IN THE HIGH COURT OF KARNATAKA, AT BANGALORE

(Original Jurisdiction)

W.P No.: /2021 (PIL)

BETWEEN:

Sri. Mathew Thomas & Ors — Petitioner

AND

The Government of India & Ors — Respondent

SYNOSIS

Date	Event
15-03-2020	Dead body management Protocol
01-01-2021	Summary of product details Covishield
03-01-2021	Press release by respondent
03-01-2021	Permission granted under NDCT Rules 2019
11-01-2021	Restrictive use of Covaxin, implementation plan published
11-02-2021	Permission granted under NDCT Rules 2019
15-01-2021	Summary of the product characteristics Covaxin
05-03-2021	AEFI Report published by NAEFI committee
17-03-2021	AEFI Report published by NAEFI committee

BRIEF FACTS

1. The Public Interest Litigation is preferred seeking direction To Respondent No.01 and 02 to take appropriate steps to direct all Hospitals to conduct autopsy in order to attribute the cause of death in accordance with the AEFI surveillance and response

Guidelines,2015; direction to Respondent no 3 and 4 to publish all the data with respect to the vaccines as according to the principle of transparency and accountability as mentioned in National ethical guidelines for biomedical and health research involving Human Participants 2019; direction to Respondent No 1 and 2 to stop mass vaccination process until all the stages of the clinical trials are completed as according to the New Drugs and clinical trial rules 2019 and the National Guidelines for Gene Therapy Product Development and Clinical Trials-2019; and Declare that the vaccines now administered in India are Gene Therapeutic products and not a vaccine in the interest of full disclosure, informed consent and as stated in National Guidelines for Gene Therapy Product Development and Clinical Trials-2019.

2. The permission under the NDCT rules 2019 are for a defined population and cannot be to the entire country and also the permission are granted for clinical trials and the violation of National Guidelines for Gene Therapy Product Development and Clinical Trials-2019. Hence with no other alternative remedy available the petitioner has approached before this Hon'ble court by way of this Writ petition.

Bangalore
Date:

Adv. for Petitioner

IN THE HIGH COURT OF KARNATAKA, AT BANGALORE

(Original Jurisdiction)

W.P No.: /2021 (PIL)

BETWEEN:

1. Sri. Mathew Thomas,
S/o late T.P. John,
Aged about 82 years,
Resident of No.2, 'Aristos',
Sobha City, Thanisandra Main Road,
Bengaluru – 560 064.

2. Mr. Sriram M.S
S/o Mr. Sundhararaghavan
Aged about
R/a #304, Skyland Golden Race,
KEG Nagar, Bangalore-560018

3. Mr. Niswarth Kochar
S/o Mr.
Aged about
R/a Flat A 602,
ND Passion Apartments,
Silver Country Road, Kudlu,
Bangalore, Karnataka-560068 **PETITIONER**

AND

1. **The Government of India**,
Represented by The Secretary,
Ministry of Health and Family Welfare
Room No. 348; 'A' Wing,
Nirman Bhavan, New Delhi-110011

2. State of Karnataka
Represented by its Chief Secretary,
Government of Karnataka,
Vidhana Soudha, Bengaluru 560 001

3. Indian Council of Medical Research
Director General ICMR
Address: V. Ramalingaswami Bhawan,
P.O. Box No 4911, Ansari Nagar,
New Delhi-110029

4. Central Drugs Standard Control Organization
Rep by the Drug Controller General of India
Ministry of health and family welfare,
Directorate general of health services,
Government of India FDA Bhavan,
ITO, Kotla Road, new Delhi – 110002 **RESPONDENTS**

MEMORANDUM UNDER ARTICLE 226 AND 227 OF THE CONSTITUTION OF INDIA

The Petitioner begs to submit as follows:

1. The address of the Petitioner for the purpose of service of summons, court notice from this Hon'ble court is as stated in the cause title and Petitioner is represented by Shri. NITIN AM, NAGESH A Advocate at No.14, Second floor, Kamal Prash, Deena Bank Colony, Ganganagar, Bangalore – 560 032.
2. The address of the respondent for the above said purpose is as stated in the cause title.
3. The Public Interest Litigation is preferred seeking direction To Respondent No.01 and 02 to take appropriate steps to direct all Hospitals to conduct autopsy in order to attribute the cause of death in accordance with the AEFI surveillance and response Guidelines,2015; direction to Respondent no 3 and 4 to publish all the data with respect to the vaccines as according to the principle of transparency and accountability as mentioned in National ethical guidelines for biomedical and health research involving Human Participants 2019; direction to Respondent No 1 and 2 to stop mass vaccination process until all the stages of the clinical trials are completed as according to the New Drugs and clinical trial rules

2019 and the National Guidelines for Gene Therapy Product Development and Clinical Trials-2019; and Declare that the vaccines now administered in India are Gene Therapeutic products and not a vaccine in the interest of full disclosure, informed consent and as stated in National Guidelines for Gene Therapy Product Development and Clinical Trials-2019.

BRIEF FACTS OF THE CASE

4. The petitioner No 1 is a retired Army officer, 82 years of age, a Defence Scientist and Engineer, a post-graduate from the Indian Institute of Science, from where he gained valuable experience in research methodology as well as his scientific temperament. The other petitioners are public spirited citizens with knowledge on the subject stated as follows.
5. It is submitted by the petitioner that respondent number one and two have not published necessary data with respect to the permissions that is granted for restrictive use of vaccines in emergency situations. There have been press releases which state that permissions have been granted whereas none of the press release or any other document that has been published by the respondent number one and to indicate as to under which provision of law such permissions have been granted.
6. Further it is submitted that the principle of transparency and accountability has not been followed in the entire process of approvals or administration of vaccine/drug for covid-19. It is thus

submitted that based on the available information published by the respondent number 01 this writ petition has been filed.

7. The petitioner submits that the Respondents have rushed into the vaccination program violating all their own rules and guidelines which are ultra-virus.

8. It is submitted that for clarity it is necessary to first set out certain medical definitions. This is as below.

   a. Medical dictionary Definition of disease:

      "A condition of the living animal or plant body or of one of its parts that impairs normal functioning and is typically manifested by distinguishing signs and symptoms : SICKNESS, MALADY".

   b. Medical dictionary definition of vaccine:

      "A suspension of attenuated or killed microorganisms (viruses, bacteria, or rickettsiae), administered for prevention, amelioration, or treatment of infectious diseases". For preventing or treating any disease, the cause must first be identified. Influenza, flu for short, is a seasonal illness that affects all people in the world during different periods in the year and hence, it is called, "Seasonal flu", hereinafter referred to simply as "flu". The cause of flu is believed to be a class viruses commonly referred to as "corona virus". Seven (7) of these are known to infect humans. There are several thousands of corona viruses. Their name stems from their shape which resembles a crown and 'corona" in Latin means crown.

c. Medical dictionary definition of virus:

"Any member of a unique class of infectious agents, which were originally distinguished by their smallness (hence, they were described as "filtrable" because of their ability to pass through fine ceramic filters that blocked all cells, including bacteria) and their inability to replicate outside of and without assistance of a living host cell". The word, "virus" comes from the Sanskrit visam "venom, poison," and the Latin word, "viscum".

9. The Respondent no 1 has promulgated the New Drug Clinical Trial Rules, 2019. (hereafter referred to as "NDCTRules-2019"). Rule 2 of the said Rules defines "New Drug" as "a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;" The copy of the NDCT Rules 2019 is herewith attached and Marked as **ANNEXURE- A** **at *page-65.***

10. It is submitted that although vaccine is defined as a drug, it is not meant for treatment but is meant for prevention of a disease. The word, "therapeutic" means "the treatment of disease or disorders by remedial agents or methods: CURATIVE, MEDICINAL". A vaccine is not meant for therapy. It is a preventive measure.

11. This Honourable Court may kindly note that "Gene Therapeutic product" is included in the definition of "Drug". It is necessary to explain what vaccines are and how they are different from gene

therapeutic product (herein after referred to as GTP). Vaccines are "drugs" that are generally used for prevention of diseases by enabling/"training" the immune system to recognize the poison or toxin. For this, firstly the cause or more specifically, the causative agent must be identified, purified, and isolated. Once this is done, the following steps, known as Koch's postulate, after the German scientist who enunciated it. The steps are:

a. The virus must be present in ALL people with the disease.

b. It must NOT be present in person WITHOUT the disease.

c. If put into a person WITHOUT the disease, he/she must become sick and exhibit the same symptoms as the person with the said disease. (For step 3 above, animal trials are done first and then on human volunteers in what is called randomized placebo trials).

12. SARS-Cov-2 is the virus believed to cause the disease of the current pandemic, Covid-19. Viruses are extremely small, a billionth of a meter. To isolate these from body fluids (taken from throat or nasal passages, in the case of SARS-Cov-2), the fluid is to be filtered through filters with pores of the size of the virus which would filter out bacteria and other body materials.The filtered material is then centrifuged (spun in a vessel). The viruses being extremely light in weight, they are thrown to the extremities of the vessel from which they are separated and extracted. This process is called purification and isolation.

13. This has NOT been done for any virus, including SARS-Cov-2. Koch's postulate has NOT been satisfied for Covid-19. Instead what has been done is set out in simple person's language the following paragraphs in 4 steps.

i. Viewing the impure body fluid from throat / nasal passages through an electron microscope.

ii. Computer programming is used to pick its code sequence of letters, A, C, T, and G, representing the four bases - from the fragments of RNA (Ribonucleic Acid). RNA and DNA (Deoxyribonucleic Acid) are composed of 4 "bases" referred to by their first letters, adenine (A), cytosine (C), guanine (G) and thymine (T). [Acids and bases are important in living things because most enzymes can do their job only at a certain level of acidity. Cells secrete acids and bases to maintain the proper pH for enzymes to work. For example, every time you digest food, acids and bases are at work in your digestive system.] The sequence in which these bases, A,C,T,G, are found is called the genome sequence or gene code.

iii. After picking up the RNA fragments from the body fluids, the computer is programmed to assemble them in a sequence.

iv. The code so assembled is then supposed to be the gene code of the virus.

14. It is well known that cells excrete RNA fragments and that it is impossible distinguish between the cell-excreted RNA fragments

and others which may have come from outside the body. Those toxins, poisons, viruses which come from outside the body are called external pathogens.

15. This steps mentioned above at 7 (i,ii,iii & iv) are supposed to identify mRNA or "messenger RNA". RNA or ribonucleic acid, is an indispensable macromolecule (aside from DNA and proteins) of all kinds of existing life on the face of the Earth. RNA is also responsible in acting as a mediator in some of the biological processes of cells, such as directing genetic appearance, and communicating to the cell's signals for a response. On the other hand, messenger RNA (mRNA) is a type or a particle of RNA also known as the "outline" for making protein. Messenger RNA is mainly in charge in the protein synthesis of the cell which is manufactured in the ribosome. Protein synthesis is process of the production of energy needed by the human body as well as the vital function of breathing; thus, a very essential unit for survival].

16. It is also possible to use any DNA found inside the cell to insert it into a subject's cell and then extract a messenger-RNA. It is possible to do this process using the DNA found in the body fluids of the test subjects. Some Drug/vaccine manufactures use DNA found in body fluids. The crucial factor is to establish whether the RNA or DNA so extracted came from an external pathogen or from the test subject himself.

17. This is why Koch's postulate is vital to finding the causative agent of any disease. Since Koch's postulate has NOT been satisfied for SARS-Cov-2 / Covid-19, it is completely wrong to say that the so-called SARS-Cov-2 causes Covid-19. Further it is wrong to say that the Covid-19 Virus is isolated.

18. There have been attempts by numerous organisations around the world to promote what it calls mRNA vaccines. It is claimed that mRNA in the vaccines teaches your cells how to make spike proteins. Spiked proteins are what give the viruses their name. Under the microscope, those spikes can appear like a fringe or crown (and corona is Latin for crown). Spike proteins play an important role in how these viruses infect their hosts. Spiked proteins exactly resemble in shape, size, weight and behavioural characteristics, "Exosomes" which the body's immune system produces when any foreign substance enters it. There is no way to distinguish between exosomes and spiked proteins. Further, there is no need to "teach" mRNA to make proteins, as claimed by numerous international organisations. This is their function.

19. It is further submitted that mRNA is NOT a "Drug" in the conventional scientific sense and as generally understood by public. It is a GTP (Gene Therapeutic Product). It is used in gene therapy. The difference between conventional vaccines and gene therapy is that in vaccines, the causative agent virus is identified, extracted and purified and then an attenuated form (one with reduced

virulence) is injected to trigger the immune system of the body to produce antibodies, so that when a disease causing virus enters the body, the immune system recognizes it and removes it from the body; whereas in gene therapy, the mRNA takes the information from the gene code (DNA) and is supposed to produce antibodies. There is no evidence to show that they are effective in preventing infections. That is why the promoters is such "vaccines" advise continued used of masks and other precautions.

20. National Guidelines for Gene Therapy Product Development and Clinical Trials- 2019 (hereafter referred to as GTP Guidelines) is a document jointly produced by ICMR, Ministry of Health and Family Welfare (MoHFW) and others in 2019 is produced and Marked as **ANNEXURE-B at *Page-183***. It makes the following significant statements, among others.

21. The foreword by the director of the Department of Biotechnology, Ministry of Science & Technology, Government of India, and Drug controller General of India, Central drug control organisation, Ministry of Health and Family welfare, Government of India are as follows:

"India stands at the cusp of a new era wherein the ideas of personalized treatment and precision medicine are expanding within both the clinical and patient communities. Therefore, the scientific, administrative and regulatory bodies of India have taken the lead and engaged collectively to generate the rules and guidelines for

gene therapy products. Central Drugs Standard Control Organization (CDSCO) under Ministry of Health and Family Welfare recently notified New Drugs and Clinical Trials Rules, 2019 wherein gene therapy product is defined as 'new drug'. Concomitantly, ICMR and DBT took initiative to frame the ***National Guidelines for Gene Therapy Product Development and Clinical Trials 2019****. The US, FDA and EU guidelines were referred to while drafting this document. The guidelines were framed keeping in mind the existing rules and regulations. This document provides a broad framework on ethical, scientific and regulatory requirements for all those who aspire to test these advanced therapeutics;*

It is also understood that the field is still nascent in the country and the scientists and industry involved need advice and directions regarding ethical, scientific and regulatory requirements for clinical translation of gene therapy products. ***Gene Therapy Advisory and Evaluation Committee (GTAEC)*** *has been constituted and notified by Department of Health Research (DHR), Ministry of Health and Family Welfare, Government of India as an independent body of experts representing diverse areas of biomedical research, concerned government agencies and other stakeholders. Amongst other functions this committee shall provide a hand holding for the investigators/ industry and also give pre-IND consultations."*

22. *Further at Point no 1 of the GTP Guidelines:* ***What***

encompasses gene therapy and gene therapeutic products (GTPs)? Gene Therapy refers to the process of introduction, removal or change in content of an individual's genetic material with the goal of treating the disease and a possibility of achieving long term cure. It would include introduction and expression of an exogenous gene(s), chimeric or modifier sequences (DNA) to restore a missing/aberrant gene function or confer additional cellular properties. It also includes other gene therapy approaches such as: (a) expression of microRNA-adapted short-hairpin (sh)RNA, and small interfering RNA (siRNA) (b) gene editing by homologous recombination (with or without targeted DNA break) (c) clustered regularly interspaced short palindromic repeats (CRISPR) guided Cas9 (CSRISPR associated protein 9) mediated gene editing or other similar gene modifying technologies. Thus, the term gene therapy encompasses all such processes wherein a nucleotide sequence (DNA or RNA) with or without its regulatory elements required for correction of a deleterious or defective genotype or phenotype is being introduced. It would also encompass such a process for improving the therapeutic efficacy of other gene therapy products. ***A gene therapy product (GTP) is thus defined as any entity which includes a nucleic acid component being delivered by various means for therapeutic benefit. (at Page-195)***

23. All GTPS being developed with the intention of potential human

applications must adhere to these guidelines and should be used only under the purview of well-defined and approved clinical trials.

24. At Point 2 of the GTP guidelines it states: Aim of this document is to ensure development of safe and effective GTPs, adhering to the following: (*at Page-197*)

a. product quality characterization of the components and processes involved, the production process and quality control strategies for GTPs, clear chemical and biological definition of the final product;

b. The pre -clinical evaluation of the GTP to establish, with reference to its dosage and route of administration, its safety profile, potency, bio-distribution, to identify the pharmacological/toxicological characteristics that support safety as well as efficacy of the GTP for human use;

c. the clinical study design to establish safety and efficacy of GTPs in the target indication(s), GTP dosage(s), route of administration and selection procedures for patients and frequency of side effects or adverse events associated with any therapeutic strategy; and the process of regulatory approval for clinical trials.

d. Long-term patient follow-up to monitor its therapeutic benefit(s)and immune response or any adverse effect(s), if

any, due to the GTPs.

25. At Point 2.2 of the GTP Guidelines it is states that The term "GTP" is defined as a biologic (molecular therapeutic) that could introduce alterations in the genome.

26. *It is further submitted that* Research and clinical trials with GTPs must be conducted under specific requirements and guidelines described in this document.

27. At point no 5 of the GTP Guidelines it is states: **Scientific and Ethical Considerations in Gene Therapy*:*** *Mutations, insertions, deletions and similar alterations in these genes or its regulatory elements may result in reduced or absent production of the encoded proteins, or expression of structurally or functionally abnormal proteins,* ***thereby leading to genetic disorders.*** *GTPs work by repairing, replacing or deactivating dysfunctional disease-causing genes aiming to restore normal function. The biological and technical complexities of GTPs, their design and production pose challenges for their translation into clinic.* ***(At Page -201-202)***

28. The scientific considerations for GTPs include selection of appropriate gene delivery vector/modality for the disease/tissue target, design of the expression cassette to ensure clinically relevant expression levels, specificity of gene expression to prevent unwanted side effects or off-target effects and minimising immune reactions of the host. The design of preclinical and clinical studies

for GTP differ significantly from the other chemical and biological drugs, because of the complexity of the vector interaction with the host cells wherein the effects of vector uptake into host cells, response of the host immune system, the outcome of integration of genetic material into host chromosomes and levels of transgene expression from the host cells determine the final therapeutic efficiency of the GTP. The GTP involves different components, such as the transgene cassette, the transgene regulatory systems, the delivery vectors and the cellular component (in case of ex vivo modifications). The scientific and ethical concerns for gene therapy primarily stem from the profound effect that genes exert on living cells by conferring novel properties and functions.

29. At point no 6 of the GTP Guidelines it states: **Gene Therapy Advisory and Evaluation Committee (GTAEC**) with secretariat at Indian Council of Medical Research (ICMR) under the aegis of Department of Health Research (DHR), Ministry of Health and Family Welfare, Government of India GTAEC shall be an independent body of experts representing diverse areas of biomedical research, concerned government agencies and other stakeholders. This committee will be composed of a core group of scientists and clinicians who have prior knowledge of gene therapy as evidenced by publications and participation in GTP clinical trials, as well as representation of the government agencies (ICMR, DGHS, CDSCO, DBT, DST, MCI). For each disease area in GTP

trials, specific clinical consultants with extensive disease specific expertise will be co-opted to aid in the decision-making process. ***(At Page-204)***

30. It is submitted that rule 6.2 of the GTP guidelines states: It is mandatory for all institutions and entities engaged in development of GTPs to establish an Institutional Bio-safety committee (IBSC), constituted as per the Regulations and Guidelines on Bio-safety of recombinant DNA Research and Bio- containment 2017. All bio-safety related procedures should be in compliance with these guidelines. Research involving development of new GTPs needs to obtain approvals from IBSC and Ethics Committee (EC). GTPs should have prior approval of Review Committee on Genetic Manipulation (RCGM). All clinical trial applications using GTPs should be evaluated and recommended by GTAEC prior its submission to Central Drugs Standard Control Organisation (CDSCO). All clinical trials are mandated to be registered with CTRI. (***at Page-205***)

31. As detailed in Section 6, GTPs have unique scientific and ethical concerns. Hence its use needs a rational study design and rigorous oversight. Regular review of progress in this field ensures the highest degree of scientific rigor and resolution of ethical concerns.

32. The investigators and institutions involved in research, development and clinical trial bear the ethical and legal responsibilities of ensuring that research activities are in

accordance with approved protocol and in compliance with the existing national regulations and guidelines.

33. At Point no 7.8 of the GTP Guidelines: As per the Rules 1989, RCGM is the authorized regulatory authority for import/ export and exchange of all recombinant DNA products in the country. RCGM approval to be submitted along with the dossier to GTAEC and CDSCO for clinical trial approval. ***(at page-206)***

34. At Point no 7.9 of the GTP Guidelines: Any GTP of foreign origin or its modified variants that will be first in human use is not permissible for direct first in human trials in India.

35. At Point no 7.10 of the GTP Guidelines: Imported GTPs or its modified variants must undergo preclinical animal model studies with due approval of RCGM followed by GTAEC and CDSCO to apply for first in human trials in India.

36. At Point no 7.11 of the GTP Guidelines: It is mandatory to have prior approval of HMSC with information to GTAEC, for international collaborative projects/global clinical trials.

37. At Point no 7.11 of the GTP Guidelines: The study participant and/or legal representative should be provided with adequate and unbiased information about the trial protocol, its limitations and potential adverse effects.

38. It is the democratic right of the people to be aware of treatment modalities and the risks versus benefit of new/upcoming technologies such as cell-based therapies including gene therapy.

The scientific community including scientists and clinicians working in the field, policy makers including regulators own the responsibility to create awareness and update about the rightful status of the GTPs and their applications on the basis of peer reviewed scientific evidences.

39. At point 13.2 of the GTP Guidelines: Public awareness needs to be created through periodic interactions with the public/stakeholders across the country. The focus of such interactive sessions will be to educate the masses so as to avoid their exploitation and to provide a forum for free and frank exchange of views. Different print and electronic media modules can be exploited to this effect.*at page-251*

40. Further at Point 14.2 of the GTP Guidelines: The Drugs and Magical Remedies (The Objectionable Advertisements) Act- 1954 – prohibits misleading advertisements relating to drugs and magical remedies. DGHS and relevant state authorities are mandated to take necessary action for violation of this act. (***at page-252)***

41. It submitted that Making alterations to the genetic composition of an individual is a scientifically and medically challenging undertaking. (paragraph 1 page 18) and hence trials are to be conducted and the outcome of the said the trains are to be evaluated and carefully subjected to expert committee evaluation and only after which permission shall be granted.

42. It is further submitted by the petitioner that Covishield vaccine have not submitted any report with respect to toxicology to reproduction and development. It is stated that animal studies into potential toxicity to reproduction and development have not yet been completed. A vaccine which has not conducted study on reproduction if administered and later found out that there is an impact on reproduction and development in the course of mass immunisation it would lead to catastrophic effect. Reproduction, fertility, development are aspects which take time to be studied.

43. The campaign of vaccination states that the vaccine is safe and that it can be trusted. Based on the document published on 01–01–2021 the entire aspect of reproduction has been left out in the course of vaccination studies conducted by the Covishield vaccine.

44. It is further submitted that there is an ambiguity with respect to the current vaccination as to whether **Clinical Trials or Mass Immunization is being carried out by Respondent no 1?**

45. It is submitted by the petitioner that respondent number one and respondent number 02 have not published any data declaring as to under which provision of law the permission for restrictive use of drug in emergent situation. The press release dt. 03-01-2021 by the respondent no 4 stated as follows (operational part): *"After adequate examination, CDSCO has decided to accept the*

recommendations of the Expert Committee and accordingly, vaccines of M/s Serum and M/s Bharat Biotech are being approved for restricted use in emergency situation and permission is being granted to M/s Cadila Healthcare for conduct of the Phase III clinical trial." the copy of the press release is produced and marked as **ANNEXURE- C *at page-287*.**

46. The said permissions where granted on 03–01–2021 having permission number MF/BIO/21/000001 and MF/BIO/21/000002 and one more permission having number MF/BIO/21/000019 dt. 11-02-2021. The copy of the extract is marked as **ANNEXURE- D *at Page-289.***

47. It is submitted by the petitioner that a document was published on the website of respondent no 4 (CDSCO) that titled "summary of product characteristics" by Bharat Biotech international Ltd dated 15-01-2021.

At point no 4 of the said document states as follows:

"4. Clinical Particulars

It is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age and older. The use of this vaccine should be in accordance with official recommendations. ***This vaccine is permitted for restricted use in Emergency situation in Clinical Trial mode, as per***

provisions of New Drugs and Clinical Trials Rules, 2019, under Drugs & Cosmetics Act 1940. "

48. "Clinical Trials" are defined in sub-Rule (j) of Rule of 2 of NDCTRules-2019. It states, "investigational new drug in human subjects". (*Annexure- A at page 66*). Non-clinical trials are done on animals. Non-clinical trials are safety procedures done on animals before trials on human beings.

49. The Respondents have apparently used 1(2) of the second schedule of the NDCT RULES 2019 and it states as follows: ***2. Special situations for a new drug where relaxation, abbreviations, omission or deferment of data may be considered*.**

(i) Depending on categories and nature of new drugs to be imported or manufactured for sale or clinical trial to be undertaken (viz. New Chemical Entity, biological products, similar biologics, approved new drug or new dosage form or new indication or new route of administration or new strength of already approved drugs, etc.,) requirements of chemical and pharmaceutical information, animal pharmacology and toxicology data, clinical data may differ. The requirements may also differ depending on the specific phase of clinical trial proposed to be conducted as well as clinical parameters related to the specific study drug.

(ii) For drugs intended to be used in life threatening or serious disease conditions or rare diseases and for drugs intended to be used in the diseases of special relevance to Indian scenario or unmet medical need in India, disaster or special defence use e.g. haemostatic and quick wound healing, enhancing oxygen carrying capacity, radiation safety, drugs for combating chemical, nuclear, biological infliction etc., following mechanism may be followed to expedite the development of new drug and approval process.

(A) ***Accelerated Approval Process:*** Accelerated approval process may be allowed to a new drug for a disease or condition, taking into account its severity, rarity, or prevalence and the availability or lack of alternative treatments, provided that there is a prima facie case of the product being of meaningful therapeutic benefit over the existing treatment.

(a) In such case, the approval of the new drug may be based on data generated in clinical trial where surrogate endpoint shall be considered rather than using standard outcome measures such as survival or disease progression, which are reasonably likely to predict clinical benefit, or a clinical endpoint. These should be measurable earlier than irreversible morbidity or mortality (IMM) and reasonably likely to predict clinical benefit.

(b) After granting accelerated approval for such drug, the post marketing trials shall be required to validate the anticipated clinical

benefit.

(c) Accelerated approval may also be granted to a new drug if it is intended for the treatment of a serious or life-threatening condition or disease of special relevance to the country, and addresses unmet medical needs. This provision is intended to facilitate and expedite review of drugs so that an approved product can reach the therapeutic armamentarium expeditiously.

(d) If the remarkable efficacy is observed with a defined dose in the Phase II clinical trial of investigational new drug for the unmet medical needs of serious and life threatening diseases in the country, it may be considered for grant of marketing approval by the Central Licencing Authority based on Phase II clinical trial data. In such cases, additional post licensure studies may be required to be conducted after approval to generate the data on larger population to further verify and describe the clinical benefits, as per the protocol approved by the Central Licencing Authority.

(e) The type of information needed to demonstrate the potential of a drug to address an unmet medical need will depend on the stage of drug development. Early in development, such potential should be sufficiently demonstrated based on nonclinical models, a mechanistic rationale and pharmacologic data. Later in development, prior to new drug approval such potential should be demonstrated through clinical data to address an unmet medical

need.

Explanation. - For the purpose of this clause, an unmet medical need is a situation where treatment or diagnosis of disease or condition is not addressed adequately by available therapy. An unmet medical need includes an immediate need ***for a defined population*** *(i.e., to treat a serious condition with no or limited treatment) or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs).*

(B) Situations where quick or expeditious review process can be sought for approval of a new drug after clinical development: - (i) In situation where the evidence for clinical safety and efficacy have been established even if the drug has not completed the all or normal clinical trial phases, the sponsor or applicant may apply to the licencing authority for expedited review process wherein the licencing authority will examine and satisfy the following conditions.

(a) it is for a drug that is intended to treat a serious or life threatening or rare disease or condition;

(b) if approved, the drug would provide a significant advantage in terms of safety or efficacy;

(c) there is substantial reduction of a treatment-limiting adverse reaction and enhancement of patient compliance that is expected to

lead to an improvement in serious outcomes;

(ii) the sponsor or applicant may also apply to the licencing authority for expedited review process for new drugs developed for disaster or defence use in extraordinary situation, such as war time, the radiation exposure by accident or intention, sudden deployment of forces at areas with higher health risk, where specific preventive and treatment strategy is required, where new intervention in the form of new drug, route of delivery or formulation has been developed and where real life clinical trial may not be possible. The permission for manufacture of such new drug may be granted if following conditions are satisfied: -

(a) The preclinical data makes a case for claimed efficacy;

(b) there is no possibility of obtaining informed consent from the patient or his legally acceptable representative, as the case may be, adopting inclusion and exclusion criteria and strict protocol adherence by each subject;

(c) there is no established management or therapeutic strategy available as on date and proposed intervention has clear possible advantage;

(d) such approval can be used only for one time. The subsequent approval shall only be granted once detailed efficacy report of such intervention is generated.

(iii) ***the new drug is an orphan*** drug as defined in clause (x) of rule 2 of these Rules.

50. The definition of "orphan drug" in sub-Rule (x) of Rule 2 of ND_CTRules_2019 states, "orphan drug" means a drug intended to treat a condition which affects ***not more than five lakh persons in India".***

51. It is submitted by the petitioner that the basic four aspects have not been considered by the respondent number 1 to 04 as mentioned bellow.

i. Treatment: vaccine does not fall under the category of drug used for treatment. It falls under the category of the drug used to prevent a particular viral attack/disease.

ii. Restricted use: restricted use is for a defined population or a stipulated number of people/citizens. In the present scenario the entire nation is being vaccinated.

iii. Orphan drug: defines the restrictive use i.e., not more than five lakh people.

iv. One time only: the subsequent approval shall only be granted once detailed if a case report of such intervention is generated.

52. It is further submitted that under the above provisions of the act read with rule 19, 21, 31, 75, 80 and 97 permissions is granted for

"one time only" and that only if the drug is an orphan drug accelerated approval can be given, If not it cannot be given.

53. In clear violation of the above Rule, the Respondents have authorized to administration of the vaccines to the entire population, thus throwing the well being and safety of the people of India to the winds. No worse violation of the right to life enshrined in the Constitution can be imagined. Even more worse, in the present situation even non-clinical and clinical trials are dispensed with and our country is relying on foreign nation's claims of having done so. While clinical trials are still "ongoing" the Respondents have launched the vaccination program

54. Bharath Biotech-Covaxin and Serum Institute of India-Covishield are two vaccines being used in the Respondents' vaccination program. The Respondents have authorized the mass scale administration of these vaccines in violation of NDCTRules-2019.

55. Bharath Biotech-Covaxin The manufacturer of this vaccine has published as follows in the Document titled as ""RESTRICTED USE OF COVAXIN UNDER CLINICAL TRIAL MODE". Version No. 4.0; 11-01-2021. It is stated in it under the heading of Rationale as follows*:*

"COVAXIN vaccine has been approved with permission number

MF/BIO/21/000002, dated 03.01.2021, F. No: BIO/MA/20/000103. This permission is given for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, where COVAXINTM vaccine will be administered to the adult vaccine recipients and they will be followed up for safety."

The said vaccine has been permitted for "restricted use in Emergency situation Clinical Trial mode". Clinical trials of this vaccine is still on-going, as per the above summary. "Restricted use" is NOT defined in NDCTRules-2019. Surely, under any stretch of imagination, it cannot mean its use for, the entire population.

56. **Covaxin and Informed Consent:** Rule 2 on page 210 of the NDCTRules-2019 deals with Informed Consent from each study subject during trials of any drug. Yet, when the Respondents are hurrying through a mass vaccination program with unseemly haste, the manufacturer of Covaxin has a consent form which is so vague that it cannot be accepted as informed consent.

57. In a document titled, "Restricted Use of COVAXIN Under Clinical Trial Mode", (**Annexure-E at page 291**) jointly published by ICMR and Bharat Biotech (company manufacturing Covaxin), dated 11-01-2021, a claim is made that "Bharat Biotech International Limited in partnership with the National Institute of Virology (NIV), a premier institute of ICMR has developed an indigenous whole virion inactivated SARS-CoV-2 virus (COVAXINTM) Vaccine." There

is NO mention whether the virus was isolated and purified and whether Koch's postulate was satisfied. Hence, the veracity of the claims made in the publication is subject to serious doubt.

58. The petitioner has submitted in later paragraphs herein the role of ICMR is the HPV vaccination program which came in for severe criticism by the Parliamentary committee that inquired into the program. The committee castigated the officials of ICMR and asked for investigation into their conduct.

59. The above document is the statement which reads as follows, "*This permission is given for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode* ---" the petitioner submits that if the permission is granted for "restricted use" it should NOT be administered to masses of people which is what the Respondents are doing.

60. It is Among the objectives of the trials is to evaluate the number of RT-PCR positive COVID-19 cases after receipt of during stipulated post-vaccination contact days". The petitioner submits that the entire study and object of vaccination is at the end again relying upon the RT-PCR test. There have been numerous studies and documents stating facts with respect to RT-PCR test that it cannot detect if there is COVID-19 related virus or not.

61. The petitioner submits that the inventor of the PCR procedure

(Kary Mullis) is on public record stating that it cannot tell if you are sick. It is NOT a procedure for diagnosing diseases, but only a method of amplifying/replicating miniscule particles in body fluids or genetic materials. He received the Nobel prize for this invention and was against at the use of the procedure for diagnosing/identifying AIDS/HIV.

62. **On *page-299*** of the above document, is the list of diseases which if present, in those coming for vaccination, the vaccine is NOT to be give. This list is as follows. "The individuals with the following conditions will NOT be eligible for vaccination.

i. Have any history of allergies.
ii. Have fever.
iii. Have a bleeding disorder or are on a blood thinner.
iv. Are immunocompromised or are on a medicine that affects their immune system.
v. Are pregnant.
vi. Are breastfeeding.
vii. Have received another COVID-19 vaccine.
viii. Any other serious health related issues as determined by the Vaccinator/Officer supervising vaccination".

63. It is highly likely that many would neither know nor understand the implications of this and would most probably avoid mention of any such conditions. For example, a pregnant may not know that she is pregnant until she misses her periods which may happen only after one month and hardly anyone would know if they are immunocompromised.

64. ICMR is a partner with the Bharat Biotech International Limited (BBIL) in the development of Covaxin. Being a government regulator who has even issued National Guidelines for Gene Therapy and Product Development (**Annexure B**) it cannot and should NOT partner anyone for the reason that the regulator and the regulated cannot be partners. This is an obvious conflict of interest which as will be shown later in this petition was responsible for the mismanagement of the HPV vaccine program resulting in death of children and virtually destroying the lives of 490,000 of children. (**In Annexure-M *from page 528-580*)**

65. With respect to **Serum institute of India Pvt Ltd: Covishield (Oxford/Astra Zeneca)** Under Rule 1 (v) of Second Schedule (See Rules 21, 75, 80 And 97) Requirements And Guidelines For Permission To Import Or Manufacture Of New Drug For Sale Or To Undertake Clinical Trial On Page 185 Of The Ndctrules-2019, if the drug has been withdrawn in any country by the manufacturer or by regulatory authorities, such information should also be furnished along with the reasons and their relevance, if any, to India. This information must continue to be submitted by the sponsor to the Central Licencing Authority (herein after referred to as CLA) during the course of marketing of the drug in India".

66. This vaccine has been withdrawn in several countries of the world due to adverse events, including deaths. Hence, the sponsor should have informed the CLA (central licensing authority) and the

CLA should have suspended the license pending a determination of the reasons for the vaccines withdrawal in these countries and whether it is prudent to continue its administration in India.

67. It is submitted by the petitioner that the above stated drug/vaccine has been banned in most of the European countries for the reason that there had been unexpected deaths and adverse effects. It is claimed by the renowned persons from the field of science, Medicine, vaccinology that unexpected blood clots have led to multiple adverse events being recorded. Due to which the Astra Zeneca vaccine has been banned.

68. It is submitted by the petitioner that the summary of product characteristics of Covishield revised and published on 01-01–2021 and permission for use has been permitted on 03-01-2021. A copy of the said document is here with attached as **ANNEXURE-F from *Page 328***. The copy of the WHO report published on Covishield is also attached as **ANNEXURE- G at *Page 343*.**

69. It is submitted by the petitioner that in the said document at in page No 5 it is stated as follows*: (at Page 332)*

"Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID 19 Vaccine AstraZeneca. A causal relationship has not been established"

"Neuroinflammation: is inflammation of the nervous tissue. It may be initiated in response to a variety of cues, including infection, traumatic brain injury, toxic metabolites, or

autoimmunity. In the central nervous system (CNS), including the brain and spinal cord, microglia are the resident innate immune cells that are activated in response to these cues" in simple terms there will issues related to nerves, such as blockage, clot and many more.

"Cases of cerebral Venous Sinus thrombosis with Thrombocytopenia have also been reported In numerous countries.

70. A list of vaccine adverse effects that have taken place In UK which has been published is hereby attached as **ANNEXURE-H at *Page-367.*** As on date there is more than 20,500 AEFI's reported whereas the data with respect to the said AEFI has not been published in on the Respondent no 1 Website and vaccinations has been fully administered on more than 4 Cr population. The last posted Report on the website with respect to AEFI was on 17-03-2021.

71. Further submits that at point 5, in ANNEXURE-F *at page-333*

"The studies excluded participants with history of anaphylaxis or angioedema; severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with immunosuppression." It is submitted that if the above mentioned participants were not part of the clinical trial and if no information with respect to the effect of the vaccine on people with such comorbidities are not available then the vaccine should not have been administered on them and special

care should have been taken in this regard whereas the respondent no 1-4 have not made any attempt with respect to the same. The Covid-19 vaccine operational Guidelines also does not cover these aspects. The copy of the Covid-19 vaccine operational guideline is attached as **ANNEXURE-J from Page-370.**

72. Casualty assessment results following immunisation (AAFI) cases following Covid –19 vaccination approved by national AEFI committee dt. 05-03-2021 and 17-03-2021 is herewith produced and marked as **ANNEXURE-K from page-517.** It is submitted that out of 13 adverse effects reported there have been 10 death and all related to Covishield. It is further submitted that after 17 March 2021 there have not been any AEFI reports being published by the national AEFI committee.

73. It is submitted by the petitioner that most of these deaths had relation to do with cardiac related issues, and most of the cardiac related issues caused because of the block/clot in the nervous system. The respondents where in full knowledge about the possible adverse events that could occur because of administration of Covishield vaccine. It is also evident that there have not been proper autopsy being conducted and thus the actual cause of death is not known. Hence these deaths cannot be directly attributed to commissioned. In the event of any death after receiving any vaccine it is categorically stated in the AFI surveillance and

response operational guidelines 2015 that autopsy should be conducted in order to know the cause of death.

Compensation for Injury or Death

74. Compensation is provided for both injury or death due to the vaccines. Rule 42 of NDCTRules-2019 is the governing rule for this purpose. Under the said rule, compensation for injury or death is If it is determined that the SAE is related to the administration of Covaxin, compensation will be provided in accordance with the procedure in Rule 42 of the NCDT Rules.

75. A statement in the joint document ""RESTRICTED USE OF COVAXIN UNDER CLINICAL TRIAL MODE". Version No. 4.0; 11-01-2021 of ICMR and Bharat Biotech International Limited (herein after referred to as BBIL) i.e, **ANNEXURE E *at page 315* ,** reads as follows:

"The Central Licensing Authority has granted permission for administration of Covaxin for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode. This does not mean that you are being offered the vaccine as part of a clinical trial. However, you are entitled to medical management and compensation for serious adverse events related to the administration of this vaccine in the manner set out in this form and the Fact Sheet."

76. The word, "Restricted" means "Limited, especially by official rules". And compensation can be granted only by way of the provisions in rule 42 of NDCT rules 2019 . As according to the said rule "Procedure for compensation in case of injury or death during clinical trial, bioavailability and bioequivalence study". As according to the said section in case of injury or death during clinical trial compensation shall be paid. Whereas as according to the document published in the website of respondent number 04 it states that the persons being vaccinated do not fall under the category of clinical trial subjects.

77. Without clinical trials being conducted vaccines have been administered and the deaths that take place or adverse effects that take place are not being compensated either. There is no document or information with regarding to the said aspect. Since, these vaccines are permitted for restricted use in emergency situation as an abundant caution in clinical trial mode, they cannot be administered to an entire population using government propaganda machinery as seen by constant voice messages over mobile phones. The abundant caution mentioned in the official document seems to have been flushed down the drain.

78. It is further submitted that The partners, ICMR and BBIL have hedged their bets on compensation by the contradictory statement above, wherein they say that the permission for restricted use of the vaccine is for clinical trials at the same time in the very next

sentence by saying, "*This does not mean that you are being offered the vaccine as part of a clinical trial*." The petitioner submits that this is a kind of deceit.

79. It is submitted by the petitioner that neither press release by respondent number 04 or 03 states as to the mood/status of vaccination. Further since the status of the vaccine is not mentioned, the status of the citizens receiving the vaccine is also not clear. The question that arises is whether the person receiving vaccine fails under the category of clinical subjects or not.

80. There is no clarity as to the following:

a. whether the vaccination program is a clinical trial

b. if so, how is it being administered to the entire population.

c. If it is not a clinical trial, under what law or rule is the attempt to vaccinate the whole population being done.

d. And if it is not a clinical trial, will those who suffer injury or death be compensated and by whom.

Adverse event following immunization and Autopsies

81. It is the submitted by the petitioner that adverse event following immunisation surveillance and response operational guide lines 2015 published by Ministry of health and family welfare, government of India has categorically stated as to how recording and reporting of AEFI is to be conducted. Further AEFI investigation is also mentioned. It is recommended that investigation of reported AEFI death should be carried out by a team comprising clinical,

laboratory and forensic experts at the earliest possible. All information is of the events should be provided to the investigation team.

82. The said guideline also states about investigation of reported sudden unexplained deaths following vaccination. It states that the investigation of deaths due to AEFI would not be completed without an autopsy and related laboratory investigations. An autopsy must ideally be performed in every case of an AEFA death. It may be especially mandatory in those instances when there have been previous reports of similar deaths that went and investigated.

83. It is submitted that a document of the Ministry of Health and Family Welfare (herein after referred to as, MoHFW) titled "Covid-19 Dead Body Management", dated 15-03-2020, in paragraph 9 on page 5 (**Annexure - L *from page 521*)** states ***Autopsies should be avoided. Autopsy is to be performed for special reasons.*** *It* is the submission of the petitioner that death after administration of vaccine should be considered as a special reason and in conformity with the AEFI operational guidelines 2015 autopsies are to be conducted without fail.

84. If autopsies are not conducted, the cause of death cannot be determined. Further, as shown herein above, RT-PCR test cannot diagnose any disease, a statement of the inventor of the procedure himself. So, if deaths are attributed to Covid-19 by the results of the RT-PCR test that would be a completely erroneous

determination leading to policy distortion which is seen for over a year now.

85. A serious consequence of such orders are that murders could be passed off as Covid-19 deaths. Several deaths may have no external signs of criminal actions. All that the assassin needs is a Covid-19 RT-PCR positive certificate of the victim to go scot free.

Role of ICMR in the HPV vaccine program

86. The petitioner submits that it is relevant to bring out the role of ICMR in the past tragedy which led to 490,000 children being paralyzed so that this organisation is not able to do similar damage again. For this, the petitioner relies on Parliament Report No. 72 of 2013. **(Annexure-M *from page-528*)**. The most important aspects of ICMR's role are in the paragraphs extracted and given herein below:

Extracts from Parliament Report No. 72.

87. Page 17, Paragraph 1.4: Attention of the Secretary was drawn to DCGI guidelines wherein Phase III trials cannot be conducted on children until a similar trial was conducted on adults. It was admitted by the Secretary that the DCGI guidelines were not adhered to in the present case but this vaccine is given before the sexual activity begins and then it protects against cancer. That was the reason for allowing trials on girls of the age of 10-14 years. The Committee was assured that State Governments of Andhra Pradesh

and Gujarat would be asked to get the ongoing clinical trial stopped immediately.

88. Page 18, paragraph 1.8 Considering the enormity of the wrong doing/criminality involved, and the dilly-dallying attitude of the Government in taking exemplary corrective action, the Committee took it up for detailed examination.

89. Page 19, paragraph 1.11 In the very same month, an American organization called Program for Appropriate Technology in Health (PATH) embarked upon a large scale, 5-year long (June 2006 to May 2011) project with "the main objective …..to generate and disseminate evidence for informed public sector introduction of HPV vaccines" in four countries, India, Uganda, Peru and Vietnam. Interestingly these four countries have different ethnic populations: India (Indo-Aryans, Dravidians, Tribals etc.), Uganda (Negroid), Peru (Hispanics) and Vietnam (Mongoloids). The Committee has been given to understand that ethnicity is relevant in the determination of safety and efficacy of some drugs. What would be of further interest, as per World Health Organization (WHO) is that all these countries have state-funded national vaccine immunization programs, which if expanded to include Gardasil, would mean tremendous financial benefit to the then sole manufacturer.

90. Page 19, paragraph 1.12. The Indian Council of Medical Research (ICMR), which is the highest body in the Country for

medical research and related matters lent its platform to PATH in an improper and unlawful manner.

91. Page 19, paragraph 2.1. The DCGI was of the opinion that since human subjects, as part of the research, were receiving invasive intervention like vaccines, the clinical trial rules must be enforced.

92. Page 20, paragraph 2.5. (Emphasis in original) The Committee finds the entire matter very intriguing and fishy. The choice of countries and population groups; the monopolistic nature, at that point of time, of the product being pushed; the unlimited market potential and opportunities in the universal immunization progammes of the respective countries are all pointers to a well planned scheme to commercially exploit a situation. Had PATH been successful in getting the HPV vaccine included in the universal immunization programme of the concerned countries, this would have generated windfall profit for the manufacturer(s) by way of automatic sale, year after year, without any promotional or marketing expenses. It is well known that once introduced into the immunization programme it becomes politically impossible to stop any vaccination. To achieve this end effortlessly without going through the arduous and strictly regulated route of clinical trials, PATH resorted to an element of subterfuge by calling the clinical trials as "Observational Studies" or "Demonstration Project" and various such expressions. Thus, the interest, safety and well being of subjects were completely jeopardized by PATH by using

self-determined and self-servicing nomenclature which is not only highly deplorable but a serious breach of law of the land. The Committee is not aware about the strategy followed by PATH in the remaining three countries viz. Uganda, Vietnam and Peru. The Government should take up the matter with the Governments of these countries through diplomatic channels to know the truth of the matter and take appropriate necessary action, accordingly. The Committee would also like to be apprised of the responses of these countries in the matter.

93. Page 21, paragraph 3.1. (Emphasis in original). The Committee is unable to understand as to how ICMR could commit itself to support "the use of the HPV vaccine" in an MOU signed in the year 2007 even before the vaccine was approved for use in the country, which actually happened in 2008. The Committee also questions the decision of ICMR to commit itself to promote the drug for inclusion in the Universal Immunization Programme (UIP) even before any independent study about its utility and rationale of inclusion in UIP was undertaken.

94. Page 22, paragraph 3.16. The Secretary of DHR/DG, ICMR acknowledged that certain irregularities were reported in the implementation of the project. With regard to Informed Consent, he said that though the consent was taken properly in Gujarat, there were gross violations of norms in Andhra Pradesh.

95. Page 22, paragraph 3.18. (Emphasis in original). The Committee feels that there was serious dereliction of duty by many of the Institutions and individuals involved. The Committee observes that ICMR representatives, instead of ensuring highest levels of ethical standards in research studies, apparently acted at the behest of the PATH in promoting the interests of manufacturers of the HPV Vaccine.

96. Page 23. Paragraph 3.19. (Emphasis in original). It was unwise on the part of ICMR to go in the PPP mode with PATH, as such an involvement gives rise to grave Conflict of Interest. The Committee takes a serious view of the role of ICMR in the entire episode and is constrained to observe that ICMR should have been more responsible in the matter. The Committee strongly recommends that the Ministry may review the activities of ICMR functionaries involved in PATH project.

97. Page 23, paragraph 3.22. (Emphasis in original). The Committee from its examination has found that DHR/ICMR have completely failed to perform their mandated role and responsibility as the apex body for medical research in the Country. Rather, in their over-enthusiasm to act as a willing facilitator to the machinations of PATH they have even transgressed into the domain of other bodies/ agencies which deserves the strongest condemnation and strictest action against them. The Committee fails to understand as to why ICMR took so much interest and initiative in this project when the

safety, efficacy and introduction of vaccines in India is handled by National Technical Advisory Group on Immunization (NTAGI). The submissions of the Secretary, DHR/DG, ICMR before the Committee about the commencement of the project, facts of the case and the action taken have also failed to stand scrutiny during the Committee's examination of the matter. The Committee, therefore, reiterates the recommendation made in their Forty-first Report that the matter of allowing trial of the vaccine as also the approval for its marketing in the Country be inquired into by a premier investigating agency and appropriate action be taken thereafter by the Government in the matter. The Committee expects the Government not to procrastinate in this matter any further.

98. Page 23, paragraph 4.1. The Committee noted that as per Rule122-DA and Schedule Y of the Drugs and Cosmetics Rules, 1945 made under the Drugs and Cosmetics Act, 1940, no clinical trial on a drug can be conducted except under, and in accordance with the permission in writing, of the Licensing Authority i.e. DCGI. All vaccines are deemed to be drugs.

99. Page 24, paragraph 4.6. (Emphasis in original) The Committee's examination has proved that DCGI has also played a very questionable role in the entire matter. Initially, it took a call that since human subjects, as part of the studies, were receiving invasive intervention like immunization, clinical trial rules must be enforced. However, it remained as a silent spectator thereafter,

even when its own rules and regulations were being so flagrantly violated. The approvals of clinical trials, marketing approval and import licenses by DCGI appear to be irregular. Therefore, the role of DCGI in this entire matter should also be inquired into.

100. Page 26. Paragraph 6.5. Documents received by the Committee in connection with the examination of AIIMS also revealed that the individual in question availed the hospitality of these very sponsors during the said individual's visit to Seoul to attend a conference.

Parliamentary report on Informed consent:

101. Page 27, paragraph 6.12. Obtaining Informed Consent from study subjects is a core requirement in the conduct of clinical trials and protection of human rights. In case of minors, the Consent has to be signed by parents/guardians. In the case of uneducated signatories, an independent person has to explain and witness the consent process. The Informed Consent document approved by various Ethics Committees on PATH project included the sentence: "I have read the information in this consent form (or it has been read to me). I consent to allow my daughter to receive three doses of HPV vaccines." In the case of Andhra Pradesh 9,543 forms were signed, 1,948 had thumb impressions while hostel warden had signed 2,763 forms. In the case of Gujarat 6,217 forms were signed, 3,944 had thumb impressions and 545 were either signed or carried thumb impression of guardians. The data shows that a

very large number of parents/guardians were illiterate and could not even sign in their local language i.e. Telugu or Gujarati.

102. Page 27, paragraph 6.16. (Emphasis in original). The Committee observes that obtaining informed consent from study subjects is a fundamental requirement in the conduct of clinical trials to ensure that the human rights of the study subjects are ensured. In case of minors it is mandatory that the consent be signed by parents/guardians. For the uneducated subjects, the law requires an independent person to explain and witness the consent process.

103. Page 30, paragraph 6.26. (Emphasis in original). The Committee observes that the wrongful use of the NRHM logo for a project implemented by a private, foreign agency as well as the identification of this project with the UIP has adversely affected and damaged the credibility of the programme as well as that of the NRHM. The Committee, therefore, recommends that such practices of diverting public funds for advancing interests of a private agency should never be allowed in future. The Committee strongly recommends that strict action should be taken against those officials responsible for such lapses.

104. Page 30, paragraph 6.29. (Emphasis in original). Blurring the distinction between the UIP and PATH project due to the involvement of the State Governments in the project and ignoring the financial contribution of ICMR and the State Governments are very serious issues. The Committee, therefore, recommends that

the Ministry should investigate into the above acts of omissions and commissions and take necessary action against those who are found responsible for breach of rules and regulations.

105. Page 34, paragraph 7.14. (Emphasis in original). Coming to the instant case, it is established that PATH by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of observation/ demonstration project has violated all laws and regulations laid down for clinical trials by the Government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers who would have reaped windfall profits had PATH been successful in getting the HPV vaccine included in the UIP of the Country. This is a serious breach of trust by any entity as the project involved life and safety of girl children and adolescents who were mostly unaware of the implications of vaccination. The violation is also a serious breach of medical ethics. This act of PATH is a clear cut violation of the human rights of these girl children and adolescents. It also deems it an established case of child abuse. The Committee, therefore, recommends action by the Government against PATH. The Committee also desires that the National Human Rights Commission and National Commission for Protection of Children Rights may take up this matter from the point of view of the violation of human rights and child abuse. The National Commission for Women should also suo motu take cognizance of this case as all

the poor and hapless subjects are females. Four Lakhs Ninety Thousand children (490,000) were paralyzed as a result of the indiscriminate administration of the HPV vaccines without proper trials".

106. These unfortunate children have not received any compensation to the best of the knowledge and belief of the petitioner. This Honourable Court may wish to ascertain from the Respondents whether any compensation was paid or not and if paid, proof thereof.

107. It is significant to note that this vaccination program too was administered under the guise of "observational studies" to evade the process of clinical trials. While clinical trials are still "ongoing" the Respondents have launched the vaccination program.

108. Compensation for death of injury is vaguely mentioned and it is unlikely that any sufferer would receive it. ICMR's past record has evidenced by the Parliament Report No. 72 and its present partnership with BBIL prove that history is repeating itself with even worse disastrous consequences than earlier.

109. Further AEFI Surveillance and response operational guidelines 2015 at 6.2 specifically stated that in case of death after getting vaccine, autopsies are to be mandatorily conducted in order to know the cause of death. The copy of the AEFI Surveillance and response operational guidelines 2015 marked as **ANNEXURE-N** ***from Page-581.***

110. The Principle of transparency and accountability whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants. The said principal is not being followed. The copy of the national ethical Guidelines for biomedical and health research involving human participants 2017 as **ANNEXURE-P *from page 776.***

111. The communication strategy used by the respondent with respect to the current Covid scenario is totally opaque and one sided to push maximum people to get vaccinated without publishing the actual details with respect to either the vaccine or the adverse effects of the vaccine. The copy of the Covid-19 communication strategy is also attached as **ANNEXURE- Q *from Page-964.***

112. The document referred above (Covid-19 Dead Body Management (Annexure-L) states in paragraph 1 on page 2, that there were only 100 confirmed cases (of Covid-19) – perhaps, confirmed by the flawed RT-PCR test, and just two (2) *two deaths due to Novel Coronavirus disease (COVID-19) in India.* This is on 15-03-2020. On 24-03-2020, (nine days later) the entire country was placed under lockdown – all the Nation's citizens placed under house arrest. This as is well available in public knowledge resulted in untold suffering of millions of our fellow citizens, millions

rendered jobless, trekking back to their villages, with meagre belongings, a human tragedy of unimaginable proportions. The petitioner humbly submits that This Honourable Court may wish to know from the Respondents to produce any evidence or rationale on which the decision was taken in 2020 and is being done even now so that the very right to life of these poor millions is not trampled upon by executive whim.

113. It is further submitted that any decision taken by the executive or any government body should be supported by reason which is rational in nature and supported by valid facts and should adhere to the doctrine of proportionality. It is submitted that there is no publication or study by the respondents stating any rationale behind the actions taken with respect to the lockdown.

114. It is submitted by the petitioner that the reason for lock down that was called for was to break the chain of transmission of the Covid-19 virus. It is further submitted that none of the press releases and publications made by the Central government, state government, Ministry of health and family welfare, ICMR or any other body in India have stated as to how chain of transmission is in place and as to how the lockdown would break such chain. The press release made by the office of the Prime Minister and the notifications and press release made by Ministry of health and family welfare from 03-03-2020 to 06-05-2021 is here with attached and marked as **Annexure-R1 & R2.**

115. The present situation in the country is not akin to any of these although a fear psychosis and mass hysteria fuelled by media reports pervades the county. Publicly available information reveals that deaths due to other diseases like, cardiovascular diseases and cancer are several times more than due to deaths attributed Covid-19. In a document jointly published by the Ministry of Health and Family Welfare, Indian Council for Medical Research, and others, titled, National Guidelines for Gene Therapy Product Development and Clinical trials 2019, (Annexure-B) the deaths due to cancer alone is given as, 7,84,821 (page 7) which is far in excess of the deaths attributed to Covid-19. Yet, this is neither considered serious enough to warrant emergency measure nor having adequate priority for admissions to hospitals. In fact, due to unfortunate focus on Covid-19, many cancer patients will go undetected until it is too late for treatment. Further, not having resource to hospital admissions they would be condemned to suffer excruciating pain that cancer is known to affect patients with the disease. Further according to the world statistics the countries which did not impose lockdown have less cases and deaths when compared to countries that have imposed lockdown. The lockdown has destroyed livelihoods of millions and is a complete negation of the doctrine of proportionality.

116. Further the fear has made people to rush to the hospital if any symptoms arise and that has led to lack of services being offered to

other patients who go to hospitals with other serious illness and thus the right to health is violated.

117. The cause of action to file this petition has arisen due to the arbitrary decisions of Respondent no 1 with respect to vaccine such as COVAXIN and COVISHIELD, the petition is in the interest of the public at large and there is no private interest of that of the petitioner whatsoever.

118. There is no other petition filed on the same cause of action in this Hon'ble Court or any other. The petitioner does not have any other remedy available and hence this petition.

119. The petitioner has further sent representations to Respondent no 1 to 4 seeking all the relief sought below. The same is marked as **Annexure-S1 and S2.** The postal receipts are marked as **Annexure-T.**

GROUNDS

120. The virus has not been isolated but, a genome sequence generated and a claim to isolation of the virus made on this basis. Koch's postulate has Not been satisfied to prove that the virus claimed to be isolated is the causative agent of the disease, Covid-19.

121. The vaccines are not vaccines as normally administered, but gene therapeutic product. Since, the Respondents call it vaccine,

the public are deluded into assuming that what is being injected into them is vaccine, they are normally accustomed to. Serum institute Covishield (Astra Zeneca) vaccine falls under the definition of gene therapeutic product as according to the GTP Guidelines. ***Annexure-B at page-195.***

122. It submitted that Making alterations to the genetic composition of an individual is a scientifically and medically challenging undertaking and hence trials are to be conducted and the outcome of the said the trains are to be evaluated and carefully subjected to expert committee evaluation and only after which permission shall be granted.

123. The permission having no MF/BI/000001, MF/BI/000002 and MF/BI/000019 dt. 03-01-2021 and 11-02-2021 are not in conformity with GTP Guidelines. There is no approvals received from the **Gene Therapy Advisory and Evaluation Committee (GTAEC**). And if any received there is no information to this date which is published on respondent's website.

124. As according to 7.9 of the GTP Guidelines: Any GTP of foreign origin or its modified variants that will be first in human use is not permissible for direct first in human trials in India. Covishield vaccine being a GTP and a foreign origin product for which first in Human Trials are itself banned whereas in the current scenario mass human vaccinations are being carried on even without human

trials.

125. The permission is granted for restrictive use for a defined population and according to the provisions of NDCT rules 2019 both the vaccines fall under the category of Orphan Drug as defined in Rule 2 (x) and thus cannot be administered for more than 5 lakh people.

126. It is further submitted by the petitioner that Covishield vaccine have not submitted any report with respect to toxicology to reproduction and development. It is stated that animal studies into potential toxicity to reproduction and development have not yet been completed. A vaccine which has not conducted study on reproduction if administered and later found out that there is an impact on reproduction and development in the course of mass immunisation it would lead to catastrophic effect. Reproduction, fertility, development are aspects which take time to be studied.

127. The campaign of vaccination states that the vaccine is safe and that it can be trusted. Based on the document published on 01–01–2021 the entire aspect of reproduction has been left out in the course of vaccination studies conducted by the Covishield vaccine. Administering such vaccine is in violation of the Reproductive rights enshrined in the Human rights for which India is a signatory.

128. Under the guise of clinical trials, mass immunization program is launched and vigorously implemented in total contradiction of the Respondents' own rules i.e.,NDCTRules-2019.

129. Compensation required to be paid as per Rule 42 of NDCTRules-2019 are diluted and left vague by contradictory statements in fact sheets and so are the forms for informed consent.

130. The stipulated methodology that is to be followed in AEFI related issues as according to the AEFI Surveillance and response operational guidelines 2015 is not being followed by the respondent No 1 and 2.

131. Further AEFI Surveillance and response operational guidelines 2015 at 6.2 specifically stated that in case of death after getting vaccine, autopsies are to be mandatorily conducted in order to know the cause of death. The copy of the AEFI Surveillance and response operational guidelines 2015 marked as **ANNEXURE-N *at Page-638.***

132. Further if autopsy is not conducted the it becomes highly impossible to claim compensation in the event of death. Also the veracity of the numbers of the deaths being reported is highly doubtful and impossible to determine. And not doing autopsies could result in heinous crimes like, murder going undetected.

133. The is no informed consent details published by Covishield. The Covaxin has published the informed consent form. The fact sheets

and summary of the product characteristics are not in accordance with the NDCT rules 2019. All the information that should be published have not been published. All the necessary tests as directed by the NCDT rules have not been complied by and based on the partial information available and the ambiguity in the said documents are the basis on which consent is sought. Thus any such consent given cannot be considered as a consent out of free will and without any deceit.

134. The Principle of transparency and accountability whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants. The said principal is not being followed. The copy of the national ethical Guidelines for biomedical and health research involving human participants 2017 as **ANNEXURE-P at *page-794*.**

135. Compensation for death of injury is vaguely mentioned and it is unlikely that any sufferer would receive it. ICMR's past record has evidenced by the Parliament Report No. 72 and its present partnership with BBIL prove that history is repeating itself with even worse disastrous consequences than earlier.

136. Executive actions are completely contrary to the doctrine of proportionality.

GROUNDS FOR INTERIM PRAYER

137. The virus has not been isolated but, a genome sequence generated and a claim to isolation of the virus made on this basis. Koch's postulate has Not been satisfied to prove that the virus claimed to be isolated is the causative agent of the disease, Covid-19.

138. The vaccines are not vaccines as normally administered, but gene therapeutic product. Since, the Respondents call it vaccine, the public are deluded into assuming that what is being injected into them is vaccine, they are normally accustomed to. Serum institute Covishield (Astra Zeneca) vaccine falls under the definition of gene therapeutic product as according to the GTP Guidelines. **Annexure-B *at page-195.***

139. It submitted that Making alterations to the genetic composition of an individual is a scientifically and medically challenging undertaking and hence trials are to be conducted and the outcome of the said the trains are to be evaluated and carefully subjected to expert committee evaluation and only after which permission shall be granted.

140. The permission having no MF/BI/000001 and MF/BI/000019 dt. 03-01-2021 and 11-02-2021 are not in conformity with GTP Guidelines. There is no approvals received from the **Gene Therapy Advisory and Evaluation Committee (GTAEC**). And if any

received there is no information to this date which is published on respondent's website.

141. As according to 7.9 of the GTP Guidelines: Any GTP of foreign origin or its modified variants that will be first in human use is not permissible for direct first in human trials in India. Covishield vaccine being a GTP and a foreign origin product for which first in Human Trials are itself banned whereas in the current scenario mass human vaccinations are being carried on.

142. The permission is granted for restrictive use for a defined population and according to the provisions of NDCT rules 2019 both the vaccines fall under the category of Orphan Drug as defined in Rule 2 (x) and thus cannot be administered for more than 5 lakh people.

143. It is further submitted by the petitioner that Covishield vaccine have not submitted any report with respect to toxicology to reproduction and development. It is stated that animal studies into potential toxicity to reproduction and development have not yet been completed. A vaccine which has not conducted study on reproduction if administered and later found out that there is an impact on reproduction and development in the course of mass immunisation it would lead to catastrophic effect. Reproduction, fertility, development are aspects which take time to be studied.

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01–01–2021 the entire aspect of reproduction has been left out in the course of vaccination studies conducted by the Covishield vaccine. Administering such vaccine is in violation of the Reproductive rights enshrined in the Human rights for which India is a signatory.

145. Under the guise of clinical trials, mass immunization program is launched and vigorously implemented in total contradiction of the Respondents' own rules i.e.,NDCTRules-2019.

146. Compensation required to be paid as per Rule 42 of ND_CTRules_2019 are diluted and left vague by contradictory statements in fact sheets and so are the forms for informed consent.

147. The stipulated methodology that is to be followed in AEFI related issues as according to the AEFI Surveillance and response operational guidelines 2015 is not being followed by the respondent No 1 and 2.

148. Further AEFI Surveillance and response operational guidelines 2015 at 6.2 specifically stated that in case of death after getting vaccine, autopsies are to be mandatorily conducted in order to know the cause of death. ***ANNEXURE-N at page 638***

149. Further if autopsy is not conducted the it becomes highly impossible to claim compensation in the event of death. Also the veracity of the numbers of the deaths being reported is highly

doubtful and impossible to determine. And not doing autopsies could result in heinous crimes like, murder going undetected.

150. The is no informed consent details published by Covishield. The covaxin has published the informed consent form. The fact sheets and summary of the product characteristics are not in accordance with the NDCT rules 2019. All the information that should be published have not been published. All the necessary tests as directed by the NCDT rules have not been complied by and based on the partial information available and the ambiguity in the said documents are the basis on which consent is sought. Thus any such consent given cannot be considered as a consent out of free will and without any deceit.

151. The Principle of transparency and accountability whereby the research plan and outcomes emanating from the research are brought into the public domain through registries, reports and scientific and other publications while safeguarding the right to privacy of the participants. The said principal is not being followed.

152. Compensation for death of injury is vaguely mentioned and it is unlikely that any sufferer would receive it. ICMR's past record has evidenced by the Parliament Report No. 72 and its present partnership with BBIL prove that history is repeating itself with even worse disastrous consequences than earlier.

PRAYER

For the reasons stated in the petition above the petitioner humbly pray is as follows.

1. To direct Respondent No.01 and 02 to take appropriate steps to direct all Hospitals to conduct autopsy in order to attribute the cause of death in accordance with the AEFI surveillance and response Guidelines,2015.
2. To direct Respondent no 3 and 4 to publish all the data with respect to the vaccines as according to the principle of transparency and accountability as mentioned in National ethical guidelines for biomedical and health research involving Human Participants 2019.
3. To direct the Respondent No 1 and 2 to stop mass vaccination process until all the stages of the clinical trials are completed as according to the New Drugs and clinical trial rules 2019 and the National Guidelines for Gene Therapy Product Development and Clinical Trials-2019.

4. Declare that the vaccines now administered in India are Gene Therapeutic products and not a vaccine in the interest of full disclosure, informed consent and as stated in National Guidelines for Gene Therapy Product Development and Clinical Trials-2019.

INTERIM PRAYER

1. Direct the Respondent no 1 and 2 to stay the administration of vaccine in the light of permission being granted for clinical trials, for restrictive use i.e., for definite population and not for mass vaccination as stated in the New Drugs and Clinical Trial Rules

2019.

2. Direct Respondent No.01 and 02 to take appropriate steps to direct all Hospitals to conduct full and complete autopsy along with detailed investigation be conducted with respect to AEFI related death in accordance with the AEFI surveillance and response Guidelines,2015

Bangalore
Date:

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IN THE HIGH COURT OF KARNATAKA AT BANGALORE
(original jurisdiction)
W.P. NO. 2021 (PIL)

BETWEEN:

Sri. Mathew Thomas & Ors **...PETITIONER**
AND
The state of Karntaka and Ors. ...**RESPONDENTS**

VERIFYING AFFIDAVIT

I, Mathew Thomas aged about 82 years, s/o Late T. P. John, r/o Aristos #2, Sobha City, Thanisandra Main Road, Bengaluru 560077 solemnly affirm and state as follows.

1. I am the petitioner in the above case and I am aware of the facts of the case and accordingly I am swearing to this affidavit and I am authorised to swear this on behalf of the other petitioners accordingly I swear to this affidavit.
2. The statements and grounds made in paras 1 to 152 is true to the best of my knowledge, information and belief.
3. The Annexure A- T are all true to the best of my knowledge and belief.

What is stated above is true and correct, I swear accordingly.

IDENTIFIED BY ME: DEPONENT
ADVOCATE SWORN TO BEFORE ME
BANGALORE:
DATE:

IN THE HIGH COURT OF KARNATAKA, AT BANGALORE

(Original Jurisdiction)

W.P No.: /2021 (PIL)

BETWEEN:

Sri. Mathew Thomas & Ors **PETITIONERS**

AND

The Government of India and Ors **RESPONDENTS**

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Bangalore
Date:

ADVOCATE FOR PETITIONER