SECTION:PIL

IN THE SUPREME COURT OF INDIA
(CIVIL ORIGINAL WRIT JURISDICTION)

WRIT PETITION (CIVIL) NO. _____OF 2021

IN THE MATTER OF:
DR. JACOB PULIYEL .....PETITIONER

VERSUS

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

FILING INDEX

S.NO.	PARTICULARS	COPIES	C.FEE
1.	WRIT PETITION WITH AFFIDAVIT	1	520/-
2	ANNEXURE P1 TO P39	1	NIL
3.	VAKALATNAMA	1	10/-

Prashant Bhushan

(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER
301, NEW LAWYERS CHAMBER
SUPREME COURT OF INDIA
NEW DELHI 110001
CODE NO.: 515

NEW DEHI:
DATED: 12.05.2021

DOL RAJ BHANDARI , REGD. CLERK, I.D. NO. 3745, MOB. NO. 9868255076

IN THE HON'BLE SUPREME COURT OF INDIA

(CIVIL ORGINAL WRIT JURISDICTION)

WRIT PETITION (CIVIL) NO. _____OF 2021

(PUBLIC INTEREST LITIGATION)

IN THE MATTER OF

DR. JACOB PULIYEL .....PETITIONER

VERSUS

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

PAPER BOOK

(FOR INDEX KINDLY SEE INSIDE)

COUNSEL FOR THE PETITIONER: **PRASHANT BHUSHAN**

RECORD OF PROCEEDING

S. NO.	PARTICULARS	PAGRS
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

INDEX

S.No.	PARTICULARS OF DOCUMENTS	PAGE NO. OF PART TO WHICH IT BELONGS		REMARKS
(i)	(ii)	(iii)	(iv)	(v)
1.	Listing Proforma	**A1-A2**	**A1-A2**	
2.	Cover Page of Paperbook		**A3**	
3.	Index of Record of Proceedings		**A4**	
4.	Defect List		**A5**	
5.	Note Sheet		**A6 TO**	
6.	List of Dates	**B-Z**		
7.	Writ Petition of Mandamus under Article 32 of the Constitution of India along with Affidavit	**1-71**		
8.	**ANNEXURE-P1** A copy of the press statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID – 19 virus vaccine, dated 3rd January 2021	**72-73**		
9.	**ANNEXURE-P2** A copy of the Times of India report dated 3.01.2021	**74-75**		
10.	**ANNEXURE-P3** A copy of the Deccan Herald report dated 5th January 2021 "Covaxin phase-3 trials to end today, average efficacy 60-70%	**76-77**		

11.	**ANNEXURE-P4** A copy of the CTRI database regarding the Phase 3 trials details of the Covaxin	**78-85**		
12.	**ANNEXURE-P5** A copy of The Hindu Report dated 1st April 2021 titled, "Covaxin for those who got placebo"	**86-88**		
13.	**ANNEXURE-P6** A copy of the article in The Atlantic dated 27th February 2021	**89-92**		
14.	**ANNEXURE-P7** A copy of the relevant section of the revised Declaration of Helsinki	**93-96**		
15.	**ANNEXURE-P8** A copy of the 'WHO statement on Public Disclosure of Clinical Trial Results' released on 14.04.2015	**97-99**		
16.	**ANNEXURE-P9** A copy of the article dated 13th April 2019 titled, "Anti Vaccination; Pro Science; Pro-Health; Anti-Industry" by Jagannath Chatterjee	**100-110**		
17.	**ANNEXURE-P10** A copy of the RTI application and reply dated Nil	**111-112**		
18.	**ANNEXURE-P11** A copy of the letter dated 20th September 2020 to the Hon'ble Health Minister	**113-125**		
19.	**ANNEXURE-P12** A copy of the recommendations of the SEC meeting to examine COVID-19 related proposal under	**126**		

	accelerated approval process made in its 146th meeting held on 10.03.2021 at CDSCO, HQ New Delhi			
20.	**ANNEXURE-P13** A copy of the National Herald report dated 6th January 2021	**127-130**		
21.	**ANNEXURE-P14** A copy of the minutes of the SEC dated 30th December 2020, 1st January 2021 and 2nd January 2021	**131-135**		
22.	**ANNEXURE-P15** A copy of The Hindu report dated 3rd May 2021 titled "ICMR to get royalty from Covaxin sale	**136-138**		
23.	**ANNEXURE-P16** A copy of the 59th Parliamentary Standing Committee Report	**139-190**		
24.	**ANNEXURE-P17** A copy of the CIC order dated 26th May 2020	**191-201**		
25.	**ANNEXURE-P18** A copy of the paper titled, Revised World Health Organisation assessment of adverse events following immunization a critique dated 17th May 2019	**202-225**		
26.	**ANNEXURE-P19** A copy of The Hindu report dated 17th March 2021 titled, Probe sought into death and adverse effects after Covid-19 vaccinations	**226-227**		

27.	**ANNEXURE-P20** A copy of the letter dated 27.04.2021	**228**		
28.	**ANNEXURE-P21** A copy of The Hindu report dated 09April 2021 "180 deaths following vaccination reported in India"	**229-232**		
29.	**ANNEXURE-P22** A copy of the screen shot of the openvaers.com /covid data database of the US as accessed on the 10th of May 2021	**233**		
30.	**ANNEXURE-P23** A copy of the report in The Daily Expose dated 4th April 2021	**234-236**		
31.	**ANNEXURE-P24** A copy of the paper published in The Lancet titled "Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind, randomized, phase 1 trial" published on 21st January 2021	**237-246**		
32.	**ANNEXURE-P25** A copy of the report "Safety and immunogenicity clinical trial of an inactivated SARS-CoV-2 vaccine (BBV152 a phase 2, double blind, randomized control trial) and persistence of immune responses from a phase 1 follow up report	**247-280**		
33.	**ANNEXURE-P26** A copy of the Phase 3 study description titled "An Efficacy and Safety Clinical Trial of an	**281-289**		

	Investigational COVID-19 Vaccine (BBV152) in Adult Volunteers" as available on the clinical trials registry			
34.	**ANNEXURE-P27** A translated copy of the original RTI reply (in Hindi) dated 9th March, 2021	**290-291**		
35.	**ANNEXURE-P28** Copy of the RTI Reply dated 2.05.2021	**292-293**		
36.	**ANNEXURE-P29** A copy of the order dated 16.01.2021 was issued by Civil Surgeon (equivalent to CMO/CMHO) in Koderma, Jharkand	**294**		
37.	**ANNEXURE-P30** A copy of the Order dated 13th March 2021 issued by the Department of Revenue and Forest, Government of Maharasthra	**295-311**		
38.	**ANNEXURE-P31** A copy of Lokmat Times report dated 18th April 2021, "Only vaccinated citizens can step out of home after May 1.	**312**		
39.	**ANNEXURE-P32** A copy of The Indian Express report dated 11th February "Gujarat: Row over two circulars making Covid shot mandatory for school teachers	**313-318**		

40.	**ANNEXURE-P33** A copy of the order dated 23rd April 2021	**319**		
41.	**ANNEXURE-P34** A copy of the email titled, "Vaccination against Covid" dated 29.04.2021	**320-321**		
42.	**ANNEXURE-P35** (A copy of the order dated 30th April 2021	**322-324**		
43.	**ANNEXURE-P36** A copy of the order of Government of Punjab dated 2nd May 2021	**325-328**		
44.	**ANNEXURE-P37** A copy of the circular dated 22.04.2021 of the Gujarat Technological University, Govt of Gujarat	**329**		
45.	**ANNEXURE-P38** A copy of the order of the Kerala High Court dated 10th November 2017	**330-331**		
46.	**ANNEXURE-P39** A copy of the Order of the Hon'ble Delhi High Court dated 22nd January 2019	**332-340**		
47.	Filing Memo		**341**	
48.	Vakalatnama		**342**	

A1

SECTION: PIL

PROFORMA FOR FIRST LISTING

The case pertains to (Please tick/check the correct box):

☐	Central Act: (Title)	**CONSTITUTION OF INDIA**
☐	Section	**UNDER ARTICLE 14 AND 21**
☐	Central Rule : (Title)	**-NA-**
☐	Rule No(s):	**- NA -**
☐	State Act: (Title)	**- NA -**
☐	Section :	**- NA -**
☐	State Rule : (Title)	**- NA -**
☐	Rule No(s):	**- NA -**
☐	Impugned Interim Order: (Date)	**- NA -**
☐	Impugned Final Order/Decree: (Date)	**-NA-**
☐	High Court : (Name)	**-NA-**
☐	Names of Judges:	**-NA-**
☐	Tribunal/Authority ; (Name)	**-NA -**
1.	Nature of matter : Civil ☐ ☐ Criminal	
2.	(a) Petitioner/appellant No.1 :	[redacted]
	(b) e-mail ID:	[redacted]
	(c) Mobile Phone Number:	[redacted]
3.	(a) Respondent No.1:	[redacted]
	(b) e-mail ID:	**- NA -**
	(c) Mobile Phone Number:	**- NA -**
4.	(a) Main category classification:	**08 (0812)**
	(b) Sub classification:	**OTHER PIL MATTER**
5.	Not to be listed before:	
6.	(a) Similar disposed of matter with citation, if any & case details:	**NO SIMILAR MATTER IS PENDING**
	(b) Similar Pending matter with case details:	**NO DISPOSED SIMILAR MATTER**

A2

7. **Criminal Matters:**

(a) Whether accused/convict has surrendered: Yes ☐ No ☐

(b) FIR No. - **NA** - Date: - **NA** -

(c) Police Station: - **NA** -

(d) Sentence Awarded: - **NA** -

(e) Period of sentence undergone including period of Detention/ Custody Undergone: - **NA** -

8. Land Acquisition Matters: - **NA** -

(a) Date of Section 4 notification: - **NA** -

(b) Date of Section 6 notification: - **NA** -

© Date of Section 17 notification: - **NA** -

9. Tax Matters: State the tax effect: - **NA** -

10. Special Category (first Petitioner/ appellant only): - **NA** -

☐ Senior citizen > 65 year ☐ SC/S[illegible] ☐ Woman/child

☐ Disabled ☐ Legal Aid case ☐ In custody - **NA** -

11. Vehicle Number (in case of Motor Accident Claim matters): - **NA** -

Prashant Bhushan

(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER
REGISTRATION NO. 515
E-Mail: [redacted]n

NEW DELHI
DATED: 12.05.2021

SYNOPSIS

B

The petitioner herein is filing the instant writ petition under Article 32 of the Constitution of India for the enforcement of fundamental rights under Article 14 and 21 of the Constitution of India, seeking a writ directing the respondents to make public the segregated data of the clinical trials for the vaccines that are being administered to the population in India under the Emergency Use Authorisation granted by the Drugs Controller General of India (DCGI). The petitioner is a former member of the National Technical Advisory Group on Immunisation (the government's apex body on immunization). The petitioner avers and wishes to record the evidence in medical literature that, vaccines that have not been adequately tested for safety or efficacy are now licensed under Emergency Use Authorisation without the data being disclosed to the public. This is a clear violation of the basic norms of scientific disclosure and the guidelines with respect to disclosure of clinical trial data, as laid down by the World Health Organisation (WHO) and followed by the Indian Council of Medical Research (ICMR). In India, the manner in which the vaccines have been licensed vitiates and even precludes the possibility that the vaccines can be evaluated objectively in the future. Under these circumstances the petitioner is forced to appeal to this court for public disclosure of trial data and post vaccination data, as required by international medical norms.

The petitioner submits that 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

C

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. So far, the respondents have practiced complete secrecy in the matter and have not disclosed any data from trials for the vaccines that have been developed in India – Covaxin by the Bharatbiotech or for the Covishied manufactured at the Serum Institute, India (SII). The clinical trial information that is available for the COVISHIED vaccine is preliminary data of clinical trials that have been undertaken for the vaccine in other countries.

Besides this, it is important for the respondent authorities to carefully monitor vaccine recipients and publicly record all adverse events. In other countries, this type of observation has helped identify the occurrence of blood clots and strokes in vaccine recipients. Many countries stopped administering the vaccine till they evaluated this occurrence and countries like Denmark have completely banned use of the Astra Zeneca vaccine (branded as Covishield in India). India, with its huge population and numbers vaccinated, should have reported these adverse events first. But due to poor follow-up, poor Adverse Events Following Immunization (AEFI) evaluation and suppression of data, these events have not been put in the public domain – endangering many more to suffer the same fate. Under these circumstances the petitioner has approached this court also seeking that that all AEFI be actively solicited by notification in newspapers, and be made available in publicly accessible data base (Like the VAERS data base in the USA). Currently the website cowin.gov.in only mentions certain numbers of AEFI but details of those cases are not available for scientific scrutiny.

D

Further the petitioner prays that no coercive mandates for use of these inadequately tested vaccines may be issued and that the courts reiterate that vaccine mandates are repugnant to the right of humans to autonomy and right to self-determine what may be injected into their bodies. In so doing this Hon'ble Court must uphold the rights of individuals to give informed consent as the Delhi High Court did, in the Measles Rubella case. It is submitted that coercing citizens directly or indirectly to get vaccinated is unconstitutional and violates the Right to Life of citizens. While the government has clearly stated in numerous RTIs that Covid vaccines are voluntary, there are many instances from across the country where now various authorities are mandating the vaccines.

The petitioner recognises that Covid is a public health emergency and that such an emergency may require emergency use authorisations of vaccines which may not yet have been adequately tested. However, that should not mean that all information and data of relevance as to the efficacy or side effects of the vaccines which have been given such approval, should not be collected systematically and made publicly available, especially when the vaccines are being used in a universal immunisation programme. Though emergency authorisation of the vaccines may be advisable in the present situation, it does not however mean that these vaccines can be forced upon people, especially without all relevant data being available for independent public and scientific scrutiny. The present petition therefore should not be understood to be a petition challenging the present Covid vaccination programme.

For the first time in history, a universal mass vaccination programme is being undertaken in India and many other countries using vaccines

which have not been fully tested for efficacy and side effects, in the manner in which vaccines are required to be tested normally, usually over a period of three years or so, so that even long term adverse effects can be examined. The problem is further compounded due to the lack of transparency in the vaccine trial data and the manner of granting approvals to the vaccines based on that data which is withheld from disclosure to the public or not available to independent researchers for scientific scrutiny.

History has shown that vaccines can be very useful instruments for fighting disease and epidemics but vaccines can also have serious unintended side effects. That is why before vaccines are approved they need to be properly tested and studied by thorough clinical trials and the test results must be available for scrutiny by independent scientists. While there may be circumstances warranting emergency approvals to vaccines which have not been fully and properly tested, there cannot be any reason whatever for trial data (that has been collected and on the basis for which approvals have been given), to be withheld from public scrutiny. This is what the WHO and ICMR guidelines also require. In such circumstances, coercing people to take the vaccines on pain of losing their jobs or access to essential services, which has begun to happen in many parts of the country, is a violation of the fundamental rights of people, especially in a situation where emergency approvals have been given to vaccines without full and adequate testing and without any transparency of the trial data and post vaccination data.

Hence this writ petition.

F

LIST OF DATES

June 1964	World Medical Association adopts the Declaration of Helsinki, Ethical Principles for Medical Research involving Human Subjects
8.05.2012	The need for greater transparency has been noted by the Parliamentary Standing Committee on Health and Family Welfare, in its 59th Report which called for "increased transparency in decision-making" of the Central Drugs Standard Controls Organisation (CDSCO) and other regulatory authorities.
9.04.2015	World Health Organisation Statement on Public Disclosure of clinical trial results
10.11.2017	In the case of WP(C) 36065 of 2017 between the Parents Teachers Association, Government Higher Secondary School, Kokkur, Kerala and the State of Kerala **(2017 SCC Online Kerala 36408**), the Hon'ble High Court of Kerala had passed order: "If at all any parent has an objection, it has to be necessarily brought before the authorities, and there need not be any vaccination administered to such children whose parents object to the Vaccination. The learned government pleader also submits that no forceeful vaccination is attempted".
22.01.2019	In the case of W.P.(C) 343/2019 & CM Nos.1604-1605/2019 between Master Haridaan Kumar (Minor through Petitioners Anubhav Kumar and Mr. Abhinav Mukherji) Versus Union of India, &W.P.(C) 350/2019 & CM Nos.1642-1644/2019 between Baby Veda Kalaan& Others Versus Director of Education & Others ***the Hon'ble High Court of Delhi had observed that:***

G

"13. Undisputedly, there is an urgent need to disseminate information regarding the MR campaign and the assumption that children could be vaccinated forcibly or without consent is unsustainable. This Court is of the view that all efforts are required to be made to obtain the decision of the parents before proceeding with the MR campaign. In this regard, it would be apposite to ensure that the consent forms/slips are sent to each and every student. Since the time period for implementing the campaign is short, the response period should be reduced and parents / guardians of students must be requested to respond immediately and, in any case, in not more than three working days. ***If the consent forms/slips are not returned by the concerned parent, the class teacher must ensure that the said parents are contacted telephonically and the decision of such parent is taken on phone.***"

"14. ***The contention that indication of the side effects and contraindications in the advertisement would discourage parents or guardians from consenting to the MR campaign and, therefore, the same should be avoided, is unmerited.*** The entire object of issuing advertisements is to ensure that necessary information is available to all parents/guardians in order that they can take an informed decision. The respondents are not only required to indicate the

benefits of the MR vaccine but also indicate the side effects or contraindications so that the parents/guardians can take an informed decision whether the vaccine is to be administered to their wards/children."

The Hon'ble High Court of Delhi thus passed the following orders:

"15.4 ***MR vaccines will not be administered to those students whose parents/guardians have declined to give their consent.*** The said vaccination will be administered only to those students whose parents have given their consent either by returning the consent forms or by conforming the same directly to the class teacher/nodal teacher and also to students whose parents/guardians cannot be contacted despite best efforts by the class teacher/nodal teacher and who have otherwise not indicated to the contrary".

Further on the issue of informed consent, the The Hon'ble High Court of Delhi directed that:

"15.1Directorate of Family Welfare shall issue quarter page advisements in various newspapers as indicated by the respondents...The advertisements shall also indicate that the vaccination shall be administered with Auto Disable Syringes to the eligible children by Auxiliary Nurse Midwifery. ***The advertisement shall also clearly indicate the***

	side effects and contraindications as may be finalised by the Department of Preventive Medicine, All India Institute of Medical Sciences"
13.04.2019	Article in Green Medinfo "Anti Vaccination;Pro Science;Pro-Health;Anti-Industry" by Jagannath Chatterjee notes how clinical trials are known to obfuscate troublesome data. The article notes: "In September 2017, a report titled "Infanrix hexa and sudden death: a review of the periodic safety update reports submitted to the European Medicines Agency" published in the Indian Journal of Medical Ethics[35] alleged that GlaxoSmithKline (GSK) apparently excluded certain cases of infant deaths in their official report to the European Medicines Agency. GSK stated that the deaths reported after the vaccine is "coincident" and not related to the vaccine. However analysis by Puliyel and Sathyamala, authors, showed that 83% of the reported deaths occurred within 10 days of vaccination and another 17% occurred in the following ten days. "Glossing over of the deaths after vaccination has potential to result in more, unnecessary deaths which are difficult to justify ethically," they observed in a Press Release. The same vaccine and an MMR vaccine have also been embroiled in serious contamination scandals and the list grows by the day. In yet another shocking incident the Government of India preferred not to release clinical data of an indigenous Rotavirus vaccine that showed a very high incidence of a potentially lethal intestinal obstruction in vaccinated children under the plea that revealing the data would "alarm the public".

17.05.2019	A paper titled, "Revised World Health Organisation assessment of adverse events following immunization – a critique" published by the petitioner, 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.
14.03.2020	Vide the letter, dated 14.03.2020, addressed to the Chief Secretaries of all States by the Ministry of Home Affairs (Disaster Management Division), the Central Government notified COVID as disaster under Disaster Management Act, 2005
26.05.2020	CIC order in Prashant Reddy T. v. Central Public Information Officer, Drug Controller General of India & Ministry of Health, made the following observations involving files that went missing from the Office of the Drug Controller General of India (DCGI) "The Commission however expressed its serious concern over the record keeping methodology in the office of DCGI / CDSCO due to the fact that an important report relating to the review of procedures and practices followed by CDSCO for granting approval and clinical trials on certain drugs went missing from their office that had to be procured from the author after receipt of notice of hearing from the Commission. This is despite the fact that the Parliamentary Standing Committee had also taken cognizance of the lapses by the Public

K

	Authority. The intent and the conduct of the Public Authority should always be above board in matters relating to grant of approvals through a transparent and objective mechanism. The Commission advises Secretary, M/o Health and Family Welfare, Govt. of India to examine this matter appropriately for further necessary action at its end."
30.06. 2020	The Drugs Controller General of India (DGCI) approved Bharat Biotech application to conduct a Phase I and II clinical trial of Covaxin. The vaccine was being developed with the collaboration of Indian Council of Medical Research ((ICMR).
06.07.2020	An RTI was filed seeking information from the Indian Council of Medical Research, regarding the list of ingredients present in the proposed COVAXIN, the methodology and techniques used in manufacturing the vaccines, the research papers published detailing the reports of pre clinical trial of COVAXIN and details of the agreement between ICMR and Bharat Biotech. . However the ICMR refused to give any information and in its reply stated: *"Since it is the third party information sought, which is under an agreement between the same cannot be shared under PPP ethical code."*
26.08.2020	Serum Institute of India started the clinical trials of Covishield developed by Oxford University and AstraZeneca in pursuance of the approval by The Drugs Controller General of India on 30.07.2020.
20.09.2020	A letter dated was written to the Hon'ble Health Minister by a group of concerned citizens including senior doctors and health specialists, researchers and transparency activists expressing

	concerns about the opacity in clinical trials data. They highlighted that the CTRI (Clinical Trials Registry) database is valuable for doctors and researchers to learn from developments in medical research. Apart from the opacity in the clinical trial, the letter also raised issues regarding the loopholes in the CTRI database. CTRI database allows citizens to monitor the recruiting practices employed by pharma companies during the trials conducted in India. However, the Hon'ble Health Minister didn't respond to the letter.
23.10.2020	The Drugs Controller General of India (DCGI) granted permission for conducting phase-3 clinical trial of COVAXIN. The permission was granted after recommendation of subject expert committee after assessing the data from Phase I & II as well as animal challenge study.
07.12.2020	Bharat Biotech and Serum Institute of India applied to the central drug regulator seeking emergency use authorization for its COVID-19 vaccine i.e. Covaxin and Covishield.
30.12.2020	Subject Expert Committee reviewed the requests of Serum Institute and Bharat Biotech for grant of Emergency approval of their vaccines. M/s Serum Institute of India Pvt. Ltd. (SIIPL), Pune, in light of the earlier recommendations presented safety immunogenicity & efficacy data of phase II/III clinical trials of AstraZeneca vaccine carried out in UK & Brazil & South Africa along with the safety & immunogenicity data from the ongoing Phase II/III clinical trial of COVISHIELD vaccine manufactured by SIIPL in the country. The firm also presented the draft factsheet & prescribing information of the vaccine. The firm also mentioned that AstraZeneca had received Emergency Use Authorization for

M

	the vaccine in UK subject to various conditions & restrictions. The committee discussed the safety, efficacy & immunogenicity data, draft factsheet & prescribing information as provided by the firm & decided that clarification/justification on various aspects are still needed. After detailed deliberation, the committee recommended that the firm should submit complete details of the conditions & restrictions under which AstraZeneca was granted Emergency Use Authorization in UK and also present the revised factsheet & prescribing information in Indian context as required by the committee for further consideration. Also the firm was informed during the meeting regarding other requirements including clarification/justification on factsheet & prescribing information. BIO/MA/20/000103 Whole Virion, Inactivated Corona Virus Vaccine (BBV152) (EUA) M/s Bharat Biotech International limited, Hyderabad In light of the earlier recommendations of the committee, the firm presented updated recruitment status & safety data including SAE data of the ongoing Phase III clinical trial in the country. After detailed deliberation, the committee recommended that firm should update & present Immunogenicity, Safety & Efficacy data for further consideration.
01.01.2021	Subject Expert Committee meeting further reviewed the proposals and information submitted by the companies. BIO/MA/20/00010 2 ChAdOx1 nCoV19 Corona Virus Vaccine (Recombinant) (COVISHIELD) M/s Serum Institute of India Pvt Ltd. The minutes detail that in light of the recommendations of the committee in its earlier meeting dated 30.12.2020, the firm

	presented the details of the conditions & restrictions under which AstraZeneca was granted Emergency Use Authorization in UK and the revised factsheet & prescribing information in Indian context as required by the committee for further consideration. The MHRA approval dated 30.12.2020 along with its conditions/restrictions was also reviewed by the committee. The committee noted that the safety & immunogenicity data presented by the firm from the Indian study is comparable with that of the overseas clinical trial data. Considering the serious nature of the COVID-19 pandemic, emergency situation, there is an urgent need of vaccine in the country. After detailed deliberation, the committee recommended for grant of permission for restricted emergency use of the vaccine subject to various regulatory provisions. The committee with respect to Covaxin recorded: "In light of the earlier recommendations of the committee dated 30.12.2020, the firm presented safety & immunogenicity data, GMT, GMFR including SAE data from the Phase I & Phase II clinical trial along with the data from the ongoing Phase III clinical trial in the country. The committee noted that this vaccine is Inactivated Whole Virion, Corona Virus Vaccine having potential to target mutated corona virus strains. The data generated so far demonstrates a strong immune response (both antibody as well as T cell) and invitro viral neutralization. The ongoing clinical trial is a large trial on 25800 Indian subjects in which already 22000 subjects have been enrolled including subjects with comorbid conditions as well which has demonstrated safety till date. **However, efficacy is yet to be demonstrated.**

	After detailed deliberation, the committee recommended that the firm should try to expedite the recruitment and may perform interim efficacy analysis for further consideration of restricted emergency use approval."
02.01.2021	On January 2, however, the committee recommended approval of Covaxin, citing efficacy data from a challenge study on non-human primates. The minutes of the meeting states: "In light of the recommendations of the committee dated 01.01.2021, the firm further presented the updated data, justification and requested for consideration of their proposal in the wake of incidence of new mutated corona virus infection. As already noted by the committee, this vaccine is Inactivated Whole Virion, Corona Virus Vaccine having potential to target mutated corona virus strains. The data generated so far demonstrates a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization. The ongoing clinical trial is a large trial on 25800 Indian subjects in which already 22500 subjects have been enrolled including subjects with comorbid conditions as well which has demonstrated safety till date. Moreover, firm has presented the safety and efficacy data from Non-human primate challenge study where the vaccine has been found to be safe and effective. In view of above, after detailed deliberation, the committee recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains. Further, the firm shall continue the on-going Phase III clinical trial and submit data emerging from the trial as and when available."

P

03.01.2021	Drugs Controller General of India (DCGI) granted emergency approval to two COVID – 19 vaccines i.e Covaxin And Covishield . The press statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID – 19 virus vaccine is as follows: "*The Subject Expert Committee (SEC) has reviewed the data on safety and immunogenicity of the vaccine and recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains. The clinical trial ongoing within the country by the firm will continue.*" Petitioner herein submits that the grant of emergency use license to the vaccines in India foreclosed the Phase III trials, restricting it to a mere 2 months. Subsequently the population in general have been encouraged to be vaccinated, so the control group to study adverse effects and efficacy for the trials has vanished and after that the ability to compare adverse events in the vaccinated and unvaccinated is lost forever. The Emergency Use Authorization by Respondent without disclosing the data for each of the phases of clinical trials is in clear violation of Article 19 and 21 of Constitution of India and the principle of "informed consent" as held by this Hon'ble Court in various judgments. As reported in The Times of India, The Drug Controller General of India stated that the Covid-19 vaccines are "110% safe".
5.01.2021	Deccan Herald report "Covaxin phase-3 trials to end today, average efficacy 60-70%". Covaxin does not have any data from its Phase 3 trial published in a peer reviewed journal. The first

	participant was enrolled in the phase three trial on the 11th of November 2020 and as shown on the Clinical Trials Registry website, the estimated duration of the trial was one year. Yet the company is reported to have ended its phase 3 trial on 5th of January 2021, as reported in the Deccan Herald.
16.01.2021	An order was issued by Civil Surgeon (equivalent to CMO/CMHO) in Koderma, Jharkand, mandating local government health workers to take Covid-19 Vaccine or otherwise their salary will be withheld. The order was subsequently withdrawn.
11.02.2021	The Indian Express reported that, "The Circular from Garudeshwar taluka, falling in the tribal Narmada district, cites a video-conference held by the district primary education officer (DPEO) on February 8, and was issued to two nodal officers in the taluka on February 9. It said, "Teachers of the government primary schools, who have to interact with students and work among the students, have to mandatorily take the Covid-19 vaccine, which must be ensured. If any teacher refuses to take the vaccine or remains absent during the vaccination drive, and if any student thereafter contracts Covid-19 from the teacher, the entire responsibility of the same will be on the teachers." Teachers who refuse to take the vaccine shot will have to submit a certificate in writing, citing reasons for the same the circular added". While the district administration later called it a "draft copy" that was issued "by mistake", officers in

R

	charge of the nodal supervision of the vaccination drive for teachers said the decision to make teachers "accountable" was taken because many had refused to take the shot. The same news report, mentions another circular: "the circular issued by the Ahmedabad Municipal Corporation School Board made it compulsory for its teachers and other staffers to get themselves vaccinated. Municipal school teachers told the The Indian Express on conditions of anonymity, they were asked to not sign the muster roll if they did not take the vaccine."
27.02.2021	The WHO holds that the vaccine does not prevent the spread of the disease from person to person and so has little potential of stopping the pandemic or the preservation of public health. Dr Antony Fauci who heads the Center for Disease Control in the USA made the following statement recently as reported in The Atlantic: *"Anthony Fauci said last week on CNN that "it is conceivable, maybe likely," that vaccinated people can get infected with the coronavirus and then spread it to someone else, and that more will be known about this likelihood "in some time, as we do some follow-up studies."*
9.03.2021	RTI reply by the Ministry of Health and Family Welfare stated, "taking the Covid Vaccines was entirely voluntary and there is no relation whatsoever to provision of government facilities, citizenship, job etc to the vaccine".
10.03.2021	The Subject Expert Committee on Vaccines (SEC) in its meeting dated 10.03.2021, recommended for omission of the condition of

	the use of the vaccine in "clinical trial mode". The petitioner submits that this has been done in haste to enable the vaccines acceptability and use despite its phase 3 trial which is still ongoing. It is hereby submitted that despite the phase 3 trials of the Covaxin being underway, the removal of the "clinical trial mode" label attached to the emergency authorisation of the vaccine would mean that the vaccine would now be administered effectively in a phase 3 trials but without seeking informed consent of those to whom the vaccine is being administered. Thereby depriving the participants from right to get compensation in cases of adverse effect of vaccination. The reason Covaxin had been given restricted emergency use authorisation "in clinical trial mode" in the first place was because Bharat Biotech had not completed recruitment of participants for phase 3 trials and thus not been able to submit information regarding the vaccines efficacy. Therefore such recommendation should not be implemented.
13.03.2021	**T**he Government of Maharashtra Department of Revenue and Forest Disaster Management, Relief and Rehabilitation, has issued a governmental order No: *DMU/ 2020 / CR. 92 / Dis M-1, directing:* "*Essential shops owners and person working at all shops to get vaccinated at the earliest, as per criteria of GOI*"
17.03.2021	The Hindu published an article stating that a group of experts in public health, ethics, medicine, law and journalism have written to the Health Minister and the Drug Controller General of India, appealing for a time bound and transparent investigation following deaths and serious adverse effects after Covid-19

T

	vaccination. The experts underline that even as the Indian health administration continues to be indifferent to the adverse effects of vaccination, several countries across the world such as Denmark, Iceland, Norway, Italy, France, Bulgaria, Germany, Luxembourg, Estonia, Lithuania, Latvia and Ireland have paused immunisation with Astra Zeneca vaccine pending investigation of a small number of post-vaccination deaths from intravascular clotting/ thromboembolic events. Austria has even suspended the use of certain batches... They have demanded a transparent investigation into each of the adverse incidents and sought details of all serious AEFIs till date, status of their investigation, findings of AEFI probe including cause of death by clinical diagnosis, autopsy findings, causality assessment and the process undertaken by AEFI committees to arrive at their conclusions.
1.04.2021	As reported in The Hindu, the Subject Expert Committee allowed Bharat Biotech to unblind trials participants aged above 45 and offer them the vaccine free of cost. The Committee recommended that the company unblind the participants as "vaccines are already available under the immunization programme, and therefore all the eligible age groups under the immunization programme should be permitted for unblinding for vaccination."
04.04.2021	The Daily Expose reported the statement of Dr Polyakova, who is the Medical Director of a hospital in Kent has said that "the levels of sickness after vaccination is unprecedented" among NHS staff, confirming that some are even suffering neurological symptoms which is having a "huge impact on the health service

	functioning". The doctor, who progressed into medical management of the hospital over the past three years says that she is struggling with the "failure to report" adverse reactions to the Covid vaccines among NHS staff, and clarified that the young and healthy are missing from work for weeks after receiving a dose of either the Pfizer or AstraZeneca experimental vaccine"
09.04.2021	The Hindu reported in an article "180 deaths following vaccination reported in India" that according to a presentation made to the National AEFI Committee during a meeting held on March 31, there have been 617 severe and serious (including deaths) adverse events following immunisation. As on March 29, a total of 180 deaths (29.2%) have been reported following vaccination across the country. Complete documentation is available only for 236 (38.3%) cases. In all, 492 severe and serious AEFI have been classified by the AEFI Secretariat of the Immunisation Technical Support Unit (ITSU) at the Health Ministry. Classification has been completed for 124 deaths, 305 serious events that required hospitalisation, and 63 severe events that did not require hospitalization. Therefore in such case it is necessary that Respondent disclose the post vaccination data regarding adverse events, vacinees who got infected with Covid, those who needed hospitalization and those who died after such infection post vaccination.
18.04.2021	The Lokmat Times reported that "*The Maharasthra government has imposed strict restrictions until May 1 to break the coronavirus chain. After that, the Aurangabad Municipal Corporation (AMC) will not allow unvaccinated traders and general people, aged 45 and above, to step out of home. So citizens eligible for vaccination should get vaccinated as soon as*

V

	possible," said AMC administrator Astik Kumar Pandy."
22.04.2021	The Gujarat Technological University, Govt of Gujarat issued a circular regarding Covid-19 Vaccination before Winter -2021 Exam form filling. An excerpt from the circular is below: "All students who have attained age of 18 years as on 1/05/2021 are hereby informed that it is mandatory to get Covid-19 vaccination before filling Winter 2021 exam forms. Along with the prevailing GTU norms, institutes will have to allow only the students who have taken Covid 19 vaccination to fill their Winter – 2021 exam forms"
23.04.2021	In the letter number: G-1/2021/36650 dated 23-04-2021, issued by the Office of the District Education Officer, Tarn, Tarn, it is stated, *"This has reference to the meeting hled by the Deputy Commissioner on 22-04-2021, regarding COVID Vaccination and the instructions were issued and received by this office on the mandatory COVID Vaccination of all the officers/employees. It is clearly stated that if any officer/employee is unwilling or refuses to be vaccinated, the concerned DEOs shall not draw the salary of such officers/employees."*
27.04.2021	The President of the Tamil Nadu Practitioners Association, Dr. CMK Reddy flags his concern about the reported deaths after taking Covid vaccine. The letter states: "Though the Adverse Effects Following Immunisation (AEFI) Committee comforts public and profession by saying they're unrelated to the vaccine, we have to take it with a grain of salt...If they are due to reasons other than vaccination, they should be evenly distributed during every week following

	vaccination, but 75% deaths occurred and 90% were hospitalised during the first 3 days. Hence let us not take it for granted and find out if we can prevent the complications."
29.04.2021	The Administration of Whistling woods International, Goregaon East, Mumbai, sent an office Memo to All, by email titled, "Vaccination against Covid". In that mail it was stated, *"We would like everyone who plans to come to campus post lockdown to be vaccinated, this will help us build a safer work place. Please ensure that you have your dozes of vaccines before end of July 2021 so we can start our operations full force as soon as the restrictions are over. After getting vaccinated, kindly send your vaccination certificate."*
30.04.2021	In the State of Punjab, the Governmental Order No: 7/56/2020/ 2H4/2142 dated 30th April 2021, addressed to all officers of the Police department including Divisional Commissioners, Zonal IGPs, Commissioners of Police, DIGs and SSPs, the Department of Home Affairs and Justice, stated in section 1(xv), "*In Government offices – Health / frontline workers and employees over 45 years who have not got at least one vaccine dose in last 15 days or more, should be encouraged to take leave and stay home until then Employees under 45 years to be allowed only on basis of negative RT-PCR not more than 5 days old or else should take leave and stay home".*

X

2.05.2021	RTI application to the Ministry of Health and Family welfare dated 21.04.2021, applicant Rakesh Singh requested for the following information; "1. Is corona vaccine (Covid-19 vaccine compulsory? 2. Can private company force its employees to take Covid 19 vaccine? 3. Will I be debarred from public services like Metro rail, Indian railway, bus services, hospital, electricity, internet, food and inter and intra-city movement, if I don't take covid-19 vaccine? 4. what can I do it my senior officer forces me to take Covid-19 vaccine? ... 7. Can a government Health worker be suspended for not taking Covid 19 vaccine? 8. Does government or its any associate body have any reliable data of Covid 19 vaccine research so that citizens can trust the efficacy of vaccines? Vide reply dated 2nd May 2021, from the Ministry of Health and Family Welfare stated: "1. Vaccination for Covid-19 is voluntary. However it is advisable to receive the complete schedule of Covid-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers. 2-8 – in view of the reply as SI. No. 1, these questions have no relevance."

02.05.2021	The Department of Home Affairs and Justice, Government of Punjab stated in section 2(ii), In its order No: 7/56/2020/2H4/2143 stated: *"Nobody to enter the State whether by air, rail or road without either:* *a- Negative Covid report not more than 72 hours old, or* *b- Vaccination certificate (at least one dose) over 2 weeks old."* It is hereby submitted that making Covid Vaccines are experimental treatments. Those agreeing to receive them are agreeing to be participants in an ongoing medical experiment with several unknowns. There is no certainty about issues like long term safety. Coercing citizens to get the vaccines directly or directly violates Article 21 and any order which makes the administration of vaccine mandatory is liable to be set aside.
3.05.2021	Report in The Hindu titled "ICMR to get royalty from Covaxin sale". As reported in The Hindu, the ICMR is to get royalties from the sale of Covaxin and this should disqualify them from sitting on regulatory committees to license this product or similar competing products. Given all these pervasive conflicts of interest, only data transparency and its availability to independent scientists to reassess, can protect the public interest.

10.05.2021	Data released today by the Centers for Disease Control and Prevention (CDC) on the number of injuries and deaths reported to the Vaccine Adverse Event Reporting System (VAERS) following COVID vaccines revealed reports of blood clots and other related blood disorders associated with all three vaccines approved for Emergency Use Authorization in the U.S. — Pfizer, Moderna and Johnson & Johnson (J&J). So far, only the J&J vaccine has been paused because of blood clot concerns. Every Friday, VAERS makes public all vaccine injury reports received through a specified date, usually about a week prior to the release date. Today's data show that between Dec. 14, 2020 and April 30, a total of 157,277 total adverse events were reported to VAERS, including 3837 deaths, including 21623 requiring urgent care, 1132 heart attacks, 213 miscarriages, 7463 severe allergic reactions.
12.05.2021	The act of respondents in maintaining opacity with regard to data of clinical trials of the vaccines administered in India, non disclosure of the detailed minutes of the meetings of the Subject Expert Committee with regard to the vaccine emergency authorisations and the documents and information relied upon for such permissions, the failure to disclose names of the members of the SEC who were present in the meetings where emergency authorisation for the use of vaccines was granted, as well as the lack of post vaccination data regarding recording and reporting adverse events, violates Article 19 and 21 of Constitution of India and the principle of "informed consent" as held by this Hon'ble Court in various judgments. Hence, the present Writ Petition.

IN THE SUPREME COURT OF INDIA

[EXTRAORDINARY ORIGINAL JURISDICTION]

WRIT PETITION (CIVIL) NO._____OF 2021

(PUBLIC INTEREST LITIGATION)

IN THE MATTER OF:-

DR. JACOB PULIYEL
S/O LATE MR P M MAMMEN
[redacted]

[redacted]R

[redacted]

[redacted]

3. **INDIAN COUNCIL OF MEDICAL RESEARCH**
V. RAMALINGASWAMI BHAWAN,
P.O. BOX NO. 4911
ANSARI NAGAR, NEW DELHI - 110029,
E-MAIL: ICMRHQDS@SANSAD.NIC.IN
PH: 91-11-26588895

4. **BHARAT BIOTECH**
THROUGH IT'S CHAIRMAN
GENOME VALLEY SHAMEERPET
HYDERABAD – 500078
TELENGANA
PH: 40-27784084
E-MAIL: EXPORTS02@BHARATBIOTECH.COM

5. **SERUM INSTITUTE OF INDIA PVT. LTD.**
THROUGH ITS CHAIRMAN
212/2 HADAPSAR
OFF SOLI POONAWALLA ROAD
PUNE 411028
PH: 20-26993900
E-MAIL: CONTACT@SERUMINSTITUTE.COM

A WRIT PETITION UNDER ARTICLE 32 OF THE CONSTITUTION SEEKING A WRIT OF MANDAMUS OR ANY OTHER APPROPRIATE WRIT DIRECTING THE RESPONDENTS TO DISCLOSE CLINICAL TRIAL DATA, POST VACCINATION DATA AND ADVERSE EVENTS FOR THE VACCINES BEING ADMINISTERED IN INDIA UNDER THE EMERGENCY AUTHORISATION AND FOR RESTRAINING RESPONDENT NO. 1 FROM MANDATING THE USE OF THESE VACCINES WITHOUT FULL AND INFORMED CONSENT

To,

THE HON'BLE CHIEF JUSTICE OF INDIA AND HIS COMPANION JUDGES OF THE HON'BLE SUPREME COURT OF INDIA

The Humble Petition of the
Petitioner above-named

MOST RESPECTFULLY SHOWETH:-

1. The petitioner herein is filing the instant writ petition under Article 32 of the Constitution of India for the enforcement of fundamental rights under Article 14 and 21 of the Constitution of India, seeking a writ directing the respondents to make public the segregated data of the clinical trials for the vaccines that are being administered to the population in India under the Emergency Use Authorisation granted by the Drugs Controller General of India (DCGI). The petitioner avers and wishes to record the evidence in medical literature that, vaccines that have not been adequately tested for safety or efficacy are now licensed under Emergency Use Authorisation without the data being disclosed to the public. This is a clear violation of the basic norms of scientific disclosure. In India, the manner in which the vaccines have been licensed vitiates and even precludes the possibility that the vaccines can be evaluated objectively in the future. Furthermore, the Government has made illogical claims and resorted to hyperbole in its promotion of these untested vaccines with the DCGI stating that the vaccine is 110% safe which is a logical fallacy. Under these circumstances the petitioner is forced to appeal to this court for public disclosure of trial data and post vaccination data, as required by international medical norms. Further the petitioner prays that no coercive mandates for use of these inadequately tested vaccines may be issued and that the courts reiterate that vaccine mandates are repugnant to the right of humans to autonomy and right to self-determine what may be

injected into their bodies. In so doing this Hon'ble Court must uphold the rights of individuals to give informed consent as the Delhi High Court did, in the Measles Rubella case. Besides this, it is important for the respondent authorities to carefully monitor vaccine recipients and publicly record all adverse events. In other countries, this type of observation has helped identify the occurrence of blood clots and strokes in vaccine recipients. Many countries stopped administering the vaccine till they evaluated this occurrence and countries like Denmark have completely banned use of the Astra Zeneca vaccine (branded as Covishield in India). India, with its huge population and numbers vaccinated, should have reported these adverse events first. But due to poor follow-up, poor Adverse Events Following Immunization (AEFI) evaluation and suppression of data, these events have not been put in the public domain – endangering many more to suffer the same fate. Under these circumstances the petitioner has approached this court also seeking that that all AEFI be actively solicited by notification in newspapers, and be made available in publicly accessible data base (Like the VAERS data base in the USA). Currently the website cowin.gov.in only mentions certain numbers of AEFI but details of those cases are not available for public scrutiny.

The petitioner recognises that Covid is a public health emergency and that such an emergency may require emergency use authorisations of vaccines which may not yet have been adequately tested. However, that should not mean that all

information and data of relevance to the efficacy or side effects of the vaccines which have been given such approval, should not be made publicly available, especially when the vaccines are being used in a universal immunisation programme. Though emergency authorisation of the vaccines may be advisable in the present situation, it does not however mean that these vaccines can be forced upon people, especially without all relevant data being available for independent public and scientific scrutiny. The present petition therefore should not be understood to be a petition challenging the present Covid vaccination programme.

Description of petitioner

1A. Dr. Jacob Puliyel, MD MRCP MPhil, is a paediatrician who has been advising Government of India on vaccines as a member of the National Technical Advisory Group on Immunization (NTAGI) for several years, and who rotated out after over two terms on the committee. He has numerous publications in internationally peer reviewed medical journals and is very widely cited. The petitioner is a peer reviewer for international journals like the British Medical Journal and the Canadian Medical Journal. [redacted]

The petitioner has no personal interest, or private/oblique motive in filing the instant petition. There is no civil, criminal, revenue or any litigation involving the petitioner, which has or could have a legal nexus with the issues involved in the PIL.

The petitioner has not made any representations to the respondents in this regard because of the extreme urgency of the matter in issue.

That the instant writ petition is based on the information/documents which are in the public domain.

FACTS OF THE CASE

Adverse consequences for testing vaccine efficacy due to the Emergency Approval of vaccines in India

2. India's drug regulator approved two COVID – 19 vaccines on January 3rd. The press statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID – 19 vaccine states:

> "The Subject Expert Committee (SEC) has reviewed the data on safety and immunogenicity of the vaccine and recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains. The clinical trial ongoing within the country by the firm will continue."

However as shown below the trials have not been allowed to continue.

(A copy of the press statement by the Drugs Controller General of India (DCGI) on Restricted Emergency approval of COVID – 19

virus vaccine, dated 3rd January 2021 is annexed as **Annexure P1 (Page 32 to 33).**

3. On the same day as reported in the Times of India, the Drug Controller General of India stated that the Covid-19 vaccines are "110% safe". The report further quotes the DCGI as below:

"We will never approve anything if there is even slightest safety concern. Vaccines are 100 percent safe. Some side effects like mild fever, pain and allergy are common for every vaccine. It (rumors of impotency) is complete nonsense," VG Somani, Drug Controller General of India said. When asked if people would face side effects after taking the vaccine, the DCGI said, "Yes, minor side effects will be there, including a little like pain in the shoulders, a slight fever, little allergies. This occurs in every vaccine but of course, the vaccine is 110 per cent safe."

(A copy of the Times of India report dated 3.01.2021 is annexed as **Annexure P2 (Page 34 to 35).**

4. With respect to these two vaccines licensed for use in India by the Drug Controller General of India, it is important to highlight that the Covishield (Astra Zeneca) has some (intermediate analysis) efficacy data from phase 3 trials published in peer review journals. The full trial data can only be published after the trial is complete. The second, Covaxin does not have any data from its Phase 3 trial published in a peer reviewed journal. The first participant was enrolled in the phase three trial on the 11th of November 2020 and

as shown on the Clinical Trials Registry website, the estimated duration of the trial was one year. Yet the company is reported to have ended its phase 3 trial on 5th of January 2021, as reported in the Deccan Herald.

(A copy of the Deccan Herald report dated 5th January 2021 "Covaxin phase-3 trials to end today, average efficacy 60-70% is annexed as **Annexure P3 (Page 76 to 77).**
(A copy of the CTRI database regarding the Phase 3 trials details of the Covaxin is annexed as **Annexure P4 (Page 78 to 85).**

4. Given the public panic surrounding the Covid pandemic, Emergency Use Authorization has been given to these 2 vaccines. In effect, because the Covaxin vaccine is now available to the public, many (above 45 years) in the original control group have got antibody levels tested and taken the vaccine, the control trial crucial in Phase 3 has been abandoned. We cannot now evaluate most adverse effects of the vaccine compared against those receiving placebo and we have moved to Phase 4 post marketing surveillance. The disadvantage of diluting Phase 3 prematurely and going on to this Phase 4 data is that there are few controls to compare against and it is usually difficult to say what events are caused by the vaccine and what are coincidental events that can occur in some persons when a large number of people are observed with or without vaccine. But it behooves the authorities to carefully monitor all vaccine recipients and publicly record all adverse events. As reported in The Hindu on

1st April 2021, the Subject Expert Committee allowed Bharat Biotech to unblind trials participants aged above 45 and offer them the vaccine free of cost. The Committee recommended that the company unblind the participants as "vaccines are already available under the immunization programme, and therefore all the eligible age groups under the immunization programme should be permitted for unblinding for vaccination."

(A copy of The Hindu Report dated 1st April 2021 titled, "Covaxin for those who got placebo" is Annexed as **Annexure P5 (Page 86 to 88)**.

5. The petitioner submits that in order to effectively study a vaccine, it must be compared to a placebo (i.e. an inactive substance). Therefore, usually in trials the participants are divided into at least two groups: the group receiving the vaccine (study group) and the group receiving the placebo (control group). The efficacy of the vaccine is seen by looking at how many are protected from getting the disease in the study group compared to controls. Also, the numbers who develop adverse events in the two groups can also be compared. Such trials are conducted over two to five years, so that sustained efficacy and long-term adverse effects can be studied. Thus, effectively the vaccines being administered now are really still part of a gigantic clinical trial on the public at large. Unfortunately, though there is considerable anecdotal evidence and news reports about the adverse events including deaths of people who took the vaccine as well as vaccinated people getting seriously infected,

hospitalized and even dying, no information about these events is being put out on a real time basis.

6. With the emergency roll out of the vaccine, the phase three trials (meant to last for 1 year) have been severely truncated/abandoned, after about 2 months. In fact Covaxin which got approval for emergency use in 'clinical trial mode' is now no longer being administered in Clinical trial mode. Therefore such quick approvals does not inspire any confidence in the decision making process where the vaccine is initially licensed saying "The clinical trial ongoing within the country by the firm will continue" and this is then stopped without fulfilling the protocol registered by the manufacturers to CTRI and especially since the data for such trials has not been released.

7. The WHO holds that the vaccine does not prevent the spread of the disease from person to person and so has little potential of stopping the pandemic or the preservation of public health. Dr Antony Fauci who heads the Center for Disease Control in the USA made the following statement recently as reported in The Atlantic:

> "Anthony Fauci said last week on CNN that "it is conceivable, maybe likely," that vaccinated people can get infected with the coronavirus and then spread it to someone else, and that more will be known about this likelihood "in some time, as we do some follow-up studies."

(A copy of the article in The Atlantic dated 27th February 2021 is annexed as **Annexure P6 (Page 89 to 92)**.

8. While some vaccines have been useful in eradicating/controlling diseases, it is well known and established that vaccines can have serious short term and long term side effects. Quite apart from problems encountered with the Astra Zeneca vaccine administered under the name Covishield in India, such as blood clots, etc which have led to stopping the administration of the vaccine in many European countries, there could be other more serious long term side effects. Therefore it is essential that clinical trials are conducted in a rigorous manner and the results of the trials and all data be disclosed in a transparent manner for scientific scrutiny of independent scientists and researchers.

Need for transparency in publishing segregated clinical trial data of vaccines

9. The petitioner submits that 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. So far, the respondents have practiced complete secrecy in the matter and have not

disclosed any data from trials for the vaccines that have been developed in India – Covaxin by the Bharatbiotech or for the Covishied manufactured at the Serum Institute, India (SII). The clinical trial information that is available for the COVISHIED vaccine is preliminary data of clinical trials that have been undertaken for the vaccine in other countries.

10. It is submitted that the revised version of Declaration of Helsinki, developed after the horrific Nazi medical experiments on prisoners and human subjects without their consent, and the resultant Nuremberg Code for medical ethics in human medical research, and adopted by the ICMR in India, states that

> "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." And that "Researchers have a duty to make publicly available the results of their research...Negative and inconclusive as well as positive results must be published or otherwise made publicly available"

(A copy of the relevant section of the revised Declaration of Helsinki is annexed as **Annexure P7 (Page 93 to 96).**

11. The World Health Organisation (WHO) released a strong statement advocating for public disclosure of all clinical trial results. According to the statement, when data is not released it means that doctors, patients and medical regulators cannot make informed decisions

about which treatments are best. Non-disclosure of complete clinical trial results means that hundreds of thousands of patients have volunteered to take part in clinical trials where results have been kept hidden or are only selectively disclosed.

(A copy of the 'WHO statement on Public Disclosure of Clinical Trial Results' released on 14.04.2015 is annexed as **Annexure P8 (Page 97 to 99).**

12. Since trials of vaccines for testing its efficacy for side effects are normally done by the vaccine manufacturing companies themselves (which have a commercial interest in the propagation and use of their vaccines), the rules of most national regulatory institutions require the entire data for the vaccine trials to be put out in the public domain so that independent researchers could examine that data and pick up significant flaws which the vaccine manufacturers may have omitted or tried to hide. Historically there have been many cases of drug manufacturers being caught hiding or manipulating data and concealing side effects or overstating efficacy after the data was examined by independent researchers/scientists. Many drug manufacturers including many who are now involved in the manufacture of Covid vaccine, have been held guilty for manipulating data in the past and have had to pay billions of dollars as fines. An article in GreenMedinfo notes as follows:

> 'Clinical trials are also known to obfuscate troublesome data. In September 2017, a report titled "Infanrix hexa and sudden death: a review of the periodic safety update reports submitted to the European Medicines Agency" published in the Indian Journal of Medical Ethics[35] alleged that

GlaxoSmithKline (GSK) apparently excluded certain cases of infant deaths in their official report to the European Medicines Agency. GSK stated that the deaths reported after the vaccine is "coincident" and not related to the vaccine. However analysis by Puliyel and Sathyamala, authors, showed that 83% of the reported deaths occurred within 10 days of vaccination and only 17% occurred in the following ten days. "Glossing over of the deaths after vaccination has potential to result in more, unnecessary deaths which are difficult to justify ethically," they observed in a Press Release.

The same vaccine and an MMR vaccine have also been embroiled in serious contamination scandals and the list grows by the day. In yet another shocking incident the Government of India preferred not to release clinical data of an indigenous Rotavirus vaccine that showed a very high incidence of a potentially lethal intestinal obstruction in vaccinated children under the plea that revealing the data would "alarm the public".

(A copy of the article dated 13th April 2019 titled, "Anti Vaccination;Pro Science;Pro-Health;Anti-Industry" by Jagannath Chatterjee is Annexed as **Annexure P9 (Page 100 to 110).**

13. In the case of COVID vaccines, many of the standard rules for testing vaccines through clinical trials and transparency in disclosure of clinical trial data have been given a go-by by many regulators because of the panic in the media and population caused by the pandemic. However, the case of the Indian regulator is particularly pathetic and galling in as much as not even the preliminary data of Phase 3 have been put out in peer reviewed literature after all this time. Covisheild vaccine uses new recombinant genetic engineering technologies.

14. Vide RTI application dated 6.07.2020, information was sought from the Indian Council of Medical Research, regarding the list of ingredients present in the proposed COVAXIN, the methodology and techniques used in manufacturing the vaccines, the research papers published detailing the reports of pre clinical trial of COVAXIN and details of the agreement between ICMR and Bharat Biotech.

Maintaining opacity with regard to all of this information, the reply received by the ICMR stated:

"Since it is the third-party information sought, which is under an agreement between the same cannot be shared under PPP ethical code."

(A copy of the RTI application and reply are annexed as **Annexure P10 (Page 111 to 112).**

15. The petitioners are concerned about the lack of transparency in the clinical trials data which raises various concerns regarding the efficacy and safety of these vaccines. Transparency in publishing clinical trials data by the Central Drugs Standard Controls Organisation (CDSCO) that grants final approval for the vaccines by various manufactures to enter the immunization chain, flows from Section 4 of the Right to Information Act, 2005, which requires the government to make proactive disclosures of its records through the internet and other means of communications to the general public. Citizens cannot effectively assert their fundamental right to free speech against the State without access to information about the

internal workings of the State, especially in matter concerning the public health of citizens.

16. While media reports and press statements by Bharat Biotech suggest that the Covaxin has an efficacy rate of 81% based on preliminary data of its phase 3 trials, this is information that is being put out by way of a press statement in the lay press, by the vaccine manufacturer itself. The data on the basis of which the claim is being made has not been disclosed for it to be verified by independent researchers.

Non-disclosure of clinical data

17. The petitioners submit that is imperative that greater transparency of clinical trials be mandated by disclosure of both positive and negative results.

18. In a letter dated 20th September 2020 to the Hon'ble Health Minister, a group of concerned citizens, including senior doctors and health specialists, researchers and transparency activists, wrote expressing concerns about the opacity in clinical trials data. They highlighted that the CTRI database is valuable for doctors and researchers to learn from developments in medical research. Further, the CTRI database allows citizens to monitor the recruiting practices employed by pharma companies during the trials conducted in India. The letter however highlighted the following issues that the CTRI database and legal framework governing it does not address:

"(a) **Limited Disclosures:** The CTRI database does not contain three crucial pieces of information. The first piece of missing information is the **minutes of the meeting of the institutional Ethics Committee** where the clinical trial is to be carried out. These minutes are important because they will contain the details of the deliberations (including disclosure of conflict of interest) conducted by the Ethics Committee before allowing the institution to conduct the clinical trial. The second missing piece of information is **the application submitted to the DCGI for permission to conduct the clinical trial.** The application will presumably contain a host of pre-clinical data (study protocols, toxicology and pharmacology data, and other technical studies). This data needs to be made available to the public health community in order to ensure that the DCGI makes responsible decisions while granting permissions to conduct clinical trials in India. While the pharmaceutical industry would like to claim a proprietary interest in such data, it can be argued that the public interest in the disclosure of safety data outweigh any IP concerns. As per Section 8(1)(d) of the RTI Act, information can be disclosed if public interest outweighs IP concerns. The third critical piece of missing information is the reasoned **decision of the DCGI granting approval or rejecting an application for the conduct of clinical trials.** Without access to the DCGI's decision there is no way for the people to hold the DCGI accountable for its decision.

(b) **Disclosure of primary data:** The CTRI database only requires sponsors to indicate the status of the clinical trial. However, there is no legal obligation to disclose the primary datasets containing the results of the clinical trials. As a result, it has been alleged that pharmaceutical companies cherry pick the best data for publication in peer-reviewed journals while suppressing most of the damaging data. The reasons are self evident. Many in the pharmaceutical industry fear that publication of all clinical trial data may invite more public scrutiny of their claims and even adversely impact decisions by doctors to prescribe some of the riskier drugs. However, internationally, there has been a demand by the public health community for the release of all clinical trial data regardless of whether the trial succeeded or failed. Access to such health data will help both the regulatory community and the patient community in making more informed decisions regarding the true potential of a drug and the public interest in disclosure of this information outweighs the proprietary interests of the pharmaceutical companies. It maybe pertinent to mention that 'The Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subject' (2013) adopted by the World Medical Association (WMA) states "[r]esearchers have a duty to make publicly available the results of their research ... Negative and inconclusive as well as positive results must be published." ICMR also endorsed a global pledge to disclose results of trials in a timely manner. However, the disclosure is limited

to trials that are funded or supported by ICMR. The results of a vast majority of trials in India are unreported. Internationally, there has been a move in both the EU and the US to mandate the public disclosure of more clinical trial data.India should follow suit and make the disclosure of such clinical trial data a precondition to the approval of any new drug."

(A copy of the letter dated 20th September 2020 to the Hon'ble Health Minister, is annexed as **Annexure P11 (Page 113 to 125)**.

19. The petitioners submit that the disclosure of regulatory safety data under the RTI Act, have come before Central Information Commission. In Divya Raghunandan v. Dept. of Biotechnology(2007) and Kavita Kuruganti v. MoEF (2016)10 the CIC required the public disclosure of raw trial data (viz., biosafety, toxicity and allergencity data)pertaining to genetically modified brinjal studies because the public interest in making such data public, over-rode all other considerations such as commercial confidence, trade secrets or intellectual property. In the Kavita Kuruganti case,the CIC went as far as to require the publication of regulatory data even if the trials were a failure.

20. In Divya Raghunandan v. Dept. of Biotechnology (CIC/WB/A/2009/000668 (June 16, 2009), the CIC held:

""At the heart of the representation of Shri Deshpande of MAHYCO is the plea for exemption from disclosure u/s 8(1)(d) on the ground that "Information supplied in documents to the Department of Biotechnology (DBT) or other regulatory bodies contain undisclosed information (trade secrets) like protocols, confidential standard operating procedures, parental line information, event ID information, data generated from biosafety studies, methods, testing locations, etc, all of which may either be sensitive business information of the company, the unrestricted publication of which may adversely affect its business". Sec. 8(1)(d) reads as follows:

Sec. 8(1) (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.

As has been quoted above, Shri Deshpande has dealt both on trade secrets and intellectual property being disclosed, thus harming their competitive position. However, both in this sub clause of Sec. 8(1) and in sub clause (2) of Sec. 8, access may be allowed to information "if public interest in disclosure outweighs the harm to the protected interests." The question here as per the orders of Dr. S. Natesh, a matter of recommending for large scale field trial the

products adjudicated upon by GEAC. In this case it is only toxicity and allergenicity data that Dr. Nitish has directed should be disclosed and that too after examination by GEAC There is therefore no question of "unrestricted publication", as emphasized by us in the plea of appellant Shri Deshpande It goes without saying that toxicity and allergenicity of any product to be put on large scale field trial is a matter of overriding public interest. The order of 18.5.06 of Dr. S. Natesh, Scientist H can indeed be faulted for not having clearly enunciated the requirement of public interest for disclosure. However, we would agree with learned Counsel for respondents Dr. Dubey that the exercise of processing by the GEAC is indeed an exercise in assessing public interest. The decision of Dr. S. Natesh is, therefore, upheld to this extent in the context of appeal CIC/WB/A/2009/000668. Issue No 3 is decided accordingly.

In light of our decision in File No. CIC/WB/A/2009/00668 upholding the orders of the Dep't. of 16.5.06, Public Information Officer Ms. Rajalaxmi M.V. Ramdharan Scientist D will now proceed to comply with our decision of 22.11.07 with regard to providing the existing data with regard to other agricultural products and obtain this data to be provided to the appellant, within ten working days of the receipt of this decision notice. However, this is with reference to "the existing data with regard to the other agricultural products" whether or not referred to GEAC. The

disclosure in this case will therefore adhere to exemption from disclosures provided u/s 8(1) (d), but keeping in mind our ruling above on disclosure before any massive farm trial. This disposes of Issue No 1."

21. In Kavita Kuruganti v. MoEF (CIC/SA/A/2015/901798 (April 01, 2016), the CIC held as follows:

The Commission had directed the public authority, Ministry of Environment, Forest and Climate Change to proactively publish information related to bio-safety data regarding transgenic mustard hybrid DMH -11 as well as agenda of meeting of Genetic Engineering Appraisal Committee and minutes of such meetings, which they are under statutory obligation to disclose.

The resolution of bio-safety with the crop developer has also been finalized; it should have been in public domain. Public authority is attempting to keep vital information out of public discussion. It amounts to prevention of Constitutionally guaranteed freedom of speech and expression of the appellant, who are interested in discussing the pros and cons of GMO related issues of GM Mustard, which if permitted would cause serious impact on the public health of consumers in large scale.

Justice Holmes (Abrams v US, 250 US 616 (1919)) characterized the discussion of public matters as essential to see that "the ultimate good desired is better reached by a free trade in ideas". One of the fathers of the American Constitution, James Madison, (1751--1836) said:

"Nothing could be more irrational than to give the people power, and to withhold from them information without which power is abused. A people who mean to be their own governors must arm themselves with power which knowledge gives. A popular government without popular information or the means of acquiring it is but a prologue to a farce or a tragedy, or perhaps both.

22. The petitioners submit that in the context of pharmaceutical safety data, the CIC in the past mandated the disclosure of clinical study reports of observational studies relating to HPV vaccines after redaction of the names of the patients and any information that may be considered the intellectual property of the pharmaceutical companies. (Deepa Venkatachalam v. Directorate General of Health Services). In a subsequent decision, Amresh Chandra Mathur v. Directorate General of Health Services, CIC/DTGHS/A/2018/609161-BJ+ (April 09, 2019), the CIC ordered the DCGI to suo motu disclose Regulatory Information redacting/obliterating the information exempted u/s 8 (1)/9 of the RTI Act, 2005 for the benefit of public at large. This order, however, has not been complied with by the DCGI. In, the CIC held:

"Keeping in view the facts of the case and the submissions made by both the parties, the Commission instructs the Respondent to suo motu disclose Regulatory Information redacting/ obliterating the information exempted u/s 8 (1)/9 of the RTI Act, 2005 for the benefit of public at large, within a period of 30 days from the date of receipt of this order, as agreed. No further intervention of the Commission is required in the matter. For redressal of his grievance, the Appellant/ Complainant is advised to approach an appropriate forum."

23. The petitioners therefore submit that the CDSCO has a legal obligation to disclose regulatory data especially primary datasets for all clinical trials authorized in India, after redacting private patient information. The information should be available in a searchable online database that can be freely accessed by citizens.

Removal of Clinical trial mode

24. Based on Bharat Biotech's own interim safety and efficacy data, which has also not been put out in the public domain for any oversight or independent scrutiny, the Subject Expert Committee on Vaccines (SEC) in its meeting dated 10.03.2021, recommended for omission of the condition of the use of the vaccine in "clinical trial mode". The petitioner submits that this has been done in haste to enable the vaccines acceptability and use despite non availability of any data on its phase 3 trial, which is still ongoing. They have thus removed the need to collect and report on adverse effects of the

vaccine. Given that Emergency Use Authorisation was granted before the completion of mandatory Phase 3 trials, such collection of data is crucial for ensuring safety of the product and thereby enhancing public confidence in the prophylactic measure. The arbitrary decision to take it off clinical trial mode is inimical to the public interest and dangerous.

(A copy of the recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 146th meeting held on 10.03.2021 at CDSCO, HQ New Delhi, is annexed as **Annexure P12 (Page 126 to -)**.

25. Furthermore, the petitioner submits, that despite the phase 3 trials of the Covaxin being underway, the removal of the "clinical trial mode" label attached to the emergency authorisation of the vaccine would mean that the vaccine would now be administered effectively in a phase 3 trials but without seeking informed consent of those to whom the vaccine is being administered. In clinical trial mode, informed consent is sought from participants in the trials and they are also compensated for any major adverse effects. The reason Covaxin had been given restricted emergency use authorisation "in clinical trial mode" in the first place was because Bharat Biotech had not completed recruitment of participants for phase 3 trials and thus not been able to submit information regarding the vaccines efficacy. No justification has been given for this, seemingly irrational, decision to administer the untested drug outside of clinical trial mode.

Lack of transparency in regulatory approvals, minutes and constitution of exert bodies

26. The minutes of the National Technical Advisory Group on Immunisations (NTAGI) do not specify which member raised an objection nor the evidence quoted by the member to support his contention. The NTAGI is the primary advisory committee advising the Ministry of Health and Family Welfare on all immunization-related issues. Whereas in countries like the US the public are admitted to the NTAGI equivalent (called ACIP in the USA) meetings, secrecy shrouds the deliberations of the NTGAI. The petitioner submits that this raises serious concerns regarding potential conflicts of interest and that cloak of secrecy cannot then be used to cloak conflicts of interests. Actions speak louder than words. A bland declaration of conflicts of interest by members cannot by itself reassure the public. The court must mandate that for the records there must be faithful recording of minutes specifying all the discussions and who participated. When the proceedings of parliament are broadcast nationwide the deliberation of a scientific committee does not need great secrecy.

27. As reported in the National Herald, the SEC meeting minutes do little to inspire confidence in the process. A perusal of the minutes of the Subject Expert Committee (SEC) meetings show that the SEC changed its mind about Bharat Biotech's Covaxin within a span of two days. The report states:

> "Minutes of the SEC's meetings show that on December 30, the members had asked Bharat Biotech to present the

immunogenicity, safety and efficacy data for consideration. On January 1, 2021, the committee noted that efficacy was yet to be demonstrated through the clinical trials and requested the company to expedite recruitment for Phase 3 trial. The committee members noted that the company could perform interim efficacy analysis, which could then be submitted for consideration of restricted use.

But on January 2, the firm presented 'updated data', though it was not specified what the 'updated data' was. The company only presented efficacy data from the non-human primate challenge study. At the meeting, Bharat Biotech provided justification for the data provided and additionally requested consideration of their proposal in the wake of incidence of new mutated corona virus infection.

Eventually, the SEC "recommended for grant of permission for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains".

... "If you look at the minutes of the meeting from December 30 and Jan 1, 2, there is an intellectual leap. On the first two days, they are asking for data on immunogenicity and efficacy and then on Jan 2, they are saying they have considered Bharat Bio's request and will be giving them

'emergency approval'. There is no mention of data. The minutes do not reveal what made the SEC change its mind about the data submitted by Bharat Biotech over the course of two days," said Chinu Srinivasan of All India Drug Action Network (AIDAN).

Similarly, with respect to the SII vaccine, the report states:

"...The Serum Institute of India (SII) on December 30 submitted safety immunogenicity and efficacy data of phase 2 and 3 clinical trials of AstraZeneca vaccine carried out in UK, Brazil and South Africa. Along with it, safety and immunogenicity data from the ongoing Phase 2/3 clinical trial of Covishield vaccine being manufactured by SII was also submitted. The SII informed the committee that AstraZeneca had received emergency use authorisation for the vaccine in UK subject to various conditions and restrictions.

Then on January 1, SEC observed that the safety and immunogenicity data presented by the firm from the Indian study is comparable with that of the overseas clinical trial data."

(A copy of the National Herald report dated 6th January 2021 is annexed as **Annexure 13 (Page 127 to 130).**

(A copy of the minutes of the SEC dated 30th December 2020, 1st January 2021 and 2nd January 2021 are annexed as **Annexure P14 (Page 131 to 135).**

28. 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.

29. Even the publicly funded Indian Council of Medical Research (ICMR) which is both supporting research and co-sponsoring some of the vaccine trials, has maintained opacity with regard to ICMRs terms of engagement, persons involved and quantum of public funds involved.

30. As reported in The Hindu, the ICMR is to get royalties from the sale of Covaxin and this should disqualify them from sitting on regulatory committees to license this product or similar competing products. Given all these pervasive conflicts of interest, only data transparency and its availability to independent scientists to reassess, can protect the public interest.

(A copy of The Hindu report dated 3rd May 2021 titled "ICMR to get royalty from Covaxin sale" is annexed as **Annexure P15 (Page 136 to 138)**

Parliamentary Standing Committee reports on need for transparency in drug regulation

31. The petitioners submit 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.

(A copy of the 59th Parliamentary Standing Committee Report is Annexed as **Annexure P16 (Page 139 to 190).**

32. The Central Information Commission (CIC) has repeatedly called upon the CDSCO and other regulatory bodies to take proactive steps to keep the public informed about various regulatory activities. Vide its order dated 26.05.2020, the CIC made the following observations in *Prashant Reddy T. v. Central Public Information Officer, Drug Controller General of India & Ministry of Health*, involving files that went missing from the Office of the Drug Controller General of India (DCGI)

"The Commission however expressed its serious concern over the record keeping methodology in the office of DCGI / CDSCO due to the fact that an important report relating to the review of procedures and practices followed by CDSCO for granting approval and clinical trials on certain drugs went missing from their office that had to be procured from the author after receipt of notice of hearing from the Commission. This is despite the fact that the Parliamentary Standing Committee had also taken cognizance of the lapses by the Public Authority. The intent and the conduct of the Public Authority should always be above board in matters relating to grant of approvals through a transparent and objective mechanism. The Commission advises Secretary, M/o Health and Family Welfare, Govt. of India to examine this matter appropriately for further necessary action at its end."

(A copy of the CIC order dated 26th May 2020 is annexed as **Annexure P17 (Page 191 to 201)** Prashant Reddy T. v. Central Public Information Officer, Drug Controller General of India & Ministry of Health)

33. 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.

(i) 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;

(ii) 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."

(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".

Change in how the vaccine adverse effects are being evaluated in India

34. The petitioner submits that Adverse Event following Immunisation (AEFI) happen in people who may have an allergy or genetic predisposition to react to a vaccine. This is often rare and may happen only one in a few 1000 vaccinated. Phase three trials involve small controlled trials of a limited number of persons and may not find a significant increase in adverse events but when it is given to

the masses after licensure, rare reactions show up. That is why the law requires mandatory Phase 4 post marketing trials.

35. However, under the changed rules for investigating AEFI, all reactions that are not "known reactions" to the vaccine are not considered AEFI. By this rule now, all the reactions picked up in Phase 4 post marketing trials are now simply considered "Not an AEFI".

36. 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.

> "After licensure, deaths and all new serious adverse reactions are labeled as 'coincidental deaths/events' or 'unclassifiable', and the association with vaccine is not acknowledged. The resulting paradox is evident...
>
> The definition of causal association has also been changed. It is now used only if there is 'no other factor intervening in the processes'. Therefore, if a child with an underlying congenital heart disease (other factor), develops fever and cardiac decompensation after vaccination, the cardiac failure would not be considered causally related to the vaccine."

(A copy of the paper titled, "Revised World Health Organisation assessment of adverse events following immunization – a critique" dated 17th May 2019 is annexed as **Annexure P18 (Page 202 to 225).**

37. Till date there have been many adverse impacts and severe side effects including deaths post vaccination both in India and abroad. As reported in The Hindu a group of experts in public health, ethics, medicine, law and journalism have written to the Health Minister and the Drug Controller General of India, appealing for a time bound and transparent investigation following deaths and serious adverse effects after Covid-19 vaccination. The reports quotes from the letter and states as follows:

> "We understand that at least 65 deaths have occurred following vaccination for COVID-19 since the vaccination campaign started on January 16. However, the National AEFI (adverse event following immunisation) Committee's investigation findings of only two of these deaths have been made public. We believe that due to the possible linkages of vaccination and blood clotting, all these deaths and adverse events should be reviewed together for a possible causal relationship with the vaccine," reads the letter.
>
> The experts underline that even as the Indian health administration continues to be indifferent to the adverse

effects of vaccination, several countries across the world such as Denmark, Iceland, Norway, Italy, France, Bulgaria, Germany, Luxembourg, Estonia, Lithuania, Latvia and Ireland have paused immunisation with Astra Zeneca vaccine pending investigation of a small number of post-vaccination deaths from intravascular clotting/ thromboembolic events. Austria has even suspended the use of certain batches...

They have demanded a transparent investigation into each of the adverse incidents and sought details of all serious AEFIs till date, status of their investigation, findings of AEFI probe including cause of death by clinical diagnosis, autopsy findings, causality assessment and the process undertaken by AEFI committees to arrive at their conclusions.

"The vaccine programme should provide people complete information on the vaccines, a vaccination protocol that minimises the risk of harm, and an assurance of thorough and transparent investigation of injuries and death following immunisation. They are also owed medical care, and compensation for harm suffered post vaccination. The government has not met these obligations."

(A copy of The Hindu report dated 17th March 2021 titled, "Probe sought into death and adverse effects after Covid-19 vaccinations" is annexed as **Annexure P19 (Page 226 to 227).**

38. In a letter dated 27th April by the President of the Tamil Nadu Practitioners Association, Dr. CMK Reddy flags his concern about the reported deaths after taking Covid vaccine. The letter states:

> "Though the Adverse Effects Following Immunisation (AEFI) Committee comforts public and profession by saying they're unrelated to the vaccine, we have to take it with a grain of salt...
> If they are due to reasons other than vaccination, they should be evenly distributed during every week following vaccination, but 75% deaths occurred and 90% were hospitalised during the first 3 days. Hence let us not take it for granted and find out if we can prevent the complications."

(A copy of the letter dated 27.04.2021 is Annexed as **Annexure P20 (Page 228 to ___)**.

39. According to a presentation made to the National AEFI Committee during a meeting held on March 31, there have been 617 severe and serious (including deaths) adverse events following immunisation. As on March 29, a total of 180 deaths (29.2%) have been reported following vaccination across the country. Complete documentation is available only for 236 (38.3%) cases. In all, 492 severe and serious AEFI have been classified by the AEFI Secretariat of the Immunisation Technical Support Unit (ITSU) at the Health Ministry. Classification has been completed for 124 deaths, 305 serious events that required hospitalisation, and 63 severe events that did not require hospitalisation.

(A copy of The Hindu report dated 09April 2021 "180 deaths following vaccination reported in India" is annexed as **Annexure P21 (Page 229 to 232).**

40. Since the ongoing vaccination is like gigantic vaccine trial, in order to assess the efficacy of the vaccine, especially with respect to the variants which are supposed to be significantly responsible for the current second wave of Covid in India, it was essential for the government to closely monitor Covid infections (variant wise) among vaccinees as also the vaccinees who get sick enough to be hospitalised and more importantly who die due to Covid. Only such data would reveal the true efficacy of these vaccines on getting infected with Covid. However even this data has not been made available.

41. Data released today by the Centers for Disease Control and Prevention (CDC) on the number of injuries and deaths reported to the Vaccine Adverse Event Reporting System (VAERS) following COVID vaccines revealed reports of blood clots and other related blood disorders associated with all three vaccines approved for Emergency Use Authorization in the U.S. — Pfizer, Moderna and Johnson & Johnson (J&J). So far, only the J&J vaccine has been paused because of blood clot concerns. Every Friday, VAERS makes public all vaccine injury reports received through a specified date, usually about a week prior to the release date. Today's data show that between Dec. 14, 2020 and April 30, a total of 157,277 total adverse events were reported to VAERS,

including 3837 deaths, including 21623 requiring urgent care, 1132 heart attacks, 213 miscarriages, 7463 severe allergic reactions.

(A copy of the screen shot of the openvaers.com/covid data database of the US as accessed on the 10th of May 2021 is annexed at **Annexure P22 (Page 233 to -)**.

42. In the UK, all spontaneous reports received post Covid-19 vaccination are available in the public domain. A March 16, 2021, report of Covid-19 vaccine Astra Zeneca analysis reported a total of 2,28,337 reactions from the drug, with 289 fatal outcomes from January 4, 2021 to March 7, 2021. Similar reporting in the UK is available even for the Pfizer vaccine analysis.

The reactions for Pfizer Vaccine as on 12th April 2021 are as follows:

Blood Disorders 4210, Cardiac Disorders 1675, Congenital Disorders 12, Ear Disorders: 1374, Endocrine Disorders: 28, Eye disorders 2034, Gastrointestinal disorders 14140, General Disorders 38,968, Immune System disorders 723, Infections: 3070, injuries 847". Detailed reports of the adverse events for Astra Zenca and Pfizer are submitted.

43. In another report of the The Daily Expose on 4th April 2021, Dr Polyakova, who is the Medical Director of a hospital in Kent has said that "the levels of sickness after vaccination is unprecedented"

among NHS staff, confirming that some are even suffering neurological symptoms which is having a "huge impact on the health service functioning". The doctor, who progressed into medical management of the hospital over the past three years says that she is struggling with the "failure to report" adverse reactions to the Covid vaccines among NHS staff, and clarified that the young and healthy are missing from work for weeks after receiving a dose of either the Pfizer or AstraZeneca experimental vaccine"

(A copy of the report in The Daily Expose dated 4th April 2021 is annexed as **Annexure P23 (Page 234 to 236).**

44. While these are only some of the adverse impacts with respect to the current vaccines, we do not know yet how these vaccines and their ingredients will affect the vaccinated population in the long term.

Vaccines not tested against a placebo

45. In order to test efficacy of a vaccine, every vaccine candidate in all trials must be tested against a saline placebo. However as indicated below, the trials were not conducted using a placebo in various phase of the trials. Using inert placebos are important, as only then would we be able to notice any statistically significant difference in deaths and adverse events between both groups. If other vaccines or adjuvants are used in the controls, then it is likely that both groups will experience side effects, and hence no difference will be

seen, hence the vaccine will be touted as being safe when it actually isn't.

46. In Phase 1 trials for Covaxin by Bharat Biotech participants were randomly assigned to receive either one of three vaccine formulations (3 µg with Algel-IMDG, 6 µg with Algel-IMDG, or 6 µg with Algel) or an Algel only control vaccine group. Among the enrolled participants, 100 each were randomly assigned to the three vaccine groups, and 75 were randomly assigned to the control group (Algel only).

(A copy of the paper published in The Lancet titled "Safety and immunogenicity of an inactivated SARS-CoV-2 vaccine, BBV152: a double-blind, randomized, phase 1 trial" published on 21st January 2021 is annexed as **Annexure P24 (Page 237 to 246).**

47. In the Bharat Biotech Covaxin Phase 2 trial no placebo group was used at all, instead a comparison done between different vaccine doses. A total of 380 healthy children and adults were randomised to receive two vaccine formulations (n=190 each) with 3 µg with Algel-IMDG and 6 µg with Algel-IMDG. The primary outcome was seroconversion (≥4-fold above baseline) based on wild-type virus neutralisation (PRNT50). Secondary outcomes were reactogenicity and safety.

A copy of the report "Safety and immunogenicity clinical trial of an inactivated SARS-CoV-2 vaccine (BBV152 a phase 2, double blind,

randomized control trial) and persistence of immune responses fom a phase 1 follow up report" is Annexed as **Annexure P25 (Page** 247 **to** 280 **).**

48. Bharat Biotech Phase 3 trail data is not published yet while interim efficacy results have been reported in the media. Details of which placebo was used can be found on this clinical trials website https://clinicaltrials.gov/ct2/show/NCT04641481. A total of 25,800 subjects will be enrolled and randomized in a 1:1 ratio to receive the BBV152 vaccine and control.

Arm	**Intervention/treatment**
Experimental: Study vaccine BBV152B (6µg-Algel-IMDG)	Biological: BBV152 BBV152 (6µg-Algel - Imidazoquinoline)
Placebo Comparator: Placebo Phosphate buffered saline with Alum (without antigen)	Biological: Placebo Placebo (PBS+Alum, without antigen)

(A copy of the Phase 3 study description titled "An Efficacy and Safety Clinical Trial of an Investigational COVID-19 Vaccine (BBV152) in Adult Volunteers" as available on the clinical trials registry is Annexed as **Annexure P26 (Page** 281 **to** 289 **).**

49. For the Astra Zeneca vaccine, as published in The Lancet, a phase 1/2 single-blind, randomised controlled trial of ChAdOx1 nCoV-19 compared with a licensed meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY; Nimenrix, Pfizer, UK), as control vaccine, in healthy adults in the UK. For the phase 2/3 participants were recruited to a low-dose cohort, and within each age group, participants were randomly assigned to receive either intramuscular ChAdOx1 nCoV-19 ($2{\cdot}2 \times 10^{10}$ virus particles) or a control vaccine, MenACWY. An interim analysis was published in The Lancet in January 2021, for the safety and efficacy of the vaccine from an analysis of four randomized controlled trials in Brazil, South Africa and the UK. In this group, saline was used, but in the analysis, results of saline group & meningococcal group were pooled together, making it impossible to say which adverse events came from the saline group vs meningococcal vaccine group. Participants aged 18 years and older were randomly assigned (1:1) to ChAdOx1 nCoV-19 vaccine or control (meningococcal group A, C, W, and Y conjugate vaccine or saline).

Indemnity for Vaccine Manufacturers

50. The petitioners submit that coupled with the above changed policy for assessing vaccine side effects, earlier, vaccine manufacturers had sought indemnity from the Central Government in case of an adverse event during the vaccination drive. However, the government is yet to decide on the matter. If the companies are indemnified, they would be absolved from legal consequences arising out of adverse

clinical events in the vaccination drive and will embolden them to be more reckless on vaccine safety issues.

Mandating the use of the vaccines in the absence of informed consent is unconstitutional and violative of the principle of informed self determination which flows from Article 21

51. That some disturbing orders have been issued which directly or indirectly coerce citizens to get vaccinated. It appears to be a part of the public policy of the Union and State Governments to maximize the number of people receiving Covid 19 vaccines in as short a duration as is possible even without putting all 'information' in the public domain, enabling a citizen to make an 'informed' choice. It is submitted that coercing citizens directly or indirectly to get vaccinated is unconstitutional and violates the Right to Life of citizens on the grounds below mentioned. While the government has clearly stated in numerous RTIs that Covid vaccines are voluntary, there are many instances from across the country where now various authorities are mandating the vaccines.

52. In a reply dated 9th March 2021 to the RTI application filed by Anurag Sinha of Jharkhand, the Central Ministry of Health and Family Welfare has stated very clearly that "taking the Covid Vaccines was entirely voluntary and there is no relation whatsoever to provision of government facilities, citizenship, job etc to the vaccine".

(A translated copy of the original RTI reply (in Hindi) dated 9th March is annexed as **Annexure P27 (Page 290 to 291).**

53. In another RTI application to the Ministry of Health and Family welfare dated 21.04.2021, applicant Rakesh Singh requested for the following information;

"1. Is corona vaccine (Covid-19 vaccine compulsory?

2. Can private company force its employees to take Covid 19 vaccine?

3. Will I be debarred from public services like Metro rail, Indian railway, bus services, hospital, electricity, internet, food and inter and intra-city movement, if I don't take covid-19 vaccine?

4. what can I do it my senior officer forces me to take Covid-19 vaccine?

...

7. Can a government Health worker be suspended for not taking Covid 19 vaccine?

8. Does government or its any associate body have any reliable data of Covid 19 vaccine research so that citizens can trust the efficacy of vaccines?

Vide reply dated 2nd May 2021, from the Ministry of Health and Family Welfare stated:

"1. Vaccination for Covid-19 is voluntary.

However it is advisable to receive the complete schedule of Covid-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers.

2-8 – in view of the reply as SI. No. 1, these questions have no relevance."

(Copy of the RTI reply dated 2.05.2021 is annexed as **Annexure P28 (Page 292 to 293).**

54. An order dated 16.01.2021 was issued by Civil Surgeon (equivalent to CMO/CMHO) in Koderma, Jharkand, mandating local government health workers to take Covid-19 Vaccine or otherwise their salary will be withheld. The order was subsequently withdrawn.

(A copy of the order is annexed as **Annexure P29 (Pages 294 to _____).**

55. The Government of Maharashtra Department of Revenue and Forest Disaster Management, Relief and Rehabilitation, has issued a governmental order No: *DMU/ 2020 / CR. 92 / Dis M-1,* on the 13th of March 2021. In that Order under Section 3 (b) it was ordered that:

> "Essential shops owners and person working at all shops to get vaccinated at the earliest, as per criteria of GOI"

(A copy of the Order dated 13th March 2021 issued by the Department of Revenue and Forest, Government of Maharasthra is annexed as **Annexure P30 (Page 295 to 311).**

56. In a news item in the Lokmat Times, dated 18th April 2021, states:

"The Maharasthra government has imposed strict restrictions until May 1 to break the coronavirus chain. After that, the Aurangabad Municipal Corporation (AMC) will not allow unvaccinated traders and general people, aged 45 and above, to step out of home. So citizens eligible for vaccination should get vaccinated as soon as possible," said AMC administrator Astik Kumar Pandy."

(A copy of Lokmat Times report dated 18th April 2021, "Only vaccinated citizens can step out of home after May 1", is annexed as **Annexure P31 (Page 312 to -)**.

57. In the state of Gujarat, on 11th February 2021 The Indian Express reported that,

"The Circular from Garudeshwar taluka, falling in the tribal Narmada district, cites a video-conference held by the district primary education officer (DPEO) on February 8, and was issued to two nodal officers in the taluka on February 9. It said, "Teachers of the government primary schools, who have to interact with students and work among the students, have to mandatorily take the Covid-19 vaccine, which must be ensured. If any teacher refuses to take the vaccine or remains absent during the vaccination drive, and if any student thereafter contracts Covid-19 from the teacher, the entire responsibility of the same will be on the teachers."

Teachers who refuse to take the vaccine shot will have to submit a certificate in writing, citing reasons for the same the circular added".

While the district administration later called it a "draft copy" that was issued "by mistake", officers in charge of the nodal supervision of the vaccination drive for teachers said the decision to make teachers "accountable" was taken because many had refused to take the shot.

The same news report, mentions another circular: "the circular issued by the Ahmedabad Municipal Corporation School Board made it compulsory for its teachers and other staffers to get themselves vaccinated. Municipal school teachers told the The Indian Express on conditions of anonymity, they were asked to not sign the muster roll if they did not take the vaccine."

(A copy of The Indian Express report dated 11th February "Gujarat: Row over two circulars making Covid shot mandatory for school teachers" is annexed **as Annexure P32 (Page 313 to 318).**

58. In the letter number: G-1/2021/36650 dated 23-04-2021, issued by the Office of the District Education Officer, Tarn, Tarn, it is stated,

"This has reference to the meeting held by the Deputy Commissioner on 22-04-2021, regarding COVID Vaccination and the instructions were issued and received by this office on the mandatory COVID Vaccination of all the

officers/employees. It is clearly stated that if any officer/employee is unwilling or refuses to be vaccinated, the concerned DEOs shall not draw the salary of such officers/employees."

(A copy of the order dated 23rd April 2021 is annexed as **Annexure P33 (Page 319 to -)**.

59. On April 29 2021, the Administration of Whistling woods International, Goregaon East, Mumbai, sent an office Memo to All, by email titled, "Vaccination against Covid". In that mail it was stated, "We would like everyone who plans to come to campus post lockdown to be vaccinated, this will help us build a safer work place. Please ensure that you have your doses of vaccines before end of July 2021 so we can start our operations full force as soon as the restrictions are over. After getting vaccinated, kindly send your vaccination certificate."

(A copy of the email is annexed as **Annexure P34 (Page 320 to 321)**.

60. In the state of Punjab, the Governmental Order No: 7/56/2020/ 2H4/2142 dated 30th April 2021, addressed to all officers of the Police department including Divisional Commissioners, Zonal IGPs, Commissioners of Police, DIGs and SSPs, the Department of Home Affairs and Justice, stated in section 1(xv),

"In Government offices – Health / frontline workers and employees over 45 years who have not got at least one vaccine dose in last 15 days or more, should be encouraged to take leave and stay home until then Employees under 45 years to be allowed only on basis of negative RT-PCR not more than 5 days old or else should take leave and stay home".

(A copy of the order dated 30th April 2021 is annexed as **Annexure P35 (Page 322 to 324).**

61. In its order No: 7/56/2020/2H4/2143 dated 2nd May 2021, the Department of Home Affairs and Justice, Government of Punjab stated in section 2(ii),

"Nobody to enter the State whether by air, rail or road without either:

a- Negative Covid report not more than 72 hours old, or

b- Vaccination certificate (at least one dose) over 2 weeks old."

(A copy of the order of Government of Punjab dated 2nd May 2021 is annexed as **Annexure P36 (Page 326 to 328).**

62. In a circular issued on 22.04.2021 the Gujarat Technological University, Govt of Gujarat issued a circular regarding Covid-19 Vaccination before Winter -2021 Exam form filling. An excerpt from the circular is below:

"All students who have attained age of 18 years as on 1/05/2021 are hereby informed that it is mandatory to get Covid-19 vaccination before filling Winter 2021 exam forms. Along with the prevailing GTU norms, institutes will have to allow only the students who have taken Covid 19 vaccination to fill their Winter – 2021 exam forms"

A copy of the circular dated 22.04.2021 of the Gujarat Technological University, Govt of Gujarat is annexed as **Annexure P37 (Page 329 to -)**.

63. In the state of Telangana, on instruction from the District Collector of Bhadradri Kotthagudem district the Mandal Development Officer, MRO, Medical Officer and the Sub Inspector of Police of Sujathanagar Tehsil have been forcing the beneficiaries of the MNREGA that they can come to work only if they take the vaccines.

64. In the case of WP(C) 36065 of 2017 between the Parents Teachers Association, Government Higher Secondary School, Kokkur, Kerala and the State of Kerala **(2017 SCC Online Kerala 36408)**, the Hon'ble High Court of Kerala had passed order:

"If at all any parent has an objection, it has to be necessarily brought before the authorities, and there need not be any vaccination administered to such children whose parents object to the Vaccination. The learned government pleader also submits that no forceeful vaccination is attempted".

(A copy of the order of the Kerala High Court dated 10th November 2017, is annexed as **Annexure P38 (Page 330 to 331).**

65. Also, in the case of W.P.(C) 343/2019 & CM Nos.1604-1605/2019 between Master Haridaan Kumar (Minor through Petitioners Anubhav Kumar and Mr. Abhinav Mukherji) Versus Union of India, &W.P.(C) 350/2019 & CM Nos.1642-1644/2019 between Baby Veda Kalaan& Others Versus Director of Education & Others

the Hon'ble High Court of Delhi had observed that:

"13. Undisputedly, there is an urgent need to disseminate information regarding the MR campaign and the assumption that children could be vaccinated forcibly or without consent is unsustainable. This Court is of the view that all efforts are required to be made to obtain the decision of the parents before proceeding with the MR campaign. In this regard, it would be apposite to ensure that the consent forms/slips are sent to each and every student. Since the time period for implementing the campaign is short, the response period should be reduced and parents / guardians of students must be requested to respond immediately and, in any case, in not more than three working days. ***If the consent forms/slips are not returned by the concerned parent, the class teacher must ensure that the said parents are contacted telephonically and the decision of such parent is taken on phone.*** The concerned teacher ought to keep full records of such decisions received telephonically. In respect of those parents/guardians that

neither return the consent slips nor are available telephonically despite efforts by the concerned teacher, their consent can be presumed provided respondent nos. 1 and 2 ensure that full information regarding the commission is provided to all parents."

"14. ***The contention that indication of the side effects and contraindications in the advertisement would discourage parents or guardians from consenting to the MR campaign and, therefore, the same should be avoided, is unmerited.*** The entire object of issuing advertisements is to ensure that necessary information is available to all parents/guardians in order that they can take an informed decision. The respondents are not only required to indicate the benefits of the MR vaccine but also indicate the side effects or contraindications so that the parents/guardians can take an informed decision whether the vaccine is to be administered to their wards/children."

The Hon'ble High Court of Delhi thus passed the following orders:

"15.4 ***MR vaccines will not be administered to those students whose parents/guardians have declined to give their consent.*** The said vaccination will be administered only to those students whose parents have given their consent either by returning the consent forms or by conforming the same directly to the class teacher/nodal teacher and also to students whose

parents/guardians cannot be contacted despite best efforts by the class teacher/nodal teacher and who have otherwise not indicated to the contrary".

Further on the issue of informed consent, the The Hon'ble High Court of Delhi directed that:

"15.1Directorate of Family Welfare shall issue quarter page advisements in various newspapers as indicated by the respondents...The advertisements shall also indicate that the vaccination shall be administered with Auto Disable Syringes to the eligible children by Auxiliary Nurse Midwifery. ***The advertisement shall also clearly indicate the side effects and contraindications*** as may be finalised by the Department of Preventive Medicine, All India Institute of Medical Sciences"

(A copy of the Order of the Hon'ble Delhi High Court dated 22nd January 2019 is annexed as **Annexure P39 (Page 332 to 340)**

66. Covid Vaccines are experimental treatments. Those agreeing to receive them are agreeing to be participants in an ongoing medical experiment with several unknowns. There is no certainty about issues like long term safety. Coercing citizens to get the vaccines directly or directly violates the Nuremberg Code. The Nuremberg Trials Codes established, in the wake of horrific scientific abuse by

the German government during World War II, that coercion is *Verboten* and informed consent essential for participants of medical experiments. The ten point Nuremberg code given in the section of the Judges' verdict in the case of USA v Brandt entitled "Permissible Medical Experiments" states that: "The voluntary consent of the human subject is absolutely essential."

67. That the petitioner has not filed any other petition, suit or application in any manner regarding the matter is disputing in this Hon'ble court, or any High Court or any other court throughout the territory of India. The petitioner has no other better remedy available.

GROUNDS

A. BECAUSE the respondents have maintained opacity with respect to clinical trial data of the two vaccines being administered through emergency authorisation in India. Non disclosure of this important data violates the basic ethics of clinical research that requires results of clinical research studies to be published and brought to the knowledge of the medical community, participants to the research and the general population. The lack of transparency in the clinical trials data raises various concerns regarding the efficacy and safety of these vaccines.

B. Because the non publication of trial data violation the Declaration of Helsinki, an international document providing ethical guidance on research and adopted by the ICMR in India, which states that

"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." And that "Researchers have a duty to make publicly available the results of their research...Negative and inconclusive as well as positive results must be published or otherwise made publicly available"

C. BECAUSE the World Health Organisation (WHO) released a strong statement advocating for public disclosure of all clinical trial results. According to the statement, when data is not released it means that doctors, patients and medical regulators cannot make informed decisions about which treatments are best.

D. BECAUSE Transparency in publishing clinical trials data by the Central Drugs Standard Controls Organisation (CDSCO) that grants final approval for the vaccines by various manufactures to enter the immunization chain, flows from Section 4 of the Right to Information Act, 2005, which requires the government to make proactive disclosures of its records through the internet and other means of communications to the general public.

E. BECAUSE in Reserve Bank of India Versus Jayantilal N. Mistry Transferred Case (Civil) No. 91 Of 2015, a 2 judge bench of the Supreme Court while upholding peoples' right to access information, made the following observations regarding the Right to Information:

"Because an informed citizen has the capacity to reasoned action and also to evaluate the actions of the legislature and executives, which is very important in a participative democracy and this will serve the nation's interest better which as stated above also includes its economic interests. Recognizing the significance of this tool it has not only been made one of the fundamental rights Under Article 19 of the Constitution but also a Central Act has been brought into effect on 12th October 2005 as the Right to Information Act, 2005."..."The ideal of 'Government by the people' makes it necessary that people have access to information on matters of public concern. The free flow of information about affairs of Government paves way for debate in public policy and fosters accountability in Government. It creates a condition for 'open governance' which is a foundation of democracy."

F. BECAUSE despite the phase 3 trials of the Covaxin being underway, the removal of the "clinical trial mode" label attached to the emergency authorisation of the vaccine would mean that the vaccine would now be administered effectively in a phase 3 trials but without seeking informed consent of those to whom the vaccine is being administered. In clinical trial mode, informed consent is sought from participants in the trials and they are also compensated for any major adverse effects. Further under clinical trial mode there was the need to solicit from vaccine recipients any adverse events after 7 days as per the trial protocol. This is essential so that all early adverse events are recorded. The reason

Covaxin had been given restricted emergency use authorisation "in clinical trial mode" in the first place was because Bharat Biotech had not completed recruitment of participants for phase 3 trials and thus not been able to submit information regarding the vaccines efficacy.

G. BECAUSE disclosure of trial data has been held by this Hon'ble Court and by the CIC to be mandatory. In Aruna Rodrigues & Ors v UOI & Ors (WP C no. 260/2005) this Hon'ble Court vide order dated 8.04.2008, had considered the applications for data regarding toxicity and allergenicity to be placed in public domain by those conducting trials, in regard to nine crops to be field tested. It was submitted that unless the toxicity and allergenicity data are made known to the public the applicants and concerned scientists in the country would not be in a position to make effective representations to the concerned authorities and therefore the government was directed to make the disclosure. Further vide order dated 12.08.2008, the Court had directed the government to provide copy of guidelines for granting approval as well as to file satisfactory proof regarding compliance with its order regarding providing the data on the crops which were being field tested.

In Divya Raghunandan v. Dept. of Biotechnology(2007) and Kavita Kuruganti v. MoEF (2016)10 the CIC required the public disclosure of raw trial data (viz., biosafety, toxicity and allergencity data)pertaining to genetically modified brinjal studies because the public interest in making such data public, over-rode all other

considerations such as commercial confidence, trade secrets or intellectual property. In the Kavita Kuruganti case, the CIC went as far as to require the publication of regulatory data even if the trials were a failure.

H. BECAUSE, the Delhi High Court has held that mandates for vaccines without informed consent violate Article 21 rights. By order dated 22.01.2019 in W.P. (C) No. 343/2019, the Hon'ble Delhi High Court has struck down a notification by the State Government purportdedly in the public interest mandating all children to get the Measles Ruebella Vaccine without their parents explicit consent. The High Court directed that consent must be 'explicit' and 'implicit' consent or 'opt out' consent was not good enough. It was further directed that so as to allow parents to make an 'informed choice' the State was duty bound to disseminate widely the ill effects of the vaccine as well as under:

> *2. The petitioners are, essentially,* ***aggrieved by the decision of the respondents to forcibly administer MR vaccination without the consent of the parents/guardians*** *or family members of the beneficiaries (children aged between nine months to fifteen years). The petitioners in W.P.(C) 350/2019 pray that the impugned notification be set aside and further directions be issued that no vaccination be administered in cases where there is parental objection to such vaccination. The petitioners in W.P.(C) 343/2019, interalia, pray that an order be issued to the respondents restraining them from forcibly administering*

vaccinations to children without the consent of their parents/guardians.

5. Plainly, in order for any parent or guardian to give his/her consent (whether expressly or by inference), it would be necessary for such parent or guardian to have complete information with regard to the proposed vaccination campaign. Clearly, ***for any parent or guardian to take an informed decision, it would be necessary for such parent to be aware of (a) the vaccine proposed to be administered; (b) contraindications or side effects of such vaccine; (c) the date on which such vaccine administered to the ward/children; and (d) the personnel who would administer the same.***

7. In view of the above, ***impugned notification, to the extent it provides that no consent is required for the beneficiaries and/or their parents, is quashed.***

9. In view of the above, the ***controversy between the parties was narrowed down, essentially, on two issues, (a) whether an express consent of the parents/guardians was necessary or whether the same could be inferred by silence on the part of the concerned parents/guardians; and (b) whether the respondents were required to indicate the contraindications and the side effects of the vaccines in the newspaper advertisements as well as in other literature to be provided to parents/guardians of the beneficiaries.***

13. Undisputedly, **there is an urgent need to disseminate information regarding the MR campaign and the assumption that children could be vaccinated forcibly or without consent is unsustainable.** This Court is of the view that all **efforts are required to be made to obtain the decision of the parents before proceeding with the MR campaign.** In this regard, it would be apposite to ensure that the consent forms/slips are sent to each and every student. Since the time period for implementing the campaign is short, the response period should be reduced and parents / guardians of students must be requested to respond immediately and, in any case, in not more than three working days. If the consent forms/slips are not returned by the concerned parent, the class teacher must ensure that the said parents are contacted telephonically and the decision of such parent is taken on phone. The concerned teacher ought to keep full records of such decisions received telephonically. In respect of those parents/guardians that neither return the consent slips nor are available telephonically despite efforts by the concerned teacher, their consent can be presumed provided respondent nos. 1 and 2 ensure that full information regarding the commission is provided to all parents.

14. The contention that indication of the side effects and contraindications in the advertisement would discourage parents or guardians from consenting to the MR campaign and, therefore, the same should be

avoided, is unmerited. The entire object of issuing advertisements is to ensure that necessary information is available to all parents/guardians in order that they can take an informed decision. The respondents are not only required to indicate the benefits of the MR vaccine but also indicate the side effects or contraindications so that the parents/guardians can take an informed decision whether the vaccine is to be administered to their wards/children.

15. In view of the above, it is directed as under:

- ***(4) MR vaccines will not be administered to those students whose parents/guardians have declined to give their consent. The said vaccination will be administered only to those students whose parents have given their consent either by returning the consent forms or by conforming the same directly to the class teacher/nodal teacher and also to students whose parents/guardians cannot be contacted despite best efforts by the class teacher/nodal teacher and who have otherwise not indicated to the contrary.***

I. BECAUSE, this Hon'ble Court has held that no individual's bodily integrity can be violated without her explicit informed consent. A citizen has many available courses of treatment for any particular

medical concern and the State cannot mandate a particular course of treatment to her. This Hon'ble Court has affirmed the 'Principle of Self Determination' to the higher extent that a citizen even has the 'Right to Refuse Medical Treatment' as part of her right to live with dignity and make an informed choice. **In *Aruna Ramachandra Shanbaug v. Union of India*, (2011) 4 SCC 454 : (2011) 2 SCC (Cri) 294 : (2011) 2 SCC (Civ) 280** it was held;

At Page 482

Two of the cardinal principles of medical ethics are patient autonomy and beneficence:

1. ***Autonomy means the right to self-determination, where the informed patient has a right to choose the manner of his treatment. To be autonomous, the patient should be competent to make decisions and choices.*** *In the event that he is incompetent to make choices, his wishes expressed in advance in the form of a living will, or the wishes of surrogates acting on his behalf (substituted judgment) are to be respected.*

2. Omitted

at page 497

67. .... In India, if a person consciously and voluntarily refuses to take life-saving medical treatment it is not a crime.....

at page 500

> ***78.*** *.....First,* ***it is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so*** *[see Schloendorff v. Society of New York Hospital [211 NY 125 : 105 NE 92 (1914)] , NE at p. 93, per Cardozo, J.; S. v. McC. (Orse S.) and M (D.S. Intervener) [1972 AC 24 (HL)] , W v. W; AC at p. 43, per Lord Reid; and Sidaway v. Board of Governors of the Bethlem Royal Hospital [1985 AC 871 : (1985) 2 WLR 480 : (1985) 1 All ER 643 (HL)] AC at p. 882, per Lord Scarman]. To this extent,* ***the principle of the sanctity of human life must yield to the principle of self-determination****...*

J. BECAUSE, this Hon'ble Court has held that 'autonomy' of the individual which can interchangeably be said to be her right to 'self determine' when it comes to her health flows from Article 21 and is a facet of her Right to Privacy. As much has been observed in Puttaswamy (Right to Privacy case) which was relied upon in ***Common Cause v. Union of India*****, (2018) 5 SCC 1,** wherein a Constitutional Bench [5 Judges] of this Hon'ble Court further affirmed Right of Self Determination as under:

at page 170 (JUSTICE SIKRI):

300. *In* ***K.S. Puttaswamy [K.S. Puttaswamy v. Union of India, (2017) 10 SCC 1] , the Constitution Bench*** *has recognised the dignity of existence. Liberty and autonomy are regarded as the essential attributes of a life with dignity. In this manner, sanctity of life also stands acknowledged, as part of Article 21 of the Constitution. That apart, while holding the right of privacy as an intrinsic part of right to life and liberty in Article 21, various facets thereof are discussed by the learned Judges in their separate opinions. A common theme which flows in all these opinions is that that privacy* ***recognises the autonomy of the individual; every person has right to make essential choices which affect the course of life; he has to be given full liberty and freedom in order to achieve his desired goals of life; and the concept of privacy is contained not merely in personal liberty, but also in the dignity of the individual.*** *Chelameswar, J. in K.S. Puttaswamy [K.S. Puttaswamy v. Union of India, (2017) 10 SCC 1] , made certain specific comments which are reflective of euthanasia, though this term is not specifically used. He observed: (SCC p. 530, para 373)*

> ***"373. ... Forced feeding of certain persons by the State raises concerns of privacy. An individual's right to refuse life prolonging medical treatment***

or terminate his life is another freedom which falls within the zone of privacy."

at page 177 (JUSTICE ASHOK BHUSHAN:)

316. *Dignity implies, apart from a right to life enjoyment of right to be free of physical interference.* ***At common law, any physical interference with a person is, prima facie, tortious.*** *If it interferes with freedom of movement, it may constitute a false imprisonment. If it involves physical touching, it may constitute a battery. If it puts a person in fear of violence, it may amount to an assault. For any of these wrongs, the victim may be able to obtain damages.*

317. When it comes to medical treatment, even there the general common law principle is that any medical treatment constitutes a trespass to the person which must be justified, by reference either to the patient's consent or to the necessity of saving life in circumstances where the patient is unable to decide whether or not to consent.

318. *Rights with regard to medical treatment fall essentially into two categories: first,* ***rights to receive or be free of treatment as needed or desired,*** *and not to be subjected involuntarily to experimentation which,* ***irrespective of any benefit which the subjects may derive, are intended to advance scientific knowledge and benefit people other than the subject in the long term;*** *secondly, rights connected incidentally with the*

provision of medical services, such as ***rights to be told the truth by one's doctor.***

PRAYER

In view of the abovementioned facts and in the interest of public safety, it is respectfully submitted that this Hon'ble Court may be pleased to

a) Direct the respondents to release the entire segregated trial data for each of the phases of trials that have been undertaken with respect to the vaccines being administered in India; and

b) Direct the respondent no 2 to disclose the detailed minutes of the meetings of the Subject Expert Committee and the NTGAI with regard to the vaccines as directed by the 59th Parliamentary Standing Committee Report and the members who constituted the committee for the purpose of each approval meeting; and

c) Direct the respondent no 2 to disclose the reasoned decision of the DCGI granting approval or rejecting an application for emergency use authorization of vaccines and the documents and reports submitted to the DCGI in support of such application; and

d) Direct the respondents to disclose the post vaccination data regarding adverse events, vacinees who got infected with Covid, those who needed hospitalization and those who died after such infection post vaccination and direct the respondents to widely publicize the data collection of such adverse event through the

advertisement of toll free telephone numbers where such complaints can be registered; and

e) Declare that vaccine mandates, in any manner whatsoever, even by way of making it a precondition for accessing any benefits or services, is a violation of rights of citizens and unconstitutional; and

f) Pass any other orders as this Hon'ble Court deems fit.

PETITIONER

THROUGH:

Prashant Bhushan

(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER

DRAWN BY: CHERYL D'SOUZA, ADVOCATE
DRAWN ON: 10TH MAY 2021

FILED ON: 12.05.2021
NEW DELHI