results of a JIPMER sero-survey have found."

(A copy of the Hindu article dated 25th September 2020 titled, "One in five in U.T. has COVID-19 antibodies: sero-survey" and available at https://www.thehindu.com/news/national/tamil-nadu/one-in-five-in-ut-has-covid-19-antibodies-sero-survey/article32689856.ece is Annexed as **Annexure R4 (Page 36 to 38)**

11. An article in the Business Standard titled "Madhya Pradesh has highest Covid-19 antibodies, Sero Survey data shows" reported that:

> "ICMR has conducted the recent National Sero-survey in 70 districts of India. The findings of this survey reveal that

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

Madhya Pradesh has the highest seroprevalence with 79 per cent, followed by Rajasthan with 76.2 per cent, Bihar with 75.9 per cent, Gujarat with 75.3 per cent, Chhattisgarh with 74.6 per cent and Uttarakhand with 73.1 per cent."

(A copy of the Business Standard article dated 29th July 2021 titled, "Madhya Pradesh has highest Covid-19 antibodies, Sero Survey data shows" and available at https://www.business-standard.com/article/news-ani/conduct-sero-surveys-to-generate-district-level-data-centre-to-states-uts-121072801503_1.html is Annexed as **Annexure R5 (Page 39 to 40)**

Vaccinated Population do not Reduce Sources of Transmission

12. In an Lancet article titled "The epidemiological relevance of the COVID-19-vaccinated population is increasing" and dated 19th November 2021, the author asserts that:

"High COVID-19 vaccination rates were expected to reduce transmission of SARS-CoV-2 in populations by reducing the number of possible sources for transmission and thereby to reduce the burden of COVID-19 disease. Recent data, however, indicate that the epidemiological relevance of COVID-19 vaccinated individuals is increasing. In the UK it was described that secondary attack rates among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% for vaccinated vs 23% for unvaccinated). 12 of 31 infections in fully vaccinated household contacts (39%) arose from fully vaccinated epidemiologically linked index cases. Peak viral load did not differ by vaccination

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

status or variant type [1]....The US Centres for Disease Control and Prevention (CDC) identifies four of the top five counties with the highest percentage of fully vaccinated population (99.9–84.3%) as "high" transmission counties [[5]]. Many decision makers assume that the vaccinated can be excluded as a source of transmission. It appears to be grossly negligent to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures."

(A copy of the Lancet article dated 19th November 2021 titled "The epidemiological relevance of the COVID-19-vaccinated population is increasing" and available at https://www.thelancet.com/journals/lanepe/article/PIIS2666-7762(21)00258-1/fulltext?s=08 is Annexed as **Annexure R6 (Page 41 to 42)**

13. The United Kingdom Parliamentary Committee report dated 9th September 2021 held that COVID passport policy lacks scientific evidence base and must be done away with. Based on this report the government decided not to issue any vaccine mandates. Recently, the House of Lords committee has held that there is insufficient evident to back mandatory NHS staff vaccination. A report in the British Medical Journal states:

"A House of Lords committee has raised several concerns about the proposed legislation to make vaccination against SARS-CoV-2 mandatory for all NHS staff in England, particularly whether the benefits of vaccinating the remaining 8% of NHS workers were

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

proportionate and how the NHS would cope with losing the 5.4% who don't want to be vaccinated.

...

But in a report published on 30 November the committee said that the benefit of increasing the protection from vaccinating staff who had not yet taken up offers of the jab "may be marginal" and that the government had failed to publish any contingency plans on how it would cope with the loss of staff who do not want the vaccine.

The report said that of the 208 000 NHS staff who weren't currently vaccinated 54 000 (26%) would take up the vaccine under the law and 126 000 (61%) would leave their jobs.

"Given the legislation is anticipated to cause £270m in additional recruitment and training costs and major disruption to the health and care provision at the end of the grace period, very strong evidence should be provided to support this policy choice. DHSC [Department for Health and Social Care] has not provided such evidence," it said."

(A copy of the report in the British Medical Journal titled "Evidence is insufficient to back mandatory NHS staff vaccination, says House of Lords committee", dated 3rd December 2021, is annexed as **Annexure R7 (Page 43 to 45).**

Judicial review of government policy on compulsory vaccination

14. The preliminary objections raised by the Respondent No. 1 and Respondent No. 2 in their reply preclude a fair and accountable disclosure of segregated data of vaccine clinical trials on the

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

pretext that this petition might result in vaccine hesitancy. The Petitioner is a former member of the National Technical Advisory Group on Immunisation (NTAGI) and fully acknowledges the need for emergency health measures during a pandemic, which are not being questioned through this petition. The Petitioner only prays that the information and data related to the vaccination response of the government be collected systematically and be made publicly available. The Petitioner submits that the prayers sought for include public disclosure of entire segregated trial data for the vaccines, for the data of adverse events related to these vaccines to be made public and for vaccine mandates, which impinge on personal liberty, to be declared unconstitutional.

15. It is submitted that simply because vaccinations and permissions thereof deal with aspects of science does not mean they do not come under the purview of judicial review. Judicial Intervention in matters dealing with scientific procedures undertaken by domain expertise is not excluded. This should specifically be the case for vaccines for COVID-19 considering they are meant to be used in universal immunisation programmes and have been introduced in clinical trial mode under emergency use authorisation. Information related to the same should be available for public and independent scientific scrutiny.

16. Internationally, several Courts have intervened on matters relating to the vaccinations for COVID-19. It is submitted that the Petitioners would like to reiterate the contents of the Additional Affidavit dated 27.10.2021 submitted by the Petitioners herein.

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

Some relevant paragraphs of the same have been reproduced below:

"20. The Slovenia Constitutional Court has blocked the government plan to make coronavirus vaccines mandatory for public employees, hours before it was due to come into force:

"In its decision the court said that "despite the very serious epidemic situation", it considered that "implementing the potentially unconstitutional (measure) ... would have worse consequences than delaying implementation".

21. In New York, a federal appeals court blocked New York City's coronavirus vaccine mandate days before the mandate goes into effect.

"The 2nd circuit Court of Appeals granted an expedited injunction on Friday blocking the city from mandating that all public school employees submit proof of their first coronavirus vaccine dose by Monday."

22. In Gainesville, Florida a lower court has issued an injuction against vaccine mandates for employees.

"A Circuit Court judge has issued a temporary injunction preventing the City of Gainesville from requiring a COVID-19 vaccine for employees or terminating employees that do not get the vaccine."

24. A court in Galicia, Spain, overturned regional governments requirement for Covid passports in bars and restaurants.

25. In Andalusia, Spain, "Andalusian justice rejects the requirement of the covid certificate to enter the nightclubs.

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

The magistrates consider that the measure requested by the Board violates the right to privacy and the principle of non-discrimination and is neither suitable nor necessary."
(A copy of the article, 'Andalusian justice rejects the requirement of the Covid certificate to enter the nightclubs" dated 12 Aug 2021, is annexed as Annexure AA 25 At Page to

26. The Scandinavian countries of Sweden, FinLand, Norway, Denmark have all done away with all Covid restrictions; Denmark had briefly considered vaccine passports but recently decided to do away with such a system."

17. Thus, several Courts internationally have recognised that vaccine mandates impinge on the constitutional freedoms of individuals. In the United States, on 6th November, 2021, the U.S. Court of Appeals for the Fifth Circuit temporarily stayed the regulation mandating vaccinations for workplaces with 100 or more employees in **BST Holdings, LLC v. OSHA No. 21-60845** and made it clear that vaccine mandates substantially threaten constitutional freedoms, thus staying the vaccine mandate regulations. This case has now been transferred to the Court of Appeals for the Sixth Circuit. The 6th Circuit of Appeals denied a motion requested by the Biden administration to move the location of the OSHA vaccine mandate case and denied the US Government's motion to shorten the stay briefing

.

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

(A copy of the Order dated 3rd December 2021 in N Re: MCP No. 165, Occupational Safety and Health Administration Rule on Covid-19 Vaccine And Testing, 86 Fed. Reg. 61402 No. 21-7000 has been annexed as **Annexure R8 (Page 46 to 49)**

18. It is therefore important for this Hon'ble Court to step in and exercise its powers of judicial review of executive policy which is manifestly arbitrary and irrational and set aside any vaccine mandates that has been brought in by the government or private bodies and thereby safeguard citizens fundamental rights. In **Distribution of Essential Supplies and Services During Pandemic, In re, 2021 SCC OnLine SC 411**, this Hon'ble Court held that:

> "...16. Similarly, courts across the globe have responded to constitutional challenges to executive policies that have directly or indirectly violated rights and liberties of citizens. Courts have often reiterated the expertise of the executive in managing a public health crisis, but have also warned against arbitrary and irrational policies being excused in the garb of the "wide latitude" to the executive that is necessitated to battle a pandemic. This Court in Gujarat Mazdoor Sabha vs State of Gujarat, albeit while speaking in the context of labour rights, had noted that policies to counteract a pandemic must continue to be evaluated from a threshold of proportionality to determine if they, inter alia, have a rational connection with the object that is sought to be achieved and are necessary to achieve them.

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

In grappling with the second wave of the pandemic, this Court does not intend to second-guess the wisdom of the executive when it chooses between two competing and efficacious policy measures. However, it continues to exercise jurisdiction to determine if the chosen policy measure conforms to the standards of reasonableness, militates against manifest arbitrariness and protects the right to life of all persons. This Court is presently assuming a dialogic jurisdiction where various stakeholders are provided a forum to raise constitutional grievances with respect to the management of the pandemic. Hence, this Court would, under the auspices of an open court judicial process, conduct deliberations with the executive where justifications for existing policies would be elicited and evaluated to assess whether they survive constitutional scrutiny."

19. The respondents claim that the petitioner cannot, under the garb of a petition under Article 32 of the Constitution, pray before this Hon'ble Court to sit in appeal over a scientific process undertaken by the domain experts and take a different view on a subject which is not the subject of expertise of any judicial forum, is completely erroneous. In the present petition the decision of the domain experts is not being questioned. On the other hand, the petitioner is asking that the decision of the experts be carried out rigorously and faithfully. As stipulated by the experts and as admitted in the counter, the emergency use authorisation has been given only for use in 'clinical trial mode'. The court must

ensure that this stipulation of the experts is followed rigorously. This goes well beyond passively monitoring AEFI.

Disclosure of the details and procedure for approval of vaccines

20. The Counter Affidavit of the respondents only reproduces existing rules and regulations which have already been understood, referred to and cited in the Pleadings and Additional Affidavits of the Petitioner and as such needs no reply. It is reiterated that the petitioner has not questioned the right of the Government to issue Emergency use authorization in an emergency after a small Phase II trial of a mere 300 odd subjects. In the procedure for grant of approval the counter states that post licensure studies may be required to be conducted after approval to generate the data on larger population and to describe clinical benefits and further after various deliberations, the SEC recommended for the grant of permission for restricted use of Covaxin in emergency situation in public interest in clinical trial mode. The petitioner has sought that such post marketing data be collected rigorously in 'clinical trial mode' as the respondent has stipulated.

21. Nearly two months after the writ petition was filed, on 2 July 2021 a preprint article (which has not been peer-reviewed) was uploaded on the internet (mentioned on page 211 of the counter). The authors themselves admit as follows:

Line 393 to 397 at page 224 of the counter states "This study has several limitations. Due to the low number of cases reported

between doses 1 and 2, we cannot calculate vaccine efficacy after a single dose. This report contains a median safety follow-up of 146 days for all participants, so long-term safety follow-up of BBV152 is required and is currently underway. The data presented on efficacy against variants other than Delta must be considered preliminary as the numbers reported are small."

Furthermore line 402 to 406, the authors report they have broken the study protocol and unblinded the study and given vaccination to the controls long before the end of the 1 year study protocol. We now have no control group or comparator to measure the long term adverse effects of the vaccine and every adverse event can use the spacious excuse that cause and effect is unproven.

22. The information that has been provided for the Covishield vaccine in the counter affidavit is largely based on the studies of Astra Zeneca vaccine done overseas. The results and analysis of the Indian study referred to has not been disclosed. The Indian study of AstraZeneca is not the protocol mandated trail which requires over thirty thousand people. The study referred to has used only 1600 participants.

23. The petitioner therefore seeks disclosure of the raw data which can be independently scrutinized by scientists. The counter states in the approval granting process various safety and immunogenicity data was presented to the Subject Expert Committee, however none of this data has been disclosed. The information that has been presented via this counter affidavit is not the raw data on the basis of which the approval was granted.

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

It is merely some pre print studies that have been put out by the vaccine manufacturers themselves and contains the analysis done by the company themselves.

24. The petitioner submits that in the specific context of drug regulation in India, the need for greater transparency has been noted by the Parliamentary Standing Committee on Health and Family Welfare, in its 59th Report (2012) and 66th Report (2013), which called for "increased transparency in decision-making" of the Central Drugs Standard Controls Organisation (CDSCO) and other regulatory authorities. The report has been annexed with the writ petition. The Parliamentary Standing Committee Report discussed the lapses and omission of the current Drug Approval System and their maintenance of public records. Some of the important findings of the report are quoted below. The lapses pointed out in the report make it even more urgent for data with regard to mass vaccination to be disclosed considering that the manner in which drug approvals are being given by the CDSCO. The lack of clinical trials for new drugs:

> In para 7.14 of the PSC Report, the Committee observed the following:
>
> "In the case of 11 drugs (28%) Phase III clinical trials mandated by Rules were not conducted. These drugs are i, Everolimus (Novartis), ii. Colistimethate (Cipla), iii. Exemestane (Pharmacia), iv. Buclizine (UCB), v. Pemetrexid (Eli Lilly), vi. Aliskiren (Novartis), vii. Pentosan (West Coast), viii. Ambrisentan (GlaxoSmithKline), ix. Ademetionine (Akums), x. Pirfenidone (Cipla), and xi. FDC of Pregabalin,

Methylcobolamine, Alpha Lipoic Acid, Pyridoxine & Folic Acid (Theon); In the case of 2 drugs (Dronedarone of Sanofi and Aliskiran of Novartis), clinical trials were conducted on just 21 and 46 patients respectively as against the statutory requirement of at least 100 patients; In one case (Irsogladine of Macleods), trials were conducted at just two hospitals as against legal requirement of 3-4 sites; In the case of 4 drugs (10%) (Everolimus of Novartis; Buclizine of UCB; Pemetexid of Eli Lilly and FDC of Pregabalin with other agents**), not only mandatory Phase III clinical trials were not conducted but even the opinion of experts was not sought. The decision to approve these drugs was taken solely by the non-medical staff of CDSCO on their own;**

(i) Files that have gone "missing" from the CDSCO regarding certain controversial drugs.

In para 7.12 of the PSC Report, the following was observed:

"All these drugs had been approved on different dates and different years creating doubt if disappearance was accidental. Strangely, all these cases also happened to be controversial drugs; one was never marketed in US, Canada, Britain, Australia and other countries with well-developed regulatory systems while the other two were discontinued later on. In India, all the three drugs are currently being sold."

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

(iii) The dubious process of clearing certain drugs, based on suspicious expert medical opinions.

The relevant excerpt from para 7.31 of the PSC Report is reproduced as followed:

"A review of the opinions submitted by the experts on various drugs shows that an overwhelming majority are recommendations based on personal perception without giving any hard scientific evidence or data. Such opinions are of extremely limited value and merely a formality. Still worse, there is adequate documentary evidence to come to the conclusion that many opinions were actually written by the invisible hands of drug manufacturers and experts merely obliged by putting their signatures"

(iv) The PSC also included certain letters supposedly written by medical experts, addressed to a drug manufacturer "Themis Medicare Ltd.", approving their drugs. Themis Medicare Ltd. sought the approval of Drotaverine (80 mg) plus Aceclofenac(100 mg) tablets as a fixed dose Combination. The PSC observed that the Fixed Dose Combination of Aceclofenac with Drotaverine was not permitted in any developed country including in North America, Europe or Australia. Upon closer examination, the PSC realised that these letters supposedly written by medical experts to the drug manufacturer, were in fact, drafted by the manufacturers themselves to gain approval of their drugs in an unscrupulous and illegal manner. The PSC recommended that the DCGI should conduct an enquiry

and take action against such malpractices, in para 7.33 of the report. The relevant extract is reproduced hereunder:

"7.32 If the above cases are not enough to prove the apparent nexus that exists between drug manufacturers and many experts whose opinion matters so much in the decision making process at the CDSCO, nothing can be more outrageous than clinical trial approval given to the Fixed Dose Combination of Aceclofenac with Drotaverine which is not permitted in any developed country of North America, Europe or Australia. In this case, vide his letter number 12-298/06- DC dated 12-2-2007, an official of CDSCO advised the manufacturer, Themis Medicare Ltd. not only to select experts but get their opinions and deliver them to the office of DCGI. No wonder that many experts gave letters of recommendation in identical language apparently drafted by the interested drug manufacturer."

"7.33 In the above case, the Ministry should direct DCGI to conduct an enquiry and take appropriate action against the official(s) who gave authority to the interested party to select and obtain expert opinion and finally approved the drug".

25. The disclosure of clinical trial data including data relating to adverse events is significant as has been revealed from the Pfizer vaccine data that was disclosed as a result of a Freedom of Information court order in the United States. In the case of the Pfizer vaccine, the company in its analysis understated the adverse events and overstated the efficacy. The truth can only be

ascertained when the raw data can be seen by independent scientists.

> "Document released by Pfizer apparently as a result of a Freedom of information court order in the USA reveals a vast array of previously unknown vaccine adverse effects compiled from official sources around the world.
> Pfizer concedes this is 'a large increase' in adverse event reports and that even this huge volume is under reported. Over 100+ diseases are listed, many very serious."

(A copy of the report in the dailytelegraph dated 5th December 2021 titled, "Pfizer document concedes that there is a large increase in types of adverse event reaction to its vaccine" is annexed as **Annexure R9 (Page 50 to 61).**

26. A researcher working with Pfizer also turned whistleblower and revealed data integrity issues with the Pfizer vaccine trial. A Report in the British Medical Journal states:

> "A regional director who was employed at the research organisation Ventavia Research Group has told The BMJ that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug Administration (FDA). Ventavia fired her later the same day. Jackson has provided The BMJ with dozens of internal company documents, photos, audio recordings, and emails."

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

(A copy of the report in the British Medical Journal dated 2nd November 2021 is annexed as **Annexure R10 (Page 62 to 69)**

27. An RTI application with the Ministry of Health and Family Welfare sought "raw data that SII and Bharat Biotech had to make available to the committee approving covid-19 vaccines." It asked whether the "..committee look[ed] at the raw data and/or discuss it?". It also sought data provided by SII and Bharat Biotech related to teratogenicity, genotoxicity, carcinogenicity, fertility and death. In their reply dated 03.09.2021, the Central Drugs Control Standard Organization stated the following:

> "The brief of interim clinical trial results/information containing safety, immunogenicity and efficacy results along with side-effects, contraindications precautions and instructions for use of Covishield & Covaxin COVID-19 vaccines are available in Summary of Product Characteristics (SmPC) & factsheet which along with recommendations of Subject Expert Committee are publicly available on CDSCO website i.e. www.cdsco.gov.in. **Further, the sought information is exempted under Sec 8(1) (d) and (e) of RTI Act 2005 & consent is required for disclosure from such information.**"

The Applicant filed an Appeal stating that the information he/she sought for cannot be withheld on the pretext that it is against the public interest. In their final reply dated 29.11.2021, the First Appellate Authority, while refusing to reveal any data that is not

publicly available, stated that the companies Serum Institute of India and Bharat Biotech have refused to disclose this information publicly. The relevant parts of the same have been reproduced below:

> "..Further, this office had issued third party notice to M/s Serum Institute of India Pvt Ltd and M/s Bharat Biotech International Ltd to make their submissions in writing or orally, as per section 11 of RTI Act 2005 as to whether the information/records asked for by you should be disclosed or not **The firms submitted their response with request not to disclose the information/documents submitted by them.** Accordingly, the RTI appeal is disposed off..."

(A copy of the RTI request (RTI Ref. No. MOHFW/R/E/21/04550) dated 19.07.2021, the Reply of the aforementioned RTI by the Central Drugs Standard Control Organisation (Register No. CDSCO/R/T/21/00650) dated 03.09.2021, RTI Appeal (Registration number CDSCO/A/E/21/00120) and the final reply dated 29.11.2021 is collectively annexed as **Annexure R11 (Page 70 to 74)**

Ethical review Rules and Patient Confidentiality

28. The counter affidavit of the Respondent quotes extensively from various rules about ethical review and the need for confidentiality of patient-identified data. The respondent has also stated various national and international rules and instruments that stipulate that privacy and confidentiality of the patient, trial subject needs to be protected. However it is pertinent to note that petitioner

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT. OF INDIA

has not sought patient-identified data. The petitioner has not sought disclosure of trial data which would not in any manner be a breach of rules or expose any information on the participants of clinical trials. The petitioner has prayed that data collected during the post-marketing study done as stipulated by the emergency use authorisation in 'clinical trial mode' to be placed in the public domain. This will provide information on what parameters are being followed up rigorously as stipulated by the EUA granting experts. This is needed so that patients can make an informed decision and give informed consent to vaccination with a vaccine that has not been fully licensed as yet.

29. The importance of disclosure of segregated data of vaccine clinical trials (segregated for each vaccine and for each age group) that have been undertaken with respect to the two vaccines being administered in India, cannot be undermined and must be disclosed through peer reviewed scientific journals. The disclosure of such information is essential to ascertain whether a certain section of the population is more susceptible to adverse effects, to determine what are the adverse effects in various age groups and on differing populations, etc.

30. So far, the respondents have not updated post-marketing in the CTRI data sets given for both these vaccines. The Respondents are liable to make this data publicly available in accordance with 59th Parliamentary Standing Committee Report on "increased transparency in decision-making" of the CDSCO, the WHO Statement on Public Disclosure of Clinical Trial Results', and the

Declaration of Helsinki which has been adopted by the ICMR in India as have been stated in the writ petition.

31. The petitioner reiterates that the minutes of the meetings of the subject expert committee and the NTGAI are not available on the websites as stated in the counter affidavit. What is available are the bare decisions and not the basis, discussions and deliberations on the basis of which those decisions were made. Neither is any of the material that was presented to the expert committees to form their opinion publicly available for individual scrutiny.

32. Further, the petitioner states that the government does not disclose the names and institutional relationships of the experts present during each SEC meeting for COVID -19 vaccines. These subject expert committees review the proposals and send recommendations to the government's Central Drug Standard Control Organisation (CDSCO), which decided their approval. The opacity makes it impossible to evaluate potential conflicts of interest. If the committee of experts is representing the public, the people have the right to know who these experts are. The members present on each SEC must be disclosed in the minutes of each meeting. This is not done and it must be made mandatory.

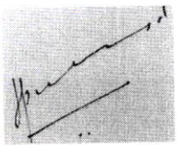
Adverse Events from Immunisation

33. The Respondents in the aforesaid paragraph state the number of adverse events that have been reported through AEFI, however, it is pertinent to note that this data is not public and no analysis

of the same has been published publicly till date. As has been pointed out in the petition and additional affidavits, the adverse event reporting system is non transparent. Various groups of renowned scientists and doctors have written to the government that the adverse events reporting system in India has serious flaws and there is no transparent investigation or follow up of deaths and other serious adverse events after COVID -19 vaccination. These have been stated in the petition and additional affidavits and are not being reproduced here for brevity.

34. The problems with the AEFI system in India is at several levels. Firstly, very few people are aware that there is any such system in place where they could report adverse events from the vaccine. Secondly, even when they report it, it goes through several levels of the system (the doctor/health worker administering the vaccine, etc) who are then supposed to report it further up. In a paper published by the petitioner, he describes how the 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. A copy of the paper has been annexed with the writ petition.

NOTARY
VIJAY KUMAR
Delhi
Regn. No.-17819
GOVT. OF INDIA

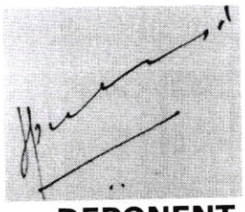


DEPONENT

VERIFICATION:

I, the above named Deponent, do hereby verify that the contents of the above Affidavit are believed to be true and correct to the best of my knowledge, no part of it is false and nothing material has been concealed there from.

Verified at New Delhi on this 10th day of December, 2021.



DEPONENT

NOTARY VIJAY KUMAR Delhi Regn. No.-17819 GOVT OF INDIA

ATTESTED

NOTARY PUBLIC DELHI

10 DEC 2021

ANNEXURE: R1

The Indian Express

2 of 3 Indians have Covid-19 antibodies: ICMR serosurvey findings explained

The survey was conducted in June and July, 2021 across 70 districts of 21 states. These are the same districts where three earlier rounds have been conducted during May-June (2020); August-September (2020); and December-January (2020-2021).

Written by Harikishan Sharma , Edited by Explained Desk | New Delhi | Updated: July 26, 2021 11:27:23 am

Covid, serosurveyAt a market in New Delhi (Express Photo/File)

Two-third of Indians above the age of 6 had SARS-CoV-2 antibodies, show findings of the fourth nationwide serological survey conducted by the Indian Council of Medical Research (ICMR) in June-July. The survey results also suggest that about 40 crore people or one-third of the country's population is still vulnerable to the novel coronavirus.

The survey was conducted across the country in June and July. Its findings are significant because this is for the first time children aged 6-17 years were included in the national serosurvey. The results of the survey were released by DG, ICMR, Dr Balram Bhargava.

Don't miss |Healthcare in India: rarely an election issue, despite limited access

What is the ICMR serosurvey?

The ICMR has conducted the fourth round of national blood serum survey which tests for antibodies, known as a serosurvey, for Covid-19. The aim of the survey was to estimate the sero-prevalence of SARS-C0V-2 antibodies.

The survey was conducted in June and July, 2021 across 70 districts of 21 states. These are the same districts where three earlier rounds have been conducted during May-June (2020); August-September (2020); and December-January (2020-2021).

Who all did the survey cover?

The survey was conducted among 28,975 people. For the first time children aged 6-17 years were included in the survey. Besides, it included 7,252 healthcare workers.

What are the findings of the fourth round of national serosurvey?

The results of the IMCR's fourth round of national serosurvey shows that the overall sero-prevalence in the country was 67.6% in June and July, which is higher than the sero-prevalence rate recorded during the three earlier surveys – 0.7 percent during May-June (2020); 7.1 percent during August-September (2020); and 24.1 percent during December-January (2020-2021).

So, the latest findings of the survey suggest that two-third of the general population above 6 years have SARS-CoV-2 antibodies, which means that two-third of Indians have been exposed to novel coronavirus. It also shows

that one-third of the population does not have antibodies, which suggests that about 40 crore people are still vulnerable to the novel coronavirus.

"In conclusion, two-thirds of the general population that is above the age of six years had SARS-CoV-2 infection. More importantly, a third of the population did not have any antibodies… 40 crore population of this country is still vulnerable," Bhargava said, addressing a press conference.

"States/districts/areas without antibodies run the risk of infection waves," Bhargava said.

The survey also shows that sero-prevalence was similar in rural and urban areas. It also suggests that 85 per cent healthcare workers had antibodies against SARS-CoV-2.

What does the survey say about children?

The survey findings shows that more than half of the children (6 -17 years) were seropositive. It means they have been exposed to Covid-19 in the past months. The sero-prevalence among children was 57.2 per cent in the age group 6-9 years and 61.6 per cent in the age group 10-17 years.

Link:https://indianexpress.com/article/explained/explained-icmr-covid-fourth-serosurvey-findings-7413949/

Prashant Bhushan

(TRUE COPY)

ANNEXURE: R2

The Indian Express

Serosurvey finds 70 per cent in Tamil Nadu have anti-bodies against Covid-19

The Directorate of Public Health and Preventive Medicine on Thursday released the report of the 'state wide cross sectional Sero Survey', conducted in July-August across 827 clusters covering 24,586 samples.

By: PTI | Chennai |
Updated: October 8, 2021 12:06:24 pm
A cluster consists of 30 participants who were randomly selected from a village in a rural area, while it was a street in urban locality. (File)
Tamil Nadu has witnessed an increase in the overall sero-prevalence among the people at 70 per cent, suggest the findings of a latest round of serosurvey by the state government.

The Directorate of Public Health and Preventive Medicine on Thursday released the report of the 'state wide cross sectional Sero Survey', conducted in July-August across 827 clusters covering 24,586 samples.

Chennai Live |liveFollow live updates and news
A cluster consists of 30 participants who were randomly selected from a village in a rural area, while it was a street in urban locality.

Also Read |Tamil Nadu breaches the 5 crore mark in Covid-19 vaccines
"The overall sero prevalence was 70 per cent and the highest sero positivity was observed in Virudhunagar at 84 per cent," the report said.

Serosurvey or Seroprevalence studies are based on analysis of antibodies collected through blood sample collection.

Also Read |89% of Covid deaths in Aug and Sep months were among the unvaccinated, shows TN study
In the earlier state-wide sero-surveys conducted by the department in October-November 2020, the sero-positivity was at 32 per cent while in March-April 2021 it was 29 per cent.

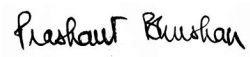
According to the findings released today of the 24,586 samples tested July-August 2021, 17,090 individuals have developed IgG antibodies against the SARS-CoV-2 Virus.

Also Read |Tamil Nadu aims to vaccinate 1.50 crore people in October: Ma Subramanian
Chennai, Tenkasi, Madurai and Theni districts reported sero positivity of above 75 per cent while Karur reported the lowest with 51 per cent. Perambalur, Ariyalur, Nilgiris reported less than 60 per cent of the sero positivity, the report said.

The blood samples were collected from the 24,586 participants while the presence of SARS CoV-2 IgG antibodies was tested using the Chemiluminescence based Immuno Assay (CLIA) method.

The samples were tested at the six laboratories of the Department of Public Health in Chennai, Tiruchirappalli, Madurai, Coimbatore, Salem, Tirunelveli for the detection of IgG antiobodies.

Link: https://indianexpress.com/article/cities/chennai/serosurvey-finds-70-per-cent-in-tn-have-anti-bodies-against-covid-19-7559335/



(TRUE COPY)

ANNEXURE: R3

The Indian Express

97% people have Covid-19 antibodies, shows sero survey Delhi: 97% people have Covid-19 antibodies, shows sero survey Positivity in vaccinated people is 97-98%, while in non-vaccinated, it is 90%.

By: Express News Service | New Delhi |
Updated: October 28, 2021 4:21:26 pm

Health Minister Satyendar Jain said that a large part of Delhi's population has been affected by Covid-19 and the rest have been vaccinated. (Express photo by Praveen Khanna)

Delhi has a seropositivity of 97 per cent for Covid-19 antibodies, the sixth serological survey conducted in the city has revealed, Delhi Health Minister Satyendar Jain said Thursday. Every district has a seropositivity of above 95 per cent, he said.

Samples for the survey were collected in the last week of September. A total of 28,000 samples were collected — 100 each from 280 civic wards. This was the first such survey conducted after the deadly second wave hit the national capital in April and May.

A survey planned in April had to be abandoned midway because of the soaring case count.

"The seropositivity in women is slightly higher than that in men. In children below the age of 18, the sero prevalence is 88 per cent, while it is 97 per cent to 98 per cent in adults. The survey included vaccinated and unvaccinated people. The unvaccinated have a prevalence of 90 per cent, and those who have been vaccinated is above 97 per cent," said Jain.

The minister said that a large part of Delhi's population has been affected by Covid-19 and the rest have been vaccinated. He, however, declined to comment on whether Delhi has now achieved herd immunity.

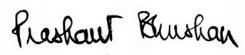
"The data shows clearly that sero positivity has increased slowly in Delhi. When the prevalence was 56 per cent, we thought it was a sign that a lot of people have got antibodies. Now it has increased to 97 per cent," he said.

Speaking about the status of vaccinated people, Jain said that sero prevalence was high in both vaccinated and unvaccinated people, but it was higher in those who have been vaccinated.

Sero surveys in other cities, conducted after the second wave and vaccination drives, also show high sero prevalence.

In the survey conducted in Mumbai in August this year, the prevalence of Covid-19 antibodies was 86.64 per cent. It was 80.2 per cent in a survey started in Chandigarh in July, and 78.3 per cent in the survey conducted in Gurgaon in September.

Link: https://indianexpress.com/article/cities/delhi/people-in-delhi-have-covid-19-antibodies-shows-sero-survey-7595390/



(TRUE COPY)

ANNEXURE: R4

The Hindu

One in five in U.T. has COVID-19 antibodies: sero-survey

SPECIAL CORRESPONDENTPUDUCHERRY, SEPTEMBER 25, 2020 00:14 IST
UPDATED: SEPTEMBER 25, 2020 00:14 IST

Of 898 adults tested, 186 had antibodies against SARS CoV-2 by August-end, says Jipmer

One in every five persons in Puducherry district was infected with COVID-19 by August-end, the results of a Jipmer sero-survey have found.

The findings of the sero-survey, launched in two rounds in August and September, showed that between July-end and August, the antibody sero-prevalence showed a 4.2-fold increase.

This is in keeping with the 4.1-fold rise in the number of confirmed cases over the same period in Puducherry (from 2987 to 12,331), Jipmer said in a press note.

The first sero-survey had indicated that one in 20 persons in the district showed evidence of COVID-19 infection.

The second round data indicates that Puducherry had a high rate of transmission in August. Also, the prevalence of serological evidence with antibodies in the

population is much higher than detected by RT-PCR as found at two time points; 19.6 (4.9/0.25) and 20.1 (20.7/1.03) fold respectively on July 30 and on August 30.

"Thus, by the end of August, nearly one-fifth of population in Puducherry had been infected with the Covid-19 infection," the Jipmer release said.

According to the press note, two community-based serological surveys were conducted at intervals of four weeks in an attempt to find information on the extent of spread and trend of infection.

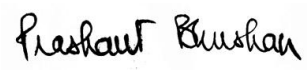
Blood samples were collected from randomly selected adults from 30 clusters in a ratio of 21 urban and 9 rural areas to replicate the population distribution in Puducherry. The two surveys were conducted during August 11-16 and September 10-16.

In the first round in August, 869 adults were tested and 43 (4.9%) had antibodies against SARS CoV-2 with a higher positivity in urban areas (5.7% versus 3.1%) and among women (6.3% versus 3.6%). The first round data reflects the cumulative proportion of Puducherry population infected as on July 30.

In the second round, of the 898 adults tested, 186 (20.7%) had antibodies against the SARS CoV-2 infection. In the second round, the positivity rate was similar in urban and rural population (20.7% versus 20.8%) and among men and women (21.4% versus 20%).

The second-round data reflects the cumulative proportion of Puducherry population which had been infected with COVID-19 as on August 30. The number of cases recorded in the district population on July 30 and August 30 respectively were 2,987 and 12,331 with incidence rates (population estimate for year 2020 is 12,00,000) of 0.25% and 1.03% respectively, the press note said.

Link: https://www.thehindu.com/news/national/tamil-nadu/one-in-five-in-ut-has-covid-19-antibodies-sero-survey/article32689856.ece



(TRUE COPY)

ANNEXURE: R5

Business Standard

Madhya Pradesh has highest Covid-19 antibodies, Sero Survey data shows

The Central government on Wednesday advised all States and UTs to conduct sero-prevalence surveys in consultation with the Indian Council of Medical Research (ICMR) to generate district-level data.

ANI

Last Updated at July 29, 2021 09:47 IST

The Central government on Wednesday advised all States and Union Territories (UTs) to conduct sero-prevalence surveys in consultation with the Indian Council of Medical Research (ICMR) to generate district-level data.

As per a letter written by the Union Health Secretary to Additional Chief Secretary/Principal Secretary/Secretary (Health) of all States, sero-prevalence survey is essential in formulating localised public health response measures.

"The Union Health Ministry has referred to the findings of the 4th round of National Sero-Prevalence Survey done by ICMR and has advised the States to conduct the sero-prevalence studies in their own States/UTs in consultation with ICMR, so that such studies follow a standardized protocol, and the findings of such studies can then be utilized quickly by the respective

State/UT to guide objective, transparent and evidence-based public health response to COVID-19," read the release by the Central government.

ICMR has conducted the recent National Sero-survey in 70 districts of India. The findings of this survey reveal that Madhya Pradesh has the highest seroprevalence with 79 per cent, followed by Rajasthan with 76.2 per cent, Bihar with 75.9 per cent, Gujarat with 75.3 per cent, Chhattisgarh with 74.6 per cent and Uttarakhand with 73.1 per cent.

It further said that the national sero-survey by ICMR was designed to capture the extent of the spread of Covid infection at the national level.

Therefore, the national sero-survey results do not reflect the heterogeneity of sero-prevalence between districts and even between States, read the release.

(Only the headline and picture of this report may have been reworked by the Business Standard staff; the rest of the content is auto-generated from a syndicated feed.)

Link: https://www.business-standard.com/article/news-ani/conduct-sero-surveys-to-generate-district-level-data-centre-to-states-uts-121072801503_1.html

Prashant Bhushan

(TRUE COPY)

The Lancet Regional Health - Europe 11 (2021) 100272

Contents lists available at ScienceDirect

The Lancet Regional Health - Europe

journal homepage: www.elsevier.com/lanepe

Letter

The epidemiological relevance of the COVID-19-vaccinated population is increasing

Günter Kampf*

University Medicine Greifswald, Institute for Hygiene and Environmental Medicine, Greifswald, Germany

ARTICLE INFO

Article History:
Received 1 November 2021
Accepted 3 November 2021
Available online 20 November 2021

High COVID-19 vaccination rates were expected to reduce transmission of SARS-CoV-2 in populations by reducing the number of possible sources for transmission and thereby to reduce the burden of COVID-19 disease. Recent data, however, indicate that the epidemiological relevance of COVID-19 vaccinated individuals is increasing. In the UK it was described that secondary attack rates among household contacts exposed to fully vaccinated index cases was similar to household contacts exposed to unvaccinated index cases (25% for vaccinated vs 23% for unvaccinated). 12 of 31 infections in fully vaccinated household contacts (39%) arose from fully vaccinated epidemiologically linked index cases. Peak viral load did not differ by vaccination status or variant type [1]. In Germany, the rate of symptomatic COVID-19 cases among the fully vaccinated ("breakthrough infections") is reported weekly since 21. July 2021 and was 16.9% at that time among patients of 60 years and older [2]. This proportion is increasing week by week and was 58.9% on 27. October 2021 (Figure 1) providing clear evidence of the increasing relevance of the fully vaccinated as a possible source of transmission. A similar situation was described for the UK. Between week 39 and 42, a total of 100.160 COVID-19 cases were reported among citizens of 60 years or older. 89.821 occurred among the fully vaccinated (89.7%), 3.395 among the unvaccinated (3.4%) [3]. One week before, the COVID-19 case rate per 100.000 was higher among the subgroup of the vaccinated compared to the subgroup of the unvaccinated in all age

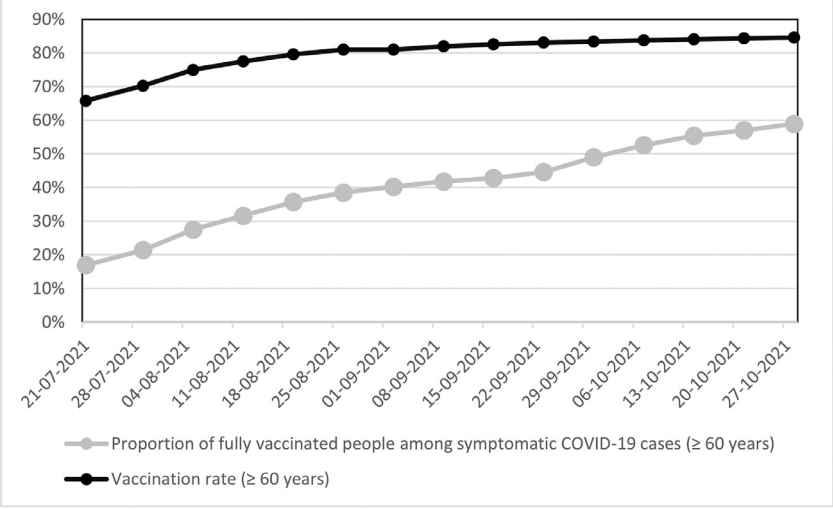


Figure 1. Vaccination rates and proportions of fully vaccinated people among symptomatic COVID-19 cases (≥ 60 years) in Germany between 21. July and 27. October 2021 based on the weekly reports from the Robert Koch-Institute [2].

* Correspondence to: Prof. Dr. Günter Kampf, University Medicine Greifswald, Institute for Hygiene and Environmental Medicine, Ferdinand-Sauerbruch-Strasse, 17475 Greifswald, Germany
E-mail address: guenter.kampf@uni-greifswald.de

https://doi.org/10.1016/j.lanepe.2021.100272

groups of 30 years or more. In Israel a nosocomial outbreak was reported involving 16 healthcare workers, 23 exposed patients and two family members. The source was a fully vaccinated COVID-19 patient. The vaccination rate was 96.2% among all exposed individuals (151 healthcare workers and 97 patients). Fourteen fully vaccinated patients became severely ill or died, the two unvaccinated patients developed mild disease [4]. The US Centres for Disease Control and Prevention (CDC) identifies four of the top five counties with the highest percentage of fully vaccinated population (99.9−84.3%) as "high" transmission counties [5]. Many decisionmakers assume that the vaccinated can be excluded as a source of transmission. It appears to be grossly negligent to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures.

Author Contribution statement

GK as the sole author of this Letter, contributed to all aspects of the text.

Declaration of Competing Interests statement

The author has no competing interests to declare

References

[1] Singanayagam A, Hakki S, Dunning J, et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. Lancet Infect Dis 2021. doi: 10.1016/S1473-3099(21)00648-4.

[2] Robert Koch-Institut. Wöchentlicher Lagebericht des RKI zur Coronavirus-Krankheit-2019 (COVID-19). AKTUALISIERTER STAND FÜR DEUTSCHLAND 22. Juli 2021. https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2021-07-22.pdf?__blob=publicationFile (accessed 28. September 2021).

[3] UK Health Security Agency. COVID-19 vaccine surveillance report. Week 4328. Oktober 2021. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1029606/Vaccine-surveillance-report-week-43.pdf (accessed 1. November 2021).

[4] Shitrit P, Zuckerman NS, Mor O, Gottesman BS, Chowers M. Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021. Euro Surveill 2021;26(39):2100822. doi: 10.2807/1560-7917.ES.2021.26.39.2100822.

[5] Subramanian SV, Kumar A. Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. Eur J Epidemiol 2021. doi: 10.1007/s10654-021-00808-7.

Prashant Bhushan

(TRUE COPY)

ANNEXURE: R7

The BMJ

News

Evidence is insufficient to back mandatory NHS staff vaccination, says House of Lords committee

BMJ 2021; 375 doi: https://doi.org/10.1136/bmj.n2957 (Published 03 December 2021) Cite this as: BMJ 2021;375:n2957

Zosia Kmietowicz

A House of Lords committee has raised several concerns about the proposed legislation to make vaccination against SARS-CoV-2 mandatory for all NHS staff in England, particularly whether the benefits of vaccinating the remaining 8% of NHS workers were proportionate and how the NHS would cope with losing the 5.4% who don't want to be vaccinated.1

The Secondary Legislation Scrutiny Committee said that the government's plans had not been thoroughly thought through, leaving the House of Lords unable to scrutinise the proposed legislation.

On 9 November England's health and social care secretary, Sajid Javid, announced that all staff who work in health and social care settings regulated by the Care Quality Commission will have to be fully vaccinated by 1 April 2022.2 "We must avoid preventable harm and protect patients in the NHS, protect colleagues in the NHS, and protect the NHS itself," he said.

But in a report published on 30 November the committee said that the benefit of increasing the protection from vaccinating staff who had not yet taken up offers of the jab "may be marginal" and that the government had failed to publish any contingency plans on how it would cope with the loss of staff who do not want the vaccine.

The report said that of the 208 000 NHS staff who weren't currently vaccinated 54 000 (26%) would take up the vaccine under the law and 126 000 (61%) would leave their jobs.

"Given the legislation is anticipated to cause £270m in additional recruitment and training costs and major disruption to the health and care provision at the end of the grace period, very strong evidence should be provided to support this policy choice. DHSC [Department for Health and Social Care] has not provided such evidence," it said.

The committee also criticised the department for failing to include in the legislation practical detail about how expressions such as "face to face" or "otherwise engaged" would be applied, referring instead to guidance to be produced in the future.

The committee's chair, Robin Hodgson, said, "We fully support high levels of vaccination, but DHSC is accountable to parliament for its decisions and needs to give us a clear statement of the effect of these regulations, the effect of doing nothing, and any other solutions considered, so parliament fully understands all the consequences of what it is being asked to agree to. This is particularly important when the NHS is already under such pressure.

"DHSC has provided no single coherent statement to explain and justify its intended policy, and this undermines the ability of the House to undertake effective scrutiny of the proposed legislation."

References↵

House of Lords Secondary Legislation Scrutiny Committee. 21st Report of Session 2021-22 drawn to the special attention of the House. Draft Health and Social Care Act 2008 (Regulated Activities) (Amendment) (Coronavirus) (No. 2) Regulations 2021. Nov 2021. https://committees.parliament.uk/publications/7989/documents/82445/default.

Rimmer A. Covid vaccination to be mandatory for NHS staff in England from spring 2022. BMJ2021;375:n2733. doi:10.1136/bmj.n2733 pmid:34758984

Link: https://www.bmj.com/content/375/bmj.n2957

Prashant Bhushan

(TRUE COPY)

No. 21-7000

ANNEXURE: P8

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Dec 03, 2021
DEBORAH S. HUNT, Clerk

IN RE: MCP NO. 165, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION RULE ON COVID-19 VACCINE AND TESTING, 86 FED. REG. 61402

ORDER

On November 23, 2021, OSHA filed an Emergency Motion to Dissolve the Stay that was issued by the Fifth Circuit Court of Appeals and consolidated herein (Dkt. 69). Given the Government's pending motion, the motions to stay the agency's ruling and related motions, including Dkt. Entry Nos. 148, 150, 154, 157, 160, 161, 165, 168, 170, 171, 172, 175, 176, 182, and 197, are hereby DENIED AS MOOT.

A. Responses to Government's Motion to Dissolve (Dkt. 69) and Reply Thereto

Per this Court's November 23, 2021, Scheduling Order (Dkt. 141), responses to the Government's Motion to Dissolve Stay (Dkt. 69) may be filed no later than December 7, 2021. Parties may choose to respond, pursuant to the instructions in the Initial Case Management Order (Dkt. 8), by one of the following methods:

(1) Filing a direct response to the Government's Motion, limited to 5,200 words (motions for leave to file an oversized response will not be entertained); OR

(2) Filing a notice of joinder in another filed response, specifying the joined document by its docket number in case 21-7000; OR

(3) Filing a notice to adopt their previously filed motion for stay, specified by docket number in case 21-7000, to which the word limit designated in subsection (1) does not apply.

The Government and the parties that joined in the Government's motion may each file their own single consolidated reply that addresses all responses, which is due no later than December 10, 2021, and limited to 5,200 words.

B. Government's Motion to Amend Briefing Schedule and Set Merits Briefing (Dkt. 131)

The Court DENIES the Government's motion to amend the briefing schedule established in Dkt. 141. The Court reserves judgment on setting a merits briefing schedule. Finally, the Court encourages the parties to consider the option noted above in A(2) and group their responses by joinder, but given practical considerations of the expedited proceedings, declines to set any requirements. Parties are advised to continue to adhere to the briefing schedule set forth in Dkt. 141.

C. Motions to Transfer (Dkt. 95, 213)

The Court hereby DENIES the motions to transfer the matter to the Fifth Circuit (Dkt. 95) and the D.C. Circuit (Dkt. 213).

D. Motion to Hold Case in Abeyance Pending the Outcome of Initial En Banc (Dkt. 99)

The Court hereby DENIES the motion to hold the case in abeyance pending the outcome of initial en banc. Parties are advised to continue to adhere to the briefing schedule set forth in Dkt. 141.

E. Motions for Leave to File Amicus Briefs (Dkt. 87, 88, 100, 101, 167, 208, 235, 241, 243)

Several parties (Dkt. 87, 88, 167, 208) previously filed motions for leave to file an amicus curiae brief and/or related motions regarding the initial motions for to stay. Because these motions for stay were herein denied as moot, the above-referenced amicus motions are also DENIED AS MOOT. Amici are advised that they may designate their previously filed amicus brief as their response to the Government's motion to dissolve the stay (Dkt. 69) by filing a notice adopting their initial amicus filing, such notice being filed in accordance with the schedule in Dkt. 141 and the procedures in the initial case management order.

The current motions for leave to file amicus brief regarding the Government's motion to dissolve stay (Dkt. 100, 101, 235, 241, 243) are hereby GRANTED.

F. Motion to Dismiss and Reimburse Filing Fee (Dkt. 147)

The motion to dismiss is GRANTED and the party is DISMISSED without prejudice. The motion to reimburse filing fee is DENIED.

G. Motion to Add an Additional Party (Dkt. 164)

The motion is GRANTED, and IEC and IEC – FL will be added as petitioners.

H. Motions to Intervene (Dkt. 174, 234)

Intervention is DENIED. The parties are advised that all circuit cases have been consolidated in 21-7000, where the parties may file directly for relief.

ENTERED BY ORDER OF THE COURT

Deborah S. Hunt, Clerk

(TRUE COPY)

ANNEXURE: R9

DAILY TELEGRAPH

GUY HATCHARD: PFIZER DOCUMENT CONCEDES THAT THERE IS A LARGE INCREASE IN TYPES OF ADVERSE EVENT REACTION TO ITS VACCINE

By Guy Hatchard

December 5, 2021

Document released by Pfizer apparently as a result of a Freedom Of Information court order in the USA reveals a vast array of previously unknown vaccine adverse effects compiled from official sources around the world.Pfizer concedes this is 'a large increase' in adverse event reports and that even this huge volume is under reported.Over 100+ diseases are listed, many very serious.This document was compiled by Pfizer in the very early days of the vaccine rollout in NZ but was possibly not supplied to our government.We examine the implications for government.

Up until now, New Zealand GPs and hospitals have been provided with a fact sheet from Pfizer listing 21 possible adverse events as a result of vaccination.

All of these are minor, requiring little or no treatment other than rest, with the exception of severe allergic reactions, myocarditis and pericarditis (inflammation of the heart). As a result, most of the many

thousands of New Zealanders reporting adverse effects post vaccination have been sent home with little more than advice to take an aspirin and rest. Some have been told that their conditions may be unrelated medical events, psychosomatic, or due to anxiety on their part.

Relying on the short official Pfizer fact sheet as a guide, Medsafe, our NZ medicines regulatory body, has only accepted one out of the 100+ deaths actually reported to them as related to vaccination. Most are listed as unrelated, under investigation, or unknowable. By contrast, the NZ Health Forum and other groups have collected unofficial reports of adverse effects and death proximate to vaccination. Out of 670+ reports of death compiled by the Forum, 270 have already been investigated by medical professionals and closely linked to known adverse effects. Following the publication of the new Pfizer document many more are expected to be connected with vaccination. Reports describe symptoms such as chest pain, brain fog, extreme fatigue, neurological symptoms, tachycardia, stroke, heart attacks, and many more. Collected data suggests that as many as two-thirds of adverse event enquiries made to medical staff by vaccine recipients have not been reported to CARM—the NZ system of adverse event reporting. Medsafe itself estimates in its Guide to Adverse Reaction Reporting that in NZ only 5% of adverse events are reported. As a result the NZ public is completely unaware of the extent of reported possible risks of vaccination.

The just released Pfizer document which is being circulated widely in the public domain and can downloaded from websites is entitled:

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Therefore the reported side effects predate the vaccine rollout in New Zealand. The report itself was finalised by Pfizer on 30 April 2021. Did Pfizer supply this information to our government during the early days of our universal vaccination programme? If so the results should have been shared with our medical professionals, politicians, and the public. Many of the new 100+ listed new adverse event types now released by Pfizer in this 38 page document pose long term risks to health. Until very recently, the document was being withheld by Pfizer who maintained it should be kept confidential. There is a strong possibility that very large numbers of New Zealanders will suffer long term injury as a result.

How did this happen without anyone's knowledge?

Even though the Pfizer vaccine had undergone very short trials and had provisional approval only, Medsafe did not update its CARM

adverse event reporting system to make it mandatory rather than voluntary.

Medsafe did not advise GPs and Hospital staff to be on high alert for adverse events and report them rapidly and in detail.

The Government ignored the unprecedented numbers of adverse events being reported to Medsafe and circulating in the community and on social media.

The Government instituted a public relations, promotional, and media campaign advising the public that the Pfizer covid-19 mRNA vaccine was completely safe and free of serious side effects, giving the impression that there were no side effects—not even the known serious effects of heart inflammation that Pfizer had already admitted.

Unaccountably, conditions imposed by the contract that our Government signed with Pfizer for the supply of vaccines have not been made public. We suspect that the contract contains standard clauses similar to those used with drugs that have completed safety trials, such as a provision that public discussion of adverse events may only be undertaken in conjunction with the company supplying the drug. If this is the case, it will have hamstrung Medsafe and our Government in their approach to assessment and public discussion of adverse events.

What are the new risks of vaccination?

Anyone reading the new Pfizer adverse event report compilation will be staggered. The sheer density of the technical medical terms and disease names are nevertheless broken down into recognisable and serious categories of illness—kidney failure, stroke, cardiac events, pregnancy complications, inflammation, neurological disease, autoimmune failure, paralysis, liver failure, blood disorders, skin disease, musculoskeletal problems, arthritis, respiratory disease, DVT, blood clots, vascular disease, haemorrhage, loss of sight, Bell's palsy, and epilepsy.

How has this affected New Zealand?

Whilst even the official Medsafe record of adverse effects and the unofficial lists show that the immediate risks of covid vaccination could be as much as 50 – 300 times greater than even the most risky of previous traditional vaccines (such as the smallpox jab), and whilst the long term effects are unknown, 90% of eligible New Zealanders have gone ahead with vaccination having accepted the assurances of safety and efficacy from the government, or having been forced to get vaccinated under threat of loss of employment and freedom of movement. Feeling the fear of covid that has been generated by reports in the international and local media, most people completing

vaccination heaved a great sigh of relief—that is one huge worry off my mind, now I can get on with my life.

Those finding that no immediate insurmountable reaction had surfaced (the majority) understandably agreed with the government: "What is all the fuss about? Why shouldn't everyone do this, or be made to do this? It is a social good that will protect everyone"

BUT there is a huge iceberg in the path of the good ship New Zealand hidden under the waves of relief. Thousands are quietly suffering debilitating illness, unacknowledged and in some cases untreated by their doctors. For those who survived vaccination without immediate injury this was not a problem because they didn't know about it apart from one or two complaints from friends that might just be random coincidences.

This has brought about a division in New Zealand society which the government created in the name of public safety. Thousands of dedicated servants of the nation including teachers, health workers, and others are being stigmatised and forced out of their jobs in a manner horrifyingly reminiscent of the treatment of Jews in Nazi Germany. The government did this despite knowing that the Pfizer vaccine was neither fully tested, safe, nor particularly effective. Judges handed down decisions in courts supporting the government mandates unaware of crucial mRNA vaccine safety data, all because Pfizer had

withheld this information, and the government had not done its due diligence. Had the true position been known, the High Court's NZ Bill of Rights analysis may well have been different and its provision which guarantees that every individual should be able to make their own medical choices might still be intact.

Pfizer's conclusions

Pfizer concludes the released document with a statement "Review of the available data for this cumulative PM experience, confirms a favorable benefit:risk balance for BNT162b2." PM stands for the Post Marketing data set they are evaluating of 42,086 reported adverse events. Pfizer makes this bald claim of benefit despite admitting that "the magnitude of underreporting is unknown". This document contains no further substantive information in support of this claim of benefit:risk balance other than a mysterious reference to "the known safety profile of the vaccine".

The benefit:risk argument is in essence saying: covid-19 is a serious illness and our calculations show that more people will be injured by the disease than are being injured by the vaccine, therefore there will be a net benefit. This argument falls over because of at least three very important factors: Firstly treatment options have improved and thereby the risk of serious illness and death from covid has been greatly reduced.

Secondly the risk of covid is not evenly spread. People with comorbidities (other conditions) and the elderly are at very high risk. Most other people are at very low risk. Thus vaccination could subject people at low risk from covid to a higher risk from vaccination. Approaches to preventive health education can reduce the covid risk to people with comorbidities more than vaccination can. For example a study published in the BMJ found that people following a plant based diet have a 73% reduced risk of serious illness. Data from the UK Biobank has been analysed by researchers from Manchester and Oxford Universities and the West Indies who found that shift workers (who typically have disrupted bioclocks) have three times the risk of being hospitalised with covid. Preventive remedies include changes in diet such as the introduction of more fresh fruit, vegetables, and fibre, and reductions in known unhealthy habits such as smoking, excess alcohol consumption, an overly sedentary lifestyle, a predominance of ultra processed foods, and many more.

The third and most significant reason the benefit:risk argument falls over is the sheer range of adverse reaction types observed by Pfizer and kept hidden until now.

How could a single vaccine have such a wide range of effects?

The technical reasons why mRNA vaccines can have such broad effects on human health are understood by those working in gene therapy. Perfectly stable DNA function is critical to life. In turn, cell function integrity is critical to maintaining DNA. Individual cells contain mechanisms to repair their own DNA as many as 70,000 times a day. From this perspective, the in vitro laboratory study recently published in Viruses 2021, 13,2056, is indicative. It suggests a possible mechanism for vaccine harm. The study found that the spike protein localises in the nucleus and inhibits DNA damage repair by impeding access of key DNA repair proteins. The findings reveal a potential molecular pathway by which the covid spike protein might impede adaptive immunity. They underscore the potential side effects of the full-length spike-based mRNA vaccines.

Despite a degree of cellular autonomy, the nervous system and the physiology must and does function as a whole. The entire nervous system including the immune system is a 'part and whole' network. The whole is in every part, the DNA is in every cell, but cell function is also related to a generalised and interconnected genetic network—the holistic functioning of the physiological network is critical to its efficiency. Thus physiological network stability (health) can be impaired by the introduction of pieces of active genetic code (biologic instructions) like those contained in mRNA vaccines.

An analogy will make this clear. We are familiar with computer networks. A very common backbone of most commercial systems is produced by Microsoft. Each computer contains the Microsoft system and the network also runs under its system. The system is supported by computer code—a set of complex instructions written by Microsoft. Individual computers can perform standalone tasks and can communicate with other computers to keep the organisation running smoothly. This can be compared to our physiology. There are many systems in the body: immune system, circulatory system, digestive system, limbic system, homeostatic mechanisms, musculoskeletal structure, neural networks, and so on. They perform apparently stand alone functions, but all run on the basis of the same genetic code contained in our DNA and communicate with one another during the process of maintaining health. Back to our analogy: office staff sometimes send messages full of spelling errors to one another but this doesn't harm the network. If however a computer virus written in code is sent by one computer it can overwhelm and crash network function because it affects the operating system. Some networks are protected by good firewalls and others are vulnerable. The Covid vaccine introduces a sequence of information written in genetic code into our physiology. It is no wonder that it could elicit such a very broad range of adverse effects, some of which are so serious as to be analogous to a computer network crash. Some individuals have strong immune systems and are little affected, others experience problems in one or other systems. The fact that a sequence of foreign code has

been introduced into the physiology produces major risks to health, risks that those working in gene therapy for the last few decades are very familiar with.

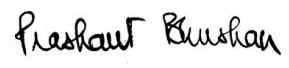
The extremely broad range of adverse effects revealed by the Pfizer document is the physiological signature of a general control system failure, a failure of the body's overall integration and function. It is not plausible to suggest otherwise. That is why experts in genomics, even as I write, are pondering fundamental questions about the action and safety of mRNA vaccines. They are also urging caution.

Conclusion

The NZ government agreed commercial terms with a single company for vaccine supply. It is possible that vital information was withheld. The public was kept in ignorance of known risks. This has divided our society and undermined our fundamental Kiwi tolerance on the basis of not only incomplete but misleading safety data. The government is asleep at the wheel. Knowing full well that safety trials were incomplete, the government apparently accepted information supplied by multinational commercial interests at face value. This should be a 'never again' moment. There are huge lessons to be learned and an apology owed to the whole population. The provisions of the NZ BIll of Rights should be given constitutional status. The vaccine mandates

should be withdrawn and those affected by them compensated. The proposed vaccination of 5 -11 year olds should be stopped.

Link: https://dailytelegraph.co.nz/news/pfizer-document-concedes-that-there-is-a-large-increase-in-types-of-adverse-event-reaction-to-its-vaccine/?s=08



(TRUE COPY)

ANNEXURE: R10

Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial

BMJ 2021; 375 doi: https://doi.org/10.1136/bmj.n2635 (Published 02 November 2021)

Paul D Thacker, investigative journalist

Revelations of poor practices at a contract research company helping to carry out Pfizer's pivotal covid-19 vaccine trial raise questions about data integrity and regulatory oversight. **Paul D Thacker** reports

In autumn 2020 Pfizer's chairman and chief executive, Albert Bourla, released an open letter to the billions of people around the world who were investing their hopes in a safe and effective covid-19 vaccine to end the pandemic. "As I've said before, we are operating at the speed of science," Bourla wrote, explaining to the public when they could expect a Pfizer vaccine to be authorised in the United States.

But, for researchers who were testing Pfizer's vaccine at several sites in Texas during that autumn, speed may have come at the cost of data integrity and patient safety. A regional director who was employed at the research organisation Ventavia Research Group has told *The BMJ* that the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase III trial. Staff who conducted quality control checks were overwhelmed by the volume of problems they were finding. After repeatedly notifying Ventavia of these problems, the regional director, Brook Jackson, emailed a complaint to the US Food and Drug

Administration (FDA). Ventavia fired her later the same day. Jackson has provided *The BMJ* with dozens of internal company documents, photos, audio recordings, and emails.

Poor laboratory management

On its website Ventavia calls itself the largest privately owned clinical research company in Texas and lists many awards it has won for its contract work.[2] But Jackson has told *The BMJ* that, during the two weeks she was employed at Ventavia in September 2020, she repeatedly informed her superiors of poor laboratory management, patient safety concerns, and data integrity issues. Jackson was a trained clinical trial auditor who previously held a director of operations position and came to Ventavia with more than 15 years' experience in clinical research coordination and management. Exasperated that Ventavia was not dealing with the problems, Jackson documented several matters late one night, taking photos on her mobile phone. One photo, provided to *The BMJ*, showed needles discarded in a plastic biohazard bag instead of a sharps container box. Another showed vaccine packaging materials with trial participants' identification numbers written on them left out in the open, potentially unblinding participants. Ventavia executives later questioned Jackson for taking the photos.

Early and inadvertent unblinding may have occurred on a far wider scale. According to the trial's design, unblinded staff were responsible for preparing and administering the study drug (Pfizer's vaccine or a placebo). This was to be done to preserve the blinding of trial participants and all other site staff, including the principal investigator. However, at Ventavia, Jackson told *The BMJ* that drug assignment confirmation printouts were

being left in participants' charts, accessible to blinded personnel. As a corrective action taken in September, two months into trial recruitment and with around 1000 participants already enrolled, quality assurance checklists were updated with instructions for staff to remove drug assignments from charts.

In a recording of a meeting in late September2020 between Jackson and two directors a Ventavia executive can be heard explaining that the company wasn't able to quantify the types and number of errors they were finding when examining the trial paperwork for quality control. "In my mind, it's something new every day," a Ventavia executive says. "We know that it's significant."

Ventavia was not keeping up with data entry queries, shows an email sent by ICON, the contract research organisation with which Pfizer partnered on the trial. ICON reminded Ventavia in a September 2020 email: "The expectation for this study is that all queries are addressed within 24hrs." ICON then highlighted over 100 outstanding queries older than three days in yellow. Examples included two individuals for which "Subject has reported with Severe symptoms/reactions … Per protocol, subjects experiencing Grade 3 local reactions should be contacted. Please confirm if an UNPLANNED CONTACT was made and update the corresponding form as appropriate." According to the trial protocol a telephone contact should have occurred "to ascertain further details and determine whether a site visit is clinically indicated."

Worries over FDA inspection

Documents show that problems had been going on for weeks. In a list of "action items" circulated among Ventavia leaders in early August 2020,

shortly after the trial began and before Jackson's hiring, a Ventavia executive identified three site staff members with whom to "Go over e-diary issue/falsifying data, etc." One of them was "verbally counseled for changing data and not noting late entry," a note indicates.

At several points during the late September meeting Jackson and the Ventavia executives discussed the possibility of the FDA showing up for an inspection (box 1). "We're going to get some kind of letter of information at least, when the FDA gets here . . . know it," an executive stated.

Box 1

A history of lax oversight

When it comes to the FDA and clinical trials, Elizabeth Woeckner, president of Citizens for Responsible Care and Research Incorporated (CIRCARE),[3] says the agency's oversight capacity is severely under-resourced. If the FDA receives a complaint about a clinical trial, she says the agency rarely has the staff available to show up and inspect. And sometimes oversight occurs too late.

In one example CIRCARE and the US consumer advocacy organisation Public Citizen, along with dozens of public health experts, filed a detailed complaint in July 2018 with the FDA about a clinical trial that failed to comply with regulations for the protection of human participants.[4] Nine months later, in April 2019, an FDA investigator inspected the clinical site. In May this year the FDA sent the triallist a warning letter that substantiated many of the claims in the complaints. It said, "[I]t appears that you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations and the protection of human subjects."[5]

"There's just a complete lack of oversight of contract research organisations and independent clinical research facilities," says Jill Fisher, professor of social medicine at the University of North Carolina School of Medicine and author of *Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials*.

Ventavia and the FDA

A former Ventavia employee told *The BMJ* that the company was nervous and expecting a federal audit of its Pfizer vaccine trial.

"People working in clinical research are terrified of FDA audits," Jill Fisher told *The BMJ*, but added that the agency rarely does anything other than inspect paperwork, usually months after a trial has ended. "I don't know why they're so afraid of them," she said. But she said she was surprised that the agency failed to inspect Ventavia after an employee had filed a complaint. "You would think if there's a specific and credible complaint that they would have to investigate that," Fisher said.

In 2007 the Department of Health and Human Services' Office of the Inspector General released a report on FDA's oversight of clinical trials conducted between 2000 and 2005. The report found that the FDA inspected only 1% of clinical trial sites.**6** Inspections carried out by the FDA's vaccines and biologics branch have been decreasing in recent years, with just 50 conducted in the 2020 fiscal year.**7**

RETURN TO TEXT

The next morning, 25 September 2020, Jackson called the FDA to warn about unsound practices in Pfizer's clinical trial at Ventavia. She then reported her concerns in an email to the agency. In the afternoon Ventavia fired Jackson—deemed "not a good fit," according to her separation letter.

Jackson told *The BMJ* it was the first time she had been fired in her 20 year career in research.

Concerns raised

In her 25 September email to the FDA Jackson wrote that Ventavia had enrolled more than 1000 participants at three sites. The full trial (registered under NCT04368728) enrolled around 44 000 participants across 153 sites that included numerous commercial companies and academic centres. She then listed a dozen concerns she had witnessed, including:

- Participants placed in a hallway after injection and not being monitored by clinical staff
- Lack of timely follow-up of patients who experienced adverse events
- Protocol deviations not being reported
- Vaccines not being stored at proper temperatures
- Mislabelled laboratory specimens, and
- Targeting of Ventavia staff for reporting these types of problems.

Within hours Jackson received an email from the FDA thanking her for her concerns and notifying her that the FDA could not comment on any investigation that might result. A few days later Jackson received a call from an FDA inspector to discuss her report but was told that no further information could be provided. She heard nothing further in relation to her report.

In Pfizer's briefing document submitted to an FDA advisory committee meeting held on 10 December 2020 to discuss Pfizer's application for emergency use authorisation of its covid-19 vaccine, the company made no mention of problems at the Ventavia site. The next day the FDA issued the authorisation of the vaccine.[8]

In August this year, after the full approval of Pfizer's vaccine, the FDA published a summary of its inspections of the company's pivotal trial. Nine of the trial's 153 sites were inspected. Ventavia's sites were not listed among the nine, and no inspections of sites where adults were recruited took place in the eight months after the December 2020 emergency authorisation. The FDA's inspection officer noted: "The data integrity and verification portion of the BIMO [bioresearch monitoring] inspections were limited because the study was ongoing, and the data required for verification and comparison were not yet available to the IND [investigational new drug]."

Other employees' accounts

In recent months Jackson has reconnected with several former Ventavia employees who all left or were fired from the company. One of them was one of the officials who had taken part in the late September meeting. In a text message sent in June the former official apologised, saying that "everything that you complained about was spot on."

Two former Ventavia employees spoke to *The BMJ* anonymously for fear of reprisal and loss of job prospects in the tightly knit research community. Both confirmed broad aspects of Jackson's complaint. One said that she had worked on over four dozen clinical trials in her career, including many large trials, but had never experienced such a "helter skelter" work environment as with Ventavia on Pfizer's trial.

"I've never had to do what they were asking me to do, ever," she told *The BMJ*. "It just seemed like something a little different from normal—the things that were allowed and expected."

She added that during her time at Ventavia the company expected a federal audit but that this never came.

After Jackson left the company problems persisted at Ventavia, this employee said. In several cases Ventavia lacked enough employees to swab all trial participants who reported covid-like symptoms, to test for infection. Laboratory confirmed symptomatic covid-19 was the trial's primary endpoint, the employee noted. (An FDA review memorandum released in August this year states that across the full trial swabs were not taken from 477 people with suspected cases of symptomatic covid-19.)

"I don't think it was good clean data," the employee said of the data Ventavia generated for the Pfizer trial. "It's a crazy mess."

A second employee also described an environment at Ventavia unlike any she had experienced in her 20 years doing research. She told *The BMJ* that, shortly after Ventavia fired Jackson, Pfizer was notified of problems at Ventavia with the vaccine trial and that an audit took place.

Since Jackson reported problems with Ventavia to the FDA in September 2020, Pfizer has hired Ventavia as a research subcontractor on four other vaccine clinical trials (covid-19 vaccine in children and young adults, pregnant women, and a booster dose, as well an RSV vaccine trial; NCT04816643, NCT04754594, NCT04955626, NCT05035212). The advisory committee for the Centers for Disease Control and Prevention is set to discuss the covid-19 paediatric vaccine trial on 2 November.

Prashant Bhushan

(TRUE COPY)

Online RTI Request Form Details

ANNEXURE: R11

RTI Request Details :-

RTI Request Registration number	MOHFW/R/E/21/04550
Public Authority	Department of Health & Family Welfare

Personal Details of RTI Applicant:-

Name	Loretta Rodrigues
Gender	Male
Address	Khalap Vaddo , Canca Parra Bardez, Goa 403510
Pincode	403510
Country	India
State	Goa
Status	Details not provided
Educational Status	Details not provided
Phone Number	Details not provided
Mobile Number	Details not provided
Email-ID	rodrigues[dot]loretta[at]gmail[dot]com

Request Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No

(Description of Information sought (upto 500 characters)

Description of Information Sought
To DCGI Please share raw data that SII and Bharat Biotech had to make available to the committee approving covid-19 vaccines. Did this committee look at the raw data and/or discuss it? Please share data provided by SII and Bharat Biotech related to the following from their trials: 1. Teratogenicity (risk of harm to foetus) 2. Genotoxicity (gene mutations) 3. Carcinogenicity (risk of cancer) 4. Fertility 5. Death

Concerned CPIO	Shambhu Kumar
Supporting document ***(only pdf upto 1 MB)***	Supporting document not provided

Print Close

सत्यमेव जयते

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	MOHFW/R/E/21/04550
Name	Loretta Rodrigues
Date of filing	19/07/2021
Public Authority	Department of Health & Family Welfare
Status	REQUEST TRANSFERRED TO OTHER PUBLIC AUTHORITY
Date of action	21/07/2021
Details of Public Autority :- CENTRAL DRUGS STANDARD CONTROL ORGANISATION. vide registration number :- CDSCO/R/T/21/00650 respectively. Note:- Further details will be available on viewing the status of the above-mentioned new request registration number. View Status of CDSCO/R/T/21/00650	
Nodal Officer Details :-	
Telephone Number	011-23061831
Email Id	r[dot]attri54[at]nic[dot]in

Print RTI Application Print Status Go Back

सत्यमेव जयते

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

Online RTI Status Form

Note:Fields marked with * are Mandatory.

Enter Registration Number	CDSCO/R/T/21/00650
Name	Loretta Rodrigues
Date of filing	21/07/2021
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Status	REQUEST DISPOSED OF
Date of action	03/09/2021
Reply :- The brief of interim clinical trial results/information containing safety, immunogenicity and efficacy results along with side-effects, contraindications precautions and instructions for use of Covishield & Covaxin COVID-19 vaccines are available in Summary of Product Characteristics (SmPC) & factsheet which along with recommendations of Subject Expert Committee are publicly available on CDSCO website i.e. www.cdsco.gov.in. Further, the sought information is exempted under Sec 8(1) (d) and (e) of RTI Act 2005 & consent is required for disclosure from such information.	
CPIO Details :-	Sushanta Sarkar Phone: 011-23216367 rti.cell@cdsco.nic.in
First Appellate Authority Details :-	A. K. Pradhan Phone: 011-23216367 rti.cell@cdsco.nic.in
Nodal Officer Details :-	
Telephone Number	011-23236973
Email Id	jayantwz[at]gmail[dot]com

Print RTI Application Print Status Go Back

Online RTI Appeal Form Details

RTI Appeal Details :-

RTI Appeal Registration number	CDSCO/A/E/21/00120
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION

Personal Details of Appellant:-

Request Registration Number	CDSCO/R/T/21/00650
Request Registration Date	21/07/2021
Name	Loretta Rodrigues
Gender	Male
Address	Khalap Vaddo , Canca Parra Bardez, Goa 403510
Pincode	403510
Country	India
State	Goa
Status	Details not provided
Educational Status	Details not provided
Phone Number	Details not provided
Mobile Number	Details not provided
Email-ID	rodrigues[dot]loretta[at]gmail[dot]com

Appeal Details :-

Citizenship	Indian
Is the Requester Below Poverty Line ?	No
Ground For Appeal	Refused access to Information Requested
CPIO of Public Authority approached	Sushanta Sarkar
CPIO's Order/Decision Number	Details not provided
CPIO's Order/Decision Date	

(Description of Information sought (upto 500 characters)

Prayer or Relief Sought
Sec 8(1) (d) and (e) state the following: (d) information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information; (e) information available to a person in his fiduciary relationship, unless the competent authority is satisfied that the larger public interest warrants the disclosure of such information; The information that I am seeking is of utmost public interest as Teratogenicity, Genotoxicity, Carcinogenicity, Fertility, and Death are serious consequences of these vaccines (and any vaccine for that matter). The clinical trial data that I am asking should be sent to me and should be made public.

Supporting document ***(only pdf upto 1 MB)***	Supporting document not provided

Print Close

Z-28020/984/2021-DC
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(RTI CELL)
FDA Bhawan, Kotla Road, New Delhi

To,

Date: 29.11.2021

Sh. Loretta Rodrigues,
Khalap VaddoCanca Parra Bardez, Goa-403510

Sub: Information under RTI Act, 2005 -Reg.

Sir,

This has reference to your RTI appeal application no. CDSCO/A/E/21/00120 dated 21.10.2021 with regards to your RTI application no. CDSCO/R/T/21/00650 dated 21.07.2021 on the subject cited above.

The matter was examined and it was found that the reply of above cited RTI application was already provided by the CPIO vide letter of even number dated 03.09.2021 through online portal.

However, on your appeal reply is mentioned as below:

Covishield and Covaxin vaccines are approved for restricted use in emergency situation for prevention of COVID-19 in the country. Various details of pre-clinical data of Covishield and Covaxin are available in Summary of Product Characteristics (SmPC) which are publically available on CDSCO website i.e. www.cdsco.gov.in on the following link:

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzI2MQ== and

https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzI2Mw==

Further, this office had issued third party notice to M/s Serum Institute of India Pvt. Ltd and M/s Bharat Biotech International Ltd to make their submissions in writing or orally, as per section 11 of RTI Act 2005, as to whether the information/records asked for by you should be disclosed or not. The firms submitted their response with request not to disclose the information/documents submitted by them.

Accordingly, the RTI appeal is disposed off.

In case the applicant is not satisfied with same, he/she may prefer appeal to the Central Information Commission within the prescribed time-limit.

Yours faithfully,

(A .K. Pradhan)
JDC (I) & First Appellate Authority

Address of Second appellate authority is as below:
The Chairman,
Central Information Commission
CIC Bhawan, Baba Gang Nath Marg, Munirka,
New Delhi- 110067

Prashant Bhushan
(TRUE COPY)