IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CRIMINAL APPELLATE JURISDICTION

CRIMINAL WRIT PETITION NO. OF 2021

Smt. Kiran Yadav **....Petitioner**

Vs.

The State of Maharashtra & Ors. **....Respondents**

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NOTARY Adv. Shivaji N. Chavan Mumbai Maharashtra Reg. No. [illegible] GOVT. OF INDIA

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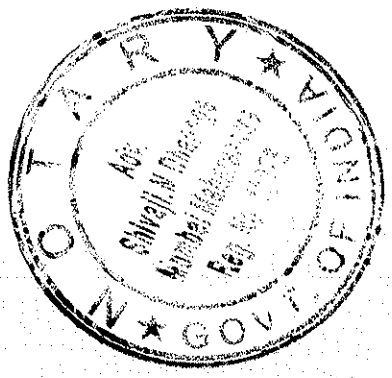

(A)

IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CRIMINAL APPELLATE JURISDICTION

CRIMINAL WRIT PETITION NO. OF 2021

Smt. Kiran Yadav **....Petitioner**

Vs.

The State of Maharashtra & Ors. **....Respondents**

SYNOPSIS

SR. NO.	DATES	PARTICULERS
1.	29.09.2021	The Petitioner's son was compelled to take vaccine as State of Maharashtra unlawfully and illegally restricted non-vaccinated people from traveling by train. Also they run false narratives that the vaccines are 110% safe.
2.	29.09.2021	The Petitioner's son died due to side effects of Covi-shield vaccine.
3.	30.09.2021	The Petitioners son's death Punchnama report prepared by the Virar Police Station.
4.	-	As per law laid down by the Hon'ble Supreme Court and Hon'ble High Court and more particularly in the case of **Registrar General Vs. State of Meghalaya 2021 SCC Online Megh 130**, if the person is

(9)

GOVT. OF INDIA
NOTARY
Reg. No. 15375
Exp. Dt. 13-11-2024

(B)

		vaccinated under deception or by force then, it is a civil and criminal wrong.
5.	**07.10.2021**	The Petitioner gave an application for registration of F.I.R. to Police Commissioner of Mira-Bhayander.
6.	**25.10.2021**	The Petitioner gave a complaint to Respondent No. 2 and other higher authorities on Affidavit.
		Hence this Petition.

POINTS TO BE URGED

As set out in the Petition.

Acts to be referred to:

1. Constitution of India.
2. Criminal Procedure Code, 1973.
3. Indian Penal Code.
4. Disaster Management Act, 2005.
5. Others, if any, with the leave of this Hon'ble Court.

Authorities to be relied upon at the time of arguments.

Advocate for the Petitioner

NOTARY INDIA Adv. Shivaji N. Thorave Mumbai Maharashtra Reg. No. 15378 Dt. 13-11-2024

IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CRIMINAL APPELLATE JURISDICTION

WRIT PETITION NO. _____OF 2021

DIST. – THANE

Smt. Kiran Yadav)

[redacted])

)

) **...Petitioner**

Versus

1. The State of Maharashtra)

Through Chief Secretary)

The Government of Maharashtra)

Mantralaya, Mumbai - 400 023.)

2. Director-General of Police)

Maharashtra State Police Headquarters,)

Old Council Hall, Shaeed Bhagat Singh)

Marg, Mumbai - 400 001.)

3. Commissioner of Police)
Shanti Gardens Rd, Panchmukhi Marg)
Sector 5, Srishti Complex, Mira Road)
Bldg No. 9, Ramnagar Development)
Corporation, near MBMC Office, Gaurav)
Galaxy, Mira Road, Mira Bhayandar,)
Maharashtra 401 107.)

4. Central Bureau of Investigation)
6th Floor, Lodhi Road, Plot No. 5-B,)
Jawaharlal Nehru Stadium Marg,)
CGO Complex, New Delhi, Delhi 110 003.)

5. Principal Secretary,)
Ministry of Health & Family Welfare)
Room No. 346; 'A' Wing, Nirman Bhavan,)
New Delhi - 110 011.) ...**Respondents**

TO,
THE HON'BLE THE CHIEF JUSTICE AND
OTHER HON'BLE PUISNE JUDGES OF
THIS HON'BLE COURT

THE HUMBLE PETITION OF THE PETITIONER ABOVENAMED.

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MOST RESPECTFULLY SHEWETH:

That, the Petitioner is a citizen of India and residing at above mentioned address.

1. That, the petitioner is lone mother of deceased **Shri Hitesh Kadve,** Age-23 Yrs, who lost his life due to act of wilful commission and omission attributable to some public servants who are misusing their position to bring policies to help the pharma mafia and thereby responsible mass murders.

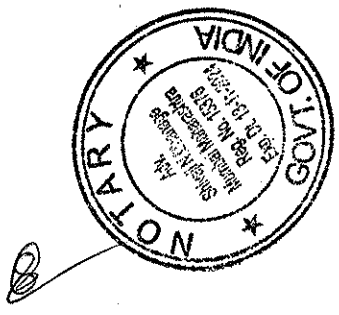
2. The petitioner's son was died due to side effects of vaccines which was unwillingly taken by him due to condition put by the officials of State of Maharashtra that, only vaccinated people can travel through the local train or enter mall and also the direction that the office staff of all private establishment should get vaccinated.

3. That, the abovesaid restrictions are against the Central Government's policy that, there cannot be any discrimination between vaccinated and unvaccinated people.

The Central Government's reply dated **09.03.2021** to an application under RTI is as under;

"RTI reply by Government of India's Health Ministry on 09.03.2021 to Shri. Anurag Sinha

प्रश्न १: कोरोना वैक्सीन लेना स्वैच्छिक है या अनिवार्य, जबरदस्ती?



उत्तर : कोरोना वैक्सीन लेना स्वैच्छिक है।

प्रश्न २ : क्या वैक्सीन नहीं लेने पर सारी सरकारी सुविधाए बंद कर दी जायगी, सरकारी योजना पेंशन?

उत्तर : आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।

प्रश्न ३ : क्या वैक्सीन नहीं लेने पर नौकरी नहीं मिलेगा, ट्रेन, बस, मेट्रो में चढ़ने नहीं मिलेगी?

उत्तर : आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।

प्रश्न ४: यदि कोई IAS, IPS स्वास्थ्य या पुलिस कर्मचारी नागरिक को धमकी दे की वैक्सीन ले नही तो ये कर देगे तो नागरिक क्या कर सकती क्या कोर्ट जा सकते हैं?

उत्तर : आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।

प्रश्न ५: क्या वैक्सीन नहीं लेने पर स्कूलों, कॉलेज, विश्वविद्यालय, गैस कनेक्शन, पानी, बिजली कनेक्शन, राशन आदि के लिए क्या वैक्सीन नहीं मिलेगे?

उत्तर : आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।

प्रश्न ६ : क्या वैक्सीन नही लेने पर नौकरी से निकला जा सकता है वेतन रोका जा सकत है, निजी और सरकारी विभाग दोनों मे?

उत्तर : आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है। "

A copy of said reply is annexed herewith at "**Exhibit - A**".

4. The abovesaid policy decision of Central Government was also considered by Hon'ble High Court in **Re Dinthar Incident Vs. State of Mizoram 2021 SCC OnLine Gau 1313** & **Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503.**

In the said judgment, Hon'ble Division Bench quashed the SOP, circulars issued by the state to restrict the entry to vaccinated people at some places.

5. That in the affidavit dated **08.10.2021** filed by Shri. Satyendra Singh, Under Secretary of Health Ministry of India, the policy and stand taken by the Government is once again made clear. The relevant paras of the affidavit read thus;

*"9. That, it is further humbly submitted that **the directions and guidelines released by Government of India and Ministry of Health***

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and family Welfare, do not entail compulsory or forcible vaccination against COVID-19 disease implying that COVID-19 vaccination is completely voluntary for all citizens of India. Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between citizens of India on the basis of their vaccination status.

10. ***That, it is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, but this in no way implies that any person can be forced to be vaccinated against her / his wishes.***

11. ***That, as per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid Vaccination on Co-WIN or visiting Covid Vaccination Centre for vaccination*** *if a person above the age of 18 years visits a Covid Vaccination Centre by her / his choice for vaccination and asks for the same, it implies that she / he is voluntarily coming to the center to get the benefit of Covid Vaccination."*

A copy of said Affidavit dated 08.10.2021 is annexed here at **"Exhibit – B."**

6. That, as per **section 38(1)** and **39(a)** of **Disaster Management Act, 2005** the state government cannot formulate any rules against the guidelines of the National Authority.
Said section reads thus;

> ***Section 38 (1) State Government to take measures.***
>
> *(1) Subject to the provisions of this Act, **each State Government shall take all measures specified in the guidelines laid down by the National Authority** and such further measures as it deems necessary or expedient, for the purpose of disaster management.*
>
> ***Section 39 (a) Responsibilities of departments of the State Government.***
>
> ***(a) take measures necessary for prevention of disasters**, mitigation, preparedness and capacity building **in accordance with the guidelines laid down by the National Authority** and the State Authority;*

7. Needless to mention here that, if any state authority acts in violation of Central Governments guidelines, then such state authority including head of the said department are liable for punishment under section 51(b) and 55 of the Disaster Management Act.
It is reads thus;

> ***"51 Punishment for obstruction, etc.***

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Whomsoever:

(b) refuses to comply with any direction given by or on behalf of the Central Government *or the State Government or the National Executive Committee or the State Executive Committee or the District Authority under this Act, shall on conviction be punishable with imprisonment for a term which may extend to one year or with fine, or with both, and if such obstruction or refusal to comply with directions results in loss of lives or imminent danger thereof, shall on conviction be punishable with imprisonment for a term which may extend to two years. notes on clauses Clauses 51 to 58 (Secs. 51 to 58) seeks to lay down what will constitute an offence in terms of obstruction of the functions under the Act, false claim for relief, misappropriation of relief material or funds, issuance of false warning, failure of an officer to perform the duty imposed on him under the Act without due permission or lawful excuse, or his connivance at contravention of the provisions of the Act. The clauses also provide for penalties for these offences.*

55. Offences by Departments of the Government.

(1) Where an offence under this Act has been committed by any Department of the Government, the head of the Department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly unless he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a Department of the Government and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any officer, other than the head of the Department, such officer shall be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly."

8. Needless to mention here that, earlier also Maharashtra and few other State governments put some restrictions on inter-state and intra-state movement by acting against the guidelines of Central Government at that time Home Secretary, Shri. Ajay Kumar Bhalla, issued or letter on **22.08.2021** warning them about violation of the Central Governments guidelines.

Said letter reads thus;

"D.O. No. 40-3/2020-DM-I(A)

Dear Chief Secretary,

Please refer to Ministry of Home Affairs' Order of even number dated 29.07.2020 whereby Guidelines for Unlock-3 have been issued.

2. I would like to draw your kind attention to para-5 of these guidelines which clearly state that ***there shall be no restriction on inter-State and Intra-State movement of persons and goods. No separate permission, approval/e-permit will be required for such movements.*** *This includes movement of persons & goods for cross land border trade under Treaties with neighboring countries.*

3. It has, however, been reported that local level restrictions on movement are being imposed by various districts/States. Such restrictions are creating problems in inter-State movement of goods and services and are impacting the supply chain, resulting in disruption of economic activities and employment, besides affecting supply of goods and services.

4. ***<u>Such restrictions at local level imposed by the District Administration or by the State Government, amount to violation of the guidelines issued by MHA under the</u>***

provisions of Disaster Management Act, 2005.

5. I would, therefore, request that no restrictions may be imposed on inter-State and intra State movement of persons and goods and services and instructions issued to ensure that MHA guidelines mentioned above are strictly followed."

A copy of the said letter is annexed at "**Exhibit - C**".

9. That, the legal position in India is very clear that, everyone has a right to choose or refuse the medicine or treatment. No doctor or anyone can force a person to get a particular treatment only.

[Common Cause Vs. Union of India (2018) 5 SCC 1, Montgomery Vs. Lanarkshire Health Board [2015] UKSC 11, Airdale NHS Trust Vs. Bland (1993) 1 All ER 821, Registrar General Vs. State of Meghalaya 2021 SCC Online Megh 130, Osbert Khaling Vs. State of Manipur 2021 SCC OnLine Mani 234.

10. Law is also very well settled that whenever anything is prohibited then it is prohibited from being done indirectly.

In **Noida Entrepreneurs Association Vs Noida (2011) 6 SCC 508**, it is ruled as under;

"25. It is a settled proposition of law that whatever is prohibited by law to be done, cannot legally be affected by an indirect and

circuitous contrivance on the principle of quando aliquid prohibetur, prohibetur at omne per quod devenitur ad illud, which means "whenever a thing is prohibited, it is prohibited whether done directly or indirectly". (See Swantraj v. State of Maharashtra [(1975) 3 SCC 322 : 1974 SCC (Cri) 930 : AIR 1974 SC 517] , CCE v. Acer India Ltd. [(2004) 8 SCC 173] and Sant Lal Gupta v. Modern Coop. Group Housing Society Ltd. [(2010) 13 SCC 336 : (2010) 4 SCC (Civ) 904 : JT (2010) 11 SC 273])

***26.** In Jagir Singh v. Ranbir Singh [(1979) 1 SCC 560 : 1979 SCC (Cri) 348 : AIR 1979 SC 381] this Court has observed that an authority cannot be permitted to evade a law by "shift or contrivance". While deciding the said case, the Court placed reliance on the judgment in Fox v. Bishop of Chester [(1824) 2 B&C 635 : 107 ER 520] , wherein it has been observed as under: (Jagir Singh case [(1979) 1 SCC 560 : 1979 SCC (Cri) 348 : AIR 1979 SC 381] , SCC p. 565, para 5)*

*"5. ... **'To carry out effectually the object of a statute, it must be so construed as to defeat all attempts to do, or avoid doing, in an indirect or circuitous manner that which it has prohibited or enjoined**.' [Ed.: As observed in Maxwell on the*

Interpretation of Statutes, 11th Edn., p. 109. See SCC p. 565, para 5 of Jagir Singh case, (1979) 1 SCC 560.]"

11. That, the discrimination done by the accused official between vaccinated and unvaccinated people is not based on any logic or public good. It is only **based on the one-line agenda to give wrongful profit to the vaccine companies**.

12. The ulterior motives and malafide intention of the accused officer can be easily seen from the material available on record and also from the law laid down by the Division Bench of Hon'ble Government High Court in **Re: Dinthar Incident Vs. State of Mizoram 2021 SCC OnLine Gau 1313 & Madan Mili Vs. UOI 2021 SCC OnLine Gau 1503,** where it is ruled that the vaccinated people can also get infected with corona and can spread infection as that of unvaccinated people and therefore there cannot be any discrimination between vaccinated and unvaccinated people and any rule made by the state should be treated as violative of Art. 14,19 & 21 of the constitution of India.

A copy of said judgment is annexed at "**Exhibit – D Colly**".

A copy of judgment in **Osbert Khaling Vs State of Manipur 2021 SCC OnLine Mani 234** is annexed at **"Exhibit - M"**. **[Page No. 222-223]**

13. Needless to mention here that, the above said judgments are passed on the basis of Central Government policy decision and after hearing the Union of India and they are regarding the

interpretation of Constitution of India and therefore, they are binding on all the authorities in India including authorities of state of Maharashtra.

14. This Hon'ble Court in the case of **Maharashtra Govt., through G. B. Gore, Food Inspector, Nanded Vs Rajaram Padamwar 2011 SCC OnLineBom 2021**, it is ruled as under;

> *"**JUDICIAL DISCIPLINE** – Judgement of another High court – Observations of trial Magistrate that the judgement of Kerala High Court is not binding on him – Further observing the legality and correctness of the judgement of another High Court is against the judicial discipline and propriety – Registrar General directed to take suitable action against concerned Judge.*

15. That, as per **section 52** of the Indian Penal Code the act of **accused authorities cannot be said to have done in good faith because it is not done with due case and caution.**

In **Noor Mohamed Vs. Nadirshah Ismailshah Patel 2004 ALL MR (CRI.) 42,** it was held that;

> *"It has to be kept in mind that **nothing can be said to be done in good faith which is not done with due care and caution**. If these ingredients are indicated by the complaint, the Magistrate is obliged to take the cognizance of the complaint so presented before him unless there are the other grounds for acting*

otherwise which has to be justified by reasons recorded in writing."

16. That, the malafides of the accused authorities can also be seen from the very fact that, they have not considered the crucial suggestions and research data by the domain experts of the country more particularly by Dr. Sanjiv Rai of **AIIMS.**

The summary of around **81 research paper** summaries that;

(i) The person who developed antibodies (Natural Immunity) due to Covid infection or coming in contact with Sars-Covi-2 virus are the safest person in the world as there is no chance of these people getting corona infection again or spreading of infection by these people **"[Exhibit - E]"**
So, any relaxation can be given to such persons with natural immunity only.

(ii) The natural immunity is **13 times more** rebust & better than that of vaccine generated immunity. Vaccines are not proven to be effective on other variants like Delta variant.

(iii) Giving vaccines to people with natural immunity causes damages and harm to such person's body. There is no study which proves any benefit of such person in giving vaccine to him.
It is also a huge loss of thousands of crores of public funds.

(iv) All people should be asked to get Antibody Test (IGG) if antibodies are developed amongst a person then he should be given relaxation from **'Covid**

appropriate behaviour' Such person should not be vaccinated and there is no sense in asking such persons to get RTPCR Test done and follow other time consuming and expensive methods.

17. But the State Authority ignored the abovesaid factual, logical and scientific suggestions and adopted the method for giving undue profit to vaccine manufacturing and RTPCR test companies. This was done at the cost of public money and putting the life of the citizen in danger.

18. Needless to mention that, as per principles laid down in catena of decisions it is the duty of state authority and more particularly of the authority promoting vaccines to **publish the side effects of vaccines so that people will be able to take the informed decision about vaccination.**

Relied on:-

1. Master Haridaan Kumar (Minor through Petitioners Anubhav Kumar and Mr. Abhinav Mukherji) Vs. Union of India, **W.P.(C) 343/2019 & CM Nos.1604-1605/2019.**
2. Airedale NHS Trust v Bland **(1993) 2 WLR 316.**
3. Montgomery Vs. Lanarkshire Health Board **[2015] UKSC 11.**
4. Universal Declaration on Bioethics & Human Rights, 2005.

19. Hon'ble Delhi High Court in While dealing with the issue of MR vaccines in the case of **Master Haridaan Kumar (Minor through Petitioners Anubhav Kumar and Mr. Abhinav**

Mukherji) Versus Union of India, W.P.(C) 343/2019 & CM Nos.1604-1605/2019, the Hon'ble High Court of Delhi directed that;

> ***"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"*

20. The provisions of Universal Declaration on Bioethics & Human Rights, 2005 reads thus;

> ***"Article 3 – Human dignity and human rights***
>
> *1. Human dignity, human rights and fundamental freedoms are to be fully respected.*
>
> ***2. The interests and welfare of the individual should have priority over the sole interest of science or society.***
>
> ***Article 6 – Consent***
>
> *1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person*

concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 10 – Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Application of the principles

21. In **Montgomery's case [2015] UKSC 11**, it is ruled as under;

"77. These developments in society are reflected in professional practice. The court has been referred in

particular to the guidance given to doctors by the General Medical Council, who participated as interveners in the present appeal. ***One of the documents currently in force (Good Medical Practice (2013)) states, under the heading "The duties of a doctor registered with the General Medical Council":***

*"**Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients' right to reach decisions with you about their treatment and care.**"*

78. Another current document (Consent: patients and doctors making decisions together (2008)) describes a basic model of partnership between doctor and patient:

*"**The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides***

whether to accept any of the options and, if so, which one. *" (para 5)*

In relation to risks, in particular, the document advises that the doctor must tell patients if treatment might result in a serious adverse outcome, even if the risk is very small, and should also tell patients about less serious complications if they occur frequently (para 32). The submissions on behalf of the General Medical Council acknowledged, in relation to these documents, that an approach based upon the informed involvement of patients in their treatment, rather than their being passive and potentially reluctant recipients, can have therapeutic benefits, and is regarded as an integral aspect of professionalism in treatment.

80. *In addition to these developments in society and in medical practice, there have also been developments in the law. Under the stimulus of the Human Rights Act 1998, the courts have become increasingly conscious of the extent to which the common law reflects fundamental values. As Lord Scarman pointed out in Sidaway's case, these include the value of self-determination (see, for example, S (An Infant) v S [1972] AC 24, 43 per Lord Reid; McColl v Strathclyde Regional Council 1983 SC 225, 241; Airedale NHS Trust v Bland [1993] AC 789, 864 per Lord Goff of Chieveley). As well as underlying aspects of the common law, that*

value also underlies the right to respect for private life protected by article 8 of the European Convention on Human Rights. The resulting duty to involve the patient in decisions relating to her treatment has been recognised in judgments of the European Court of Human Rights, such as Glass v United Kingdom (2004) EHRR 341 and Tysiac v Poland (2007) 45 EHRR 947, as well as in a number of decisions of courts in the United Kingdom. The same value is also reflected more specifically in other international instruments: see, in particular, article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, concluded by the member states of the Council of Europe, other states and the European Community at Oviedo on 4 April 1997.

82. <u>In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure that a patient is aware of material risks of injury that are inherent in treatment.</u> *This can be understood, within the traditional framework of negligence, as a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk. The existence of that entitlement, and the fact that its exercise does not depend exclusively*

on medical considerations, are important. They point to a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.

***83.** The former role is an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling within the expertise of members of the medical profession. But it is a non sequitur to conclude that the question whether a risk of injury, or the availability of an alternative form of treatment, ought to be discussed with the patient is also a matter of purely professional judgment. The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the courts, not with the medical professions.*

***87.** The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in Sidaway by Lord Scarman, and by Lord Woolf MR in Pearce, subject*

to the refinement made by the High Court of Australia in Rogers v Whitaker, which we have discussed at paras 77-73. ***An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.*** *The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.*

89. *Three further points should be made. First, it follows from this approach that the assessment of* ***whether a risk is material cannot be reduced to percentages****. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-*

sensitive, and sensitive also to the characteristics of the patient.

90. *Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible.* ***The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form****.*

116. *As NICE (2011) puts it, "Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about their care and treatment" (para 1.1.1.1). Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being.*

22. In **Common Cause Vs. Union of India (2018) 5 SCC 1**, it is ruled as under;

"169. *In the context of health and medical care decisions, a person's exercise of self-determination and autonomy involves the exercise of his right to*

decide whether and to what extent he/she is willing to submit himself/herself to medical procedures and treatments, choosing amongst the available alternative treatments or, for that matter, opting for no treatment at all which, as per his or her own understanding, is in consonance with his or her own individual aspirations and values.

Q. Conclusions in seriatim

202. *In view of the aforesaid analysis, we record our conclusions in seriatim:*

> ***202.8.*** *An inquiry into Common Law jurisdictions reveals that* ***all adults with capacity to consent have the right of self-determination and autonomy. The said rights pave the way for the right to refuse medical treatment which has acclaimed universal recognition. A competent person who has come of age has the right to refuse specific treatment or all treatment or opt for an alternative treatment, even if such decision entails a risk of death.*** *The "Emergency Principle" or the "Principle of Necessity" has to be given effect to only when it is not practicable to obtain the patient's consent for treatment and his/her life is in danger. But where a patient has already made a valid Advance Directive which is free from reasonable doubt and specifying that he/she*

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does not wish to be treated, then such directive has to be given effect to.

202.9. *Right to life and liberty as envisaged under Article 21 of the Constitution is meaningless unless it encompasses within its sphere individual dignity. With the passage of time,* ***this Court has expanded the spectrum of Article 21 to include within it the right to live with dignity as component of right to life and liberty.***

202.12. *Though the sanctity of life has to be kept on the high pedestal yet in cases of terminally ill persons or PVS patients where there is no hope for revival, priority shall be given to the Advance Directive and the right of self-determination.*

202.13. *In the absence of Advance Directive, the procedure provided for the said category hereinbefore shall be applicable.*

202.14. *When passive euthanasia as a situational palliative measure becomes applicable,* ***the best interest of the patient shall override the State interest.***

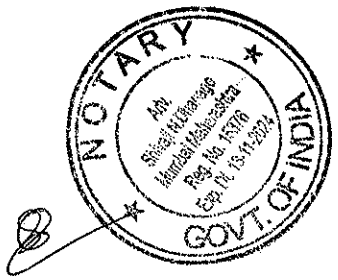
306. *In addition to personal autonomy, other facets of human dignity, namely, "self-expression" and "right to determine" also support the argument*

that ***it is the choice of the patient to receive or not to receive treatment.***

517. The entitlement of each individual to a dignified existence necessitates constitutional recognition of the principle that an individual possessed of a free and competent mental state is entitled to decide whether or not to accept medical treatment. The right of such an individual to refuse medical treatment is unconditional. ***Neither the law nor the Constitution compel an individual who is competent and able to take decisions, to disclose the reasons for refusing medical treatment nor is such a refusal subject to the supervisory control of an outside entity;"***

23. In **Osbert Khaling Vs. State of Manipur and Ors. 2021 SCC OnLine Mani 234,** it is ruled as under;

"8.... *Restraining people who are yet to get vaccinated from opening institutions, organizations, factories, shops, etc., or* ***denying them their livelihood by linking their employment****, be it NREGA job card holders or workers in Government or private projects,* ***to their getting vaccinated would be illegal on the part of the State, if not unconstitutional. Such a measure would also trample upon the freedom of the individual to get vaccinated or choose not to do so."***



24. That, the State authorities for the reasons best known to them have not followed the abovesaid legal mandate.

On the other hand, few accused officials hatched a well-orchestrated conspiracy and run various false narratives and conspiracy theories and made a total false and misleading claim that, **vaccines are completely safe**. This was done with only intention to cheat the public at large and to give wrongful benefit to the vaccine manufactures companies.

24.1. The two most glaring evidences exposing falsity, dishonesty and cheating campaign by the accused are as under;

(a) Doctor D.G. Somani, Drug Controller General of India in furtherance of the said conspiracy had made a false and misleading statement that, the vaccines are 110% safe.

The excerpts in his interview on **4th January 2021,** with NDTV are as under;

> *"Drug Controller General of India VG Somani said,.* ***"We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe".***

Link: https://www.ndtv.com/india-news/oxford-covid-19-vaccine-bharat-biotechs-covaxin-get-final-approval-by-drug-regulator-will-be-indias-first-vaccines-2347053

[Detail news is at "**Exhibit - F**"]

(b) Dr. Randeep Guleria of AIIMS gave a statement in various media and also on YouTube in a special campaign **'know from experts'** that vaccines are completely safe and everyone should get vaccinated.

Link: https://fb.watch/7u26q6CL59/

25. The falsity of claims by the above accused officials and doctors is ex facie proved from the following evidences and government's own records.

25.1. Dr. Snehal Lunawat died due to side effects of Covi-Shield vaccine. The government of India's AEFI committee accepted it as death due to side effects of vaccines.

The reply given under RTI, reads thus;

"Information in response to RTI Appeal Registration No. MOHFW/A/E/21/00586 dated 06.08.2021 filed by Ms. Sapna Dilip Lunawat

Point 1: *Details of all the Cases of specific embolic and thrombotic events in combination with low levels of blood platelets (thrombocytopenia) found in the patients all over India reported with you post Covishield vaccination. Details should contain Name, Age, Gender, Place, Hospital name.*

Information: *Two suspected cases of embolic and thrombotic events in combination with low levels of blood platelets (thrombocytopenia)*

following Covishield vaccination were identified in 498 cases rapidly reviewed and assessed by medical experts. Both these cases were in females above 50 years of age. Personal details the reported cases are not shared under Section 8(1)(j) of the RTI Act, 2005."

25.2. That the World Health Organization (WHO) had warned about serious side effects of Covishield (AstraZeneca).

Link: https://www.who.int/news/item/26-07-2021-statement-of-the-who-gacvs-covid-19-subcommittee-on-gbs

25.3. 18 European countries banned Covishield (AstraZeneca) due to death causing side effects in young people.

Link:

i) https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/covishield-coronavirus-vaccine-with-covishield-astrazeneca-banned-in-some-countries-should-we-be-worried-about-its-safety/photostory/83398722.cms

ii) https://www.theguardian.com/society/2021/apr/08/spain-belgium-and-italy-restrict-astrazeneca-covid-vaccine-to-older-people

26. The above data ex-facie proves the malafides and callous criminal attitude of the accused official that they omitted to perform their duty as per law and blatantly cheated the citizens of this country and therefore they are responsible for knowingly pushing the citizens to death.

27. Since the result of conspiracy and overt act of accused resulted in death of petitioner's son, therefore, all the accused officials are liable for prosecution under section **420, 409,115, 302, 120(B), 34, 109, 52 etc. of IPC, Section 51(b), 55, 54** etc of Disaster Management Act, 2005 and provisions of Prevention of Corruption Act, 1988.

28. That, the main beneficiary of the crime is **Mr. Adar Poonawalla & ors.** who are the owner and employees of the company **Serum Institute** which is manufacturing **'Covi-Shield'** vaccine.

They are complicit in the crime because they never objected to the false propaganda run by accused Dr. V.G. Somani & Dr. Randeep Guleria.

29. The another example of falsity, dishonesty and malafides of Serum Institute can be seen from their emails sent to family members of deceased Dr. Snehal Lunawat.

29.1. That, when Dr. Snehal Lunawat had suffered serious side effects of vaccines and when she was in hospital, the family members sent an email to Serum Institute on 13th February, 2021 requesting to help to save her life by providing research to deal with such side effects. The Serum Institute's representative, Dr. Chetanraj Bhamre in his reply mail dated 15th February, 2021 falsely stated that **'Covishield do not cause thrombosis or any cardiovascular events'.**

The falsity of Serum Institute is exposed from the decision taken by the **AEFI (Adverse Events Following Immunization)** committee. They admitted that the death was due to side effects of vaccines.

30. The information given by the Health Ministry reads thus;

> ***"Information in response to RTI Appeal Registration No. MOHFW/A/E/21/00586 dated 06.08.2021 filed by Ms. Sapna Dilip Lunawat***
>
> ***Point No. 7:*** *Detailed analysis and report of the investigation done by you on the death of a 32 years old doctor from Nashik, Maharashtra, Dr. Snehal Lunawat case, as published in The Economics Times dated 29.04.2021 and Times of India dated 23.04.2021 wherein the government officials have said that they have investigated the case and have not found anything unusual and there was no major concern found in this case.*
>
> ***(i)*** *Investigation reports of the case given by Government Officials.* ***Information:*** *As per COVID-19 operational guideline, the case reporting form (CRF) and the Case Investigation Form (CIF) along with the relevant case records (hospital records or post-mortem report or verbal autopsy report in case of death cases) for all*

suspected serious/severe AEFI cases are to be filled/collected and submitted by the District Immunization Officer to the District AEFI committee. These are also uploaded on the CoWIN portal. Since investigation is the function of the DIO and District AEFI committee, the Appellant may approach the District authorities to share the investigation reports of the case with the Appellant (According to the guidelines given at Para 3(iv) of D/o Personal & Training, Government of Indio's O.M. No. 10/2/2008-IR dated 12.06.2008 (copy enclosed as Enclosure-1), if a person makes an application to a public authority for some information which is the concern of a public authority under any State Government or Union Territory Administration, the Central Public Information Officer (CPIO) of the public authority receiving the application should inform the applicant that the information may be had from the concerned State Government/UT Administration and the application, in such case, need not be transferred to the State Government/UT Administration. Thus,

the Appellant may obtain the information from the State Government concerned as the same will be available with the authorities of the State concerned). After receipt of investigation reports from the State/UT, the causality assessment done at National level and as approved by the National AEFI committee that AEFI death belongs to A1 category meaning by that it is related to vaccine product related reaction.

(ii) *Basis of your conclusions in the above case.*

Information: *The case records for the above-mentioned case has been reviewed by the National AEFI Committee. The causality assessment of the case is completed and approved by the National AEFI Committee, the results will be shared with the State Government as well as with CDSCO (Central Drugs Standard Control Organization).*

(iii) *Date-wise procedure carried out by you to perform investigation of the above case.*

Information: *The investigation reports and case documents (hospital records, etc.) have been received on 8th June 2021 at the national level through CoWIN. These were screened on 29th June 2021 as well as put up for causality assessment meeting held online on 17th September 2021 and on 25th September 2021 the National AEFI Committee reviewed and approved the case."*

31. Hon'ble Supreme court in the case of **Raman Lal Vs State 2001 Cri. L. J. 800,** had ruled that, the conspiracies are hatched on secrecy and therefore, no direct evidence is required to prove it. The offence can be proved from circumstantial evidences.
It is read thus;

"Conspiracy – I.P.C. Sec. 120 (B) *– Apex court made it clear that an inference of conspiracy has to be drawn on the basis of circumstantial evidence only because it becomes difficult to get direct evidence on such issue – The offence can only be proved largely from the inference drawn from acts or illegal omission committed by them in furtherance of a common design – Once such a conspiracy is proved, act of one conspirator becomes the act of the others – A Co-conspirator who joins subsequently and*

commits overt acts in furtherance of the conspiracy must also be held liable – Proceeding against accused cannot be quashed."

32. Hon'ble Bombay High Court in the case of **CBI VS Bhupendra Champaklal Dalal 2019 SCC OnLine Bom 140**, it is ruled as under;

CHARGE FOR THE OFFENCE OF CRIMINAL BREACH OF TRUST :-

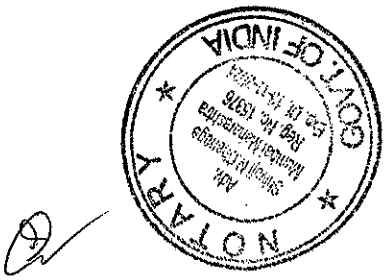
*Hon'ble Apex Court in the case of **Ram Narain Poply Vs. Central Bureau of Investigation, AIR 2003 SC 2748,** wherein the Hon'ble Apex Court has, at length, dealt with the charge of criminal conspiracy, in the backdrop of the similar allegations, in a case arising out of the decision of this Court in the matter of Harshad Mehta and others. While dealing with the essential ingredients of the offence of criminal conspiracy, punishable u/s. 120 B IPC, the **Hon'ble Court was, in paragraph No.349 of its Judgment, pleased to hold that, "349. Privacy and secrecy are more characteristics of a conspiracy, than of a loud discussion in an elevated place open to public view.** Direct evidence in proof of a conspiracy is seldom available, offence of conspiracy can be proved by either direct or circumstantial evidence. It is not always possible to give*

affirmative evidence about the date of the formation of the criminal conspiracy, about the persons who took part in the formation of the conspiracy, about the object, which the objectors set before themselves as the object of conspiracy, and about the manner in which the object of conspiracy is to be carried out, all this is necessarily a matter of inference."

[Emphasis Supplied]

177. This Court can also place reliance on another landmark decision of the Hon'ble Apex Court in the case of State of Maharashtra Vs. Som Nath Thapa, (1996) 4 SCC 659, wherein the Hon'ble Apex Court was pleased to observe as follows :-

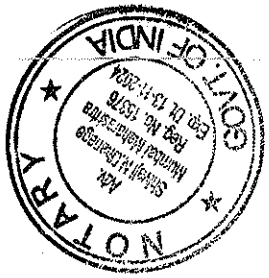
> *"24. The aforesaid decisions, weighty as they are, lead us to conclude that to establish a charge of conspiracy knowledge about indulgence in either an illegal act or a legal act by illegal means is necessary. In some cases, intent of unlawful use being made of the goods or services in question may be inferred from the knowledge itself. This apart, the prosecution has not to establish that a particular unlawful use was intended, so long as the goods or service in question could not be put to*



any lawful use. Finally, when the ultimate offence consists of a chain of actions, it would not be necessary for the prosecution to establish, to bring home the charge of conspiracy, that each of the conspirators had the knowledge of what the collaborator would do, so long as it is known that the collaborator would put the goods or service to an unlawful use." [See State of Kerala v. P. Sugathan, (2000) 8 SCC 203, SCC p. 212, para 14]"." [Emphasis Supplied]

178. While dealing with the offence of criminal conspiracy in respect of the financial frauds, the Hon'ble Apex Court in the case of Ram Narain Poply (supra), in paragraph No.344, was pleased to observe that,

"344. ..... The law making conspiracy a crime, is designed to curb immoderate power to do mischief, which is gained by a combination of the means. The encouragement and support which co-conspirators give to one another rendering enterprises possible which, if left to individual effort, would have been impossible, furnish the ground for visiting conspirators and



abettors with condign punishment. The conspiracy is held to be continued and renewed as to all its members wherever and whenever any member of the conspiracy acts in furtherance of the common design."

[Emphasis Supplied]

179. In the context of Section 10 of the Indian Evidence Act, it was held by the Hon'ble Apex Court, in paragraph No.348, that, the expression "in furtherance to their common intention" in Section 10 is very comprehensive and appears to have been designedly used to give it a wider scope than the words "in furtherance of" used in the English Law : with the result anything said, done or written by co- conspirator after the conspiracy was formed, will be evidence against the other before he entered the field of conspiracy or after he left it. Anything said, done or written is a relevant fact only.

186. The Hon'ble Apex Court has further quoted with approval in paragraph No.101, the observations made in the case of State (NCT of Delhi) Vs. Navjot Sandhu @ Afsan Guru, (2005) 11 SCC 600, wherein it was held that, "The cumulative effect of the proved circumstances should be taken into account in

determining the guilt of the accused rather than adopting an isolated approach to each of the circumstances."

33. That, the recent data proved that, the vaccination is no guaranteed protection from corona infection or death. In fact, it proved that the infection and death amongst vaccinated person is much higher than the unvaccinated people.

The recent data is summarised as under;

i) In K.E.M hospital 27 out of 29 covid positive patients are fully vaccinated. Means 93% of new patients are from fully vaccinated category. "**[Exhibit - G]**"

Link: https://www.freepressjournal.in/mumbai/mumbai-29-mbbs-students-at-kem-hospital-test-positive-for-covid-19-27-were-fully-vaccinated

"29 MBBS students at KEM hospital test positive for COVID-19, 27 were fully vaccinated

SOURCE:- FREE PRESS JOURNAL"

ii) In Nagpur City where 12 out of 13 covid positive patients are fully vaccinated. "**[Exhibit - H]**"

Link: https://www.freepressjournal.in/mumbai/covid-19-third-wave-has-entered-nagpur-guardian-minister-nitin-raut-urges-people-to-avoid-crowding

Source Name: Free Press Journal

'COVID-19 third wave has entered Nagpur': Guardian Minister Nitin Raut urges people to avoid crowding

iii) In Bangalore more than 56% of hospitalization of covid positive patient are vaccinated. **"[Exhibit - I]"**

Link: https://www.deccanherald.com/amp/state/top-karnataka-stories/more-than-half-of-hospitalised-covid-19-cases-among-vaccinated-in-bengaluru-1015918.html?__twitter_impression=true&s=04%5C

"Source Name: Deccan Herald

Date:03.08.2021

More than half of hospitalised Covid-19 cases among vaccinated in Bengaluru

These hospitalisations are indicative of the extent of vaccine penetration in the public, explained BBMP Chief Commissioner, Gaurav Gupta"

iv) The reports from Israel and other countries are more serious and shows that the vaccinated people are at much more risk than the unvaccinated.

All such data are already provided to C.B.I. by Awaken India Movement in their complaint dated **28.10.2021**.

A copy of said complaint is at **"Exhibit - J"** Page No. **132 to 154**.

34. It is an attempt to destroy Evidence of people with natural immunity by directing 100% vaccination the authorities are trying to destroy evidences of natural immunity and thereby to help vaccine syndicate.

35. Under these circumstances it is clear that, the accused officials are working for the welfare of the vaccine companies only and in furtherance of said conspiracy they are making rules to give wrongful benefit of thousands of crores to the vaccine manufactures. While acting as a co-conspirator in the crime, they are committing mass murders of citizen and therefore they need to be arrested forth with to save the life of others.

36. Mastermind accused **Bill Gates**, who is manufacturing **'CoviShield'** in partnership with Serum Institute is habitual offender of Mass Murders by vaccination in conspiracy with Government officials.

36.1. That, the parliamentary committee in its 72nd report found that, the government officials are earlier involved in such serious offences and responsible for death of 8 female children.

36.2. That, the parliamentary committee in its **72nd** report gave clear and specific findings about the serious offences of murder of **8 female children** and recommended investigation and prosecution of office bearers of **NGO PATH** related with **Bill & Milinda Gates foundation along with official of ICMR and other government officials involved in the conspiracy**. **"[Exhibit - K]"**

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36.3. The Constitution Bench in **Kalpana Mehta v. Union of India, (2018) 7 SCC 1**, have upheld the evidentiary value of 72nd report by Parliamentary Committee.

36.4. The Bill Gates in partnership with Serum Institute is now manufacturing the **'Covishield'** vaccine.

Hence, it is clear that the accused are habitual offenders of earning profits by selling vaccines with death causing side effects and therefore, they are in the category of **'Mass Murderers'.** The minimum punishment for such offences is death penalty.

36.5. The polio program of enhancing polio doses in children as designed by the Bill Gates has caused a death of thousands of children in Indian and around 4,90,000 children suffered new type of paralysis.

The relevant news article published in The Hindu and Great Game India are as under;

(a) Link:

https://www.thehindu.com/news/cities/Delhi/vaccine-induced-paralysis-calls-for-action-says-study/article24740588.ece

"Vaccine-induced paralysis calls for action, says study

Frequency of pulse polio administration is directly or indirectly related to incidence of non-polio acute flaccid paralysis, say researchers

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Over 4.9 lakh persons in India developed paralysis between 2000 and 2017 because of oral polio vaccine (OPV), say leading doctors in two reputed hospitals here.

AFP is defined as a sudden onset of paralysis or weakness in any part of the body of a child less than 15 years of age. The surveillance allows nations to detect paralytic poliomyelitis due to wild poliovirus transmission in the population.

"These are all cases of non-polio paralysis, which increased dramatically as polio paralysis was brought down with repeated doses of OPV. This report shows that the rate of paralysis is now coming down where OPV doses have decreased and this is additional proof that paralysis is caused by OPV," says Dr. Puliyel.

For instance, there were an additional 47,500 children with paralysis in 2011, which was over and above the assumed NPAFP rate of 2 per 1 lakh cases and the NPAFP rate started to decrease from 2012, when the number of pulse polio rounds decreased.

"From the results, NPAFP rate shows a decline with reduction in pulse polio doses suggesting that OPV vaccinations are responsible for the paralysis. A total of 6.4 lakh children developed NPAFP from 2000 to 2017, suggesting that there were an additional 4.91 lakh paralysed children above the numbers expected to develop NPAFP," they add.

The report says that "repeated doses of live vaccine virus delivered to the intestine may colonise the gut and alter the viral microbiome of the intestine".

Also, studies from Finland and Turkey suggest that Guillain-Barré Syndrome (GBS) is causatively associated with OPV vaccination campaigns

"While the mechanism involved is speculative, our findings support the hypothesis that the frequency of pulse polio administration is directly or indirectly related to the incidence of NPAFP. Now that India has been polio-free for over six years, we may be able to reduce NPAFP by further reducing pulse polio rounds," the report says."

(b) Link:

https://greatgameindia.com/bill-gates-agenda-in-india-exposed-by-robert-kennedy-jr/

"Bill Gates Activities in India exposed by Robert Kennedy Jr.

Vaccines, for Bill Gates, are a strategic philanthropy that feed his many vaccine-related businesses (including Microsoft's ambition to control a global vaccination ID enterprise) and give him dictatorial control of global health policy.

Promising his share of $450 million of $1.2 billion to eradicate Polio, Gates took control of India's National Technical Advisory Group on Immunization (NTAGI) which mandated up to 50 doses (Table 1) of polio vaccines through overlapping immunization programs to children

before the age of five. Indian doctors blame the Gates campaign for a devastating non-polio acute flaccid paralysis (NPAFP) epidemic that paralyzed 490,000 children beyond expected rates between 2000 and 2017. In 2017, the Indian government dialed back Gates' vaccine regimen and asked Gates and his vaccine policies to leave India. NPAFP rates dropped precipitously."

37. That the Petitioner approached Senior Police Inspector, Vasai, Police Station and requested him to register F.I.R.

The complaint of Petitioner revealed serious cognizable and non-bailable offences publishable under section **115, 302, 409, 120(B) and 34** etc. of IPC but the concerned police officer refused to register FIR and thereby violated the guidelines given by the constitution Bench in **Lalitha Kumari's case (2014) 2 SCC 1**, and recently reiterated by this Hon'ble court in the case of **Param Bir Singh Vs. The State of Maharashtra 2021 SCC Online Bom 516**.

Therefore, in view of para 111 of the **Lalita Kumari Vs. Govt. of U.P. (2014) 2 SCC 1**, strict action is required to be taken against the concerned police officer.

Said guidelines reads thus;

"111. In view of the aforesaid discussion we hold:

(i) Registration of FIR is mandatory under section 154 of the Code, if the information discloses commission of a cognizable offence and no

preliminary inquiry is permissible in such a situation."

(ii) The police officer cannot avoid his duty registering offence if cognizable offence is disclosed. Action must be taken against erring officers who do not register the FIR, if the information received him discloses a cognizable offence."

38. That, the petitioner on **25.10.2021** sent a complaint on affidavit to the respondent no. 2 and other higher authorities. But till date no action is taken on the complaint lodged by the petitioner.

A copy of the said complaint dated **25.10.2021** is annexed at "**Exhibit - L**".

39. That, the present case involves various accused including Chief Secretary of Maharashtra Government, concerned Ministers and also deals with the corruption done by the officers of Central government such as Dr. V. G. Somani of DCGI & Dr. Randeep Guleria of AIIMS. Therefore, the proper investigating agency will be the C.B.I. Even otherwise as per law the charges of corruption against Central Government employee has to be investigated by the C.B.I.

40. This Hon'ble court in the case of **Param Bir Singh Vs. The State of Maharashtra 2021 SCC Online Bom 516**, *(supra)* had taken a similar view.

41. Hence, it is just and necessary that this Hon'ble Court may be pleased to direct the CBI to treat this petition as on FIR and initiate immediate prosecution of the accused as has been done by Hon'ble Supreme Court in the case of **Noida Entrepreneurs Association Vs Noida (2011) 6 SCC 508**.

42. Compensation in Public Law Remedy:-

42.1. That, the law is very well settled by this Hon'ble Court and Hon'ble Supreme Court in catena of judgment that whenever fundamental rights of any persons are violated or if any person lost his/her life due to act of commission and omission on the part of a public servant then the High Court can direct the State Government to pay interim compensation to the victim or their family members under writ jurisdiction and the state can recover the said amount from erring public servant later.

Relied on:- **i)** **Nambi Narayan Vs. Siby Mathews (2018) 10 SCC 804**.

ii) **Veena Sippy Vs. Narayan Dumbre 2012 SCC OnLine Bom 339**.

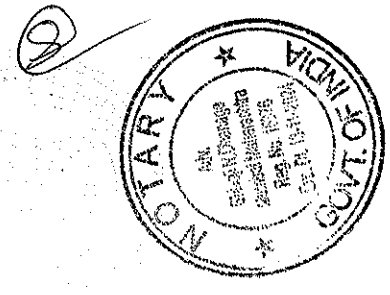
iii) **Chairman Railway Board Vs. Mrs. Chandrima Das (2000) 2 SCC 465.**

iv) **Nina Rajan Pillai Vs. Union of India 2011 (5) AD (Del) 36.**

42.2. In **Sanjeevani Vs. State MANU/MH/0469/2021**, it is ruled as under;

"13.. Apex Court in the case of D.K. Basu Vs. State of West Bengal reported in MANU/SC/0157/1997 : AIR 1997 Supreme Court 610(1) wherein it has been held thus:-

> *55. Thus, to sum up, it is now a well accepted proposition in most of the jurisdiction, that monetary or pecuniary compensation is an appropriate and indeed an effective and sometimes perhaps the only suitable remedy for redressal of the established infringement of the fundamental right to life of a citizen by the public servants and the Sate is vicariously liable for their acts. The claim of the citizen is based on the principle of strict liability to which the defence of sovereign immunity is not available and the citizen must receive the amount of compensation from the State, which shall have the right to be indemnified by the wrong doer. In the assessment of compensation, the emphasis has to be on the compensatory and not on punitive element.* ***The objective is to apply balm to the wounds and not to punish the transgressor or the offender, as awarding appropriate***



punishment for the offence (irrespective of compensation) must be left to the Criminal Courts in which the offender is prosecuted, which the State in law, is duly bound to do. The award of compensation in the public law jurisdiction is also without prejudice to any other action like civil suit for damages which is lawfully available to the victim or the heirs of the deceased victim with respect to the same matter for the tortious act committed by the functionaries of the State. The quantum of compensation will, of course, depend upon the peculiar facts of each case and no strait-jacket formula can be evolved in that behalf. The relief to redress the wrong for the established invasion of the fundamental rights of the citizens, under the public law jurisdiction is, thus, in addition to the traditional remedies and not in derogation of them*. The amount of compensation as awarded by the Court and paid by the State to redress the wrong done, may in a given case, be adjusted against any amount which may be awarded to the*

claimant by way of damages in a civil suit."

42.4 That in a case of side effects of vaccines, the United States Government has set up the **'National Vaccine Injury Compensation Program'**. In a case of side effects of MMR vaccines the court granted a settlement of 101 Million U.S Dollars (7,50,34,31,400 Crores).

A Copy of the news published and Court's judgment is at Annexed at **"Exhibit - N Colly"**.

42.5. That, in another case related with negligence causing side effects of medicine, the investigating agency of US at their own investigated and recovered an amount 10.2 Billion U.S. Dollars around **7,57,71,92,40,000** Crore Rupees from the pharma companies. The excerpts from the news published on **July 2, 2012** in The United States' Department of Justice are as under;

Source:- The United States' Department of Justice.
Date:- July 2, 2012

GLAXOSMITHKLINE TO PLEAD GUILTY AND PAY $3 BILLION TO RESOLVE FRAUD ALLEGATIONS AND FAILURE TO REPORT SAFETY DATA

Largest Health Care Fraud Settlement in U.S. History

---

*"1. **The United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message.** The United States also alleges that the company sponsored programs suggesting*

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cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.

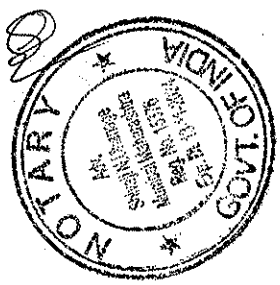
2. In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the

company. Among other things, the ***CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.***

Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management.

Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; *the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program*



Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

The company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices.

GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further

alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended.

Between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug.

The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack).

GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these

drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million."

The details of abovesaid report is annexed at **"Exhibit – O".**

42.6. That, the case of Petitioner is on highest footing of getting compensation because here the case is of loss of life. Constitution Bench of Hon'ble Supreme Court in the case of **Anita Kushwaha Vs. Pushap Sadan (2016) 8 SCC 509,** has ruled that the life of Indian Citizen is not less pricy than the life of people in England or anywhere. But in India the rights are more precious.

It is ruled that;

"18... *Bose, J. emphasised the importance of the right of any person to apply to the court and demand that he be dealt with according to law. He said: (Prabhakar Kesheo case [Prabhakar Kesheo Tare v. Emperor, AIR 1943 Nag 26 : 1942 SCC OnLine MP 78] , SCC OnLine MP para 1)*

*"1. ... **The right is prized in India no less highly than in England, or indeed any other part of the Empire**, perhaps even more highly here than elsewhere; and it is zealously guarded by the courts."*

42.7. That, Hon'ble Civil Court in Pune has granted a compensation of Rs. 100 Crores for defamation of half an hours news mistaken identity. Said fact was also taken in to consideration by Hon'ble Bombay High Court in the case of **Veena Sippy Vs. Mr. Narayan Dumbre & Ors. 2012 SCC OnLine Bom 339**. It is observed as under;

> ***"20....****We must state here that the Petitioner in person has relied upon an interim order passed by this Court in First Appeal arising out of a decree passed in a suit. The decree was passed in a suit filed by a retired Judge of the Apex Court wherein he claimed compensation on account of act of defamation. Considering the evidence on record, the Trial Court passed a decree for payment of damages of* ***Rs. 100/- crores****. While admitting the Appeal and while considering the prayer for grant of stay, this Court directed the Appellant-Defendant to deposit a sum of Rs. 20/- crores in the Court and to furnish Bank Guarantee for rest of the decretal amount as a condition of grant of stay. However, this Court directed investment of the amount of Rs. 20/- crores till the disposal of the Appeal. The interim order of this Court has been confirmed by the Apex Court.*
>
> ***23....***

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i. *We hold that the detention of the Petitioner by the officers of Gamdevi Police Station from 5th April, 2008 to 6th April, 2008 is illegal and there has been a gross violation of the fundamental right of the Petitioner guaranteed by Article 21 of the Constitution of India.*

ii. *We direct the 5th Respondent-State of Maharashtra to pay compensation of Rs. 2,50,000/- to the Petitioner together with interest thereon at the rate of 8% per annum from 5th April, 2008 till the realization or payment. We direct the State Government to pay costs quantified at Rs. 25,000/- to the Petitioner. We grant time of six weeks to the State Government to pay the said amounts to the Petitioner by an account payee cheque. It will be also open for the fifth Respondent - State Government to deposit the amounts in this Court within the stipulated time. In such event it will be open for the Petitioner to withdraw the said amount.*

iii. *We clarify that it is open for the State Government to take proceedings for recovery of the amount of compensation and costs from the officers responsible for the default, if so advised.*

iv. *Petition stands dismissed as against the Respondent No. 4.*

vi. *We make it clear that it will be open for the Petitioner to adopt a regular remedy for recovery of compensation/damages in addition to the amount directed to be paid under this Judgment.*

42.8. That, based on the abovesaid principles and comparing with the seriousness of the loss of life caused and consequential harm caused to the Petitioner the Petitioner is at least entitled for a compensation of Rs. 1000 Crores. For which the Petitioner is going to initiate a separate appropriate legal proceedings for getting compensation of Rs. 1000 Crores. Which will take some time.

42.9. That the Petitioner lost her only son. Who was just 23 year old. Her loss can neither be explained in words nor can be compensated in terms of money. Only some sort of succor can be done by awarding compensation. The petitioner's claim for compensation is more intended to put deterrence among other officials and thereby to save similar deaths. Hence, it is just and necessary that an interim compensation of Rs. 100 Crores be granted to the Petitioner in the writ jurisdiction.

PRAYERS: It is therefore humbly prayed for;

i) C.B.I. be directed to treat this petition as F.I.R. and prosecute the offender as done by Hon'ble Supreme Court in the case of **Noida Entrepreneurs Association Vs. Noida (2011) 6 SCC 508** and

followed by this Hon'ble Court in the matter between **Param Bir Singh v. State of Maharashtra, 2021 SCC OnLine Bom 516**.

ii) C.B.I. be further directed to immediately start custodial interrogation of the accused and take use of scientific tests like Lie Detector Test, Brain Mapping Test and Narco Analysis Test to unearth the complete conspiracy and to save the life of Indian Citizen;

iii) Direction to Respondent No. 1 i.e. State of Maharashtra to pay an interim compensation of Rs. 100 crores to the Petitioner forthwith and then to recover it from the guilty officials responsible for death of the Petitioners citizen by their deliberate and unlawful act of commission and omission.

iii) Any other order which this Hon'ble Court deems fit and proper in the facts and circumstances of the case.

AND FOR THIS ACT OF KINDNESS THE PETITIONER AS IN DUTY BOUND SHALL EVER PRAY.

Advocate for Petitioner

Petitioner

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VERIFICATION

I, **Smt. Kiran Yadav**, the petitioner do hereby on solemn affirmation state and declare that whatever stated above is true and correct to my own knowledge and belief and what is stated in abovesaid paragraphs is based on the information and legal advice which I believe to be true and correct.

Solemnly affirmed at Bombay)

This day of November, 2021) **BEFORE ME**

Smt. Kiran Yadav

(Petitioner)

BEFORE ME

Shivam Mehra & Siddhi Dhamnaskar

(I-23521) MAH/5888/2018 & (I-30853)MAH/5734/2020

Address: 2 & 3, Kothari House,
5/7 Oak Lane, A R Allana Marg,
Near Burma Burma Restaurant,
Fort, Mumbai 400 023.

Email: advsiddhidhamnaskar@gmail.com

Adv. S. N. Dhanage
Notary Govt. Of India
Regd. No. 15376 MUMBAI (MS)
404-405, 4th Floor, Davar House,
197/199, Near Central Camera Bldg..
D.N. Road. Fort, Mumbai - 400001.

NOTED & REGISTERED

Page No. 27 Sr. No. 175

Dated 22/11/2021

NOTARY GOVT. OF INDIA Adv. Shivaji N. Dhanage Mumbai Maharashtra Reg. No. 15376

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"EXHIBIT A"

मिसिल संख्या जेड.60011/06/2020-सीवीएसी
भारत सरकार
स्वास्थ्य और परिवार कल्याण मंत्रालय
सीवीएसी अनुभाग

निर्माण भवन, नई दिल्ली
दिनांक09 मार्च, 2021

To,

Sh. Anurag Sinha,
Qtr no. 10 po swang bokaro
Jharkhand, gomia, 829128
Jharkhand

विषय: आरटीआई अधिनियम, २००५ के अंतर्गत मांगी गई जानकारी के संबंध में।

महोदय,

कृपया आप अपनी आर.टी.आई. एमओएचएफ़डब्ल्यू/आर/ई/21/00630, आर.टी.आई. अधिनियम, 2005 के संदर्भ ले जोकि अधोहस्ताक्षरी को दिनांक 27.02.2021 को प्राप्त हुआ था जिसमें आर.टी.आई.(RTI) अधिनियम, २००५ के तहत जानकारी मांगी गई है

संख्या क्रम	आवेदक के प्रश्न	उत्तर
i.	कोरोना वैक्सीन लेना स्वैच्छिक है या अनिवार्य, जबरदस्ती	कोरोना वैक्सीन लेना स्वैच्छिक है।
ii	क्या वैक्सीन नहीं लेने पर सारी सरकारी सुविधाएं बंद कर दी जायगी, सरकारी योजना पेंशन	आवेदन मे लिखी बातें निराधार है । किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नही है ।
iii	क्या वैक्सीन नहीं लेने पर नौकरी नहीं मिलेगा, ट्रेन, बस, मेट्रो मे चढ़ने नहीं मिलेगी	
iv	यदि कोई ias ips स्वास्थ्य या पुलिस कर्मचारी नागरिक को धमकी दे की वैक्सीन ले नही तो ये कर देगे तो नागरिक क्या कर सकती क्या कोर्ट जा सकते है	
v	क्या वैक्सीन नहीं लेने पर स्कूलों, कॉलेज, विश्वविद्यालय, गैस कनेक्शन, पानी, बिजली कनेक्शन, राशन आदि के लिए क्या वैक्सीन नहीं मिलेगे	
vi	क्या वैक्सीन नही लेने पर नौकरी से निकला जा सकता है वेतन रोका जा सकत है, निजी और सरकारी विभाग दोनों मे ।	

TRUE COPY
ADVOCATE FOR Petitioner

"EXHIBIT "B" "

65

IN THE HIGH COURT OF BOMBAY AT GOA

WRIT PETITION No. 1820 of 2021

IN THE MATTER OF:

Mr. Nelson Paulo Fernandes & Another

.....Petitioners

Versus

The State of Goa & Ors.

.....Respondents

COUNTER AFFIDAVIT ON BEHALF OF ANSWERING RESPONDENT NO. 6 (MINISTRY OF HEALTH & FAMILY WELFARE, GOVT. OF INDIA)

I, Satyendra Singh, S/o Sh. Phool Singh, aged about 41 years, working as Under Secretary COVID Vaccination Administration Cell in the Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi do hereby solemnly affirm and sincerely state as follows:

1. That, I am well acquainted with the facts of the case from the records. I am filing this Counter Affidavit on behalf of the Ministry of Health & Family Welfare, Govt. of India, as I am authorized to do so.

NOTARY PUBLIC M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024 GOVT. OF INDIA

NOTARY GOVT. OF INDIA

08 OCT 2021

TRUE COPY

ADVOCATE FOR Petitioners

66

2. I have perused the Writ Petition of the petitioner and I deny the averments made therein, except those that are specifically admitted hereunder.

3. I humbly submit that, the Petitioner has filed this writ petition seeking directions predominantly as against the State Government. However, since we are also made a party, I am filing this counter affidavit.

4. That, it is humbly submitted by the Answering Respondent No. 6 that, instead of traversing various allegations para-wise, this respondent deems it appropriate to counter the whole set of the facts in this matter as follows:

It is submitted that in the Writ Petition the petitioner has prayed the interim prayer as follows: -

"1. For an appropriate Writ, order or direction, thereby quashing the circular dated 13/07/2021 issued by respondent no. 2 (Director, Directorate of Education, Govt of Goa).

2. For an appropriate Writ, order or direction, thereby directing the respondent no. 1 and 2 (State of Goa and Director, Directorate of Education, Govt of Goa) to consider the petitioner's representations dated 30/07/2021 and 11/08/2021 and to issue a corrigendum

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NOTARY PUBLIC GOVT. OF INDIA M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024

08 OCT 2021

thereby making the vaccination by the teaching and non-teaching staff voluntary.

3. *For an interim relief, staying the operation of circulars dated 16/07/2021, 28/07/2021 and 16/08/2021 thereby directing the respondent No 2 and 3 (Headmistress, Little Flower of Jesus High School) not to take any coercive measures/actions against the petitioners pending the hearing and final disposal of petition.*

4. *For ex parte relief in terms of prayer clause 3.*

5. It is further humbly submitted that the matter has been examined and from the prayer (at para 1, 2 & 3 above) and the statements of the petitioner in the writ petition, it is evidently clear that the grievances of the petitioner in the prayer is related to the Departments of State Government of Goa (Respondent No. 1 and 2).

6. That, it is further humbly submitted that the annexures as mentioned in the Writ Petition by the petitioner have been issued by the Departments under State Government of Goa.

NOTARY PUBLIC * M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024 * GOVT. OF INDIA

NOTARY * Adv. Shirish N. Dhamale Mumbai Maharashtra Regd. No. 45076 Exp. 15.12.2024 * GOVT. OF INDIA

08 OCT 2021

(68)

7. That, it is further submitted that the subject matter of the present Petition does not fall within the domain of the Answering Respondent No. 6 (Union of India).

8. That, it is further humbly submitted that however, since this matter is related to vaccination, and Union of India is the respondent no. 6; thus, it is pertinent to present the stand of Union of India with regards to vaccination. It is humbly submitted that vaccination for Covid-19 is a matter of social obligation and is of a larger public interest. As a responsible citizen looking to contribute in the nation and humanity's fight against the Pandemic of Covid-19 infection, it is natural that every person would get her/himself vaccinated against Covid-19 so as to prevent the spread of Covid-19 infection in the community.

9. That, it is further humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and family Welfare, do not entail compulsory or forcible vaccination against COVID-19 disease implying that COVID-19 vaccination is completely voluntary for all citizens of India. Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between

NOTARY PUBLIC * GOVT. OF INDIA * M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024

08 OCT 2021

citizens of India on the basis of their vaccination status.

10. That, it is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, but this in no way implies that any person can be forced to be vaccinated against her/his wishes.

11. That, as per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid Vaccination on Co-WIN or visiting Covid Vaccination Center for vaccination. if a person above the age of 18 years visits a Covid Vaccination Centre by her/his choice for vaccination and asks for the same, it implies that she/he is voluntarily coming to the center to get the benefit of Covid Vaccination.

12. Therefore, it is humbly submitted that in order to prevent the transmission and spread of Covid-19 pandemic, it is expected that all responsible citizens especially the teachers who are also the role models and influencers for the society get themselves vaccinated as soon as possible against Covid-19 and meticulously follow Covid Appropriate Behaviour.

NOTARY PUBLIC * M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024 * GOVT. OF INDIA

NOTARY Adv. Shreejith Dhanoje Mumbai Maharashtra Regd. No. 15376 Exp. 04.11.2024 GOVT. OF INDIA

Shreejith

08 OCT 2021

(20)

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13. **Prayer:**

It is therefore most humbly prayed that, this Hon'ble Court may be pleased to admit this Counter Affidavit on behalf of Answering Respondent No. 6 (Union of India) on this petition for the ends of justice.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

Identified by

VERIFICATION:

Verified at New Delhi on October 08, 2021 that the contents of this affidavit are true and correct to the best of my knowledge and belief and no part of it is false thereof, and no material fact has been canceled therefrom.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

NOTARY GOVT. OF INDIA

NOTARY PUBLIC
M. P. SHUKLA
Regd. No. 17617
DELHI
Expiry Date:
22.12.2024
GOVT. OF INDIA

08 OCT 2021

M. P. SHUKLA
Notary Public, Delhi

CERTIFIED THAT THE DEPONENT
Shri/Smt/Km. Satyendra Singh
S/o, W/o, D/o, Sh. [illegible]
identified by [illegible]
has solemnly affirmed before me on 21/10/2021
that the contents of this affidavit are true to his/her knowledge.

M. P. SHUKLA
Notary Public, Delhi

"EXHIBIT "C" "

71

AJAY BHALLA, IAS

सत्यमेव जयते

गृह सचिव
Home Secretary
भारत सरकार
Government of India
North Block,
New Delhi

D.O. No. 40-3/2020-DM-I(A)

22nd August, 2020

Dear Chief Secretary,

Please refer to Ministry of Home Affairs' Order of even number dated 29.07.2020 whereby Guidelines for Unlock-3 have been issued.

2. I would like to draw your kind attention to para-5 of these guidelines which clearly state that **there shall be no restriction on inter-State and Intra-State movement of persons and goods. No separate permission/ approval/ e-permit will be required for such movements.** This includes movement of persons & goods for cross land border trade under Treaties with neighboring countries.

3. It has, however, been reported that local level restrictions on movement are being imposed by various districts/States. Such restrictions are creating problems in inter-State movement of goods and services and are impacting the supply chain, resulting in disruption of economic activities and employment, besides affecting supply of goods and services.

4. Such restrictions at local level imposed by the District Administration or by the State Government, amount to violation of the guidelines issued by MHA under the provisions of Disaster Management Act, 2005.

5. I would, therefore, request that no restrictions may be imposed on inter-State and intra State movement of persons and goods and services and instructions issued to ensure that MHA guidelines mentioned above are strictly followed.

With regards,

NOTARY Adv. Shailesh N. Dhanesha Mumbai-Maharashtra Regn. No. 15018 GOVT. OF INDIA

Yours sincerely,

22/08/2020

(Ajay Bhalla)

Chief Secretaries of All States
(As per Standard List attached)

TRUE COPY
Mehra
ADVOCATE FOR Petitioners

"EXHIBIT "D" Colly "

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2021 SCC OnLine Gau 1313

In the High Court of Gauhati

(BEFORE MICHAEL ZOTHANKHUMA AND NELSON SAILO, JJ.)

Re Dinthar Incident

Versus

State of Mizoram and Others

WP(C)/37/2020

Decided on July 2, 2021

Advocates who appeared in this case :

Advocate for the Petitioner: Mr. Zochhuana (Amicus Curiae)

Advocate for the Respondent: Mr. C. Zoramchhana

ORDER

1. The proceeding is conducted via remote Video Conference.

2. Heard Mr. Zochhuana, the learned Amicus Curiae and Mr. C. Zoramchhana, learned Additional Advocate General for the State of Mizoram.

3. The case has been listed today as opportunity had been given to the learned Additional Advocate General to obtain instructions with regard to Clause 5(2), 6(1) and 6(5) of the Standard Operating Procedure (SOP) dated 29.06.2021.The above clauses requires all persons in the State of Mizoram to be vaccinated or else they would not be allowed to leave their houses to procure/obtain essential items/goods or earn their livelihood by working in shops/stores, driving public/commercial transport vehicles etc. The other issue to be taken up today is with regard to the requirement of obtaining a pass or permit from the Deputy Commissioner, Aizawl for travelling outside Mizoram in terms of the notice No. C.16011/298/2020-DC(A)/PT-II dated 26.06.2021.

4. With regard to the requirement of obtaining a pass or permit from the Deputy Commissioner, Aizawl for travelling outside Mizoram in terms of the notice No. C.16011/298/2020-DC(A)/PT-II dated 26.06.2021, the learned Additional Advocate General has submitted Notice No. C.16011/298/2020-DC(A)/Misc dated 01.07.2021 issued by the Deputy Commissioner, Aizawl, the content of which is as follows:—

"***NOTICE***

Movement of vehicles have been restricted in some parts of Assam due to the area being declared as a containment zone/area. And it is learnt that due to this restriction some people used to have difficulties moving around. Therefore, in an effort to facilitate easy movement of travelers passing through Assam from Mizoram (by road) to Exit Permit may be issued on being applied as stated below.

This will supersede the earlier Notification issued vide No. C.16011/298/2020-DC (A)/Pt-II Dt. 26.06.2021.

1. *The application may be submitted to the Deputy Commissioner, Aizawl through mcovid19.mizoram.gov.in (mPASS Exit Permit)*
2. *The applicant shall specify his/her name, address, phone number, final destination and the date and time of his/her proposed journey along with the reason for his/her journey and vehicle Registration number as prescribed in the Permit application form."*

5. On perusal of the above Notice dated 01.07.2021 issued by the Deputy Commissioner, Aizawl, which has been made in supercession of the earlier notification dated 26.06.2021, we are of the view that the Notice dated 01.07.2021 has clarified

NOTARY Adv. Shivaji Dhanraj Mumbai Maharashtra Reg. No. 15376 Exp. Dt. 12-11-2021 GOVT. OF INDIA

TRUE COPY

ADVOCATE FOR Petitioner

the earlier notification dated 26.06.2021, besides showing that Exit Permit is not a mandatory requirement for people wanting to leave the State. Accordingly, the said issue is closed. However, the State respondents will ensure that if similar notifications, like the earlier notification dated 26.06.2021, has been issued by other Deputy Commissioners from other Districts, the Deputy Commissioners in the other Districts should also issue a similar Notice dated 01.07.2021, which is reproduced above.

6. For a better understanding of the other issue involved, i.e. the legality of Clause 5(2), 6(1) and 6(5) of the Standard Operating Procedure (SOP) dated 29.06.2021, the Order dated 01.07.2021 passed by this Court is reproduced below:—

"The proceeding is conducted via remote Video Conference.

2. Heard Mr. Zochhuana, the learned Amicus Curiae as well as Mr. C. Zoramchhana, learned Additional Advocate General.

3. The learned Additional Advocate General submits that though he has received some instructions from the Deputy Commissioner, Aizawl with regard to the Notice dated 26.06.2021, he needs further instruction on the matter and in this regard, he will be communicating with the concerned Deputy Commissioner today.

4. In view of the partial opening up of the current restrictions in place in the State, the Chief Secretary, Mizoram has issued Order dated 29.06.2021 along with the Standard Operating Procedure (SOP) to be implemented w.e.f. 4:00 AM of 30.06.2021 till midnight of 15.07.2021. The specific restrictions that had been brought to the notice of this Court is with respect to Clause 5(2) which in effect does not allow non-vaccinated individuals to go outside their house/compound. Clause 6(1) and 6(5) restricts non-vaccinated individuals from manning shops, stores, undertaking any works and driving of public transports and commercial vehicles.

5. Clause 5(2), 6(1) and 6(5) of the latest SOP dated 29.06.2021 are reproduced below:—

*"**5.** Other restrictions*

2)** Persons going outside shall mandatorily cover their faces (with face mask or other materials). **In case of compelling circumstances, only vaccinated individuals of the family members may be detailed for errands within and around localities having significant COVID-19 active cases.

***6.** Permitted And Regulated Activities*

*1) **Only vaccinated individuals should be engaged for manning shops and stores or undertaking any works. Shop/stores attendants and other employees should be able to produce proof of vaccination, which will be regularly checked by the police/LLTF/VLTF/COVID-19 executive duty.***

*5) **Commercial passenger vehicles (city bus, taxi and two wheeler taxi) allowed to resume operation shall mandatorily provide hand-sanitizer for their passenger and they shall not exceed their seating capacity. Only Drivers and conductors who had been vaccinated should be allowed to operate public transports."***

***6.** A perusal of the above clauses implies that all persons would require to be vaccinated or else they cannot leave their houses or earn their livelihood with regard to activities mentioned in the said clauses.*

***7.** The question that would arise for consideration with regard to the above clauses is whether a person can be vaccinated against his will and whether the non-vaccination of the said individual can debar him from earning his livelihood, keeping in mind the fundamental right of a person to practice any profession, or to carry on any occupation or trade or business under Article 19(1)(g) and his right to livelihood in terms of Article 21 of the Constitution. Though the State can make a*

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law imposing reasonable restrictions in the exercise of any of the rights conferred under Article 19, so long as the said restriction is a reasonable restriction, no such law has been made by the Government and in any event, the above mentioned clauses do not appear to be reasonable.

8. *In the case* Registrar General, High Court of Meghalaya *v.* State of Meghalaya, *PIL No. 6/2021, the Division Bench was seized of a matter, wherein the State of Meghalaya, through various orders of the Deputy Commissioners, had made it mandatory for shopkeepers, vendors, local taxi drivers and others to get themselves vaccinated before they could resume their businesses. The Division Bench of the Meghalaya High Court in its Order dated 23.06.2021 in PIL No. 6/2021 held that vaccination cannot be mandatory and non-vaccination can never affect a major fundamental right, i.e. right to life, personal liberty and livelihood, especially when there exists no reasonable nexus between vaccination and prohibition of continuance of occupation and/or profession.*

9. *In the meantime, it has also been brought to our notice that a notification was issued by one association which allows the participation of only vaccinated individuals to participate in a particular sport. The said instructions seem to have been made in pursuance to the SOP dated 29.06.2021. There being a possibility of many interpretations of the above mentioned clauses being made by various Local Level Task Force/Village Level Task Force (LLTFs/VLTFs) or associations etc, while issuing guidelines, directions and orders, it would be prudent to reconsider them, lest it causes chaos. Though the above mentioned clauses of the SOP have been made for the greater good, the authorities shall have to bear in mind the fact that executive instructions have to be issued in consonance with the fundamental rights of the citizens and the Constitution.*

10. *Though we are prima facie inclined to stay the above clauses, the learned Additional Advocate General has submitted that he will take up the matter with the authorities today itself so that necessary amendments are made to the SOP issued on 29.06.2021.*

11. *In view of the undertaking given by the learned Additional Advocate General, the case be listed again tomorrow i.e., 02.07.2021."*

7. With respect to the validity of Clause 5(2), 6(1) and 6(5) of the SOP dated 29.06.2021, the learned Additional Advocate General has submitted a letter dated 01.07.2021 issued by the Under Secretary to the Government of Mizoram, Disaster Management & Rehabilitation Department, which is to the effect that the State Government can make restrictions under the Disaster Management Act, 2005, curtailing the fundamental rights of a citizen, for the purpose of preventing the spread of Covid-19 and for mitigation of disaster. It is also stated in the said letter dated 01.07.2021 that unless shopkeepers, drivers and their employees have been vaccinated, they could become a super spreader of the covid virus.

8. The learned Additional Advocate General also submits that the State Government has made arrangements for mass vaccination of the people of the State free of cost and the said vaccination process is under way. He submits that the first dose of Covishield vaccination has been given to 5,19,452 persons (i.e. 67% of the eligible persons) as on date. He submits that the target for Covishield vaccination (first dose) is 7,75,106 persons. However, he submits that he cannot say as to how many more months would be required for completion of the first dose of the vaccine on the targeted eligible persons.

9. The learned Additional Advocate General submits that as the restrictions imposed are reasonable restrictions made in larger public interest, the State Government would like to retain the above clauses in question in the SOP dated 29.06.2021.

10. Mr. Zochhuana, the learned Amicus Curiae submits that restrictions made

NOTARY Adv. Shivaji N. Dhanopa Mumbai Maharashtra Reg. No. 15276 Exp. On 13-11-2024 GOVT. OF INDIA

under Disaster Management Act, 2005 cannot be said to be reasonable restrictions, as provided under Article 19(2) of the Constitution. Further, the restrictions imposed in the SOP discriminates between vaccinated and un-vaccinated persons, thereby violating Article 14 of the Constitution. He further submits that the restrictions that are imposed against un-vaccinated persons in the above mentioned three clauses, being in violation of the fundamental right to life and livelihood, the said clauses should be set aside or modified. He further submits that besides the above three clauses, Serial Nos. 31 & 42 of Annexure-3 of the SOP dated 29.06.2021 would also have to be set aside or modified as un-vaccinated persons are being discriminated against.

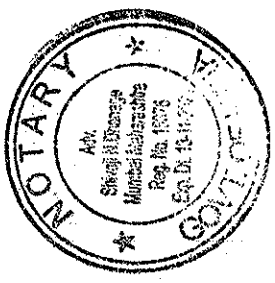
11. We have heard the learned counsels for the parties.

12. As per Clause 5(2) of the SOP dated 29.06.2021, un-vaccinated persons cannot leave their houses vis-à-vis vaccinated persons (first dose). The submission made by the learned Additional Advocate General clearly shows that 33% of the targeted persons are still to be vaccinated. There can be any number of reasons for a person to leave their house, for example, it could be for the purpose of procuring essential supplies, like food-stuff, medicines, attending to their near and dear/sick ones etc. However, the said clause has virtually put them under house arrest in violation of Article 21 of the Constitution of India, while persons who have been given the first dose of vaccine are allowed to leave their houses/compounds. Thus, on the ground of discrimination alone, Clause 5(2) is arbitrary. When the SOP requires all persons to cover their faces and to adhere to covid protocols as mentioned in the above SOP, there should not be any discrimination against un-vaccinated persons, as the Covid protocols are also applicable to un-vaccinated persons.

13. With respect to Clause 6(1) and 6(5) of the SOP, there is discrimination at large, as persons who have been vaccinated with the first dose of the vaccine are allowed to earn their livelihood, but not the un-vaccinated persons. There is nothing to show that vaccinated persons (first dose) cannot be infected with the corona virus or that they cannot be spreaders. If the vaccinated person and un-vaccinated person cover their face with a mask, as per the covid behavior protocols laid down by the State respondents, there is no reason to discriminate only against un-vaccinated persons.

14. It has been brought to our notice that even persons who have been vaccinated can still be infected with the covid virus, which would in turn imply that vaccinated persons who are covid positive, can also spread the said virus to others. It is not the case of the State respondents that vaccinated persons cannot be infected with the covid virus or are incapable of spreading the virus. Thus, even a vaccinated infected covid person can be a super-spreader. If vaccinated and un-vaccinated persons can be infected by the covid virus and if they can both be spreaders of the virus, the restriction placed only upon the un-vaccinated persons, debarring them from earning their livelihood or leaving their houses to obtain essential items is unjustified, grossly unreasonable and arbitrary. As such, the submission made by the learned Additional Advocate General that the restrictions made against the un-vaccinated persons vis-à-vis the vaccinated persons is reasonable does not hold any water. As the vaccinated and un-vaccinated persons would have to follow the covid proper behavior protocols as per the SOP, there is no justification for discrimination.

15. Due to the above reasons, we find that Clause 6(1) and 6(5) of the SOP are also violative of Article 14 of the Constitution, especially when achieving the target for vaccinating the targeted population may take many more months, in which case unvaccinated persons would be deprived of their right to livelihood, which would in turn violate their right to life, which are guaranteed under Article 21 of the Constitution. The above mentioned clauses in the SOP basically implies that all



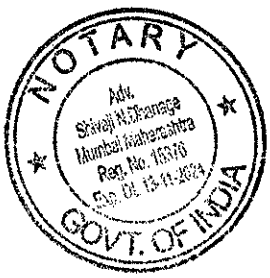
individuals should be vaccinated, thereby giving rise to an inference that an individual cannot be allowed to opt out from being vaccinated. As can be seen from the earlier Order dated 01.07.2021 which has been reproduced, the Division Bench of the Meghalaya High Court in *Registrar General, High Court of Meghalaya* v. *State of Meghalaya*, PIL No. 6/2021 held that though vaccination is an absolute necessity, "a harmonious and purposive construction of the provisions of law and the principles of equity, good conscience and justice reveals that mandatory or forceful vaccination does not find any force in law leading to such acts being liable to be declared *ultra vires ab initio*.

16. The issue at hand is the embargo placed against un-vaccinated individuals from being employed in shops and driving public/commercials vehicles. The fact that the State Government has not achieved its target of vaccinating all the eligible persons as stated by the learned Additional Advocate General, the State respondents cannot debar un-vaccinated persons from being employed in shops or driving commercial/public transport vehicles. The un-vaccinated citizens of the State cannot be faulted, due to the States' failure in not completing the vaccination of the targeted population.

17. With regard to the contention of the learned Additional Advocate General that the State Government can make restrictions curtailing the Fundamental Rights of the citizens under the Disaster Management Act, 2005 (hereinafter referred to as the "Act"), by way of the SOP, the same in our considered view is clearly not sustainable, as the said clauses in the SOP which are in issue in the present case cannot be said to be reasonable restrictions made in terms of Article 19(6). A restriction cannot be arbitrary or of a nature that goes beyond the requirement of the interest of the general public. Though no general pattern or a fixed principle can be laid down so as to be universal in application, as conditions may vary from case to case, keeping in view the prevailing conditions and surroundings circumstances, the requirement of Article 19(6) of the Constitution is that the restriction has to be made in the form of a law and not by way of an executive instruction. The preamble of the Act clearly states that it is an Act to provide an effective management of the disasters and for matters connected therewith or incidental thereto. There is nothing discernible in the Act, to show that the said Act has been made for imposing any restriction on the exercise of the rights conferred by Article 19 of the Constitution. Further, the SOP dated 29.06.2021 is only an executive instructions allegedly made under Section 22(2)(h) & Section 24(1) of the Act and not a law. The provisions of Sections 22 & 24 only provides for the functions and powers of the State Executive Committee in the event of threatening disaster situation or disaster. It does not give any power to the State Executive Committee to issue executive instructions discriminating persons with regard to their right to liberty, livelihood and life and violating the fundamental rights of the citizens, which is protected by the Constitution.

18. The SOP provides that vaccinated persons who are employed in shops/stores and to drive transport/commercial vehicles should wear mask and adhere to all proper covid protocols. If an un-vaccinated person is to be made to adhere to the same protocols, there can be no difference in the work of a vaccinated or un-vaccinated person. As such, the restriction placed upon un-vaccinated persons only due to non-vaccination is unreasonable and arbitrary.

19. In view of the reasons stated above, we hold that the restrictions placed upon un-vaccinated individuals vis-à-vis vaccinated individuals in terms of Clause 5(2), 6 (1), 6(5), Serial No. 31 & 42 of Annexure-3 of the SOP dated 29.06.2021 are arbitrary and not in consonance with the provisions of Article 14, 19 & 21 of the Constitution. The said impugned clauses are interfered with, to the extent that the allowances available and given to vaccinated persons in the above clauses shall also be made equally applicable to un-vaccinated persons. The State respondents are accordingly



directed to issue a corrigendum of the SOP dated 29.06.2021 at the earliest incorporating the above directions.

20. The Order dated 29.06.2021 issued by the Chief Secretary Mizoram with the enclosed SOP dated 29.06.2021, the letter dated 01.07.2021 issued by the Under Secretary to the Government of Mizoram, Disaster Management & Rehabilitation Department and the Notice dated 01.07.2021 issued by the Deputy Commissioner, Aizawl are made a part of the record and marked as Annexure-X, Y & Z respectively.

21. List the matter again on 14.07.2021.

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† Principal Bench at Guwahati

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2021 SCC OnLine Gau 1503

In the High Court of Gauhati[1]
(BEFORE NANI TAGIA, J.)

Madan Mili
Versus
Union of India, Represented by the Honble Home Secretary and Others

Case No.: PIL 13/2021
Decided on July 19, 2021

Advocates who appeared in this case :

Advocate for the Petitioner: Debasmita Ghosh, Ebo Mili, Chanya Bangsia, S. Dey

Advocate for the Respondent: Marto Kato, ASG R. H. Nabam, Addl. Adv. General, A.P.

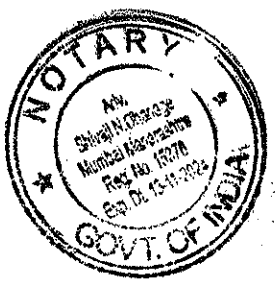
The Order of the Court was delivered by

NANI TAGIA, J.:— Heard Ms. D. Ghosh, learned counsel for the petitioner. Also heard Mr. R. Karga, learned counsel appearing on behalf of Mr. M. Kato, learned ASG for the respondent No. 1 and Mr. R. H. Nabam, learned Additional Advocate General representing respondent Nos. 2 & 3.

2. By means of this Public Interest Litigation, the petitioner has put to challenge Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, to the extent it provides that for developmental works in both public and private sector, temporary permits may be issued provided such persons are vaccinated for Covid-19.

3. The petitioner contends that as per the RTI Information furnished by the Ministry of Health & Family Welfare, which is available in the website of the Ministry of Health and Family Welfare, Government of India, Covid-19 vaccination is not a mandatory but a voluntary. A copy of the RTI Information available in the website of the Ministry of Health & Family Welfare, Government of India, has been annexed by the petitioner as Annexure 3 to the petition. The petitioner also refers to an answer given on 19.03.2021 in the Lok Sabha to an Unstarred Question No. 3976 by the Minister of State in the Ministry of Health & Family Welfare, Government of India (Annexure 4 to the petition) stating that there is no provision of compensation for recipients of Covid-19 Vaccination against any kind of side effects or medical complication that may arise due to inoculation. The Covid-19 Vaccination is entirely voluntary for the beneficiaries.

4. By referring to the fact that the Covid-19 Vaccination is entirely a voluntary exercise at the choice of an individual as indicated in the RTI answer and the answer given in the Lok Sabha by the Minister of State in the Ministry of Health and Family Welfare, Government of India, as referred to hereinabove, the learned counsel for the petitioner has contended that provision under Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, allowing temporary permits to be issued for developmental works in both public and private sector to only those persons who are vaccinated for Covid-19, have interfered with the rights of the citizens provided under Article 19 (1) (d) of the Constitution of India to move freely throughout the territory of India. The learned counsel for the petitioner, therefore, has argued that since the Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum



Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, by allowing to issue temporary permits for developmental works in both public and private sector only to persons who have vaccinated for Covid-19 Virus, have interfered with the fundamental rights granted under Article 19 (1) (d) of the Constitution of India and the same may be struck down by this Court in exercise of power under Article 226 of the Constitution of India.

5. Mr. R. H. Nabam, learned Additional Advocate General, on the other hand, has submitted that due to the rising cases of Covid-19 positive in the State of Arunachal Pradesh, the restrictions provided in Clause 11 vide Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, are reasonable restriction as the same has been issued with the sole objective of containing the Covid -19 pandemic and its further spread in the State of Arunachal Pradesh.

6. Issue notice, returnable on 28.07.2021.

7. As Mr. R. Karga, learned counsel appearing on behalf of Mr. M. Kato, learned ASG for the respondent No. 1 and Mr. R. H. Nabam, learned Additional Advocate General representing respondent Nos. 2 & 3, have entered appearance and accepted notices on behalf of their respective respondents, no formal notice need be issued to them. However, they shall be provided with requisite extra-copies of the petition along with relevant annexure appended thereto during the course of the day.

8. Heard on the prayer for interim relief.

9. Ms. D. Ghosh, learned counsel for the petitioner, has prayed for an interim order as the Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, in so far as it discriminates between persons vaccinated and unvaccinated for Covid-19 Virus in so far as issuance of temporary permits for developmental works in both public and private sector, have violated the fundamental rights granted under Article 19 (1) (d) of the Constitution of India to those unvaccinated persons and the order being valid on and from 30.06.2021 to 01.08.2021, the said Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, may be suspended in the meanwhile.

10. The Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, appears to have been issued in exercise of powers conferred under Section 22 (2) (H) of the Disaster Management Act, 2005, setting out various directives to be followed in the management of Covid-19 pandemic to remain in force w.e.f. 6.00 p.m. of 30.06.2021 till 5.00 a.m. of 01.08.2021. The object of issuing the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, appears to be to contain Covid-19 pandemic and its further spread in the State of Arunachal Pradesh. It is in that light, vide Clause 11 of the Order dated 30.06.2021, it appears, that vaccinated and unvaccinated persons for Covid-19 virus have been discriminated/classified into 2 (two) groups for the purpose of issuing temporary permits for developmental works in both public and private sector. Clause 11 of the Order dated 30.06.2021 reads as under:

> *"11. Tourist ILPs shall remain suspended during the period of this order, however for developmental works in both public and private sector, temporary permits may be issued provided such persons are vaccinated for COVID 19."*

11. While persons who are vaccinated for Covid-19 have been allowed to be issued with a permit to visit Arunachal Pradesh, persons who are not vaccinated with Covid-

19 vaccine have not been allowed to be issued with a temporary permit to visit Arunachal Pradesh for developmental works in both public and private sector.

12. The right granted under Article 19 (1) (d) of the Constitution of India to move freely throughout the territory of India, however, is not absolute and the State may impose a reasonable restrictions on the exercise of the rights under Article 19 (1) (d) of the Constitution of India either in the interest of the general public or for the protection of the interest of the Schedule Tribe. While putting any restrictions, as above, such restrictions, however, must be a reasonable one conforming to the requirement of Article 14 of the Constitution of India as well. Article 14 of the Constitution of India guarantees to every persons the right not to be denied equality before the law or the equal protection of laws. "Equality before the law" means that amongst equals the law should be equal and should be equally administered and that like should be treated alike. Classification of persons into groups for different treatment of such groups is permissible if there is a reasonable basis for such difference. Article 14 of the Constitution of India forbids class legislation, but does not forbid classification or differentiation which rests upon reasonable grounds of distinction. The power of making classification, however, is not without limit. A classification to be valid must be reasonable. It must always rest upon some real and substantial distinction bearing reasonable and just needs in respect of which the classification is made. In order to pass the test of permissible classification, 2 (two) conditions must be fulfilled, namely, (i) the classification must be founded on an intelligible differentiation which distinguishes persons or things that are grouped together from others left out of the group; and (ii) the differentia must have a rational relation to the object sought to be achieved by such classification.

13. In the instant case, the classification sought to be made between the vaccinated and unvaccinated persons for Covid-19 by Clause 11 of the Order dated 30.06.2021 for the purpose of issuing a temporary permit for developmental works in both public and private sector in the State of Arunachal Pradesh is undoubtedly to contain Covid-19 pandemic and its further spread in the State of Arunachal Pradesh. There is no evidence available either in the record or in the public domain that Covid-19 vaccinated persons cannot be infected with Covid-19 virus, or he/she cannot be a carrier of a Covid-19 virus and consequently, a spreader of Covid-19 virus. In so far as the spread of Covid-19 Virus to others is concerned, the Covid-19 vaccinated and unvaccinated person or persons are the same. Both can equally be a potential spreader if they are infected with Covid-19 Virus in them. This aspect of the matter came up for consideration by this Court in WP(C)/37/2020 (*In Re Dinthar Incident Aizawl* v. *State of Mizoram* Aizawl; in which case, this Court vide Order dated 02.07.2021, in paragraph 14 thereof, had observed as follows -

> *"14. It has been brought to our notice that even persons who have been vaccinated can still be infected with the covid virus, which would in turn imply that vaccinated persons who are covid positive, can also spread the said virus to others. It is not the case of the State respondents that vaccinated persons cannot be infected with the covid virus or are incapable of spreading the virus. Thus, even a vaccinated infected covid person can be a super-spreader. If vaccinated and un-vaccinated persons can be infected by the covid virus and if they can both be spreaders of the virus, the restriction placed only upon the un-vaccinated persons, debarring them from earning their livelihood or leaving their houses to obtain essential items is unjustified, grossly unreasonable and arbitrary. As such, the submission made by the learned Additional Advocate General that the restrictions made against the un-vaccinated persons vis-à-vis the vaccinated persons is reasonable does not hold any water. As the vaccinated and un-vaccinated persons would have to follow the covid proper behavior protocols as per the SOP, there is no justification for discrimination."*

14. Thus, if the sole object of issuing the Order dated 30.06.2021, by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, is for containment of the Covid-19 pandemic and its further spread in the State of Arunachal Pradesh, the classification sought to be made between vaccinated and unvaccinated persons for Covid-19 virus for the purpose of issuing temporary permits for developmental works in both public and private sector, vide Clause 11 thereof, *prima facie*, appears to be a classification not founded on intelligible differentia nor it is found to have a rational relation/nexus to the object sought to be achieved by such classification, namely, containment and further spread of Covid-19 pandemic.

15. For the reasons stated hereinabove, it *prima facie* appears to this Court that Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, in so far it makes a classification of persons who are Covid-19 vaccinated and persons who are Covid-19 unvaccinated for the purpose of issuance of temporary permits for developmental works in both public and private sector in the State of Arunachal Pradesh violates Articles 14, 19 (1) (d) & 21 of the Constitution of India calling for an interim order in the case. Accordingly, till the returnable date, Clause 11 of the Order dated 30.06.2021, issued by the Chief Secretary cum Chairperson-State Executive Committee, Government of Arunachal Pradesh, vide Memo No. SEOC/DRR&DM/01/2011-12, in so far it discriminates between Covid-19 vaccinated persons and Covid-19 unvaccinated persons for issuance of temporary permits for developmental works in both public and private sector in the State of Arunachal Pradesh, shall remain stayed.

16. List it on 28.07.2021.

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† Itanagar Bench

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"EXHIBIT "E" "

Source: The Defender – Children's Health Defense News & Views

Link:- https://childrenshealthdefense.org/defender/research-natural-immunity-covid-brownstone-institute/

Date:- 10/19/21

By Paul Elias Alexander, Ph.D.

81 Research Studies Confirm Natural Immunity to COVID 'Equal' or 'Superior' to Vaccine Immunity.

The Brownstone Institute lists 81 of the highest-quality, complete, most robust scientific studies and evidence reports/position statements on natural immunity as compared to the COVID-19 vaccine-induced immunity.

We should not force COVID vaccines on anyone when the evidence shows that naturally acquired immunity is equal to or more robust and superior to existing vaccines. Instead, we should respect the right of the bodily integrity of individuals to decide for themselves.

Public health officials and the medical establishment with the help of the politicized media are misleading the public with assertions that the COVID-19 shots provide greater protection than natural immunity.

Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky, for example, was deceptive in her October 2020 published LANCET statement that "there is no evidence for lasting protective immunity to SARS-CoV-2 following natural infection" and that "the consequence of waning

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ADVOCATE FOR Petitioners.

immunity would present a risk to vulnerable populations for the indefinite future."

Immunology and virology 101 have taught us over a century that natural immunity confers protection against a respiratory virus's outer coat proteins, and not just one, e.g., the SARS-CoV-2 spike glycoprotein.

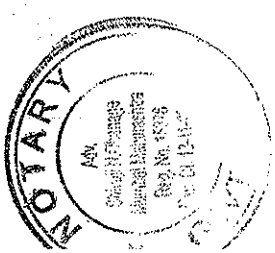
There is even strong evidence for the persistence of antibodies. Even the CDC recognizes natural immunity for chicken-pox and measles, mumps and rubella, but not for COVID-19.

The vaccinated are showing viral loads (very high) similar to the unvaccinated, and the vaccinated are as infectious. Riemersma et al. also report Wisconsin data that corroborate how the vaccinated individuals who get infected with the Delta variant can potentially (and are) transmit(ting) SARS-CoV-2 to others (potentially to the vaccinated and unvaccinated).

This troubling situation of the vaccinated being infectious and transmitting the virus emerged in seminal nosocomial outbreak papers by Chau et al. (HCWs in Vietnam), the Finland hospital outbreak (spread among HCWs and patients), and the Israel hospital outbreak (spread among HCWs and patients).

These studies also revealed that the personal protective equipment (PPE) and masks were essentially ineffective in the healthcare setting. Again, the Marek's disease in chickens and the vaccination situation explains what we are potentially facing with these leaky vaccines (increased transmission, faster transmission, and more 'hotter' variants).

Moreover, existing immunity should be assessed before any vaccination, via an accurate, dependable and reliable antibody test (or T cell immunity test) or be



based on documentation of prior infection (a previous positive PCR or antigen test). Such would be evidence of immunity that is equal to that of vaccination and the immunity should be provided the same societal status as any vaccine-induced immunity.

This will function to mitigate the societal anxiety with these forced vaccine mandates and societal upheaval due to job loss, denial of societal privileges etc. Tearing apart the vaccinated and the unvaccinated in a society — separating them — is not medically or scientifically supportable.

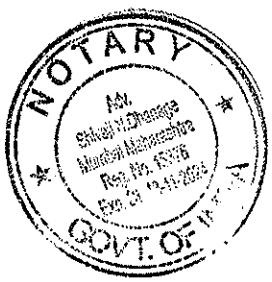
The Brownstone Institute previously documented 30 studies on natural immunity as it relates to COVID-19.

This follow-up chart is the most updated and comprehensive library list of 81 of the highest-quality, complete, most robust scientific studies and evidence reports/position statements on natural immunity as compared to the COVID-19 vaccine-induced immunity and allows you to draw your own conclusion.

I've benefited from the input of many to put this together, especially my co-authors:

- Dr. Harvey Risch, M.D., Ph.D. (Yale School of Public Health)
- Dr. Howard Tenenbaum, Ph.D. (Faculty of Medicine, University of Toronto)
- Dr. Ramin Oskoui, M.D. (Foxhall Cardiology, Washington)
- Dr. Peter McCullough, M.D. (Truth for Health Foundation, Texas)
- Dr. Parvez Dara, M.D. (consultant, Medical Hematologist and Oncologist)

Evidence on natural immunity versus COVID-19 vaccine induced immunity as of Oct. 15:



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Study / report title, author, and year published	Predominant finding on natural immunity
1) Necessity of COVID-19 vaccination in previously infected individuals, Shrestha, 2021	"Cumulative incidence of COVID-19 was examined among 52,238 employees in an American healthcare system. "The cumulative incidence of SARS-CoV-2 infection remained almost zero among previously infected unvaccinated subjects, previously infected subjects who were vaccinated, and previously uninfected subjects who were vaccinated, compared with a steady increase in cumulative incidence among previously uninfected subjects who remained unvaccinated. "Not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study. Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination…"
2) SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls, Le Bert, 2020	"Studied T cell responses against the structural (nucleocapsid (N) protein) and non-structural (NSP7 and NSP13 of ORF1) regions of SARS-CoV-2 in individuals convalescing from coronavirus disease 2019 (COVID-19) (n =

36).

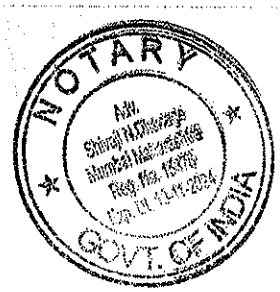
"In all of these individuals, we found CD4 and CD8 T cells that recognized multiple regions of the N protein … showed that patients (n = 23) who recovered from SARS possess long-lasting memory T cells that are reactive to the N protein of SARS-CoV 17 years after the outbreak of SARS in 2003; these T cells displayed robust cross-reactivity to the N protein of SARS-CoV-2."

3) Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections,Gazit, 2021

"A retrospective observational study comparing three groups:

"(1) SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine, (2) previously infected individuals who have not been vaccinated and (3) previously infected and single dose vaccinated individuals, found para a 13 fold increased risk of breakthrough Delta infections in double vaccinated persons, and a 27 fold increased risk for symptomatic breakthrough infection in the double vaccinated relative to the natural immunity recovered persons …

" … the risk of hospitalization was 8 times higher in the double vaccinated (para) … this



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	analysis demonstrated that natural immunity affords longer lasting and stronger protection against infection, symptomatic disease and hospitalization due to the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity."
	"Studied SARS-CoV-2–specific T cells in a cohort of asymptomatic (n = 85) and symptomatic (n = 75) COVID-19 patients after seroconversion …
4) Highly functional virus-specific cellular immune response in asymptomatic SARS-CoV-2 infection, Le Bert, 2021	"thus, asymptomatic SARS-CoV-2–infected individuals are not characterized by weak antiviral immunity; on the contrary, they mount a highly functional virus-specific cellular immune response."
	"A total of 2,653 individuals fully vaccinated by two doses of vaccine during the study period and 4,361 convalescent patients were included.
5) Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection, Israel, 2021	"Higher SARS-CoV-2 IgG antibody titers were observed in vaccinated individuals (median 1581 AU/mL IQR [533.8-5644.6]) after the second vaccination, than in convalescent individuals (median 355.3 AU/mL IQR [141.2-998.7]; p<0.001).

"In vaccinated subjects, antibody titers decreased by up to 40% each subsequent month while in convalescents they decreased by less than 5% per month …

"this study demonstrates individuals who received the Pfizer-BioNTech mRNA vaccine have different kinetics of antibody levels compared to patients who had been infected with the SARS-CoV-2 virus, with higher initial levels but a much faster exponential decrease in the first group."

Researchers recorded: "40 tentative re-infections in 14, 840 COVID-19 survivors of the first wave (0.27%) and 253 581 infections in 8, 885, 640 individuals of the remaining general population (2.85%) translating into an odds ratio (95% confidence interval) of 0.09 (0.07 to 0.13)…relatively low re-infection rate of SARS-CoV-2 in Austria.

"Protection against SARS-CoV-2 after natural infection is comparable with the highest available estimates on vaccine efficacies."

Additionally, hospitalization in only five out of 14,840 (0.03%) people and death in one out of 14,840 (0.01%) (tentative re-infection).

6) SARS-CoV-2 re-infection risk in Austria, Pilz, 2021

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7) mRNA vaccine-induced SARS-CoV-2-specific T cells recognize B.1.1.7 and B.1.351 variants but differ in longevity and homing properties depending on prior infection status, Neidleman, 2021	"Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-naïve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx. "These results provide reassurance that vaccine-elicited T cells respond robustly to the B.1.1.7 and B.1.351 variants, confirm that convalescents may not need a second vaccine dose."
8) Good news: Mild COVID-19 induces lasting antibody protection, Bhandari, 2021	"Months after recovering from mild cases of COVID-19, people still have immune cells in their body pumping out antibodies against the virus that causes COVID-19, according to a study from researchers at Washington University School of Medicine in St. Louis. "Such cells could persist for a lifetime, churning out antibodies all the while. "The findings, published May 24 in the journal Nature, suggest that mild cases of COVID-19 leave those infected with lasting antibody protection and that repeated bouts of illness are likely to be uncommon."
9) Robust neutralizing	"Neutralizing antibody titers against the

antibodies to SARS-CoV-2 infection persist for months, Wajnberg, 2021	SARS-CoV-2 spike protein persisted for at least 5 months after infection. "Although continued monitoring of this cohort will be needed to confirm the longevity and potency of this response, these preliminary results suggest that the chance of reinfection may be lower than is currently feared." "Concurrently, neutralizing activity in plasma decreases by five-fold in pseudo-type virus assays. In contrast, the number of RBD-specific memory B cells is unchanged. "Memory B cells display clonal turnover after 6.2 months, and the antibodies they express have greater somatic hypermutation, increased potency and resistance to RBD mutations, indicative of continued evolution of the humoral response …
10) Evolution of antibody immunity to SARS-CoV-2 Gaebler, 2020,	"we conclude that the memory B cell response to SARS-CoV-2 evolves between 1.3 and 6.2 months after infection in a manner that is consistent with antigen persistence."
11) <u>Persistence of neutralizing antibodies a year after SARS-CoV-2 infection in humans</u>, Haveri,	"Assessed the persistence of serum antibodies following WT SARS-CoV-2 infection at 8 and 13 months after diagnosis in 367 individuals

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2021	…
	"found that NAb against the WT virus persisted in 89% and S-IgG in 97% of subjects for at least 13 months after infection."
	"Eleven large cohort studies were identified that estimated the risk of SARS-CoV-2 reinfection over time, including three that enrolled healthcare workers and two that enrolled residents and staff of elderly care homes. "Across studies, the total number of PCR-positive or antibody-positive participants at baseline was 615,777, and the maximum duration of follow-up was more than 10 months in three studies. "Reinfection was an uncommon event (absolute rate 0%–1.1%), with no study reporting an increase in the risk of reinfection over time."
12) Quantifying the risk of SARS-CoV-2 reinfection over time, Murchu, 2021	
13) Natural immunity to COVID is powerful. Policymakers seem afraid to say so, Makary, 2021	Makary writes "it's okay to have an incorrect scientific hypothesis. But when new data proves it wrong, you have to adapt. "Unfortunately, many elected leaders and public health officials have held on far too long

	to the hypothesis that natural immunity offers unreliable protection against covid-19 — a contention that is being rapidly debunked by science. "More than 15 studies have demonstrated the power of immunity acquired by previously having the virus. "A 700,000-person study from Israel two weeks ago found that those who had experienced prior infections were 27 times less likely to get a second symptomatic covid infection than those who were vaccinated. "This affirmed a June Cleveland Clinic study of health-care workers (who are often exposed to the virus), in which none who had previously tested positive for the coronavirus got reinfected. "The study authors concluded that 'individuals who have had SARS-CoV-2 infection are unlikely to benefit from covid-19 vaccination.' "And in May, a Washington University study found that even a mild covid infection resulted in long-lasting immunity."
14) SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity, Nielsen,	"203 recovered SARS-CoV-2 infected patients in Denmark between April 3rd and July 9th 2020, at least 14 days after COVID-19

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2021	symptom recovery … "report broad serological profiles within the cohort, detecting antibody binding to other human coronaviruses … the viral surface spike protein was identified as the dominant target for both neutralizing antibodies and CD8+ T-cell responses. "Overall, the majority of patients had robust adaptive immune responses, regardless of their disease severity."
15) <u>Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel</u>, Goldberg, 2021	"Analyze an updated individual-level database of the entire population of Israel to assess the protection efficacy of both prior infection and vaccination in preventing subsequent SARS-CoV-2 infection, hospitalization with COVID-19, severe disease, and death due to COVID-19 … "vaccination was highly effective with overall estimated efficacy for documented infection of 92·8% (CI:[92·6, 93·0]); hospitalization 94·2% (CI:[93·6, 94·7]); severe illness 94·4% (CI:[93·6, 95·0]); and death 93·7% (CI:[92·5, 94·7]). "Similarly, the overall estimated level of protection from prior SARS-CoV-2 infection

	for documented infection is 94·8% (CI: [94·4, 95·1]); hospitalization 94·1% (CI: [91·9, 95·7]); and severe illness 96·4% (CI: [92·5, 98·3])…results question the need to vaccinate previously-infected individuals."
	"Employees were divided into three groups: (1) SARS-CoV-2 naïve and unvaccinated, (2) previous SARS-CoV-2 infection, and (3) vaccinated.
	"Person-days were measured from the date of the employee first test and truncated at the end of the observation period. SARS-CoV-2 infection was defined as two positive SARS-CoV-2 PCR tests in a 30-day period …
	"4313, 254 and 739 employee records for groups 1, 2, and 3 … previous SARS-CoV-2 infection and vaccination for SARS-CoV-2 were associated with decreased risk for infection or re-infection with SARS-CoV-2 in a routinely screened workforce.
16) <u>Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees</u>, Kojima, 2021	"There was no difference in the infection incidence between vaccinated individuals and individuals with previous infection."
17) <u>Having SARS-CoV-2 once confers much greater</u>	"Israelis who had an infection were more protected against the Delta coronavirus variant

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immunity than a vaccine — but vaccination remains vital, Wadman, 2021	than those who had an already highly effective COVID-19 vaccine … "the newly released data show people who once had a SARS-CoV-2 infection were much less likely than never-infected, vaccinated people to get Delta, develop symptoms from it, or become hospitalized with serious COVID-19."
	"A systematic antigen-specific immune evaluation in 101 COVID-19 convalescents; SARS-CoV-2-specific IgG antibodies, and also NAb can persist among over 95% COVID-19 convalescents from 6 months to 12 months after disease onset. "At least 19/71 (26%) of COVID-19 convalescents (double positive in ELISA and MCLIA) had detectable circulating IgM antibody against SARS-CoV-2 at 12m post-disease onset. "Notably, the percentages of convalescents with positive SARS-CoV-2-specific T-cell responses (at least one of the SARS-CoV-2 antigen S1, S2, M and N protein) were 71/76 (93%) and 67/73 (92%) at 6m and 12m, respectively."
18) **One-year sustained cellular and humoral immunities of COVID-19 convalescents, Zhang, 2021**	

	"Recovered individuals developed SARS-CoV-2-specific immunoglobulin (IgG) antibodies, neutralizing plasma, and memory B and memory T cells that persisted for at least 3 months. "Our data further reveal that SARS-CoV-2-specific IgG memory B cells increased over time. "Additionally, SARS-CoV-2-specific memory lymphocytes exhibited characteristics associated with potent antiviral function: memory T cells secreted cytokines and expanded upon antigen re-encounter, whereas memory B cells expressed receptors capable of neutralizing virus when expressed as monoclonal antibodies.
19) Functional SARS-CoV-2-Specific Immune Memory Persists after Mild COVID-19, Rodda, 2021	"Therefore, mild COVID-19 elicits memory lymphocytes that persist and display functional hallmarks of antiviral immunity."
20) Discrete Immune Response Signature to SARS-CoV-2 mRNA Vaccination Versus Infection, Ivanova, 2021	"Performed multimodal single-cell sequencing on peripheral blood of patients with acute COVID-19 and healthy volunteers before and after receiving the SARS-CoV-2 BNT162b2 mRNA vaccine to compare the immune responses elicited by the virus and by this

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vaccine …

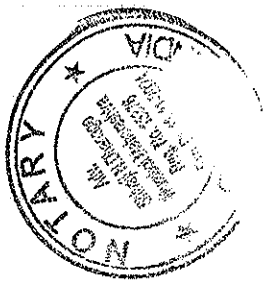
"both infection and vaccination induced robust innate and adaptive immune responses, our analysis revealed significant qualitative differences between the two types of immune challenges.

"In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was largely absent in vaccine recipients.

" Increased interferon signaling likely contributed to the observed dramatic upregulation of cytotoxic genes in the peripheral T cells and innate-like lymphocytes in patients but not in immunized subjects.

"Analysis of B and T cell receptor repertoires revealed that while the majority of clonal B and T cells in COVID-19 patients were effector cells, in vaccine recipients clonally expanded cells were primarily circulating memory cells …

"we observed the presence of cytotoxic CD4 T cells in COVID-19 patients that were largely absent in healthy volunteers following immunization.



	"While hyper-activation of inflammatory responses and cytotoxic cells may contribute to immunopathology in severe illness, in mild and moderate disease, these features are indicative of protective immune responses and resolution of infection."
	"Bone marrow plasma cells (BMPCs) are a persistent and essential source of protective antibodies …
	"durable serum antibody titres are maintained by long-lived plasma cells — non-replicating, antigen-specific plasma cells that are detected in the bone marrow long after the clearance of the antigen …
	"S-binding BMPCs are quiescent, which suggests that they are part of a stable compartment.
	"Consistently, circulating resting memory B cells directed against SARS-CoV-2 S were detected in the convalescent individuals.
21) <u>SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans</u>, Turner, 2021	"Overall, our results indicate that mild infection with SARS-CoV-2 induces robust antigen-specific, long-lived humoral immune memory in humans …
	"overall, our data provide strong evidence that

	SARS-CoV-2 infection in humans robustly establishes the two arms of humoral immune memory: long-lived bone marrow plasma cells (BMPCs) and memory B-cells."
	"The SARS-CoV-2 Immunity and Reinfection Evaluation study… 30 625 participants were enrolled into the study …
22) <u>SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN)</u>, Jane Hall, 2021	"a previous history of SARS-CoV-2 infection was associated with an 84% lower risk of infection, with median protective effect observed 7 months following primary infection. "This time period is the minimum probable effect because seroconversions were not included. This study shows that previous infection with SARS-CoV-2 induces effective immunity to future infections in most individuals."
23) <u>Pandemic peak SARS-CoV-2 infection and seroconversion rates in London frontline health-care workers</u>, Houlihan, 2020	"Enrolled 200 patient-facing HCWs between March 26 and April 8, 2020 … represents a 13% infection rate (i.e. 14 of 112 HCWs) within the 1 month of follow-up in those with no evidence of antibodies or viral shedding at enrolment. "By contrast, of 33 HCWs who tested positive

	by serology but tested negative by RT-PCR at enrolment, 32 remained negative by RT-PCR through follow-up, and one tested positive by RT-PCR on days 8 and 13 after enrolment."
	"Critical to understand whether infection with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) protects from subsequent reinfection …
24) Antibodies to SARS-CoV-2 are associated with protection against reinfection, Lumley, 2021	"12219 HCWs participated…prior SARS-CoV-2 infection that generated antibody responses offered protection from reinfection for most people in the six months following infection."
25) Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells, Cohen, 2021	"Evaluate 254 COVID-19 patients longitudinally up to 8 months and find durable broad-based immune responses. "SARS-CoV-2 spike binding and neutralizing antibodies exhibit a bi-phasic decay with an extended half-life of >200 days suggesting the generation of longer-lived plasma cells … "most recovered COVID-19 patients mount broad, durable immunity after infection, spike IgG+ memory B cells increase and persist post-infection, durable polyfunctional CD4 and CD8 T cells recognize distinct viral epitope

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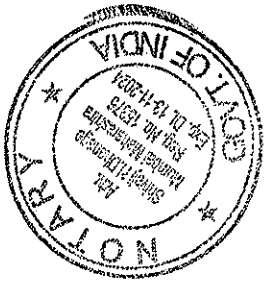
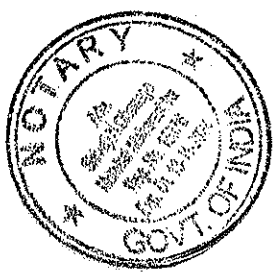
	regions."
	"Used single-cell RNA sequencing and functional assays to compare humoral and cellular responses to two doses of mRNA vaccine with responses observed in convalescent individuals with asymptomatic disease …
26) <u>Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine</u>, Sureshchandra, 2021	"natural infection induced expansion of larger CD8 T cell clones occupied distinct clusters, likely due to the recognition of a broader set of viral epitopes presented by the virus not seen in the mRNA vaccine."
27) <u>SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy</u>, Abu-Raddad, 2021	"SARS-CoV-2 antibody-positive persons from April 16 to December 31, 2020 with a PCR-positive swab ≥14 days after the first-positive antibody test were investigated for evidence of reinfection, 43,044 antibody-positive persons who were followed for a median of 16.3 weeks … reinfection is rare in the young and international population of Qatar. "Natural infection appears to elicit strong protection against reinfection with an efficacy ~95% for at least seven months."
28) <u>Orthogonal SARS-CoV-2</u>	"Conducted a serological study to define



Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humoral Immunity, Ripperger, 2020	correlates of immunity against SARS-CoV-2. "Compared to those with mild coronavirus disease 2019 (COVID-19) cases, individuals with severe disease exhibited elevated virus-neutralizing titers and antibodies against the nucleocapsid (N) and the receptor binding domain (RBD) of the spike protein…neutralizing and spike-specific antibody production persists for at least 5–7 months … "nucleocapsid antibodies frequently become undetectable by 5–7 months." "In the general population using representative data from 7,256 United Kingdom COVID-19 infection survey participants who had positive swab SARS-CoV-2 PCR tests from 26-April-2020 to 14-June-2021 … "we estimated antibody levels associated with protection against reinfection likely last 1.5-2 years on average, with levels associated with protection from severe infection present for several years. "These estimates could inform planning for vaccination booster strategies."
29) Anti-spike antibody response to natural SARS-CoV-2 infection in the general population, Wei, 2021	



	"12,541 health care workers participated and had anti-spike IgG measured; 11,364 were followed up after negative antibody results and 1265 after positive results, including 88 in whom seroconversion occurred during follow-up …
	"a total of 223 anti-spike–seronegative health care workers had a positive PCR test (1.09 per 10,000 days at risk), 100 during screening while they were asymptomatic and 123 while symptomatic, whereas 2 anti-spike–seropositive health care workers had a positive PCR test …
30) Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers, Lumley, 2021	"the presence of anti-spike or anti-nucleocapsid IgG antibodies was associated with a substantially reduced risk of SARS-CoV-2 reinfection in the ensuing 6 months."
31) Researchers find long-lived immunity to 1918 pandemic virus, CIDRAP, 2008	"A study of the blood of older people who survived the 1918 influenza pandemic reveals that antibodies to the strain have lasted a lifetime and can perhaps be engineered to protect future generations against similar strains …
and the actual 2008 NATURE journal publication by Yu	"the group collected blood samples from 32 pandemic survivors aged 91 to 101 … the people recruited for the study were 2 to 12

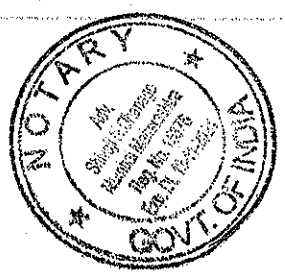
years old in 1918 and many recalled sick family members in their households, which suggests they were directly exposed to the virus, the authors report.

"The group found that 100% of the subjects had serum-neutralizing activity against the 1918 virus and 94% showed serologic reactivity to the 1918 hemagglutinin. The investigators generated B lymphoblastic cell lines from the peripheral blood mononuclear cells of eight subjects.

"Transformed cells from the blood of 7 of the 8 donors yielded secreting antibodies that bound the 1918 hemagglutinin."

"Yu: 'here we show that of the 32 individuals tested that were born in or before 1915, each showed sero-reactivity with the 1918 virus, nearly 90 years after the pandemic. Seven of the eight donor samples tested had circulating B cells that secreted antibodies that bound the 1918 HA.

"We isolated B cells from subjects and generated five monoclonal antibodies that showed potent neutralizing activity against 1918 virus from three separate donors. These antibodies also cross-reacted with the



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	genetically similar HA of a 1930 swine H1N1 influenza strain.'"
	"No significant difference was observed between the 20B and 19A isolates for HCWs with mild COVID-19 and critical patients. However, a significant decrease in neutralisation ability was found for 20I/501Y.V1 in comparison with 19A isolate for critical patients and HCWs 6-months post infection.
	"Concerning 20H/501Y.V2, all populations had a significant reduction in neutralising antibody titres in comparison with the 19A isolate.
32) <u>Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2</u>, Gonzalez, 2021	" Interestingly, a significant difference in neutralisation capacity was observed for vaccinated HCWs between the two variants whereas it was not significant for the convalescent groups … "the reduced neutralising response observed towards the 20H/501Y.V2 in comparison with the 19A and 20I/501Y.V1 isolates in fully immunized subjects with the BNT162b2 vaccine is a striking finding of the study."
33) <u>Differential effects of the</u>	"Characterized SARS-CoV-2 spike-specific

second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals, Camara, 2021	humoral and cellular immunity in naïve and previously infected individuals during full BNT162b2 vaccination …results demonstrate that the second dose increases both the humoral and cellular immunity in naïve individuals. "On the contrary, the second BNT162b2 vaccine dose results in a reduction of cellular immunity in COVID-19 recovered individuals."
34) Op-Ed: Quit Ignoring Natural COVID Immunity, Klausner, 2021	"Epidemiologists estimate over 160 million people worldwide have recovered from COVID-19. Those who have recovered have an astonishingly low frequency of repeat infection, disease, or death."
35) Association of SARS-CoV-2 Seropositive Antibody Test With Risk of Future Infection, Harvey, 2021	"To evaluate evidence of SARS-CoV-2 infection based on diagnostic nucleic acid amplification test (NAAT) among patients with positive vs negative test results for antibodies in an observational descriptive cohort study of clinical laboratory and linked claims data … "the cohort included 3 257 478 unique patients with an index antibody test … patients with positive antibody test results were initially

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	more likely to have positive NAAT results, consistent with prolonged RNA shedding, but became markedly less likely to have positive NAAT results over time, suggesting that seropositivity is associated with protection from infection."
	"Investigated the risk of subsequent SARS-CoV-2 infection among young adults (CHARM marine study) seropositive for a previous infection … enrolled 3249 participants, of whom 3168 (98%) continued into the 2-week quarantine period. 3076 (95%) participants …
	"Among 189 seropositive participants, 19 (10%) had at least one positive PCR test for SARS-CoV-2 during the 6-week follow-up (1·1 cases per person-year). In contrast, 1079 (48%) of 2247 seronegative participants tested positive (6·2 cases per person-year). The incidence rate ratio was 0·18 (95% CI 0·11–0·28; p<0·001) …
36) <u>SARS-CoV-2 seropositivity and subsequent infection risk in healthy young adults: a prospective cohort study</u>, Letizia, 2021	"infected seropositive participants had viral loads that were about 10-times lower than those of infected seronegative participants (ORF1ab gene cycle threshold difference 3·95 [95% CI 1·23–6·67]; p=0·004)."

37) <u>Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar</u>, **Bertollini, 2021**	"Of 9,180 individuals with no record of vaccination but with a record of prior infection at least 90 days before the PCR test (group 3), 7694 could be matched to individuals with no record of vaccination or prior infection (group 2), among whom PCR positivity was 1.01% (95% CI, 0.80%-1.26%) and 3.81% (95% CI, 3.39%-4.26%), respectively. The relative risk for PCR positivity was 0.22 (95% CI, 0.17-0.28) for vaccinated individuals and 0.26 (95% CI, 0.21-0.34) for individuals with prior infection compared with no record of vaccination or prior infection."
38) <u>Natural immunity against COVID-19 significantly reduces the risk of reinfection: findings from a cohort of sero-survey participants</u>, **Mishra, 2021**	"Followed up with a subsample of our previous sero-survey participants to assess whether natural immunity against SARS-CoV-2 was associated with a reduced risk of re-infection (India) … "out of the 2238 participants, 1170 were sero-positive and 1068 were sero-negative for antibody against COVID-19. "Our survey found that only 3 individuals in the sero-positive group got infected with COVID-19 whereas 127 individuals reported contracting the infection the sero-negative

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	group … "from the 3 sero-positives re-infected with COVID-19, one had hospitalization, but did not require oxygen support or critical care … "development of antibody following natural infection not only protects against re-infection by the virus to a great extent, but also safeguards against progression to severe COVID-19 disease."
	"The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset. "As seen in previous studies, the number of antibodies ranged widely between individuals. "But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection … virus-specific B cells increased over time.
39) <u>Lasting immunity found after recovery from COVID-19</u>, NIH, 2021	"People had more memory B cells six months after symptom onset than at one month afterwards… levels of T cells for the virus also

	remained high after infection. "Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus… 95% of the people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection." "The seropositive rate in the convalescent individuals was above 95% at all sampling time points for both assays and remained stable over time; that is, almost all convalescent individuals developed antibodies …
40) SARS-CoV-2 Natural Antibody Response Persists for at Least 12 Months in a Nationwide Study From the Faroe Islands, Petersen, 2021	"results show that SARS-CoV-2 antibodies persisted at least 12 months after symptom onset and maybe even longer, indicating that COVID-19-convalescent individuals may be protected from reinfection."
41) SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells, Jung, 2021	"ex vivo assays to evaluate SARS-CoV-2-specific CD4+ and CD8+ T cell responses in COVID-19 convalescent patients up to 317 days post-symptom onset (DPSO), and find that memory T cell responses are maintained during the study period regardless of the severity of COVID-19. "In particular, we observe sustained

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	polyfunctionality and proliferation capacity of SARS-CoV-2-specific T cells. Among SARS-CoV-2-specific CD4+ and CD8+ T cells detected by activation-induced markers, the proportion of stem cell-like memory T (TSCM) cells is increased, peaking at approximately 120 DPSO."
	"Analyzed 42 unexposed healthy donors and 28 mild COVID-19 subjects up to 5 months from the recovery for SARS-CoV-2 specific immunological memory.
	"Using HLA class II predicted peptide megapools, we identified SARS-CoV-2 cross-reactive CD4+ T cells in around 66% of the unexposed individuals. Moreover, we found detectable immune memory in mild COVID-19 patients several months after recovery in the crucial arms of protective adaptive immunity; CD4+ T cells and B cells, with a minimal contribution from CD8+ T cells.
42) <u>Immune Memory in Mild COVID-19 Patients and Unexposed Donors Reveals Persistent T Cell Responses After SARS-CoV-2 Infection</u>, Ansari, 2021	"Interestingly, the persistent immune memory in COVID-19 patients is predominantly targeted towards the Spike glycoprotein of the SARS-CoV-2. This study provides the evidence of both high magnitude pre-existing and persistent immune memory in Indian

	population." "Current evidence points to most individuals developing strong protective immune responses following natural infection with SARSCoV-2. "Within 4 weeks following infection, 90-99% of individuals infected with the SARS-CoV-2 virus develop detectable neutralizing antibodies. "The strength and duration of the immune responses to SARS-CoV-2 are not completely understood and currently available data suggests that it varies by age and the severity of symptoms. "Available scientific data suggests that in most people immune responses remain robust and protective against reinfection for at least 6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months)."
43) <u>COVID-19 natural immunity</u>, WHO, 2021	
44) <u>Antibody Evolution after SARS-CoV-2 mRNA Vaccination</u>, Cho, 2021	"We conclude that memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination …

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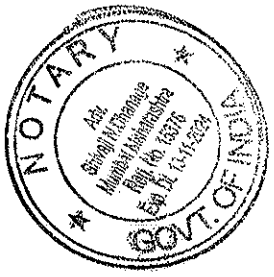
	"boosting vaccinated individuals with currently available mRNA vaccines would produce a quantitative increase in plasma neutralizing activity but not the qualitative advantage against variants obtained by vaccinating convalescent individuals."
	"Measured antibodies in serum samples from 30,576 persons in Iceland … of the 1797 persons who had recovered from SARS-CoV-2 infection, 1107 of the 1215 who were tested (91.1%) were seropositive…
45) <u>Humoral Immune Response to SARS-CoV-2 in Iceland</u>, Gudbjartsson, 2020	"results indicate risk of death from infection was 0.3% and that antiviral antibodies against SARS-CoV-2 did not decline within 4 months after diagnosis (para)."
	"Analyzed multiple compartments of circulating immune memory to SARS-CoV-2 in 254 samples from 188 COVID-19 cases, including 43 samples at ≥ 6 months post-infection … IgG to the Spike protein was relatively stable over 6+ months.
46) <u>Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection</u>, Dan, 2021	"Spike-specific memory B cells were more abundant at 6 months than at 1 month post symptom onset."



	"Fifty-four studies, from 18 countries, with a total of 12 011 447 individuals, followed up to 8 months after recovery, were included.
47) <u>The prevalence of adaptive immunity to COVID-19 and reinfection after recovery – a comprehensive systematic review and meta-analysis of 12 011 447 individuals</u>, Chivese, 2021	"At 6-8 months after recovery, the prevalence of detectable SARS-CoV-2 specific immunological memory remained high; IgG – 90.4% … pooled prevalence of reinfection was 0.2% (95%CI 0.0 – 0.7, I2 = 98.8, 9 studies). Individuals who recovered from COVID-19 had an 81% reduction in odds of a reinfection (OR 0.19, 95% CI 0.1 – 0.3, I2 = 90.5%, 5 studies)."
48) <u>Reinfection Rates among Patients who Previously Tested Positive for COVID-19: a Retrospective Cohort Study</u>, Sheehan, 2021	"Retrospective cohort study of one multi-hospital health system included 150,325 patients tested for COVID-19 infection … prior infection in patients with COVID-19 was highly protective against reinfection and symptomatic disease. "This protection increased over time, suggesting that viral shedding or ongoing immune response may persist beyond 90 days and may not represent true reinfection."
49) <u>Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a</u>	"The study results suggest that reinfections are rare events and patients who have recovered from COVID-19 have a lower risk of

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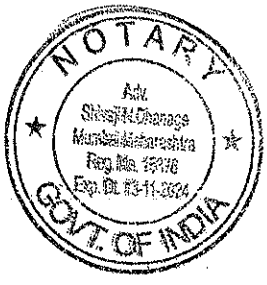
Population in Lombardy, Italy, Vitale, 2020	reinfection. "Natural immunity to SARS-CoV-2 appears to confer a protective effect for at least a year, which is similar to the protection reported in recent vaccine studies."
50) Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection, Hanrath, 2021	"We observed no symptomatic reinfections in a cohort of healthcare workers … this apparent immunity to re-infection was maintained for at least 6 months … "test positivity rates were 0% (0/128 [95% CI: 0–2.9]) in those with previous infection compared to 13.7% (290/2115 [95% CI: 12.3–15.2]) in those without (P<0.0001 $\chi 2$ test)."
51) mRNA vaccine-induced T cells respond identically to SARS-CoV-2 variants of concern but differ in longevity and homing properties depending on prior infection status, Neidleman, 2021	"In infection-naïve individuals, the second dose boosted the quantity and altered the phenotypic properties of SARS-CoV-2-specific T cells, while in convalescents the second dose changed neither. "Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-naïve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx."



	"Using HLA class I and II predicted peptide 'megapools,' circulating SARS-CoV-2-specific CD8+ and CD4+ T cells were identified in ~70% and 100% of COVID-19 convalescent patients, respectively. CD4+ T cell responses to spike, the main target of most vaccine efforts, were robust and correlated with the magnitude of the anti-SARS-CoV-2 IgG and IgA titers.
52) Targets of T Cell Responses to SARS-CoV-2 Coronavirus in Humans with COVID-19 Disease and Unexposed Individuals, Grifoni, 2020	"The M, spike, and N proteins each accounted for 11%–27% of the total CD4+ response, with additional responses commonly targeting nsp3, nsp4, ORF3a, and ORF8, among others. For CD8+ T cells, spike and M were recognized, with at least eight SARS-CoV-2 ORFs targeted."
	"Much of the study on the immune response to SARS-CoV-2, the novel coronavirus that causes COVID-19, has focused on the production of antibodies.
53) NIH Director's Blog: Immune T Cells May Offer Lasting Protection Against COVID-19, Collins, 2021	"But, in fact, immune cells known as memory T cells also play an important role in the ability of our immune systems to protect us against many viral infections, including — it now appears — COVID-19.An intriguing new study of these memory T cells suggests they

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	might protect some people newly infected with SARS-CoV-2 by remembering past encounters with other human coronaviruses. "This might potentially explain why some people seem to fend off the virus and may be less susceptible to becoming severely ill with COVID-19."
54) Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants, Wang, 2021	"Our study demonstrates that convalescent subjects previously infected with ancestral variant SARS-CoV-2 produce antibodies that cross-neutralize emerging VOCs with high potency … potent against 23 variants, including variants of concern."
	"Requiring the vaccine in people who are already immune with natural immunity has no scientific support. While vaccinating those people may be beneficial — and it's a reasonable hypothesis that vaccination may bolster the longevity of their immunity — to argue dogmatically that they must get vaccinated has zero clinical outcome data to back it.
55) Why COVID-19 Vaccines Should Not Be Required for All Americans, Makary, 2021	"As a matter of fact, we have data to the contrary: A Cleveland Clinic study found that vaccinating people with natural immunity did not add to their level of protection."

56) <u>Protracted yet coordinated differentiation of long-lived SARS-CoV-2-specific CD8+ T cells during COVID-19 convalescence</u>, Ma, 2021	"Screened 21 well-characterized, longitudinally-sampled convalescent donors that recovered from mild COVID-19 … following a typical case of mild COVID-19, SARS-CoV-2-specific CD8+ T cells not only persist but continuously differentiate in a coordinated fashion well into convalescence, into a state characteristic of long-lived, self-renewing memory."
57) <u>Decrease in Measles Virus-Specific CD4 T Cell Memory in Vaccinated Subjects</u>, Naniche, 2004	"Characterized the profiles of measles vaccine (MV) vaccine-induced antigen-specific T cells over time since vaccination. "In a cross-sectional study of healthy subjects with a history of MV vaccination, we found that MV-specific CD4 and CD8 T cells could be detected up to 34 years after vaccination. "The levels of MV-specific CD8 T cells and MV-specific IgG remained stable, whereas the level of MV-specific CD4 T cells decreased significantly in subjects who had been vaccinated >21 years earlier."
58) <u>Remembrance of Things Past: Long-Term B Cell Memory After Infection and Vaccination</u>, Palm, 2019	"The success of vaccines is dependent on the generation and maintenance of immunological memory. The immune system can remember previously encountered pathogens, and

memory B and T cells are critical in secondary responses to infection.

"Studies in mice have helped to understand how different memory B cell populations are generated following antigen exposure and how affinity for the antigen is determinant to B cell fate …

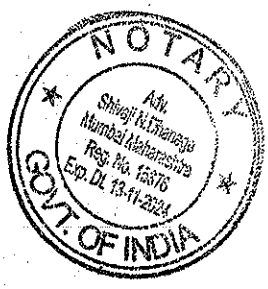
"upon re-exposure to an antigen the memory recall response will be faster, stronger, and more specific than a naïve response.

"Protective memory depends first on circulating antibodies secreted by LLPCs. When these are not sufficient for immediate pathogen neutralization and elimination, memory B cells are recalled."

59) SARS-CoV-2 specific memory B-cells from individuals with diverse disease severities recognize SARS-CoV-2 variants of concern, Lyski, 2021

"Examined the magnitude, breadth and durability of SARS-CoV-2 specific antibodies in two distinct B-cell compartments: long-lived plasma cell-derived antibodies in the plasma, and peripheral memory B-cells along with their associated antibody profiles elicited after in vitro stimulation.

"We found that magnitude varied amongst individuals, but was the highest in hospitalized subjects. Variants of concern (VoC) -RBD-



	reactive antibodies were found in the plasma of 72% of samples in this investigation, and VoC-RBD-reactive memory B-cells were found in all but 1 subject at a single time-point. "This finding, that VoC-RBD-reactive MBCs are present in the peripheral blood of all subjects including those that experienced asymptomatic or mild disease, provides a reason for optimism regarding the capacity of vaccination, prior infection, and/or both, to limit disease severity and transmission of variants of concern as they continue to arise and circulate."
60) <u>Exposure to SARS-CoV-2 generates T-cell memory in the absence of a detectable viral infection</u>, Wang, 2021	"T-cell immunity is important for recovery from COVID-19 and provides heightened immunity for re-infection. However, little is known about the SARS-CoV-2-specific T-cell immunity in virus-exposed individuals … "report virus-specific CD4+ and CD8+ T-cell memory in recovered COVID-19 patients and close contacts … close contacts are able to gain T-cell immunity against SARS-CoV-2 despite lacking a detectable infection."
61) <u>CD8+ T-Cell Responses in COVID-19 Convalescent</u>	"The CD4 and CD8 responses generated after natural infection are equally robust, showing

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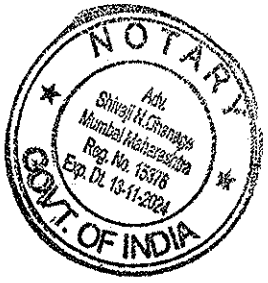
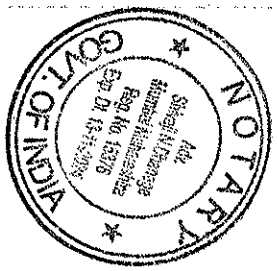
Individuals Target Conserved Epitopes From Multiple Prominent SARS-CoV-2 Circulating Variants, Redd, 2021and Lee, 2021	activity against multiple 'epitopes' (little segments) of the spike protein of the virus. "For instance, CD8 cells responds to 52 epitopes and CD4 cells respond to 57 epitopes across the spike protein, so that a few mutations in the variants cannot knock out such a robust and in-breadth T cell response … "only 1 mutation found in Beta variant-spike overlapped with a previously identified epitope (1/52), suggesting that virtually all anti-SARS-CoV-2 CD8+ T-cell responses should recognize these newly described variants."
62) Exposure to common cold coronaviruses can teach the immune system to recognize SARS-CoV-2,La Jolla, Crotty and Sette, 2020	"Exposure to common cold coronaviruses can teach the immune system to recognize SARS-CoV-2"
63) Selective and cross-reactive SARS-CoV-2 T cell epitopes in unexposed humans, Mateus, 2020	"Found that the pre-existing reactivity against SARS-CoV-2 comes from memory T cells and that cross-reactive T cells can specifically recognize a SARS-CoV-2 epitope as well as the homologous epitope from a common cold coronavirus. "These findings underline the importance of determining the impacts of pre-existing



	immune memory in COVID-19 disease severity."
	"Better understanding of antibody responses against SARS-CoV-2 after natural infection might provide valuable insights into the future implementation of vaccination policies. "Longitudinal analysis of IgG antibody titers was carried out in 32 recovered COVID-19 patients based in the Umbria region of Italy for 14 months after Mild and Moderately-Severe infection … "study findings are consistent with recent studies reporting antibody persistency suggesting that induced SARS-CoV-2 immunity through natural infection, might be very efficacious against re-infection (>90%) and could persist for more than six months.
64) Longitudinal observation of antibody responses for 14 months after SARS-CoV-2 infection, Dehgani-Mobaraki, 2021	"Our study followed up patients up to 14 months demonstrating the presence of anti-S-RBD IgG in 96.8% of recovered COVID-19 subjects."
65) Humoral and circulating follicular helper T cell responses in recovered	"Characterized humoral and circulating follicular helper T cell (cTFH) immunity against spike in recovered patients with

patients with COVID-19, Juno, 2020	coronavirus disease 2019 (COVID-19). "We found that S-specific antibodies, memory B cells and cTFH are consistently elicited after SARS-CoV-2 infection, demarking robust humoral immunity and positively associated with plasma neutralizing activity."
66) Convergent antibody responses to SARS-CoV-2 in convalescent individuals, Robbiani, 2020	"149 COVID-19-convalescent individuals…antibody sequencing revealed the expansion of clones of RBD-specific memory B cells that expressed closely related antibodies in different individuals. "Despite low plasma titres, antibodies to three distinct epitopes on the RBD neutralized the virus with half-maximal inhibitory concentrations (IC50 values) as low as 2 ng ml−1."
67) Rapid generation of durable B cell memory to SARS-CoV-2 spike and nucleocapsid proteins in COVID-19 and convalescence, Hartley, 2020	"COVID-19 patients rapidly generate B cell memory to both the spike and nucleocapsid antigens following SARS-CoV-2 infection … RBD- and NCP-specific IgG and Bmem cells were detected in all 25 patients with a history of COVID-19."
68) Had COVID? You'll probably make antibodies	"People who recover from mild COVID-19 have bone-marrow cells that can churn out

for a lifetime, Callaway, 2021	antibodies for decades … the study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting."
69) A majority of uninfected adults show preexisting antibody reactivity against SARS-CoV-2, Majdoubi, 2021	In greater Vancouver Canada, "using a highly sensitive multiplex assay and positive/negative thresholds established in infants in whom maternal antibodies have waned, we determined that more than 90% of uninfected adults showed antibody reactivity against the spike protein, receptor-binding domain (RBD), N-terminal domain (NTD), or the nucleocapsid (N) protein from SARS-CoV-2."
70) SARS-CoV-2-reactive T cells in healthy donors and patients with COVID-19, Braun, 2020	"The results indicate that spike-protein cross-reactive T cells are present, which were probably generated during previous encounters with endemic coronaviruses."
71) Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection, Wang, 2021	"A cohort of 63 individuals who have recovered from COVID-19 assessed at 1.3, 6.2 and 12 months after SARS-CoV-2 infection … the data suggest that immunity in convalescent individuals will be very long lasting."
72) One Year after Mild COVID-19: The Majority of Patients Maintain Specific	"Long-lasting immunological memory against SARS-CoV-2 after mild COVID-19."



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Immunity, But One in Four Still Suffer from Long-Term Symptoms, Rank, 2021	
	"Immune responses to SARS-CoV-2 following natural infection can persist for at least 11 months …
73) IDSA, 2021	"natural infection (as determined by a prior positive antibody or PCR-test result) can confer protection against SARS-CoV-2 infection."
74) Assessment of protection against reinfection with SARS-CoV-2 among 4 million PCR-tested individuals in Denmark in 2020: a population-level observational study, Holm Hansen, 2021	Denmark, "during the first surge (ie, before June, 2020), 533 381 people were tested, of whom 11 727 (2·20%) were PCR positive, and 525 339 were eligible for follow-up in the second surge, of whom 11 068 (2·11%) had tested positive during the first surge. "Among eligible PCR-positive individuals from the first surge of the epidemic, 72 (0·65% [95% CI 0·51–0·82]) tested positive again during the second surge compared with 16 819 (3·27% [3·22–3·32]) of 514 271 who tested negative during the first surge (adjusted RR 0·195 [95% CI 0·155–0·246])."
75) Antigen-Specific	"Adaptive immune responses limit COVID-19

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Adaptive Immunity to SARS-CoV-2 in Acute COVID-19 and Associations with Age and Disease Severity, Moderbacher, 2020	disease severity…multiple coordinated arms of adaptive immunity control better than partial responses … "completed a combined examination of all three branches of adaptive immunity at the level of SARS-CoV-2-specific CD4+ and CD8+ T cell and neutralizing antibody responses in acute and convalescent subjects. SARS-CoV-2-specific CD4+ and CD8+ T cells were each associated with milder disease. "Coordinated SARS-CoV-2-specific adaptive immune responses were associated with milder disease, suggesting roles for both CD4+ and CD8+ T cells in protective immunity in COVID-19." "Collected blood from COVID-19 patients who have recently become virus-free, and therefore were discharged, and detected SARS-CoV-2-specific humoral and cellular immunity in eight newly discharged patients.
76) Detection of SARS-CoV-2-Specific Humoral and Cellular Immunity in COVID-19 Convalescent Individuals, Ni, 2020	"Follow-up analysis on another cohort of six patients 2 weeks post discharge also revealed high titers of immunoglobulin G (IgG) antibodies. "In all 14 patients tested, 13 displayed serum-

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	neutralizing activities in a pseudotype entry assay. Notably, there was a strong correlation between neutralization antibody titers and the numbers of virus-specific T cells."
	"Analysed the magnitude and phenotype of the SARS-CoV-2 cellular immune response in 100 donors at six months following primary infection and related this to the profile of antibody level against spike, nucleoprotein and RBD over the previous six months.
77) Robust SARS-CoV-2-specific T-cell immunity is maintained at 6 months following primary infection, Zuo, 2020	"T-cell immune responses to SARS-CoV-2 were present by ELISPOT and/or ICS analysis in all donors and are characterised by predominant CD4+ T cell responses with strong IL-2 cytokine expression … "functional SARS-CoV-2-specific T-cell responses are retained at six months following infection."
78) Negligible impact of SARS-CoV-2 variants on CD4+ and CD8+ T cell reactivity in COVID-19 exposed donors and vaccinees, Tarke, 2021	"Performed a comprehensive analysis of SARS-CoV-2-specific CD4+ and CD8+ T cell responses from COVID-19 convalescent subjects recognizing the ancestral strain, compared to variant lineages B.1.1.7, B.1.351, P.1, and CAL.20C as well as recipients of the Moderna (mRNA-1273)

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	or Pfizer/BioNTech (BNT162b2) COVID-19 vaccines … "the sequences of the vast majority of SARS-CoV-2 T cell epitopes are not affected by the mutations found in the variants analyzed. "Overall, the results demonstrate that CD4+ and CD8+ T cell responses in convalescent COVID-19 subjects or COVID-19 mRNA vaccinees are not substantially affected by mutations."
79) A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: a preliminary report, Perez, 2021	Israel, "out of 149,735 individuals with a documented positive PCR test between March 2020 and January 2021, 154 had two positive PCR tests at least 100 days apart, reflecting a reinfection proportion of 1 per 1000."
80) Persistence and decay of human antibody responses to the receptor binding domain of SARS-CoV-2 spike protein in COVID-19 patients, Iyer, 2020	"Measured plasma and/or serum antibody responses to the receptor-binding domain (RBD) of the spike (S) protein of SARS-CoV-2 in 343 North American patients infected with SARS-CoV-2 (of which 93% required hospitalization) up to 122 days after symptom onset and compared them to responses in 1548 individuals whose blood samples were obtained prior to the pandemic …

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	"IgG antibodies persisted at detectable levels in patients beyond 90 days after symptom onset, and seroreversion was only observed in a small percentage of individuals. "The concentration of these anti-RBD IgG antibodies was also highly correlated with pseudovirus NAb titers, which also demonstrated minimal decay. The observation that IgG and neutralizing antibody responses persist is encouraging, and suggests the development of robust systemic immune memory in individuals with severe infection."
81) <u>A population-based analysis of the longevity of SARS-CoV-2 antibody seropositivity in the United States</u>, Alfego, 2021	"To track population-based SARS-CoV-2 antibody seropositivity duration across the United States using observational data from a national clinical laboratory registry of patients tested by nucleic acid amplification (NAAT) and serologic assays … "specimens from 39,086 individuals with confirmed positive COVID-19 … both S and N SARS-CoV-2 antibody results offer an encouraging view of how long humans may have protective antibodies against COVID-19, with curve smoothing showing population seropositivity reaching 90% within three weeks, regardless of whether the assay detects

N or S-antibodies.

"Most importantly, this level of seropositivity was sustained with little decay through ten months after initial positive PCR."

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Exp. Dt. 03.11.2022
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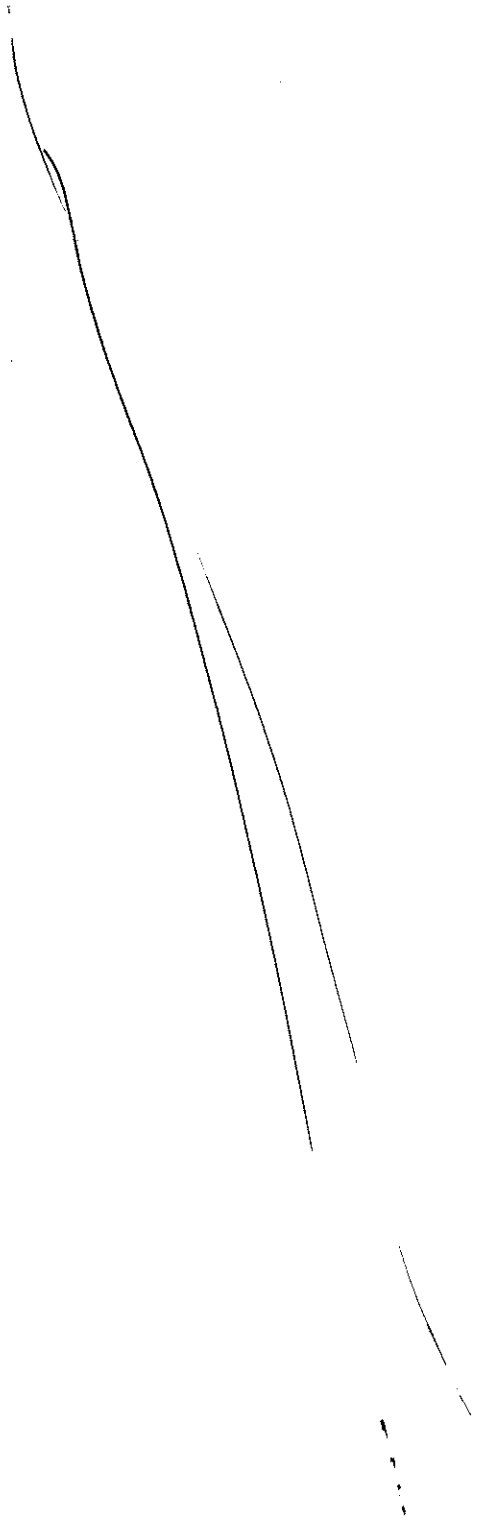

"EXHIBIT "F" "

Source: NDTV

Date: January 04, 2021

Link: https://www.ndtv.com/india-news/oxford-covid-19-vaccine-bharat-biotechs-covaxin-get-final-approval-by-drug-regulator-will-be-indias-first-vaccines-2347053

India's Wait Over, Drug Regulator Says Covid Vaccines Cleared "110% Safe"

Drug Controller General of India VG Somani said,."We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe".

All India Reported by Sukirti Dwivedi, Edited by Anindita Sanyal Updated: January 04, 2021 7:54 am IS

New Delhi: Two vaccines for coronavirus, Oxford University's Covishield, which is being developed by the Pune-based Serum Institute, and Bharat Biotech's Covaxin, received emergency approval from the country's drug regulator on Sunday. "We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe," Drug Controller General of India VG Somani said, adding Covishield was found to be 70.42 per cent effective and Bharat Biotech's Covaxin was "safe and provides a robust immune response". Hailing the scientific community and frontline Corona warriors, Prime Minister Narendra Modi tweeted, "It would make every Indian proud that the two vaccines that have been given emergency use approval are made in India". There is no word yet on when the vaccination process will begin.

Here are the top 10 points in this big story:

NOTARY Adv. Shivaji N. Dhanawade Mumbai Maharashtra Reg. No. 15376 Exp. Dt. 19-11-2021 GOVT. OF INDIA

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1. "We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe. Some side effects like mild fever, pain and allergy are common for every vaccine," Drug Controller General of India VG Somani said. The approval from the Drug Controller comes days after a government-appointed experts' panel gave clearance to the vaccines.

2. Both vaccines have to be administered in two doses and stored at temperatures between 2 and 8 degrees Celsius. The government will give priority to 1 crore healthcare workers and 2 crore frontline workers when the vaccinations begin, Union Health Minister Dr Harshvardhan said as a countrywide dry run for the vaccination process was conducted on Saturday.

3. "It would make every Indian proud that the two vaccines that have been given emergency use approval are made in India! This shows the eagerness of our scientific community to fulfil the dream of an Aatmanirbhar Bharat, at the root of which is care and compassion," PM Modi tweeted.

4. Pune-based Serum Institute, the Drug Controller General said, conducted Phase 2 and Phase 3 trials on 1,600 participants in India. Recommendation was made for restricted use and the trials will continue, he added. The vaccine, developed by the Oxford University and pharma giant AstraZenca is already in use abroad.

5. Bharat Biotech's Covaxin is conducting trials in collaboration with the Indian Council of Medical Research. The Drug Controller said that its Phase I and Phase II trials were conducted in around 800 people and the results showed that it is "safe and provides a robust immune response". The Phase III trial in on and 22,500 of the 25,800 participants have been vaccinated.

6. The health ministry said the government's expert committee has reviewed Bharat Biotech's data on "safety and immunogenicity" and gave permission for "restricted use in emergency situation in public interest". The idea was to have "more options for vaccinations, especially in case of infection by mutant strains," the ministry said, adding that the clinical trials will continue.

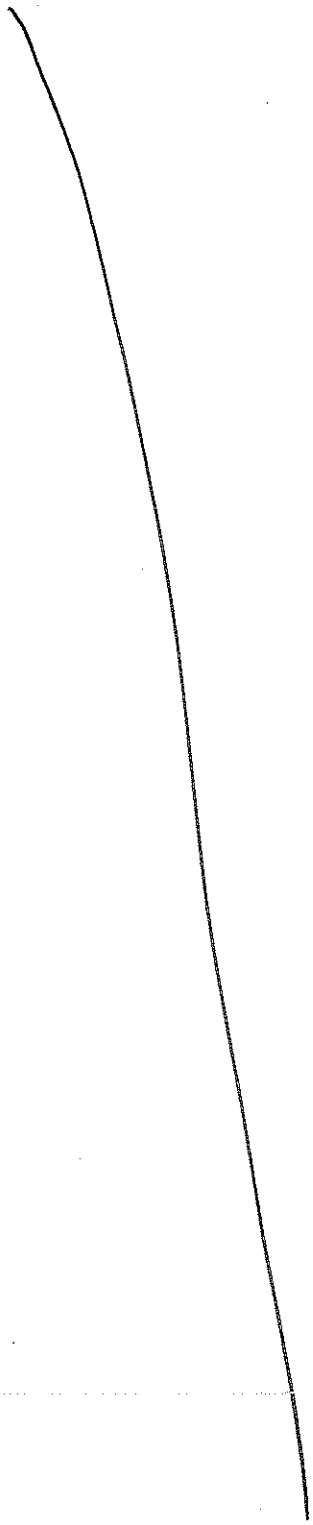
7. "Happy new year, everyone! All the risks @SerumInstIndia took with stockpiling the vaccine, have finally paid off. COVISHIELD, India's first COVID-19 vaccine is approved, safe, effective and ready to roll-out in the coming weeks," Serum Institute chief Adar Poonawalla tweeted.

8. "It has been learnt that the vaccines of Bharat Biotech and the Serum Institute have received emergency approval. All preparations are underway for the Delhi government. First health workers and frontline workers will be given the vaccine, Then those above age 50 will be given the vaccine. Health workers and frontline workers will be vaccinated under First phase," Delhi health minister Satyendar Jain said. The vaccines will be given free of cost in Delhi, the minister earlier said.

9. Flagging concerns over Bharat Biotech's Covaxin, senior Congress leader Shashi Tharoor tweeted, "The Covaxin has not yet had Phase 3 trials. Approval was premature and could be dangerous. @drharshvardhan should please clarify. Its use should be avoided till full trials are over. India can start with the AstraZeneca vaccine in the meantime".

10. India has reported 18,177 new infections in the last 24 hours - 4.7 per cent lower than yesterday - taking the total Coronavirus cases to 1,03,23,965. Data from the health ministry showed the country has also logged 217 deaths, taking the total number of fatalities to 1,49435.

NOTARY
Adv. Shivaji N. Dhanawade
Mumbai Maharashtra
Reg. No. 15376
Exp. Dt. 19-11-2021
GOVT. OF INDIA



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"EXHIBIT "G" "

Source: THE FREE PRESS JOURNAL

Date: September 30, 2021, 11:13 PM IST

Link: https://www.freepressjournal.in/mumbai/mumbai-29-mbbs-students-at-kem-hospital-test-positive-for-covid-19-27-were-fully-vaccinated

Mumbai: 29 MBBS students at KEM hospital test positive for COVID-19, 27 were fully vaccinated

Swapnil Mishra

Mumbai: A day after Mumbai Mayor Kishori Pednekar announced the standard operating procedures (SOPs) for the reopening of schools in the city from October 4, 29 medical students at the civic-run KEM Hospital in Mumbai have tested positive for Covid-19. Fourteen of them have been admitted to the SevenHills Hospital in Marol, while the rest have been quarantined at a hospital complex in Parel. Twenty-seven of the 29 MBBS students had taken both doses of the Covid vaccine, while the remaining two had only taken one dose each. According to sources, all these students contracted the infection at a cultural event organised in the hospital last week, where reportedly, none were following Covid norms. Meanwhile, the Brihanmumbai Municipal Corporation has ordered RT-PCR tests for all the medical students at the hospital and their relatives.

The incident came to light after a second-year MBBS student showed Covid symptoms and was later found positive, following which other students were tested. "Only 27 of the 1,100 MBBS students have tested positive for corona after taking both doses of Covid vaccine. It is a case of breakthrough infection. However, all of them are asymptomatic except the two who have been admitted to SevenHills Hospital," said KEM Hospital Dean Dr Hemant Deshmukh.

NOTARY Adv. Shilpaj M. Dhanage Mumbai Maharashtra Reg. No. 15578 Exp. On 12-11-2023 GOVT. OF INDIA

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"Those affected are in the first and second years of MBBS. We have been telling the students to be careful. But they have been working together and eating together. They also stay in the RMO quarters, where all of them study together till late hours," said Dr Deshmukh.

A doctor at SevenHills said that 14 of the medical undergraduates have been admitted to hospital's BMC Covid facility, the rest have been quarantined at their hostel. "Of the 14 admitted, three have mild symptoms. All are stable and under observation," said the doctor.

Additional Municipal Commissioner Suresh Kakani said they had asked the hospital administration to conduct Covid tests on all the 1,100 MBBS students who had participated in the event and directed them to trace all the close contacts and people they may have come in contact with.

"All of them have been kept under observation and the number might increase, as we will be testing everyone including the close contacts. Some of them have mild symptoms and we have kept them under observation. Most of them are vaccinated," Kakani said.

"EXHIBIT "H" "

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Source: THE FREE PRESS JOURNAL

Updated on: Monday, September 06, 2021, 11:02 PM IST

Link: https://www.freepressjournal.in/mumbai/covid-19-third-wave-has-entered-nagpur-guardian-minister-nitin-raut-urges-people-to-avoid-crowding

'COVID-19 third wave has entered Nagpur': Guardian Minister Nitin Raut urges people to avoid crowding

Sanjay Jog

The COVID 19 third wave has marked its debut in Nagpur, which is the State's second capital. The district guardian minister, Dr Nitin Raut, told the Free Press Journal after a review meeting, "The third wave has started in Nagpur, which is reporting a rise in positive cases for the last few days. Notably, on Monday, 13 people tested positive for the virus out of which 12 were already vaccinated. Besides, a twelve-year-old boy is among those who tested positive." Raut said 78 samples have been sent for genome sequencing. "Nagpur district has reported corona victims in double digits. This is a wake-up call. Therefore, it is necessary to impose restrictions. In the next two-three days, stringent corona prevention measures will be initiated in Nagpur; also, the District Disaster Management Authority will have a meeting with traders, entrepreneurs and other stakeholders," he added.

There are as on date 493192 progressive COVID 19 cases; 9131 deaths, too, have been reported in Nagpur district. Raut said apart from a COVID surge, there is a rise in Dengue cases as well.

NOTARY Adv. Shivaji N. Shewale Mumbai Maharashtra Reg. No. 15576 Dist. Dt. 13-11-2014 GOVT. OF INDIA

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"EXHIBIT "VI" "

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Source: DH Deccan Herald

AUG 03 2021, 22:50 IST

UPDATED: AUG 04 2021, 07:09 IST

Link: https://www.deccanherald.com/amp/state/top-karnataka-stories/more-than-half-of-hospitalised-covid-19-cases-among-vaccinated-in-bengaluru-1015918.html?__twitter_impression=true&s=04%5C

More than half of hospitalised Covid-19 cases among vaccinated in Bengaluru

Akhil Kadidal, DHNS, Bengaluru,

A health worker collects swab samples from a woman for Covid test at a private hospital in in Bengaluru on Tuesday. Credit: DH Photo/B K Janardhan

About 56% of people hospitalised for Covid-19 in Bengaluru in July had received at least one dose of the vaccine.

Sources in the Bruhat Bengaluru Mahanagara Palike (BBMP) said that about 2,700 people were hospitalised between July 2 and 27. Of these, 1,600 had received at least one dose of a vaccine, comprising 1,200 Covishield and 400 Covaxin receivers.

Of the 1,200 Covishield receivers, about 450 had got the second dose. Among the 400 Covaxin receivers, 180 had the second dose.

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These hospitalisations are indicative of the extent of vaccine penetration in the public, explained BBMP Chief Commissioner, Gaurav Gupta.

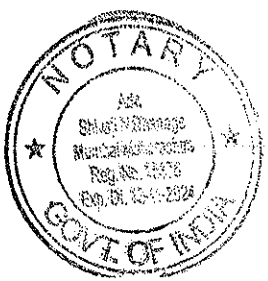
"If you take the data about the 45+ age group who are generally susceptible (to Covid-19), 82% have been vaccinated. So, I am not surprised that a lot of the hospitalised people have been vaccinated," Gupta said.

"We must ask for the doctor's comments as to whether there is any difference between those who are vaccinated and those who are not vaccinated, for severity. We still require adequate data to come to any conclusion."

Clinical indications are present in some hospitals. Research conducted at Apollo Hospital examined 500 patients with moderate to severe Covid-19 pneumonia admitted, for over 40 days between April 21 and May 30. They found that 148 patients were cases of breakthrough infection -- after being administered at least once by a vaccine.

Some 124 (84%) had received the Covishield, while 24 (16%) had received Covaxin. The median age was 58. The researchers, led by senior pulmonologist Dr Ravindra Mehta who is also a member of the BBMP's Covid-19 task force committee, said the median time for hospitalisation from first dose to hospitalisation was 25 days and it was 18 days for second dose to admission.

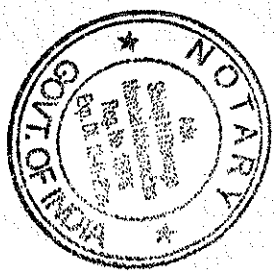
About 19.5% of the vaccinated group (29 people) had severe symptoms, as compared to 125 people (35.5%) who had not been vaccinated. In addition, 66 of the vaccinated group required respiratory support at baseline. In the end, of the 20 patients who died, all had received just one dose of the vaccine. "All patients who received two doses (14 people) were eventually discharged from the hospital," the researchers said.



CORONAVIRUS SPECIAL COVERAGE ONLY ON DH

Currently, at Aster CMI, one out of three ICU Covid-19 patients had been vaccinated (with one dose). Dr Prakash Doraiswamy, Critical Care expert, said: "We have seen many cases of vaccinated patients getting Covid infection and re-infections but they did not suffer from any serious complications."

Fortis hospitals, meantime, has seen about 15 such cases since June. "All of the ICU cases had only dose. This shows the importance of getting two doses," said Dr Pruthu Narendra Dhekane, Infectious Diseases specialist at the Bannerghatta Road branch.



AIM Awaken India Movement
awakenindiamovement.com
www.awakenindiamovement.com
mail2aim@protonmail.ch

Dt:- 28.10.2021

Case Number before Hon'ble President of India	**PRSEC/E/2021/30755**
Case Number before Hon'ble Prime Minister of India.	**PMOPG/E/2021/0556634**
Case Number before Central Vigilance Commission.	**187036/2021/vigilance-7**

COMPLAINT U/S 154 OF CR. P.C.

As per law laid down by Constitution Bench of Hon'ble Supreme Court in **Lalita Kumari Vs. Govt. of U.P. (2014) 2 SCC 1.**

To,

Shri Subodh Kumar Jaiswal,
Director General
Central Bureau of Investigation

Sub:- i) Action under section 420, 409, 199, 200, 115, 167, 302, 109, 120 (B), 34, 52, etc., of Indian Penal Code and provisions of Prevention of Corruption Act,1988 against Shri. Satyendra Singh, Under Secretary, Ministry of Health & Family Welfare, Government of India, and others for creating false and misleading record and filing false and misleading affidavit before Hon'ble High Court, with ulterior motive to play with the life of Crores Indians with ulterior motive to give wrongful profit of thousands of crores rupees to vaccine syndicate.

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ii) Action under section 115, 302, 304, 409, 420,167, 120(B), 34,109, 52 etc., of Indian Penal Code and provisions of Prevention of Corruption Act, 1988 against Dr. V.G. Somani, Drug Controller General of India, Dr. Randeep Guleria and others for mass murders of Indians by running a misinformation campaign to misguide the people with false & misleading information that vaccines are completely safe. In fact they suppressed, twisted and dishonestly concealed the proofs and data that vaccines are not safe and having serious death causing side effects.

iii) Intimation regarding exercise of power under section 43 of Cr. P. C authorizing citizens to arrest the accused involved in cognizable and non -cognizable offence.

Sir,

I undersigned is filing this complaint as under;

1. That. the from the material available on Governments own record and Court orders from the research done by world's honest scientists it is clear that;

i) Vaccines such as Covisheild and others are not having any guarantee of any protection from corona virus i.e. SARS-COV-2.

The person who is fully vaccinated can get infection, he can spread infection and he can die due to infection. There is no difference between vaccinated and non-vaccinated people. **[Re: Dinthar Incident Aizawl Vs. State of Mizoram 2021 SCC OnLine Gau 1313]**

NOTARY GOVT. OF INDIA

ii) Vaccines are under experimental stage and are not fully approved till date. They are being used under Emergency Use Authorization.

iii) The natural immunity developed due to cure from Covid infection or due to contact with the virus is more robust and 13 times better than the vaccines. Such person are safest in the world. They cannot get infection and they cannot spread infection. They cannot die with Covid-19. Total 81 studies across the world had proved it. Dr. Sanjeev Rai, AIIMS, New Delhi had also given his interview in this regard. Two links are given below;

Link : https://youtu.be/-btDk0eSi5U

iv) Giving vaccines to persons who are having developed antibodies will cause serious harm to the said persons. Even otherwise such persons were not screened & segregated in the clinical trial and therefore they should not be vaccinated.

v) as per serosurvey conducted by ICMR there are around 67 % people in India who have developed the anti-bodies. Said number is increasing day by day and therefore at least 70% of Indians need not be vaccinated. Vaccinating those people will also cause a loss of thousand of crores to public exchequer and it is a clear case of misappropriation of public money, office and property.

vi) There are dangerous and death causing side effects of vaccines. Even the vaccine manufacturers had given the warning in their fact sheets that the person in said categories should not get vaccines. Said prohibited

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categories includes the persons having allergic problems to the contents of the vaccines etc.

vii) Around 4,956 people lost their life due to side effects of vaccines. Thousands of vaccinated people are dying at early age due to cardiac arrest which is one of the major side effects of vaccines. But their deaths are deliberately not being shown in the vaccine side effects with ulterior purposes to help the vaccine syndicate.

Link :

https://drive.google.com/file/d/1uikc1a6_KDzUx7HNLrfwaI1NJRt0D_YP/view?usp=sharing

viii) About 11 European countries banned the use of Astrazeneca (Covishield) vaccines for deaths of their citizens due to side effects of said vaccine.

Link :- https://www.aljazeera.com/news/2021/3/15/which-countries-have-halted-use-of-astrazenecas-covid-vaccine

(ix) WHO also warned people about side effects of Covishield (Astrazeneca) vaccines.

(x) If you take the Covid vax, you can never achieve full immunity again – Government stats unveil the horrifying truth.

Link: https://thetattyjournal.org/2021/10/26/if-you-take-the-covid-vax-you-can-never-achieve-full-immunity-again-government-stats-unveil-the-horrifying-truth/

(xi) There are other more effective, harmless and economical medicines available for curing the people with covid-19 infection including;

(a) Anandia's Ayurvedic composition verified by the State Government and approved by the Hon'ble High Court **In Ponnekanti Mallikarjuna Rao Vs. State of Andhra Pradesh, rep. by its Chief Secretary to Government 2021 SCC OnLine AP 2171.**

(b) The naturopathy fluid diet therapy of Dr. Bishwaroop Roy Chowdhury and recommended by National Institute of Naturopathy, Pune. Said treatment is free of cost.

The observations of **National Institute of Naturopathy, Pune** are as under;

"The enquiry report submitted by National Institute of Naturopathy of Ministry of AYUSH, Government of India regarding result of successful treatment of Covid-19 patients without any side effects.

This is a report of some initial data gathered across a single center of Ahmednagar district; where people availed only Naturopathy treatment voluntarily for a week's time period from their day of COVID confirmation and were successfully treated.

None of the cases took any medication for long term due to other systemic illnesses- like Diabetes, HTN or arthritis etc.

None of the cases took any medication for COVID.

No case reported of any untoward incident or adverse reaction to their fasting experience in Nature cure regime.

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Overall it can be concluded that; in all these cases; Nature cure therapy was successful as a regimen for the COVID cases. This can serve as model for the successful handling of all mild to severe cases of COVID and also as a preventive intervention in all the future cases."

(c) Ivermectin and Vitamin D

BIRD:-

i) https://bird-group.org/

ii) https://bird-group.org/evidence-to-recommend-ivermectin/

iii) https://bird-group.org/conference-post-event/

(xii) Vaccination of all the population will not be of any help. Many countries with full vaccination are facing outbreaks. In Kerala there are 40,000 new cases amongst vaccinated people.

Link:-
https://www.onmanorama.com/news/kerala/2021/10/12/kerala-covid-cases-deaths-among-vaccinated.amp.html

(xiii) The recent results amongst vaccinated are worrying. The death rate in vaccinated is much higher than non – vaccinated.

(xiv) (a) As per ICMR survey around 20% of vaccinated people did not have developed the antibodies.
Link:- https://www.news18.com/news/india/booster-dose-likely-to-get-icmr-nod-as-clinical-trials-find-20-vaccinated-have-no-antibodies-4193873.html

GOVT. OF INDIA NOTARY

(b) Despite the abovesaid facts a false news is published in the name of Health Ministry that vaccines are having around 97% efficacy.

Link :- -https://indianexpress.com/article/india/covid-19-vaccines-effectiveness-serious-disease-death-govt-7499316/?utm_source=whatsapp_web&utm_medium=social&utm_campaign=socialsharebuttons

(c) The reply given by Health Ministry on **20.09.2021** proves falsity of news published. The reply says that, there is no data available regarding longevity of the immune response in vaccinated individuals. The relevant Question & Answer is as under;

Question-1 Detailed information on approved vaccines to prevent corona outbreaks. As well as detailed information about their time period.

Answer:- 1. Longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, hand washing, physical distancing and other COVID-19 appropriate behaviors is strongly recommended.

(xv) As per law laid down by Hon'ble Supreme Court & High Court and as per the provisions of Universal Declaration on bioethics and Human Rights, 2005. International Covenant on Civil & Political Rights, it is the duty of authorities / Doctors / Government to give the complete information to public including side effects of the vaccines and its inefficiency.

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(xvi) No decision of efficacy of vaccines and severity of pandemic can be taken on the basis of RTPCR tests because in India the cycle threshold of RTPCR is 35 and which is having possibility of 97% false positive results.

Link:

https://drive.google.com/file/d/1Fmf7u4siFfcwgQ2fNcDOcmjVW8DwLYMl/view?usp=sharing

2. That, the recent studies have also exposed the damages of vaccinations and falsity of the narratives run by the accused in active connivance with the pharma mafia.

2.1. The number of fully vaccinated people dying from COVID is rising, according to data in most countries.

Berenson said. "In the UK, at least 70% of the people who died from COVID in August were fully vaccinated, and that's straight from British government documents."

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1018547/Technical_Briefing_23_21_09_16.pdf

Israel was nearly fully vaccinated by February.

Israel saw skyrocketing numbers of cases, even after they'd hit this so-called herd immunity threshold of 70%."

2.2. More and more cases among the fully vaccinated, and more and more of them becoming very severe to the point where the majority of their cases in the hospitals and in the ICU and those dying were fully vaccinated people."

https://childrenshealthdefense.org/defender/justin-williams-robert-malone-fully-vaccinated-covid-super-spreaders/

2.3. "A majority of gravely ill patients in Israel are double vaccinated. A majority of deaths over 50 in England are also double vaccinated.
https://www.science.org/content/article/grim-warning-israel-vaccination-blunts-does-not-defeat-delta

2.4. Also, mass vaccination of the population with the highly mutating coronavirus will only evolve perfectly vaccine-resistant strains of the virus."

https://www.livescience.com/coronavirus-vaccine-resistance-mutation-model.html
As part of the study, researchers investigated the relationship between the percentage of population fully vaccinated and new COVID cases across 68 countries and 2,947 U.S. counties that had second dose vaccine, and available COVID case data.

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

2.5. A paper published Sept. 30 in Eurosurveillance raises questions about the legitimacy of "vaccine-generated herd immunity."
The study cites a COVID outbreak which spread rapidly among hospital staff at an Israeli Medical Center — despite a 96% vaccination rate, use of N-95 surgical masks by patients and full personal protective equipment worn by providers.
The calculated rate of infection among all exposed patients and staff was 10.6% (16/151) for staff and 23.7% (23/97) for patients, in a population with a 96.2% vaccination rate (238 vaccinated/248 exposed individuals).

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The paper noted several transmissions likely occurred between two individuals both wearing surgical masks, and in one instance using full PPE, including N-95 mask, face shield, gown and gloves.
https://www.eurosurveillance.org/content/10.2807/1560
7917.ES.2021.26.39.2100822

2.6. Healthy boys may be more likely to be admitted to the hospital with heart inflammation from the Pfizer-BioNTech COVID vaccine than with COVID itself, according to a new pre-print study.

U.S. researchers found boys between the ages of 12 and 15, with no underlying medical conditions, were four to six times more likely to be diagnosed with vaccine-related myocarditis than they were to be hospitalized with COVID.

https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1

2.7. An international survey21 published in mid-March 2021 surveyed 2,002 people who had received a first dose of COVID-19 vaccine, finding that those who had previously had COVID-19 experienced "significantly increased incidence and severity" of side effects, compared to those who did not have natural immunity.

https://altnews.org/2021/10/13/are-the-covid-shots-working/

Majority of Hospitalizations Are Actually in the Vaccinated.

2.8. The oft-repeated refrain is that we're in a "pandemic of the unvaccinated," meaning those who have not received the COVID jab make up the bulk of those hospitalized and dying from the Delta variant. However, we're already seeing a shift in hospitalization rates from the unvaccinated to those who have gotten one or two injections.

For example, in Israel, the fully "vaccinated" made up the bulk of serious cases and COVID-related deaths in July 2021, as illustrated in the graphs below. The red is unvaccinated, yellow refers to partially "vaccinated" and green fully "vaccinated" with two doses. By mid-August, 59% of serious cases were among those who had received two COVID injections.

2.9. Data from the U.K. show a similar trend among those over the age of 50. In this age group, partially and fully "vaccinated" people account for 68% of hospitalizations and 70% of COVID deaths.
https://cdn.altnews.org/wp-content/uploads/2021/08/new-hospitalizations-thumb.jpg

https://cdn.nexusnewsfeed.com/images/2021/8/new-severe-covid-19-patients-thumb-1631973102161.png

https://cdn.nexusnewsfeed.com/images/2021/8/deaths-trend-thumb-1631973112475.png

https://cdn.nexusnewsfeed.com/images/2021/8/covid-19-delta-variant-hospital-admission-and-death-in-england-1631973123881.png

https://www.science.org/content/article/grim-warning-israel-vaccination-blunts-does-not-defeat-delta

https://www.standard.co.uk/news/uk/england-delta-donald-trump-government-public-health-england-b951620.html

3. 81 Research Studies Confirm Natural Immunity to COVID 'Equal' or 'Superior' to Vaccine Immunity

(151)

https://childrenshealthdefense.org/defender/research-natural-immunity-covid-brownstone-institute/

3.1. A new study finds that this dominant variant can grow in the noses of vaccinated people as strongly as in unvaccinated people.

https://www.nationalgeographic.com/science/article/evidence-mounts-that-people-with-breakthrough-infections-can-spread-delta-easily

3.2. A study published Sept. 30, in the peer-reviewed European Journal of Epidemiology Vaccines found "no discernible relationship" between the percentage of population fully vaccinated and new COVID cases.
In fact, the study found the most fully vaccinated nations had the highest number of new COVID cases, based on the researchers' analysis of emerging data during a seven-day period in September.

3.3. "Most recently, researchers in Israel report that fully vaccinated persons are up to 13 times more likely to get infected than those who have had a natural COVID infection.

3.4. "In one analysis, comparing more than 32,000 people in the health system, the risk of developing symptomatic COVID-19 was 27 times higher among the vaccinated, and the risk of hospitalization eight times higher.'

NOTARY GOVT. OF INDIA Adv. Shilpa N. Dhanoa Mumbai Maharashtra Reg. No. 15375 Exp. Dt. 13-11-2024

3.5. "The study also said that, while vaccinated persons who also had natural infection did appear to have additional protection against the Delta variant, the

vaccinated were still at a greater risk for COVID-19-related-hospitalizations compared to those without the vaccine, but who were previously infected.

"This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity,' study authors said.

https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1

3.6. Pfizer Scientist: Natural Immunity Is Better Than the COVID Vaccine

Project Veritas' fourth video in its COVID vaccine investigative series quotes two Pfizer scientists who said natural immunity is better than Pfizer's vaccine, and one who called the company "evil" and said it's "run on COVID money."

https://childrenshealthdefense.org/defender/project-veritas-pfizer-scientist-nick-karl-natural-immunity-covid-vaccine/

4. An international group of physicians and scientists signed a declaration Friday accusing COVID-19 policy-makers of "crimes against humanity" for preventing the use of life saving treatments on their patients.

As of Monday morning, the Physicians Declaration had garnered more than 4,600 signatures. The signers accused policymakers of forcing a "one-size-fits-all" treatment strategy, resulting in "needless illness and death," rather than "upholding fundamental concepts of the individualized."

According to Global COVID Summit, the declaration was created by physicians and scientists during the Rome COVID Summit. The signatories are professionals, many of whom are on the front lines of treating COVID patients.

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https://globalcovidsummit.org/news/welcome-to-the-global-covid-summit

5. Paper that came out of Israel which showed that natural antibodies fall about 5% or 10 percent a month, while vaccine-induced immunity falls more than 40% per month."

5.1. One of the largest studies to date, published in Science in February 2021, found that although antibodies declined over eight months, memory B cells increased over time, and the half-life of memory CD8+ and CD4+ T cells suggests a steady presence.

https://www.science.org/doi/10.1126/science.abf4063?keytype2=tf_ipsecsha&ijkey=d4c191c8fbab5d0d2f504814b6f9b2e9d3a1f4b2

5.2. In a study by New York University published May 3, the authors studied the contrast between vaccine immunity and immunity from prior infection as it relates to stimulating the innate T-cell immunity — which is more durable than adaptive immunity through antibodies alone.
The authors concluded:

"In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was largely absent in vaccine recipients. Increased interferon signaling likely contributed to the observed dramatic upregulation of cytotoxic genes in the peripheral T cells and innate-like lymphocytes in patients but not in immunized subjects."

The study further noted:

"Analysis of B and T cell receptor repertoires revealed that while the majority of clonal B and T cells in COVID-19 patients were effector cells, in vaccine recipients, clonally expanded cells were primarily circulating memory cells."

This means natural immunity conveys much more innate immunity, while the vaccine mainly stimulates adaptive immunity — as effector cells trigger an innate response that is quicker and more durable, whereas memory response requires an adaptive mode that is slower to respond.
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3838993

5.3. According to a longitudinal analysis published July 14 in Cell Medicine, most recovered COVID patients produced durable antibodies, memory B cells and durable polyfunctional CD4 and CD8 T cells — which target multiple parts of the virus.

"Taken together, these results suggest broad and effective immunity may persist long-term in recovered COVID-19 patients," the authors said.

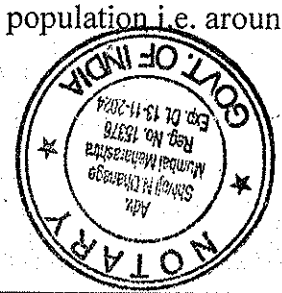
In other words, unlike with the vaccines, no boosters are required to assist natural immunity.
https://archives.simplelists.com/nfu/msg/17519290/

6. However, some dishonest, Anti Human, Money Minded and Anti National officials of Central and State Government have conspired with each other and in furtherance of their common intention and ulterior motives they are running false narratives and conspiracy theories to cheat, mislead and misguide people that :-

(a) vaccines are completely safe.

(b) Vaccines are the only protection from Covid-19 pandemic.

(c) 100 % population i.e. around 135 Crores Indians should be vaccinated.



7. Accused Doctor D.G. Somani, Drug Controller General of India in furtherance of the said conspiracy had made a false and misleading statement that, the vaccines are 110% safe.

The exact words in his interview on **4th January 2021,** with NDTV are as under;

> *"Drug Controller General of India VG Somani said,. **"We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe".***

Link: https://www.ndtv.com/india-news/oxford-covid-19-vaccine-bharat-biotechs-covaxin-get-final-approval-by-drug-regulator-will-be-indias-first-vaccines-2347053

8. The falsity of abovesaid statement of accused D. G. Somani is exposed from the proofs and evidences given in above paras.

This makes accused D.G. Somani liable for punishment under section 52, 302, 115, 420 etc of Indian Penal Code.

9. Accused Dr. Randeep Guleria and few other co-accused were hired by the YouTube to mislead the people that vaccines are completely safe.

Their videos are available on the YouTube under caption know from the experts

10. That, the accused vaccine manufacturers Shri. Adar Poonawala of Serum Institute who is manufacturing covishield in collaboration with mastermind accused Bill gates and others have proven their complete complicity in crimes as they have not given any counter and correct version in public and media to

counter the false narratives and conspiracy theories about efficacy of his vaccines.

In fact their act of commission and omission are sufficient to punish them as per section 120 (B), 34 etc., of Indian Penal Code.

11. Some action is also required against other manufactures.

12. That, because of abovementioned acts of commission and omission by the decision-making authorities in Health Ministry and supporting National Task Force the country has suffered following losses of money and life;

(i) Government of India included the vaccines in national programme and had given around **100** Crores doses to the Indians which is a misappropriation and total loss of more than **Thirty Thousand Crores** as on **24.10. 2021.**

(ii) More than 4,000 people died due to side effects of vaccination who took vaccines due to misleading advertisement and misrepresentation by Government authorities.

(iii) Crores of people faced various side effects of vaccines including permanent disabilities.

13. That, the level of conspiracy of organized crime syndicate of accused can be easily seen from the very fact that they managed the Print, Electronic and social media in such a way that the correct information was not allowed to reach the common people.

The policies framed by the YouTube, Twitter, Facebook etc., is a sufficient proof of their participation in crime.

Section 10 of Evidence Act and Section 120 (B) of Indian Penal Code makes all the concerned media persons and any other person publishing false and misleading news to facilitate conspiracy as an accused.

[Raman Lal vs. State 2001 Cri. L. J. 800, CBI Vs. Bhupendra Champaklal Dalal 2019 SCC OnLine Bom 140]

14. Hence, all the accused are liable for prosecution and severe punishment under section 52, 115, 302, 409, 304-A, 304, 323, 336, 192, 193, 199, 200, 201,202, 52, 120 (B), 34, etc., of Indian Penal Code.

And other provisions of Prevention of Corruption Act. All the provisions of IPC are annexed herewith.

15. Since, the offence are of mass murders and are gravest and heinous crimes and having punishment up to death penalty or up to life imprisonment, therefore all the accused needs to be arrested forthwith.

16. That, if accused are not arrested forthwith then they will continue to do their offences and then for each loss of life and every loss of public money and property you should be responsible and you may be liable for action u/s 166, 218, 201, 202, 120(B), 34, 52 etc., of IPC.

17. That as per law laid down by Hon'ble Supreme Court in catena of decisions the concerned Minister including Health Minister Shri. Mansukh Mandaviya will also be liable for prosecution if he don't disassociate himself from the conspiracy and fails to takes action against the guilty officials. **[Parm Bir Singh Vs. State Of Maharashtra 2021 SCC OnLine Bom 516, State of**

Maharashtra Vs. Sarangdharsingh Shivdassingh Chavan (2011) 1 SCC 577]

18. Needless to mention here that, a detailed representation is already given to Health Minister Shri Mansukh Mandviya on **23.09.2021.** A copy of which is enclosed herewith.

19. That accused Shri. Satyendra Singh, under Secretary of Health Ministry in his reply affidavit dated filed before Hon'ble Bombay High Court in Writ Petition No. 1820 of 2021 in the matter between **'Mr. Nelson Paulo vs. The State of Goa'** made a false statement and declaration as under;

> *" **I, Satyendra Singh,** S/o Sh. Phool Singh, aged about 41 years, working as Under Secretary COVID Vaccination Administration Cell in the Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi do hereby solemnly affirm and sincerely state as follows:*
>
> ***8.** That, it is further humbly submitted that however, since this matter is related to vaccination, and Union of India is the respondent no. 6; thus, it is pertinent to present the stand of Union of India with regards to vaccination. It is humbly submitted that vaccination for Covid-19 is a matter of social obligation and is of a larger public interest. **As a responsible citizen looking to contribute in the nation and humanity's fight against the Pandemic of Covid-19 infection, it is natural that every person would get her/himself vaccinated against Covid-19 so as to prevent the spread of Covid-19 infection in the community.***
>
> *12. Therefore, it is humbly submitted that **in order to prevent the transmission and spread of Covid-19 pandemic, it is expected that all responsible citizens especially the teachers who are also***

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<u>the role models and influencers for the society get themselves vaccinated</u> *as soon as possible against Covid-19 and meticulously follow Covid Appropriate Behaviour.*

VERIFICATION

Verified at New Delhi on October 08, 2021 that the contents of this affidavit are true and correct to the best of my knowledge and belief and ***<u>no part of it is false thereof, and no material fact has been canceled therefrom.</u>***

SD/-

DEPONENT"

20. From the material available on record it is clear that the above affidavit is false and drafted with ulterior purposes by dishonest concealment and suppression of material facts. Hon'ble Supreme Court and Hon'ble High Court had made it clear that such intellectually dishonest officer should be punished for filling false affidavit.

In **<u>Samson Arthur Vs. Quinn Logistic India Pvt. Ltd. and Ors. [2016] 194 Comp Cas 100 (AP)</u>** it is ruled as under;

<u>SUPPRESSIO VERI SUGGESTIO FALSI</u>

A] Suppression of relevant and material facts is as bad as Suggestion falsi i.e., a false representation deliberately made. Both are intended to dilute- one by inaction and the other by action. "Suppressio veri Suggestio falsi"-suppression of the truth is equivalent to the suggestion of what is false.

B] A false statement willfully and deliberately made, and a suppression of a relevant and material fact, interfere with the due course of justice and obstruct the administration of justice.

Dishonesty should not be permitted to bear fruit and confer benefit to the person who has made a misrepresentation.

It is the duty of the Court, once false averment of facts are discovered, to take appropriate steps to ensure that no one derives any benefit or advantage by abusing the legal process. Fraudulent and dishonest litigants must be discouraged. (A. Shanmugam24). It is the bounden obligation of the Court to neutralize any unjust and/or undeserved benefit or advantage obtained by abusing the judicial process.

21. Accused Satyendra Singh also made similar false and misleading statement in his reply dated 8.10.2021 under RTI Act, to applicant Shri Hari Ram Mali.

22. Hence, he is actively involved in the conspiracy and therefore liable for prosecution under additional offences u/s 199, 200, 167, 120(B), 34, 52 etc., of IPC.

23. Due to wrong statement & false information given by accused Satendra Singh, many people took vaccines or compelled to take vaccines. They ultimately died or suffered serious side effects including life time disabilities. Therefore, he is also liable for prosecution under section 115,302,304-A,420 etc of IPC.

24. <u>WRONGFUL BENEFITS OF LACS OF CRORES TO VACCINE SYNDICATE:-</u>

24.1. That apart from ineffectiveness of vaccines, the another offence is of corruption. The interview of Shri. Krishna Ella, Managing Director (M.D.) of Bharat Biotech (Covaxin) is sufficient to expose the corruption in bringing the vaccines in national program and its promotion by the Government's officials.

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That in his interview on August, 2020. Mr. Krishna Ella said that the vaccine will be sold below the price of a water bottle means below 20 rupess.

Link:https://twitter.com/Vini_J26/status/1398873489730960?s=20

24.2. If that is the case then how the Government is paying an amount of Rs. 283/- per vaccine. How much bribe is given to the concerned Government authorities for such a loss of around 30,000 Crores in between last 1 year.

24.3. The enquiry and Narco Analysis, Lie Detect Test of accused Satyendra Singh, Dr. Randeep Guleria will reveal the amount of bribe given to the Government's officials to help the vaccine syndicate.

24.4. Earlier in 72nd report by Parliamentary Committee the officials of ICMR and DCGI etc., were involved in corruption to help vaccine syndicate.

24.5. Other complaints exposing entire conspiracy are annexed herewith.

Link: -

1. **https://drive.google.com/file/d/15BJhuMr2GJYxaBnufUUpq2z-31lxPaII/view?usp=sharing**

2. **https://drive.google.com/file/d/1qM80s36CptHM8mRqVS5mb1VyD-V4FlCN/view?usp=sharing**

25. Hence, you are requested to forthwith register an FIR against the accused and arrest them immediately.

26. Please take a note that, you are bound to take action **within 7 days** and to arrest accused or to inform the reasons in writing to me as mandated by the Constition

Bench of Hon'ble Supreme Court in **Lalita Kumari Vs. Govt. of U.P. (2014) 2 SCC 1.** If you failed to do so then we will exercise their right under **section 43** of Cr. P.C. and they will arrest the accused

Sincerely

Ambar H. Koiri
B – 1501, Runwal Hts.
L.B.S. Marg, Mulund (W)
Mumbai – 400 080.

"EXHIBIT "K"

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REPORT NO.
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सत्यमेव जयते

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE
ON HEALTH AND FAMILY WELFARE

SEVENTY SECOND REPORT

Alleged Irregularities in the Conduct of Studies using Human Papilloma Virus (HPV) Vaccine by Path in India (Department of Health Research, Ministry of Health and Family Welfare)

(*Presented to the Rajya Sabha on* 30*th August,* 2013)
(*Laid on the Table of Lok Sabha on* 30*th August,* 2013)

भारतीय संसद, राज्य सभा
PARLIAMENT OF INDIA, RAJYA SABHA

Rajya Sabha Secretariat, New Delhi
August, 2013/Bhadra, 1935 (Saka)

NOTARY GOVT. OF INDIA

TRUE COPY
ADVOCATE FOR Petitioners

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Hindi version of this publication is also available

PARLIAMENT OF INDIA
RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON HEALTH AND FAMILY WELFARE

SEVENTY SECOND REPORT

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(*Presented to the Rajya Sabha on* 30*th August,* 2013)
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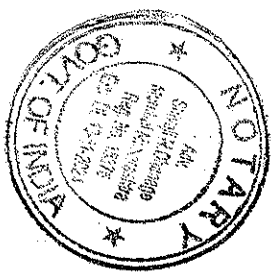
सत्यमेव जयते

Rajya Sabha Secretariat, New Delhi
August, 2013/Bhadra, 1935 (Saka)



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COMPOSITION OF THE COMMITTEE
(2009-10)

RAJYA SABHA

1. Shri Amar Singh — *Chairman*
2. Shrimati Viplove Thakur
#3. Dr. Radhakant Nayak
4. Shri Janardan Dwivedi
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
7. Shrimati Brinda Karat
8. Shrimati Vasanthi Stanley
@9. Dr. M.A.M. Ramaswamy
10. Dr. Anbumani Ramadoss

LOK SABHA

11. Shri J. M. Aaron Rashid
12. Shri Ashok Argal
13. Shrimati Sarika Devendra Singh Baghel
14. Shri Vijay Bahuguna
15. Dr. Chinta Mohan
16. Shrimati Tabassum Hasan
17. Dr. Sanjay Jaiswal
18. Shri S. R. Jeyadurai
19. Dr. (Shrimati) Kruparani Killi
20. Shri N. Kristappa
21. Dr. Tarun Mandal
22. Shri Datta Meghe
23. Dr. Jyoti Mirdha
24. Shrimati Jayshreeben Patel
25. Shri R.K. Singh Patel
26. Shri M. K Raghavan
27. Dr. Anup Kumar Saha
28. Shrimati Meena Singh
29. Dr. Arvind Kumar Sharma
30. Shri Pradeep Kumar Singh
31. Shri Ratan Singh

SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Assistant Director*
Shri Satis Mesra, *Committee Officer*

Ceased to be a Member *w.e.f.* 1st July, 2010.
@ Ceased to be a Member *w.e.f.* 30th June, 2010.

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COMPOSITION OF THE COMMITTEE
(2010-11)

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
2. Shri Janardan Dwivedi
3. Shrimati Viplove Thakur
4. Dr. Vijaylaxmi Sadho
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
@7. Shrimati Brinda Karat
8. Shrimati Vasanthi Stanley
9. Shri Rasheed Masood
*10. Shrimati B. Jayashree

LOK SABHA

11. Shri Ashok Argal
12. Shrimati Sarika Devendra Singh Baghel
13. Shri Vijay Bahuguna
14. Shrimati Tabassum Hasan
15. Dr. Sanjay Jaiswal
16. Shri S. R. Jeyadurai
17. Dr. Kruparani Killi
18. Shri Nimmala Kristappa
19. Dr. Tarun Mandal
20. Shri Datta Meghe
21. Dr. Jyoti Mirdha
22. Dr. Chinta Mohan
23. Shrimati Jayshreeben Patel
24. Shri R.K. Singh Patel
25. Shri M. K Raghavan
26. Shri J. M. Aaron Rashid
27. Dr. Anup Kumar Saha
28. Dr. Arvind Kumar Sharma
29. Shrimati Meena Singh
30. Shri Pradeep Kumar Singh
31. Shri Ratan Singh

SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*
Shri R.B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Assistant Director*
Shri Satis Mesra, *Committee Officer*

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* Ceased to be a Member *w.e.f.* 18th August, 2011.
@ Nominated to the Committee *w.e.f.* 21st September, 2010.

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COMPOSITION OF THE COMMITTEE
(2011-12)

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
*2. Shri Janardhan Dwivedi
%3. Shrimati Viplove Thakur
4. Dr. Vijaylaxmi Sadho
5. Shri Balbir Punj
6. Dr. Prabhakar Kore
7. Shrimati Vasanthi Stanley
^8. Shri Rasheed Masood
9. Shrimati B. Jayashree
10. Shri Derek O'Brien

LOK SABHA

11. Shri Ashok Argal
&12. Shrimati Harsimrat Kaur Badal
@13. Shri Vijay Bahuguna
14. Shrimati Raj Kumari Chauhan
15. Shrimati Bhavana Gawali
16. Dr. Sucharu Ranjan Haldar
17. Dr. Monazir Hassan
18. Dr. Sanjay Jaiswal
19. Shri S. R. Jeyadurai
20. Shri P. Lingam
21. Shri Datta Meghe
22. Dr. Jyoti Mirdha
23. Dr. Chinta Mohan
24. Shri Sidhant Mohapatra
25. Shrimati Jayshreeben Kanubhai Patel
26. Shri M. K Raghavan
27. Shri J. M. Aaron Rashid
28. Dr. Arvind Kumar Sharma
29. Shri Radhe Mohan Singh
30. Shri Ratan Singh
31. Dr. Kirit Premjibhai Solanki

---

* ceased to be a Member *w.e.f.* 27th January, 2012 and re-nominated to the Committee on 2nd February, 2012.
** Vacant *vide* resignation *w.e.f.* 2nd April, 2012.
% Vacant *vide* resignation *w.e.f.* 9th March, 2012 and renominated as Member *w.e.f.* 04th May, 2012.
& ceased to be a Member *w.e.f.* 29th June, 2012.
@ vacant *vide* resignation *w.e.f.* 30th April, 2012.

SECRETARIAT

Shrimati Vandana Garg, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*

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COMPOSITION OF THE COMMITTEE
(2012-13)

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
2. Dr. Vijaylaxmi Sadho
*3. Dr. K. Chiranjeevi
4. Shri Rasheed Masood
5. Dr. Prabhakar Kore
6. Shri Jagat Prakash Nadda
7. Shri Arvind Kumar Singh
&8. Shri D. Raja
9. Shri H. K. Dua
10. Shrimati B. Jayashree
^11. Shri Mohd. Ali Khan
%12. Shri Rajkumar Dhoot

LOK SABHA

@13. Shri Ashok Argal
14. Shri Kirti Azad
15. Shri Mohd. Azharuddin
16. Shrimati Sarika Devendra Singh Baghel
17. Shri Kuvarjibhai M. Bavalia
18. Shrimati Priya Dutt
19. Dr. Sucharu Ranjan Haldar
20. Mohd. Asrarul Haque
21. Dr. Monazir Hassan
22. Dr. Sanjay Jaiswal
23. Dr. Tarun Mandal
24. Shri Mahabal Mishra
25. Shri Zafar Ali Naqvi
26. Shrimati Jayshreeben Patel
27. Shri Harin Pathak
28. Shri Ramkishun
29. Dr. Anup Kumar Saha
30. Dr. Arvind Kumar Sharma
31. Dr. Raghuvansh Prasad Singh
32. Shri P.T. Thomas
#33. Shri Chowdhury Mohan Jatua

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* Ceased to be Member of the Committee *w.e.f.* 28th October, 2012.
& Ceased to be Member of the Committee *w.e.f.* 24th July, 2013.
^ Nominated as a Member to the Committee *w.e.f.* 27th August, 2013.
% Nominated as a Member to the Committee *w.e.f.* 27th August, 2013.
@ Ceased to be Member of the Committee *w.e.f.* 9th January, 2013.
\# Nominated as a Member to the Committee *w.e.f.* 14th December, 2012.

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*
Shri Pratap Shenoy, *Committee Officer*

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PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, do hereby present this Seventy Second Report of the Committee on the "Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India.

2. The Committee first took up the issue about the trial of HPV vaccine on the children in Khammam district of Andhra Pradesh and Vadodra district of Gujarat and reported deaths of the children therefrom in its meeting held on 06th April, 2010 during the course of examination of Demands for Grants (2010-11) of Department of Health Research and sought exact status in this regard from the Secretary, Department of Health Research. Subsequently, taking serious view of the procedural and ethical lapses on the part of the Ministry, the Committee sought the matter of allowing trial of the vaccine as also the approval for its marketing in the country to be enquired into. The Committee also desired the Ministry to take further appropriate action in the matter and apprise it of the follow-up action taken in this regard at the earliest. As a sequel to the Committee's recommendation, a Committee was appointed by the Government of India to enquire into"Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India on 15th April,2010. The Final Report of the Committee appointed by the Government of India to enquire into"Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health(PATH) in India was made on 15th February,2011.

3. The Committee thereafter deliberated on the subject in its meetings held on 25th July, 2011 and 24th May, 2013.

4. During the course of examination of the subject, the Committee heard the views of the Secretary, Department of Health Research and other officials of the Department on 25th July, 2011 and Secretary, Department of Health Research and Drug Controller General of India (DCGI) on 24th May, 2013.

5. During the finalization of its Report, the Committee relied upon the following documents/ papers:–

(i) Background note received from the Ministry;

(ii) Final Report of the Committee Appointed by the Government of India to enquire into "Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine" by Programme for Appropriate Technology in Health (PATH) in India;

(iii) Oral Evidences tendered by Secretary, Department of Health Research and DCGI; and

(iv) Replies to the questionnaires received from the Department of Health Research.

6. The Committee considered the Draft Report and adopted the same in its meeting held on 29th August, 2013.

7. For facility of reference and convenience, observations and recommendations of the Committee have been printed in bold letters in the body of the Report.

BRAJESH PATHAK,
Chairman,
Department-related Parliamentary Standing
Committee on Health and Family Welfare

NEW DELHI;
29th August, 2013
Bhadra 7, 1935 (*Saka*)

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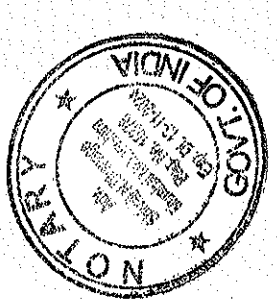
ACRONYMS

1.	AE	– Adverse Event
2.	AEFI	– Adverse Event Following Immunization
3.	ANM	– Auxiliary Nurse Midwife
4.	AP	– Andhra Pradesh
5.	AIIMS	– All India Institute of Medical Sciences
6.	ASHA	– Accredited Social Health Activist
7.	CDSCO	– Central Drugs Standard Control Organisation
8.	CTRI	– Clinical Trials Registry- India
9.	CORT	– Centre for Operations Research and Training
10.	DCGI	– Drug Controller General of India
11.	DGHS	– Director General of Health Services
12.	DHR	– Department of Health Research
13.	DG, ICMR	– Director General, Indian Council of Medical Research
14.	FCRA	– Foreign Currency Regulation Act
15.	FERA	– Foreign Exchange Regulation Act
16.	FEMA	– Foreign Exchange Management Act
17.	GCP	– Good Clinical Practice
18.	GAVI	– Global Alliance for Vaccines and Immunizations
19.	HPV	– Human Papilloma Virus
20.	HMSC	– Health Ministry Screening Committee
21.	HoD	– Head of Department
22.	ICMR	– Indian Council of Medical Research
23.	MEA	– Ministry of External Affairs
24.	MHA	– Ministry of Home Affairs
25.	MoU	– Memorandum of Understanding
26.	MEA	– Ministry of External Affairs
27.	MHA	– Ministry of Home Affairs
28.	NGO	– Non-Governmental Organization
29.	NRHM	– National Rural Health Mission

30. NTAGI	–	National Technical Advisory Group on Immunization
31. O&G	–	Obstetrics and Gynaecology
32. PATH	–	Programme for Appropriate Technology in Health
33. PBC	–	Public Benefit Corporation
34. PPP	–	Public-Private Partnership
35. PSURs	–	Periodic Safety Update Reports
36. RoC	–	Registrar of Companies
37. RBI	–	Reserve Bank of India
38. SAE	–	Serious Adverse Event
39. UIP	–	Universal Immunization Programme
40. USFDA	–	United States Food and Drug Administration
41. WHO	–	World Health Organisation



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REPORT

I. BACKGROUND

1.1 During March, 2010 the entire world was shocked by the media reports about the deaths of some female children and adolescents in Khammam district of Andhra Pradesh after being administered Human Papilloma Virus (HPV) vaccines. The vaccination trials were carried out by an American agency *viz.* Programme for Appropriate Technology in Health (PATH). The project was reportedly funded by Bill and Melinda Gates Foundation, an American charity.

1.2 Several questions were asked and concerns expressed in the media and well meaning quarters on the role of government agencies including Indian Council of Medical Research (ICMR) and Drugs Controller General of India (DCGI) in approving and facilitating the trials, which was against all laws of the land and even international ethical norms and rules; misuse of government funds, man-power, facilities and infrastructure for a private project of dubious nature; use of logo of National Rural Health Mission (NRHM), an official programme of the Union Government during these vaccination drives to give it respectability and official endorsement; and above all the blatant violation by PATH of all regulatory and ethical norms laid down by the Government of India for the purpose as also possible violations of such norms prescribed and very scrupulously enforced in the Country of its origin *viz.* United States of America.

1.3 Taking cognizance of these reports, the Committee (2009-10) which was examining the Demand for Grants (2010-11) of the Department of Health Research at that point of time sought a detailed clarification from the Government in the matter. In response the Secretary of the Department of Health Research and DG, ICMR informed the Committee that it was a vaccine against the Human Papilloma Virus which causes cervical cancer in women. The Drugs Controller General, India had given approval for marketing of HPV vaccines in India as a vaccine to be prescribed by the clinicians as per schedule 'Y' of the Drugs and Cosmetics Rules and then for a post-marketing surveillance trial. The Committee was informed that the proposal for trial came two years earlier (though later on during the Committee's examination it was proved that it began in 2006) before the ICMR through PATH, an American agency, and the logic for allowing the trial was to see acceptability of this vaccine on Indian population. Besides, these trials were approved by the National Ethical Committee and the State Ethical Committee.

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.

1.5 Hugely perturbed by these blatant violations, the Committee in its Forty first Report on Demands for Grants (2010-11) of the Department of Health Research made the following recommendations on this issue:

> "Taking serious view of procedural and ethical lapses on the part of the Ministry, the Committee sought the matter of allowing trial of the vaccine as also the approval for its marketing in the country to be enquired into by a premier investigating agency and to take further appropriate follow-up action in the matter. It also asked that findings of the investigating agency and the follow-up action taken in this regard may be furnished to the

Committee at the earliest. The Committee, taking a serious view in the matter, recommends to the Department of Health Research that in future all guidelines and norms should be adhered to before allowing trials of any drug including vaccines on Indian population. The Committee also recommends that the DCGI should observe optimum precautions and follow all norms and guidelines while allowing marketing of any drug including the vaccines in the Indian market".

1.6 The Department of Health Research in its Action Taken Note on the above recommendations submitted the following:

"PATH in partnership with State Governments of Gujarat and Andhra Pradesh was implementing an operational research study related to cancer of cervix prevention in India. ICMR is providing technical support and consultation for development of protocol and plan of monitoring.

The study utilized both the brands of HPV vaccines available in the market (Gardasil by Merck in Andhra Pradesh; and Cervarix by GSK in Gujarat). In view of certain complaints received, the State Governments have been advised not to carry out further vaccination till further orders. To ascertain the facts of the matter, Minister for Health and Family Welfare appointed a Committee comprising of Dr. S.S. Agarwal, former Director, Advanced Centre for Training, Research, Education on Cancer, Dr. S.P. Aggarwal, former DGHS and Dr. Sunita Mittal, HoD, Obstetrics and Gynaecology, AIIMS to investigate ethical issues raised in the matter."

1.7 Not being satisfied with the action taken by the Government on its Recommendations, the Committee in its Forty eighth Report further recommended the following:

"The Committee observes that as a result of its intervention, the State Governments have been advised by the Department not to carry out HPV vaccinations and a Committee has been appointed to investigate ethical issues raised in the matter. The Committee is not aware about the date of setting up of the Committee. However, the absence of any specific time-line for submission of Report of the Committee in the Action Taken Note given by the Department makes the Committee somewhat apprehensive. Like so many Committees set up by the Government, findings of this Committee, as and when received, may remain on paper only. The Committee, therefore, recommends that every effort should be made to expedite the Report of this Committee so that real facts about the HPV Vaccine trial are made known without any further delay and corrective measures not only in respect of this case but for all such ongoing/proposed clinical trials of drugs/vaccines are taken. The Committee also recommends that the Department should at least now work in close coordination with other concerned departments/organizations to undertake a comprehensive analysis of the process of granting permission to research studies having hazardous effects on health and put in place a fool-proof system for pre-empting unethical research studies."

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. The succeeding paragraphs contain the details of the matter, Committee's findings and recommendations.

1.9 Cancer of the cervix (mouth of uterus) popularly called Cervical Cancer has been there ever since the dawn of human race. Over the years, preventive and treatment protocols have been developed by medical experts.

1.10 The Committee was given to understand that on June 1, 2006 the American drug regulator, the U. S. Food and Drug Administration (USFDA) approved the first vaccine to prevent HPV virus

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that is claimed to cause 70% of cervical cancers, under the brand name of Gardasil by a US drug company namely, Merck.

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.

1.12 With this background a clinical trial under the title 'Post-licensure observational study of Human Papilloma Virus Vaccination – Demonstration Project' was undertaken by Programme for Appropriate Technology in Health (PATH), an agency of American origin. 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. The State Governments of Andhra Pradesh and Gujarat swayed by the involvement of ICMR followed suit.

II. NATURE OF PROJECT

2.1 Given the controversy surrounding the project, the Committee was keen to know from the Government the exact nature of the project. The Committee noticed that there was fundamental difference between the perceptions of Drugs Controller General of India (DCGI) and Department of Health Research (DHR)/Indian Council of Medical Research (ICMR) on the actual nature of the project. 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. Experts also upheld these views and were very clear about it. However, PATH described the project as an "observational study" since "it did not conform to the definition of clinical trial".

2.2 The Committee found from the information furnished to it that ICMR representative on the Project Advisory Committee not only opposed DCGI but also argued that the nature of the project does not require them to follow the clinical trial rules, including reporting of serious adverse effects within a specific time-frame.

2.3 The Committee in this regard took note of the expert opinion given in the Inquiry Committee report which questioned the PATH description of the project and observed that since "the demonstration project is a study of a pharmaceutical product carried out on humans and since the primary objectives include the study of serious adverse effects, it is clear that clinical trial rules and guidelines should apply".

2.4 In fact, the Inquiry Committee in one of its findings very pointedly stated that the investigators had variously labeled the research project carried out by them as "Observational Study/Demonstrational Study," etc. to establish that the study was not a clinical trial. But, since the project had been carried as research on human participants, it had to follow all the guidelines and statutory requirements applicable for research on human participants.

2.5 **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.

III. ROLE OF DEPARTMENT OF HEALTH RESEARCH/INDIAN COUNCIL OF MEDICAL RESEARCH

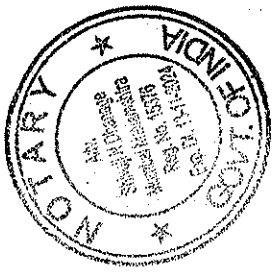
3.1 One of the functions mandated to the Department of Health Research/ICMR is promotion and coordination of basic, applied, clinical and operational research in medical, health and bio-medical field through development of infrastructure, manpower and skills. Uniform Ethical Guidelines for bio-medical Research on human subjects are incorporated in Good Clinical Practice (GCP) and ICMR documents. These guidelines outline the procedure for Ethics Committees review of clinical trials in India using the human beings as participants. All institutions and investigators in the country which carry out any form of biomedical research involving human beings are obliged to follow these guidelines in letter and spirit to protect participants.

3.2 As per the records made available to the Committee, the first documented contact made by PATH with ICMR took place, as early as, on 5th October 2006. An employee of PATH India sent an e-mail to Deputy Director of National AIDS Research Institute, ICMR expressing sorrow that she could not travel to Seattle, United States for "Formative Research Workshop" (on HPV vaccine) scheduled for October 24-26, 2006. Apparently, PATH functionaries were in touch with ICMR officials on an informal basis in the past.

3.3 Within a few days, a meeting took place between PATH and ICMR officials on 13 October, 2006 at PATH office in New Delhi where it was stated that "HPV vaccine, when available (in India), can prevent HPV and cervical cancer." The possibility of Global Alliance for Vaccines and Immunizations (GAVI) subsidizing the cost of vaccine for the first 2 - 4 years was also mentioned. Evidence (on role, utility of vaccine) made available to Government of India and States would "help to decide on public sector (State funded) introduction of the vaccine."

3.4 On 16 November, 2006, a draft Memorandum of Understanding (MoU) between PATH and ICMR was circulated by PATH which stated that "Parties (PATH and ICMR) desiring to explore collaboration to support public sector decision regarding HPV vaccine introduction in India and to generate necessary evidence to allow the possible introduction of HPV vaccine into India's Universal Immunization Programme."

3.5 Thus as early as October-November 2006, it was clear that the main objective of PATH project was to generate evidence that would facilitate the introduction of HPV vaccine Gardasil into government-funded immunization program in India. This appears to be a promotional activity for the benefit of manufacturing company because at that time only one HPV vaccine, Gardasil had been approved abroad, though not in India. Indeed "the key object of the project activities in India



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is to gather information and help the government make a decision about the introduction of HPV vaccine". The Country Director of PATH in India emphasized that "this needs to be our consistent message throughout the project." In the formal proposal submitted by PATH to the ICMR on Project Proposals involving Foreign Collaboration/Assistance, the applicant clearly stated under Para 9. Objectives of the Project: ".....Introduction of HPV vaccines into Universal Immunization Program." The Committee found repeated mention of similar objectives at several places in various documents submitted by the Ministry. The Memorandum of Understanding (MoU) was signed by PATH and ICMR on 20 February, 2007. At that time only Gardasil was marketed in some countries in the world though not approved for use in India. The MoU stated that the purpose of the project was:

(i) Increasing understanding of HPV vaccine (*i.e.* Gardasil) introduction.

(ii) To help in decision-making related to the use of HPV (*i.e.* Gardasil) vaccine in the public and private sector.

3.6 The Committee enquired from the Secretary of Department of Health Research (DHR) and DG, ICMR, as to whether the Department or CDSCO, before approving the project had really reviewed its actual design. The Committee highlighted the observations of the experts of the Inquiry Committee who have opined that the design of the project itself was faulty. For instance, in the documents there was no column whatsoever for Serious Adverse Events (SAE) and no diary was to be maintained as part of the protocol.

3.7 Moreover, much before the trials started, many expected side effects including anaphylaxis (severe allergic reaction), syncope, convulsions, asthma, central demyelinating diseases, acute disseminated encephalomyelitis, Idiopathic Thrombopenia Purpura, etc. were known. And astonishingly, as the records stated, while ICMR functionary was worried of bad publicity in case of side effects, PATH did not provide for urgent expert medical attention in case of serious adverse events whether known or unexpected.

3.8 After going through the final report and interactions with the Secretaries of the Department of Health and Family Welfare and the Department of Health Research/ICMR and DCGI, the Committee felt that it needs clarification as to under what category, permission was given to PATH to conduct such study on the Indian people and whether the programme was a clinical trial or promotional activity. The Committee took note of the fact that the Enquiry Committee meeting held on September 27, 2010, noted as under **(Annexure-A):**

> "....Besides the factual information about the terms of reference the Committee was greatly concerned with the aspect of commercial interests of manufacturers influencing the Government policy on this expensive vaccine. The committee observed that the study was initiated by PATH on its own ..... without any reference from the National Technical Advisory Group on Immunization (NTAGI), the official body of the GOI on vaccines.....It is not clear whether the State expenses were funded by PATH or came from their own resources. The monetary contributions of ICMR are also not clear. The Committee therefore felt that it would be in the fitness of the inquiry to document the sources and magnitude of funding of the study".

3.9 In this connection, the Committee also noted that one of the roles assigned to ICMR in the MOU signed by the Director General of the ICMR was "advising on plans for results dissemination to support decision making for use of the HPV vaccine".

3.10 **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.

3.11 The Committee noted that there were many gaps and missing links in the whole episode and enquired as to when ICMR came into contact with PATH. First a vaccine should get the approval from the Government and then only it can be used in UIP. Secretary, Department of Health Research/DG, ICMR while responding to the queries, informed that the first discussion with the PATH was held in 2006 followed by signing of agreement in the year 2007. At that time HPV vaccine had not been approved in India and no study was conducted on it. This was all a preparatory exercise.

3.12 The Committee was informed that the trial was on the two vaccines approved by DCGI. It was also stated that these vaccines had been tested abroad and on a limited number of people in India as per rules following which DCGI had given the approval for their marketing in the country, and then a post-marketing surveillance trial.

3.13 The Committee in this connection took note of the fact that before any drug is tested especially on a large population of 25,000-32,000 children between the age of 10 to 14, then according to the CDSCO guidelines, no such trial can be conducted on children until a similar, prior trial is conducted on adults to determine efficacy and safety.

3.14 The Secretary, Department of Health Research/DG, ICMR while deposing before the Committee in its meeting held on 25th July, 2011, stated that the terms of reference of the Enquiry Committee was to find out any relation between the deaths with the administration of vaccine and any incidents of irregularities in the implementation of the study. He stated that the Enquiry Committee concluded that the deaths reported during trial had no uniform pattern to link them to the administration of vaccines.

3.15 The Committee noted that all the seven deaths were summarily dismissed as unrelated to vaccinations without in-depth investigations. According to Inquiry Committee report, the speculative causes were suicides, accidental drowning in well (why not suicide?), maleria, viral infections, sub-arachnoid haemorrhage (without autopsy) etc. The Committee has been given to understand that suicidal ideation is caused by many drugs. Since then one more death due to suicide in case of Gardasil has been reported in addition to 5 deaths reported during 2009-10. Therefore, HPV vaccine as a possible, if not probable, cause of suicidal ideation cannot be ruled out.

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. He informed the Committee that DCGI, had sought explanation for the incidents of irregularities.

3.17 The Committee took note of Secretary's comments but sought to know as to how ethical it was on the part of ICMR to become a party to a project in the name of Public-Private Partnership (PPP mode). How ICMR, which is mandated to formulate ethical guidelines for researchers, can become a direct party in such a study. The Secretary, Department of Health Research admitted that presence of ICMR in the Project's Advisory Committee-responsible and accountable for various acts of omissions and commissions-clearly indicates Conflict of Interest. Therefore, ICMR owes full moral responsibility for numerous irregularities reportedly committed in the study.

3.18 **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.**

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3.19 **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.**

3.20 Secretary of Department of Health Research and DG, ICMR in their defense also claimed that the ICMR had fulfilled the written role entrusted to it but the irregularities that took place during the implementation of the study clearly indicate that there were certain micro (ground) level issues requiring more attention. For instance, it was noticed that States were not even capable of monitoring the adverse effects. He stated that this all was a learning exercise.

3.21 It maybe pertinent to mention here that the safety, efficacy and introduction of vaccines in India is handled by National Technical Advisory Group on Immunization (NTAGI). Thus, at the very outset, ICMR should have either referred PATH to NTAGI or at least taken NTAGI on board.

3.22 **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.**

IV. ROLE OF DRUG CONTROLLER GENERAL, INDIA (DCGI)

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. Clinical trials of pharmaceutical products are conducted on human subjects in the country to determine or verify safety and/or efficacy. Every permission for conducting clinical trials also, *inter alia*, includes a condition that in event of trial related injury or death, the sponsor will provide complete medical care as well as compensation. Statement to this effect needs to be incorporated in the Informed Consent Form. The details of compensation provided are to be intimated to the office of DCGI.

4.2 The Committee noted from the evidence available that the nature of the PATH project made it Post-marketing Phase IV Clinical Trial under Drugs and Cosmetic Rules. It was on this basis that DCGI approved the clinical trial on 22 April, 2009 and had earlier issued import licenses on 23 December, 2008 though it was incorrect on the part of DCGI to issue import licences on Form 11 under Rule 33 which states:

> *Import of drugs for examination, test or analysis:* Small quantities of drugs the import of which is otherwise prohibited under section 10 of the Act may be imported for the purpose of examination, test or analysis subject to the following conditions:

(a) No drug shall be imported for such purpose except under a licence in Form 11;

(b) the licensee shall use the substances imported under the license exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the license, or in such other places as the licensing authority may from time to time authorize.

4.3 Since both Gardasil and Cervarix had received marketing approval from CDSCO on 4 July, 2008 and 10 September, 2008 respectively, DCGI should have issued Import Licenses on Form 10 which is applicable to import of drugs already approved.

4.4 The so called Demonstration Project of PATH has the objectives as follows:

Primary Outcomes:

- Number and percentage of vaccinated girls.
- Number and percentage of vaccinated girls experiencing Serious Adverse Events (SAEs)
- Number and percentage of vaccinated girls experiencing non-Serious Adverse Events.
- Timeliness of reporting SAEs to local, state and national authorities.
- Timeliness of reporting Non-SAEs to local, state and national authorities.

4.5 Thus it is clear that PATH project had two well defined and specific objectives:

(a) The commercial objective of the project was to generate evidence, data and arguments to support inclusion of HPV vaccines into India's state-funded Universal Immunization Program (UIP), and

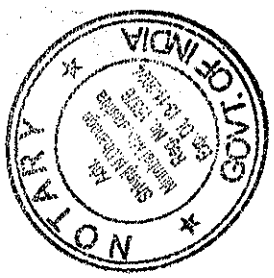
(b) The scientific purpose was to collect data on serious and non-serious adverse effects. Given that similar projects were launched in Peru, Uganda and Vietnam, the entire exercise would have collected side effect profiles of HPV vaccines in all the ethnic groups that reside in developing countries. Such data would be invaluable to promote the two branded, patented, single source HPV vaccines as safe all over the world.

4.6 **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.**

V. MARKETING APPROVAL TO HPV VACCINES IN INDIA

5.1 Before approving any new drug (including new vaccines), under Drugs and Cosmetics Rules, it is mandatory to conduct Phase III clinical trials in India to determine any ethnic differences in the safety and efficacy profiles. As per records made available to the Committee the following clinical trials, albeit, under various names, were conducted:

Gardasil (Merck): Clinical trials were conducted on 108 subjects (girls in the age group of 9-15 years). Several violations took place in the trial: (a) trials should have been conducted in adults first before exposing children to known and unknown side effects, (b) in adolescents and



children the trials should have been conducted from "top to bottom" age groups *i.e.* first in adolescents (13-15 years) followed by children (9-12 years). This was not done. Vaccines were administered to children irrespective of age at the same time.

Cervarix (GSK): Clinical trials were conducted on 162 subjects (adults in the age group of 18-35 years). Yet permission was given to use the vaccine in children (10-14 years) in violation of rules.

VI. INQUIRY COMMITTEE

(a) Composition and Terms of Reference

6.1 The Committee was informed that because of the concerns raised at different fora, the study was suspended and an Enquiry Committee was constituted by the Govt. of India vide notification No. V.25011/160/2010-HR dated 15th April, 2010, to enquire into "Alleged irregularities" in the conduct of studies using Human Papilloma Virus (HPV) vaccines by PATH in India.

The inquiry committee consisted of the following:

(1) Dr. S.S. Agarwal, former Director, Advanced Centre for Training, Research, Education on Cancer,

(2) Dr. S.P. Aggarwal, former DGHS, and

(3) Dr. Sunita Mittal, HoD, Obstetrics and Gynaecology, AIIMS

6.2 The terms of reference of the Committee were to enquire into:

(i) Link between the deaths and vaccine, if any, and

(ii) Ethical Issues of subjecting children of marginalized populations to these studies, and investigations in children without appropriate Consent.

6.3 The Committee was assisted by the following experts:

(i) Dr. Rani Kumar, Dean, AIIMS

(ii) Dr. A. K. Dutta, Head of Pediatrics, Kalawati Saran Hospital

(iii) Dr. Y. K. Gupta, Head of Pharmacology, AIIMS

(b) Conflict of Interest

6.4 The Committee sought information from the Ministry of Health and Family Welfare (MoHFW) as to whether members of the Inquiry Committee were asked to file Conflict of Interest declarations. In response the Ministry replied: "No written Conflict of Interest declarations were sought from the core members of the Inquiry Committee as well as experts. It was understood that if there is any conflict, highly learned members will point it out."

6.5 In order to verify the Ministry's claim, the Committee picked just one member *i.e.*, Professor and HoD of the Department of Obstetrics and Gynaecology (O&G) of All India Institute of Medical Sciences (AIIMS). It was found that manufacturers of Gardasil, Merck was sponsoring and funding a trial in the Department of O&G at AIIMS to determine if 2 doses of Gardasil can be used safely and effectively instead of 3 doses. 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.

The FCRA application form was, therefore, deliberately left incomplete to hide this truth. All these speaks of a serious conflict of interest of this member of the Inquiry Committee.

6.6 The Committee also found that the Ministry appointed a senior official of ICMR (described as Resource Person) to assist the Inquiry Committee. The concerned individual was the main link between ICMR and PATH, and had participated actively in all discussions, meetings and helped PATH to carry out the project proactively in every respect right from the beginning in October 2006. As such he had a clear Conflict of Interest and could not be relied upon to give correct information and unbiased opinion. Indeed he should have been summoned as a witness to answer questions and not as an official Resource Person attached to the Enquiry Committee.

(c) Adverse Events Reporting

6.7 The Committee examined the final Report of the Inquiry Committee constituted to enquire into the alleged irregularities in the conduct of studies using HPV vaccines by PATH in India. In its first meeting held on 21-4-2010, the Inquiry Committee sought details on the following core issues:

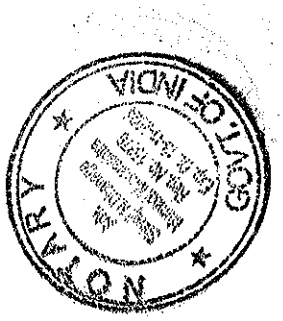
1. When did PATH approach ICMR for trial runs?
2. With whose permission was MOU signed?
3. Did President of ICMR approve?
4. Whether it had approval of the Screening Committee?
5. Approval of DCGI.
6. Details of reimbursements provided so far by PATH to ICMR
7. Names of beneficiaries.
8. Expenditure incurred by ICMR so far on all items including travel expenses.

6.8 However in its second meeting on 30 April, 2010, no discussion took place on the above crucial issues since the Inquiry Committee wished "to restrict itself to the terms of reference."

6.9 Inexplicably, however, as the records placed before the Committee proved, this decision did not prevent the Inquiry Committee from going into and recommending actions on other matters far beyond the terms of reference.

6.10 **The Committee notes that once this matter was taken up by it, the Government appointed an Inquiry Committee on 15 April, 2010 to inquire into 'alleged irregularities in the conduct of the studies using HPV vaccines by PATH in India'. The Committee has noted the serious conflict of interest of members of this Inquiry Committee with the subject matter. The Committee, therefore, strongly deprecates the Government for appointing a committee to inquire into such a serious matter in such a casual manner even without ascertaining as to whether any of the members of the said Inquiry Committee were having any conflict of interest with the subject matter of inquiry.**

6.11 **The Committee finds it very intriguing as to when the Inquiry Committee after having sought details of some core issues in the very first meeting of the Committee on 21 April, 2007 subsequently chose not to pursue them purportedly because 'it wanted to restrict itself to its terms of reference'. These core issues raised by the Inquiry Committee earlier, if pursued to their logical end, would not only have provided the Inquiry Committee a lot more clarity in unraveling the truth but also the Country would have known the exact details as to what transpired in this sordid incident.**



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(d) Informed Consent

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.

6.13 One of the experts, while going into the question of Informed consent in great detail, in two reports, has pointed out glaring discrepancies. Out of 100 consent forms for AP Project taken for study, it was found that signatures of witnesses were missing in 69 forms. In many forms there were no dates while in others the signature of just one person appeared in seven forms The legality of the Andhra Pradesh State Government circular directing all Headmasters/Wardens in all private/government/ashram schools to sign the consent forms on behalf of parents/guardians was also questionable.

6.14 The Inquiry Committee, while going through the above report, noticed the following irregularities and discrepancies in the study:

(i) The warden/teachers/headmasters were not given written permission by the parents/ guardians to sign on behalf of their girls.

(ii) On many forms witness had not signed and of the forms which are signed, it is not clear whether they are signed by full time government employees, as per rules.

(iii) Neither the photograph nor the photo ID card of parents/guardians/wardens is pasted in consent form.

(iv) On many forms investigator has not signed.

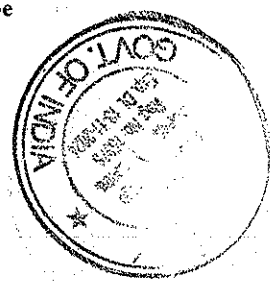
(v) On some forms signature of parents/guardians is not matching with their names.

(vi) The date of vaccination is much earlier than the date of signature of parents/guardian in the consent forms. Apparently they were obtained post-facto.

(vii) In some forms, the name is of the father but signature is of probably mother (lady's name).

6.15 Secretary, DHR and DG, ICMR while deposing before the Committee, reiterated that the regulatory approvals given to the project were in proper order and due attention was paid to the guidelines and formats for seeking consent. However, during the implementation of the project certain irregularities took place. He admitted there were cases of discrepancies in A.P. He admitted that many consent forms were filled up by the Principal on behalf of the students. He admitted to gross violation in the recording of SAEs also. He informed the Committee that keeping all these observations in view the DCGI, besides issuing immediate instructions to stop the study, had sought explanations for irregularities committed during the study.

6.16 **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. The Committee is however, deeply shocked to find that in Andhra Pradesh out of the 9543 forms, 1948 forms have thumb impressions while hostel wardens have signed 2763 forms. In Gujarat, out of the 6217 forms 3944 have thumb impressions and 5454 either signed or carried thumb impressions of guardians. The data also revealed that a very large number of parents/guardians are illiterate and could not even write in their local languages viz. Telugu or Gujarati. The Committee is further shocked to find from one of the reports that out of 100 consent forms for Andhra Pradesh project signatures of witnesses were missing in 69 forms. In many forms there were no dates. One particular person had signed seven forms. In fact the legality of Andhra Pradesh State Government directing headmasters in all private/ Government/ashram/schools to sign the consent form on behalf of parents/guardians is highly questionable. The absence of photographs of parents/guardians/wardens on consent forms, the absence of signatures of investigators; the signatures of parents/guardians not matching with their names; the date of vaccination being much earlier than the date of signature of parents/guardian in the consent forms, etc. all speak of grave irregularities.

6.17 **The Committee, accordingly, concludes that most, if not all consent forms, were carelessly filled-up and were incomplete and inaccurate. The full explanation, role, usefulness and pros and cons of vaccination had not been properly communicated to the parents/guardians. The Committee observes that there is a gross violation of the consent and legal requirement of consent which had been substantiated by the experts. The Committee takes a serious view of the violations and strongly recommends that on the basis of the above facts, PATH should be made accountable and the Ministry should take appropriate action in the matter including taking legal action against it for breach of various laws of the land and possible violations of laws of the Country of its origin.**

6.18 The Committee was informed that the basic aim of the study was to evaluate strategies for introduction and delivery of the vaccines in the public sector. Strangely four of the five primary outcome measures proposed in the study related to evaluation and determination of safety of the vaccines.

6.19 One of the experts has stated that there was lack of rigour in the design regarding reporting and dealing with serious adverse events. He has pointed out absence of preparedness in the event of any such occurrence that would put children at grave risk. The side effects mentioned by the manufacturers themselves were revised several times and now include serious health issues. Since there were contra-indications to the use of the vaccines, the reasons for not ascertaining contra-indications before the girls were vaccinated is clearly an act of willful negligence.. The design of the project neither took the possibility of Serious Adverse Event (SAE) seriously nor was there any attention paid to the need for an independent monitoring agency. Consequently action on investigations into the causes of deaths took an unacceptably long time. A number of discrepancies and gaps in the investigations of the deaths have also been pointed out. There was no diary card based reporting of adverse events for recording minor or major adverse events in the study protocol in such a large study. This resulted in gross under reporting of the adverse events.

6.20 Another expert, while analyzing deaths and Adverse Events Following Immunizations (AEFI) has observed after reviewing all seven deaths (five deaths from AP in the Gardasil group and two deaths in Gujarat from Cervarix group), that there was no common pattern to the deaths that would suggest that these were caused by the vaccine. However, the reporting system as per Government of India surveillance of vaccine preventable disease guidelines notification was not done within time limit in two cases in AP and both the cases in Gujarat. There was no uniformity in the reporting system of AEFI in both the States. The primary end point of the study was to

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find out the number of girls having serious and non serious adverse events following vaccination through routine UIP system. He has opined that in this regard first of all routine system of reporting should have been verified in both States.

6.21 Another expert has stated that the reporting of non-serious AEs was grossly under reported and hence the accuracy of SAEs is doubtful as well. It has been observed that delay in reporting and investigations of deaths could have been due to sole dependence on routine UIP protocol. It was a significant lapse in the protocol and execution of the study. While reporting on safety aspects in the study, it has been pointed out that there was absence of preparedness to handle Serious Adverse Events (SAE) like anaphylaxis, cardiac arrest, seizures, etc. occurring at the sites of vaccine administration. Though such serious adverse events might be rare but it was advisable to be well prepared for such an eventuality through adequate training of health workers. Assessment of the immune status of the participants by the ANM, ASHA or the health workers was virtually non-existent. These issues needed to be addressed as prescribing information of the HPV vaccines specifically contra-indicates administration in immune-compromised subjects (such as HIV/AIDS etc.).

6.22 **The Committee, in the light of the observations made by experts, feels that the methodology and implementation of the study at both the places was full of flaws. The Committee is of the view that since the population under study was vulnerable, utmost caution should have been exercised in the implementation of the study. The Committee also recommends that there should be an independent monitoring mechanism in such a study involving human participants so that the accurate recording of AEs and SAEs could be made. The findings of the experts clearly indicate that the safety and rights of the children in this vaccination project were highly compromised and violated. The Committee is also concerned over the fact that there was no insurance cover for the children. The Committee strongly recommends that while allowing any such trial in future, all the lapses pointed out by the experts should be addressed effectively. ICMR and DCGI should ensure strict adherence to the guidelines, methodology and monitoring.**

(e) Role of Ethics Committees

6.23 While examining the role of the Ethics Committees in both the States, one of the experts pointed out that Ethics Committees were supposed to meet periodically to evaluate and monitor the progress of the project and review SAE reports. No such meetings were held by the Committees. Only after reports of deaths appeared in the media, the meetings of these Committees were held.

6.24 **The Committee takes a serious note of the fact that both the Ethics Committees existed only as a formality and they did not play the role they were designated for. This is a clear dereliction of duty on the part of the Ethics Committees. The Committee apart from recommending suitable action in the matter, strongly recommends that there should be a mechanism in place to take appropriate action against such dereliction of duty on the part of the Ethics Committees. There should be specific guidelines for Ethics Committees and the Ethics Committees should strictly follow them. The functioning of Ethics Committees should be regularly monitored.**

(f) Use of Official Machinery

6.25 The Committee has noted that the information/publicity material displayed/distributed at trial sites implied that the Government had started a vaccination programme. Thus, the credibility of the Universal Immunization Programme (UIP) was used to promote private, foreign interests. It has

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been found that the funds meant for the NRHM were used, without authorization for monitoring and transportation of the vaccines to the fields for use in the project.

6.26 **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.**

6.27 Besides, the Committee notes that no information had been provided to Indian authorities about funding of the project except that it was reportedly funded by Bill and Melinda Gates Foundation and that the vaccines had been donated by the manufacturers. The information regarding financial investments of ICMR and State Governments in the project was not provided, though the States clearly provided cold chain and manpower for immunization. **The Committee, accordingly, observes that it might have been more prudent if the National Technical Advisory group on Immunization (NTAGI) had been brought into the picture right in the beginning to review and give its views on the study prior to its approval and implementation.**

6.28 No information is available on the total outlay on the project spent by PATH, ICMR, state governments of Andhra Pradesh and Gujarat (immunization staff, cold chain system, equipment, transportation etc.). According to the documents submitted by PATH to ICMR/Health Ministry Screening Committee, the total outlay by PATH for expenses in India was Rs. 29,76,000. However Centre for Operations Research and Training (CORT), a sub-contractor of PATH had quoted US$ 83,889 (first year) and US$ 96,472 (second year), which is not included in the figure submitted to ICMR/HMSC.

6.29 **Considering the above lapses and irregularities committed by PATH during the course of conducting the trials on hapless tribal children in Andhra Pradesh and Gujarat, the Committee is convinced that the authorities concerned did not exercise due diligence in scrutinizing the publicity material of PATH. 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.**

(g) Action taken on the Inquiry Committee Report

6.30 With a view to find out the action taken by the Government on the findings of the Inquiry Committee, the Committee again heard the Secretary, Department of Health Research/DG, ICMR along with DCGI at its meeting held on 24th May, 2013. The Secretary informed the Committee that after the submission of Report by the Inquiry Committee, they were formally called to give explanation in the year 2011. In addition, clarifications were also sought from them in between which were formally answered to. The Committee in the said meeting desired to know whether criminal inquiry, if any, has been initiated against PATH on account of the following irregularities in the conduct of trial as pointed out by the Inquiry Committee:

(i) Irregularities in obtaining consent forms and actual implementation of the consent process;

(ii) Lack of monitoring and preparedness to deal with serious adverse events;

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(iii) Inclusion of vulnerable and tribal population groups;

(iv) Blurring of distinction between Universal Immunization Programme and PATH study;

(v) Absence of insurance coverage for the study participants; and

(vi) Inclusion of the statement in the consent form that "you will not be charged for your daughter to receive the vaccine" that could be construed as covert inducement.

6.31 The Committee also sought to know as to whether any compensation was awarded to the families of children for suppression of material information before administering vaccines.

6.32 The Committee also took note of the Action Taken Note submitted by Department of Health Research wherein it was informed that subsequent to findings of the Inquiry Committee following action was taken:

(i) PATH was informed about suggestions made by the Committee;

(ii) Principal Investigators of other suspended studies on HPV vaccines were informed to get their studies re-examined from respective Ethics Committees after addressing the concerns raised by the Inquiry Committee;

(iii) DCG(I) was informed of the suggestions of the Committee for necessary action; and

(iv) Suggestions were forwarded to the relevant authority for inclusion in the Draft bill on Biomedical Research on Human Subjects.

6.33 DCG(I) informed the Committee that subsequent to findings of the Inquiry Committee; the following action was taken:

(i) Both the manufacturers of HPV vaccines have been asked to submit additional data for 4 years on PSURs (Periodic Safety Update Reports), every 6 months for first 2 years, and annually during the subsequent 2 years, and to submit protocol for approval for conducting post marketing surveillance study;

(ii) Proposal to amend the definition of "New Drug" under rule 122-E would be taken up for consideration; and,

(iii) In future the following steps would be ensured before approving a clinical trial by DCG(I): (a) every clinical trial is to be registered at ICMR's clinical trial registry of India; (b) every approval would include a condition for provision of complete medical care in case of study related injury/death and the statement to this effect is to be included in the informed consent: (c) DCG(I) should be informed about death/injury: (d) Schedule 'Y' would be amended to expand the responsibilities of sponsors, investigators and Ethics Committees; and (e) the consent forms are to be amended to include details of address and occupations of subject giving socio-economic background.

6.34 **The Committee is amazed at the audacity of DCGI to merely repeat various steps which it proposes to take as if they are new, additional measures. All these are already part of the written rules and are supposed to be followed by all sponsors. Except for slight amendment in the Informed Consent Form, there is nothing new in the ATN submitted by DCGI.**

6.35 The Committee observes that the Department has nothing fresh to offer in the status note as the same information was furnished by it in December, 2012 *vide* its updated note on Action Taken after availability of Report of enquiry Committee.

6.36 **The Committee not being convinced with the action taken by the Department or DCGI, feels that the whole issue has been diluted and no accountability has been fixed on the erring Officials/Departments for the gross violations committed in the conduct of Study. The Committee also feels that a very casual approach has been taken by the Department in the matter and their replies lack any concrete action to protect and safeguard the health of our people.**

6.37 **The Committee also noticed lack of firm action on the part of DCGI, to avoid such irregularities in future. One of the actions proposed by the DCGI to check any recurrence of such gross violations was 'proposal to amend the definition of New Drug during the next meeting'. The same assurance was given by DCGI in December, 2012. The Committee, accordingly, observes that response of the Department and DCGI is very casual, bureaucratic and lacks any sense of urgency. The Committee feels that DCGI is not very serious in bringing improvements in the system. It, therefore, desires the Ministry to ensure compliance by DCGI.**

VII. PROGRAMME FOR APPROPRIATE TECHNOLOGY IN HEALTH (PATH)

7.1 The Committee during the course of its present examination sought information from the Government about PATH in order have a better understanding of its legal status and its *locus standi* in carrying out various activities on the Indian soil including the project in question where apparently several laws of India and possibly of its country of origin had been violated.

7.2 The information furnished to the Committee reveals that PATH describes itself as an "International nonprofit, non-government organization based in the United States." Legally, it is a Public Benefit Corporation (PBC) registered (No. 600588751 dated 28th August, 1981) by the Corporation and Charities Division in the State of Washington. For all practical purposes its legal status in US is equivalent to a Registered Society in the Indian context. It is certainly not a commercial company and hence would not be subject to the jurisdiction of Company Law Board or Registrar of Companies in India. Incidentally, Ford Foundation is also a PBC (Registration number 768093 dated 15th January, 1936). Under American laws organizations such as Trusts, Fraternal Societies, Savings and Loan Associations, Municipal Utility Services etc. are all registered as PBCs.

7.3 Under Indian rules, foreign non-commercial organizations such as PATH wanting to set up an office in India are required to obtain (a) permission from the Ministry of External Affairs (MEA) from "political angle" (**Annexure B**) and (b) permission from Ministry of Home Affairs (MHA) from "security angle" (**Annexure C**). In the latter case, application needs to be forwarded through proper channel such as Ministry of Health and Family Welfare for health-related activities, Ministry of Human Resources for education related activities, Ministry of Labour for trade union or workers related activities etc. Once such an approval is accorded, then an office can be setup which should naturally abide by all other laws of the land such as income tax, shop and establishment act, municipal and other applicable laws, just to mention a few.

7.4 The Committee asked the Department to direct PATH to provide details of various mandatory permissions required by foreign agencies, including charities, for and in connection with opening office in India and the date of opening of its office in India. Unbelievably, the exact date of opening the office is not even known to its functionaries in New Delhi. To begin with vide its letter dated 5-3-2012, PATH claimed that "it has a Liaison Office status under Income Tax Rules." Since no such provision exists, after prolonged correspondence it settled for 19th April, 1999 as the date of opening office based on the fact that its PAN card (No. AAFCP2249G) is dated 19th April, 1999. The Committee was intrigued because PAN card is issued just for income tax

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purposes and nothing else. Income Tax Department does not go about permitting foreign entities to open offices in India. In any case PAN card is not a replacement for Ministry of External Affairs and Ministry of Home Affairs approvals. Besides, the application for issuance of PAN card must have been made much before 19th April 1999 there being no online system of obtaining PAN card instantaneously. It can be safely assumed that the date of opening office has to be much earlier than 19th April, 1999.

7.5 PATH also produced copy of a letter dated 16-3-1999 from PATH office in US to the Exchange Control Department of the Reserve Bank of India along with reply dated 19-4-1999 received by PATH in US on 29-4-1999. It merely stated that since PATH is "not engaged in any commercial, trading or industrial activity," it does not need "RBI permission from foreign exchange angle. *However you may seek necessary approval from the Government of India or other statutory/ regulatory bodies as applicable."* Apparently PATH paid no attention to RBI's sane advice. Even before the letter reached PATH office in the United States on 29-4-1999, it had already opened its office in India.

7.6 The Foreign Exchange Regulation Act (FERA) was replaced with Foreign Exchange Management Act (FEMA) on 1-6-2000. PATH produced post-facto permission from the Reserve Bank of India dated 25-5-2009 which clearly stated:

> *"RBI permission (is) granted from the foreign exchange angle....and should not be construed to convey the approval of any other statutory authority or Government under any other laws/regulations."* Moreover, the Liaison Office is permitted to undertake "solely liaison work for the head office" as mentioned below:
>
> 1. Representing in India the parent company/group companies
> 2. Promoting export, import from/to India.
> 3. Promoting technical/financial collaborations between parent/group companies and companies in India.
> 4. Acting as a communication channel between the parent company and Indian companies.
>
> "The office in India will not render any consultancy or any other services directly/indirectly with or without any consideration."
>
> In addition *"Permission granted by RBI is limited to and for the purpose of the provisions of FEMA-2000 and shall not be construed in any way as regularizing, condoning or in any manner validating any irregularities, contraventions and other lapses, if any, under the provisions of any other law."*

7.7 It is clear that the back dated permission obtained after 10 years of having opened its office in India was merely and exclusively from foreign exchange angle and not a substitute for approval from MEA and MHA.

7.8 Finally and belatedly PATH produced a certificate from the Registrar of Companies (RoC) dated 23-9-2009 stating that PATH, a company originally incorporated in US, had filed documents on 10-09-2009 notifying establishment of place of business in India *w.e.f.* 19.4.1999. The Certificate was apparently issued in violation of its own rules that states that documents must be submitted within 30 days of the establishment of "place of business." In any case such a certificate cannot and does not obviate the need to obtain baseline, mandatory permission from MEA and MHA. Moreover RoC deals with commercial companies, not foreign trusts, foundations and charities.

7.9 PATH also claimed that it had received "permission" from the Ministry of Health and Family Welfare to set up an office in India. The *post-facto* letter dated 27-4-2001 (two years after PATH admits having opened the office in India) is not a permission at all but a vague, non-specific statement to say that PATH was "engaged in health care related activities".

7.10 According to the published Annual Report of PATH for the year 2008, it received funding in "excess of US $ 1,000" from many governmental sources including the Ministry of Health and Family Welfare, Government of India. However, in response to Rajya Sabha Question Number 952 on 3.8.2010, the Health Minister denied any Ministry funding to PATH.

7.11 The Committee is concerned that if PATH can set up an office in India so easily without getting the required mandatory approvals/permissions, then individuals and entities inimical to the interest of the country can do the same. The Committee expresses its concern that paper and shell companies can be easily registered in many jurisdictions and then set up a place of business in India as "Liaison offices" with no questions being asked. It is surprising that security and intelligence agencies did not raise an eyebrow on the way a foreign entity entered India virtually incognito through the backdoor. The Committee desires that such incidents should not be allowed in future. The Government should tighten the rules lest one day foreign citizens, with deep roots in organizations/nations inimical to India, set up offices in the country to engage in anti-national and/or unlawful activities.

7.12 It is apparent the PATH has exploited with impunity the loopholes in our system as also the absence of a nodal point or a single window for maintaining a data bank of foreign entities entering the Country for setting up their offices. Given the multiplicity of agencies involved in processing such requests there is a definite need for a nodal agency which would keep a tab on all such existing and aspiring agencies from the point of view of having obtained all necessary clearances/permissions before commencing their operations in India. The Committee strongly recommends that government set up one such umbrella agency which should be linked to all the agencies that are involved in processing such requests. The Committee desires that within three months such an agency should be put in place and start functioning. The proposed nodal agency should be a part of MHA with a well established coordination mechanism with the MEA so that undeserving cases are dealt forthwith through diplomatic channels. All ministries/departments/agencies/state governments/other entities should be required to share details of all requests/proposals from foreign entities for setting up offices in any form with this nodal agency.

7.13 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.

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7.14 **The Ministry of Health and Family Welfare should without wasting time report the violations indulged in by PATH to international bodies like WHO and UNICEF so as to ensure that appropriate remedial action is initiated by these agencies worldwide.**

7.15 **The Committee also desires that the Ministry of Health and Family Welfare may take up the matter through the Ministry of External Affairs with the US Government so as to ensure that appropriate action is taken against PATH under the laws of its country of origin in case of any violations of laws there.**

OBSERVATIONS/RECOMMENDATIONS — AT A GLANCE

II. NATURE OF PROJECT

1. **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.** (Para 2.5)

III. ROLE OF DEPARTMENT OF HEALTH RESEARCH/INDIAN COUNCIL OF MEDICAL RESEARCH

2. **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.** (Para 3.10)

3. **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.** (Para 3.18)

4. **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.** (Para 3.19)

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5. 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. (Para 3.22)

IV. ROLE OF DRUG CONTROLLER GENERAL, INDIA (DCGI)

6. 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. (Para 4.6)

VI. INQUIRY COMMITTEE

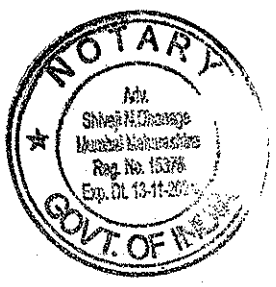
(c) Adverse Events Reporting

7. The Committee notes that once this matter was taken up by it, the Government appointed an Inquiry Committee on 15 April, 2010 to inquire into 'alleged irregularities in the conduct of the studies using HPV vaccines by PATH in India'. The Committee has noted the serious conflict of interest of members of this Inquiry Committee with the subject matter. The Committee, therefore, strongly deprecates the Government for appointing a committee to inquire into such a serious matter in such a casual manner even without ascertaining as to whether any of the members of the said Inquiry Committee were having any conflict of interest with the subject matter of inquiry. (Para 6.10)

8. The Committee finds it very intriguing as to when the Inquiry Committee after having sought details of some core issues in the very first meeting of the Committee on 21 April, 2007 subsequently chose not to pursue them purportedly because 'it wanted to restrict itself to its terms of reference'. These core issues raised by the Inquiry Committee earlier, if pursued to their logical end, would not only have provided the Inquiry Committee a lot more clarity in unraveling the truth but also the Country would have known the exact details as to what transpired in this sordid incident. (Para 6.11)

(d) Informed Consent

9. 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. The Committee is however, deeply shocked to find that in Andhra Pradesh out of the 9543 forms, 1948 forms have thumb impressions while hostel wardens have signed 2763 forms. In Gujarat, out of the 6217 forms 3944 have thumb impressions and 5454 either signed or carried thumb impressions of guardians. The data also revealed that a very large number of parents/guardians are illiterate and could not even write in their local languages viz. Telugu or Gujarati. The Committee is further shocked to find from one of the reports that out of 100 consent forms for Andhra Pradesh project signatures of witnesses were missing in 69 forms. In many forms there were no dates. One particular person had signed seven forms. In fact the legality of Andhra Pradesh State Government directing headmasters in all private/ Government/ashram/schools to sign the consent form on behalf of parents/guardians is highly questionable. The absence of photographs of parents/guardians/wardens on consent forms, the absence of signatures of investigators; the signatures of parents/guardians not matching with their names; the date of vaccination being much earlier than the date of signature of parents/guardian in the consent forms, etc. all speak of grave irregularities. (Para 6.16)

10. The Committee, accordingly, concludes that most, if not all consent forms, were carelessly filled-up and were incomplete and inaccurate. The full explanation, role, usefulness and pros and cons of vaccination had not been properly communicated to the parents/guardians. The Committee observes that there is a gross violation of the concept and legal requirement of consent which had been substantiated by the experts. The Committee takes a serious view of the violations and strongly recommends that on the basis of the above facts, PATH should be made accountable and the Ministry should take appropriate action in the matter including taking legal action against it for breach of various laws of the land and possible violations of laws of the Country of its origin. (Para 6.17)

11. The Committee, in the light of the observations made by experts, feels that the methodology and implementation of the study at both the places was full of flaws. The Committee is of the view that since the population under study was vulnerable, utmost caution should have been exercised in the implementation of the study. The Committee also recommends that there should be an independent monitoring mechanism in such a study involving human participants so that the accurate recording of AEs and SAEs could be made. The findings of the experts clearly indicate that the safety and rights of the children in this vaccination project were highly compromised and violated. The Committee is also concerned over the fact that there was no insurance cover for the children. The Committee strongly recommends that while allowing any such trial in future, all the lapses pointed out by the experts should be addressed effectively. ICMR and DCGI should ensure strict adherence to the guidelines, methodology and monitoring. (Para 6.22)

12. The Committee takes a serious note of the fact that both the Ethics Committees existed only as a formality and they did not play the role they were designated for. This is a clear dereliction of duty on the part of the Ethics Committees. The Committee apart from recommending suitable action in the matter, strongly recommends that there should be a mechanism in place to take appropriate action against such dereliction of duty on the part of the Ethics Committees. There should be specific guidelines for Ethics Committees and the Ethics Committees should strictly follow them. The functioning of Ethics Committees should be regularly monitored. (Para 6.24)

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13. 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. (Para 6.26)

14. Besides, the Committee notes that no information had been provided to Indian authorities about funding of the project except that it was reportedly funded by Bill and Melinda Gates Foundation and that the vaccines had been donated by the manufacturers. The information regarding financial investments of ICMR and State Governments in the project was not provided, though the States clearly provided cold chain and manpower for immunization. The Committee, accordingly, observes that it might have been more prudent if the National Technical Advisory group on Immunization (NTAGI) had been brought into the picture right in the beginning to review and give its views on the study prior to its approval and implementation. (Para 6.27)

15. Considering the above lapses and irregularities committed by PATH during the course of conducting the trials on hapless tribal children in Andhra Pradesh and Gujarat, the Committee is convinced that the authorities concerned did not exercise due diligence in scrutinizing the publicity material of PATH. 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. (Para 6.29)

16. The Committee is amazed at the audacity of DCGI to merely repeat various steps which it proposes to take as if they are new, additional measures. All these are already part of the written rules and are supposed to be followed by all sponsors. Except for slight amendment in the Informed Consent Form, there is nothing new in the ATN submitted by DCGI. (Para 6.34)

17. The Committee not being convinced with the action taken by the Department or DCGI, feels that the whole issue has been diluted and no accountability has been fixed on the erring Officials/Departments for the gross violations committed in the conduct of Study. The Committee also feels that a very casual approach has been taken by the Department in the matter and their replies lack any concrete action to protect and safeguard the health of our people. (Para 6.36)

18. The Committee also noticed lack of firm action on the part of DCGI, to avoid such irregularities in future. One of the actions proposed by the DCGI to check any recurrence of such gross violations was 'proposal to amend the definition of New Drug during the next meeting'. The same assurance was given by DCGI in December, 2012. The Committee, accordingly, observes that response of the Department and DCGI is very casual, bureaucratic and lacks any sense of urgency. The Committee feels that DCGI is not very serious in bringing improvements in the system. It, therefore, desires the Ministry to ensure compliance by DCGI. (Para 6.37)

VII. PROGRAMME FOR APPROPRIATE TECHNOLOGY IN HEALTH (PATH)

19. The Committee is concerned that if PATH can set up an office in India so easily

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without getting the required mandatory approvals/permissions, then individuals and entities inimical to the interest of the country can do the same. The Committee expresses its concern that paper and shell companies can be easily registered in many jurisdictions and then set up a place of business in India as "Liaison offices" with no questions being asked. It is surprising that security and intelligence agencies did not raise an eyebrow on the way a foreign entity entered India virtually incognito through the backdoor. The Committee desires that such incidents should not be allowed in future. The Government should tighten the rules lest one day foreign citizens, with deep roots in organizations/nations inimical to India, set up offices in the country to engage in anti-national and/or unlawful activities. (Para 7.11)

20. It is apparent the PATH has exploited with impunity the loopholes in our system as also the absence of a nodal point or a single window for maintaining a data bank of foreign entities entering the Country for setting up their offices. Given the multiplicity of agencies involved in processing such requests there is a definite need for a nodal agency which would keep a tab on all such existing and aspiring agencies from the point of view of having obtained all necessary clearances/permissions before commencing their operations in India. The Committee strongly recommends that government set up one such umbrella agency which should be linked to all the agencies that are involved in processing such requests. The Committee desires that within three months such an agency should be put in place and start functioning. The proposed nodal agency should be a part of MHA with a well established coordination mechanism with the MEA so that undeserving cases are dealt forthwith through diplomatic channels. All ministries/departments/agencies/state governments/other entities should be required to share details of all requests/proposals from foreign entities for setting up offices in any form with this nodal agency. (Para 7.12)

21. 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. (Para 7.13)

22. The Ministry of Health and Family Welfare should without wasting time report the violations indulged in by PATH to international bodies like WHO and UNICEF so as to ensure that appropriate remedial action is initiated by these agencies worldwide. (Para 7.14)

23. The Committee also desires that the Ministry of Health and Family Welfare may take up the matter through the Ministry of External Affairs with the US Government so as to ensure that appropriate action is taken against PATH under the laws of its country of origin in case of any violations of laws there. (Para 7.15)

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VIII

EIGHTH MEETING

(2009-10)

The Committee met at 11.00 A.M. on Tuesday, the 6th April, 2010 in Room No. 139, First Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

1. Shri Amar Singh — *Chairman*
2. Shrimati Viplove Thakur
3. Dr. Radhakant Nayak
4. Shri Janardan Dwivedi
5. Shrimati Brinda Karat
6. Shrimati Vasanthi Stanley

LOK SABHA

7. Shri Ashok Argal
8. Shrimati Sarika Devendra Singh Baghel
9. Dr. Chinta Mohan
10. Dr. Sanjay Jaiswal
11. Shri S.R. Jeyadurai
12. Dr. (Shrimati) Kruparani Killi
13. Shri N. Kristappa
14. Dr. Tarun Mandal
15. Dr. Jyoti Mirdha
16. Shri R.K. Singh Patel
17. Dr. Anup Kumar Saha
18. Shrimati Meena Singh
19. Dr. Arvind Kumar Sharma
20. Shri Ratan Singh

SECRETARIAT

Shrimati Vandana Garg, *Additional Secretary*

Shri R. B. Gupta, *Director*

Shrimati Arpana Mendiratta, *Joint Director*

Shri Dinesh Singh, *Assistant Director*

WITNESSES

* * *

Representatives from the Department of Health Research

1. Dr.Vishwa Mohan Katoch, Secretary
2. Ms. Shalini Prasad, Joint Secretary
3. Dr. Vijay Kumar, Scientist
4. Dr. Bela Shah, Head NCD Division
5. Dr. K. Satyanarayana, Head P&I Division
6. Shri Sanjiv Datta, Financial Adviser

* * *

2. At the outset, the Chairman welcomed Members to the meeting and informed them about the agenda of the meeting, *i.e.*, examination of Demands for Grants (2010-11) of the Ministry of Health and Family Welfare and taking oral evidence of the Secretaries * * *, Health Research * * * in connection therewith.

3. * * *

4. * * *

5. * * *

6. * * *

7. The Committee then adjourned at 1.30 P.M. for lunch to meet again at 2.30 P.M.

8. * * *

9. During the course of the meeting, Shrimati Brinda Karat, Member of the Committee raised the issue about the trial of HPV vaccine on the children in Khammam district of Andhra Pradesh and reported deaths of the children therefrom and sought exact status in this regard from the Secretary. The Secretary, Department of Health Research informed the Committee that the Drug Controller General of India had given approval for marketing of HPV vaccine in India as per schedule 'Y' of the Drugs and Cosmetics Act and then a post-marketing surveillance. The Committee was informed that the proposal for trial came two years back before the ICMR through PATH, an American NGO. Attention of the Secretary was drawn to DCGI guidelines whereunder third phase trial 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. The Committee was assured that State Governments of Andhra Pradesh and Gujarat would be asked to get the ongoing clinical trial stopped immediately. Taking serious view of procedural and ethical lapses on the part of the Ministry, the Committee sought the matter of allowing trial of the vaccine as also the approval for its marketing in the country to be enquired into by a premier investigating agency and to take further appropriate action in the matter. It also asked that findings of the investigating agency and the follow-up action taken in this regard may be furnished to the Committee at the earliest.

10. * * *

11. * * *

12. A verbatim record of the proceedings of the meeting was kept.

13. The Committee then adjourned at 5.15 P.M.

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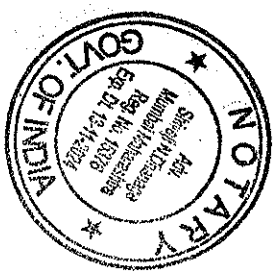
* Relate to other matters.



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XV
FIFTEENTH MEETING
(2010-11)

The Committee met at 11.00 A.M. on Monday, the 25th July, 2011 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

RAJYA SABHA

1. Shri Brajesh Pathak — *Chairman*
2. Shri Janardan Dwivedi
3. Shrimati Viplove Thakur
4. Dr. Vijaylaxmi Sadho
5. Shrimati Brinda Karat
6. Shri Rasheed Masood
7. Shrimati B. Jayashree

LOK SABHA

8. Shri Ashok Argal
9. Shrimati Sarika Devendra Singh Baghel
10. Shri Vijay Bahuguna
11. Dr. Sanjay Jaiswal
12. Shri S.R. Jeyadurai
13. Shri N. Kristappa
14. Dr. Tarun Mandal
15. Dr. Jyoti Mirdha
16. Dr. Anup Kumar Saha
17. Shrimati Meena Singh
18. Shri Pradeep Kumar Singh

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Assistant Director*

WITNESSES

* * *

Department of Health Research

1. Dr. V.M. Katoch, Secretary, Health Research
2. Ms. Shalini Prasad, Joint Secretary
3. Shri S.K. Rao, Joint Secretary

* Relate to other matters.

2. The Chairman welcomed the Members of the Committee and apprised them of the agenda of the meeting, *i.e.* to hear oral evidence on (i) * * *(ii) * * * and (iii) issues arising out of the final report of the Committee to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV)" by PATH in the country.

3. * * *

4. * * *

(The Committee adjourned at 12.20 *P.M. to meet again at* 2.30 *P.M.)*

5. In the second half of the meeting, the Committee heard the views of Secretaries of Departments of Health Research and Health and Family Welfare on the issues arising out of the final report of the Committee appointed to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) by PATH in the country". The Secretary, Department of Health Research, in his deposition, admitted before the Committee that the trials of the vaccine were not conducted by PATH according to the required protocol/guidelines in Andhra Pradesh. He admitted flaws in ethical procedure in conducting the tests such as lack of proper consent from the parents etc. He further stated that new guidelines are being issued and a moratorium has been imposed on further trials till guidelines are issued. The Members raised some queries like how far it was ethically correct for ICMR to go into Private Public Partnership (PPP) mode, faulty design of project; differences between ICMR and DCGI with respect to the project, action taken against the person involved; sale of this vaccine even before it was tested. The Members also enquired as to why the said enquiry report has not been posted on the website of the Ministry. The Secretary, Department of Health and Family Welfare submitted before the Committee that show cause notice of 15 days has been issued to PATH to seek its written views on the issue and action will be taken within three months after the reply of PATH is received. Members also raised queries like sources and magnitude of funding of this project, compensation to the affected parties and blacklisting of PATH, etc. which were partly answered. The Committee directed the witnesses to furnish written replies to queries which remained unanswered.

6. A verbatim record of the proceedings of the meeting was kept.

7. The Committee then adjourned at 3.30 P.M.

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* Relate to other matters.

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XII
TWELFTH MEETING
(2012-13)

The Committee met at 12.00 (NOON) on Friday, the 24th May, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Dr. Vijaylaxmi Sadho
3. Shri Rasheed Masood
4. Shri Jagat Prakash Nadda
5. Shri D. Raja
6. Shri H.K. Dua
7. Shrimati B. Jayashree

LOK SABHA

8. Shri Kirti Azad
9. Shri Mohd. Azharuddin
10. Shrimati Sarika Devendra Singh Baghel
11. Dr. Sucharu Ranjan Haldar
12. Dr. Monazir Hassan
13. Dr. Sanjay Jaiswal
14. Shri Tarun Mandal
15. Shrimati Jayshreeben Patel
16. Shri Harin Pathak
17. Dr. Anup Kumar Saha
18. Dr. Raghuvansh Prasad Singh

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Pratap Shenoy, *Committee Officer*

WITNESSES

Department of Health Research

1. Dr. V. M. Katoch, Secretary
2. Dr. D. K. Shukla, Scientist-F
3. Dr. Tanveer Kaur, Scientist-D

Department of Health and Family Welfare

Dr. G. N. Singh, Drug Controller General of India

I. Opening Remarks

2. At the outset, the Chairman welcomed Members of the Committee and apprised them of the agenda of the meeting, *i.e.*, to hear the Secretary, Department of Health Research along with the Drug Controller General of India (DCGI) on the Action Taken on the final report of the Committee appointed by the Government of India to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine" by PATH in India. * * *

II. Oral Evidence of the Secretary, Department of Health Research and DCGI on the final report of the Committee appointed by the Government of India to enquire into"Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine" by PATH in India

3. Thereafter, the Committee heard the Secretary, Department of Health Research on the Action Taken on the final report of the Committee appointed by the Government of India to enquire into"Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine" by PATH in India. In his deposition, the Secretary, stated that in the year 2007, PATH had applied for licence for trials which was approved in the year 2008 and trails were started on the tribal and non tribal girls of Andhra Pradesh and Gujarat in the year 2009 to see the acceptance of the vaccines. In the year 2010, five deaths in Andhra Pradesh and two deaths in Gujarat were reported. Subsequent to the reported deaths an expert Committee was set up under the Chairmanship of Prof. S.S. Aggarwal, PGIMER, Chandigarh, which in its Report submitted in February, 2011, found the discrepancies in respect of: (i) consent forms and actual implementation of the consent process; (ii) methods of monitoring of adverse effects/serious adverse effects and remedial measure for such events; (iii) inclusion of vulnerable and tribal population groups; (iv) blurring of distinction between National Immunization Programme and Path study; (v) insurance coverage for the study participants; and (vi) convert inducement and indirect coercion etc. The Secretary, apprised the Committee about the remedial action taken pursuant to the findings of the expert Committee. However, members were not satisfied with the action taken by the Department.

4. The Drug Controller General of India, in his deposition, *inter alia* stated that during the future trials for any vaccination, the following safeguards would be adopted: (i) consent form would be transparent; (ii) consent would be in audiovisual format; (iii) clear guidelines have been framed. He also informed the Committee that these guidelines are available on the website of the Ministry. Further, he informed the Committee that in future strict emphasis would be laid on enforcement and patient safety.

5. Thereafter, members raised queries on some issues including conduct of trail without guardian's approval; details of action taken, if any, against officials who had given approval to these trials; absence of complete details of postmortem conducted on the subjects who had died during the said trials; details of use of machinery of State Governments by PATH during the conduct of the trials; whether the said trials were classified as 'clinical trial'; non action on the findings of the Expert Committee, etc. The Chairman directed the witnesses to send comprehensive written replies to queries which remained unanswered, within a week's time.

6. A verbatim record of the proceedings of the meeting was kept.

7. The Committee adjourned at 12.56 P.M.

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* Relate to other matters.

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XV
FIFTEENTH MEETING
(2012-13)

The Committee met at 4.00 P.M. on Thursday, the 29th August, 2013 in Committee Room 'A', Ground Floor, Parliament House Annexe, New Delhi.

MEMBERS PRESENT

1. Shri Brajesh Pathak — *Chairman*

RAJYA SABHA

2. Shri Jagat Prakash Nadda
3. Shri Mohd. Ali Khan
4. Shri H.K. Dua

LOK SABHA

5. Shri Kuvarjibhai M. Bavalia
6. Dr. Sucharu Ranjan Haldar
7. Mohd. Asrarul Haque
8. Dr. Sanjay Jaiswal
9. Shrimati Jayshreeben Patel
10. Dr. Anup Kumar Saha
11. Shri P. T. Thomas

SECRETARIAT

Shri P.P.K. Ramacharyulu, *Joint Secretary*
Shri R. B. Gupta, *Director*
Shrimati Arpana Mendiratta, *Joint Director*
Shri Dinesh Singh, *Deputy Director*
Shri Pratap Shenoy, *Committee Officer*

* * *

I. Opening Remarks

2. At the outset, the Chairman welcomed the Members of the Committee and apprised them of the agenda of the meeting, *i.e.*, * * * and consider and adopt draft Seventy-second Report on "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India."

* Relates to other matters.

II. Adoption of the Draft Report on "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India."

3. The Committee then considered and discussed the draft Seventy-second Report on "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India." The Chairman invited Members to share their specific suggestions for incorporation in the Draft Report. After some discussion, the Committee adopted the Report with some modifications.

4. The Committee, thereafter, decided that the Report may be presented to the Rajya Sabha and laid on the Table of the Lok Sabha on Friday, the 30th August, 2013. The Committee authorized its Chairman and in his absence, Shri Shri H.K. Dua and Shri Jagat Prasad Nadda to present the Report in Rajya Sabha, and Shri Sanjay Jaiswal, and in his absence, Dr. Anup Kumar Saha to lay the Report on the Table of the Lok Sabha.

II.	*	*	*
3.	*	*	*
4.	*	*	*

5. A verbatim record of the proceedings of the meeting was kept.

6. The Committee adjourned at 5.00 P.M.

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ANNEXURES

NOTARY
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ANNEXURE-A

Committee to investigate "Alleged irregularities in conduct of studies in India using Human Papilloma Virus (HPV) vaccine"

Minutes of the 5th **Meeting** held on September 27th at the Indian Red Cross Society, (NHO), New Delhi

1. All members of the committee were present. In addition the Experts nominated to assist the committee *vide* GO no. V.250II/160/20IO-HR dated June 30th, 2010 were also invited to attend the meeting.

2. The minutes of the meeting dated June 22nd, 2010 as circulated were adopted.

3. The Experts were requested to present salient findings of their reports and the members discussed with them their findings. A summary of the discussions is as follows:

   (a) Dr. Rani Kumar, Dean, AIIMS –

      (i) She was requested to carry out numerical analysis of the consent forms – under headings already identified – separately for the AP and Gujarat. (Action: Dr. Rani Kumar)

      (ii) She requested the list of members of the two ethics committees at AP and Gujarat. In particular she asked about the membership of a lawyer in the committee. She also asked about the functioning of these committees – the number and dates of meetings, and any monitoring of the PATH study prior to repots in the Press. (Action: Dr. Kishore Chaudhry)

      (iii) Opined that the trial in adolescent girls was justified as this is the target group to benefit, but authorization of school authorities by the AP Govt. to give consent on behalf of the girls was not correct. Also, implementation of the procedure of taking consent lacked rigor.

   (b) Dr. Y.K. Gupta, HOD Pharmacology, AIIMS – made the following points:

      (i) Bridging trials in India, as required under Schedule Y for drugs/vaccines already approved and in use abroad, for licensing in India were carried out as required. One of the studies was in Adults and the other one was in adolescent girls.

      (ii) The DCGI has licensed the GSK HPV vaccine Cervarix for " .... females from 10-45 years of age for prevention of cervical cancer. ... ", and MSD vaccine Gardasil for " .. girls and women 9-26 years of age for prevention of cervical cancer ..."

      (iii) There is wide international experience, including that in India, regarding use of HPV vaccines in adolescent girls.

      (iv) HPV vaccines are quite safe. Millions of doses of HPV vaccines of both types have been used abroad. By the end of May, 2010, there were 16, 410 VARES reports of AE following Gardasil vaccination licensed in the US in 2006. 8% of these have been considered serious, including syncope, GB syndrome, blood clots, and anaphylaxis. A total of 53 deaths have been recorded following vaccination

but they do not seem to be related to the vaccine. The use of the vaccine continues all over the world. Several countries have incorporated it in their national programmes.

(v) Both the GSK and MSD have submitted the required Periodic Safety Update Reports to the DCGI. These are international reports, and not India specific. There has been some delay in submission of these reports. The last six monthly report for 18th November to 17th May, 2010 which should have covered the reports the deaths from India has not been submitted yet.

(vi) A critical analysis of the First Information Reports of SAE/Deaths, Medical records related to these events and the Post-mortem reports do not support the possibility of deaths to be related to vaccine but it can not be ruled out with certainty. This was mainly because the alternate cause of death as listed can not be fully substantiated on the basis of medical records in all the cases. The quality of the medical records was not adequate. The capability of the local staff and preparedness to deal with SAEs/Critical illnesses leading to death is also suspect. Most of the deaths were detected when the ANMs were mobilizing the recipients for the next vaccination. These events were not reported and investigated timely. In most cases the treatment was provided by private medical practitioners and the subjects had to be shifted to a better facility while they died on the way. There was no plan to deal with the crisis as it emerged.

(vii) There is a strong need to strengthen the post-licensing surveillance.

(c) Dr. A.K. Dutta, Head of Pediatrics, Kalavati Saran Hospital, New Delhi –

(i) Dr. Dutta focused on analysis of Deaths and AE, both serious and minor, under the HPV vaccination project carried out in AP and Gujarat, by PATH in collaboration with the respective State Governments.

(ii) Dr. Dutta highlighted that the Primary Outcome measures of the project were:

- Number and percent of eligible girls fully vaccinated, partially vaccinated or not vaccinated at all according to vaccine delivery strategy
- Number and percent of vaccinated girls experiencing serious adverse events, as reported spontaneously through routine mechanisms of UIP programme
- Number and percent of vaccinated girls experiencing non-serious adverse events, as reported spontaneously through routine mechanisms of UIP programme
- Timelines of reporting serious adverse events to local, state and National authorities, as per the usual UIP protocol and
- Timelines of reporting non-serious adverse events to local, state and National authorities, as per the usual UIP protocol

(iii) Since 4 out of the 5 outcome measures related to monitoring and reporting of AE the project should not have totally relied on the existing UIP AEFI reporting system. There should have been a parallel research based monitoring system for AEFI to compare with the State system. Alternatively the effectiveness of the State system should have been pre-verified before initiating the study.

(iv) Dr. Dutta found that 3 of the 7 deaths have occurred within 30 days of last vaccine dose (one in AP and 2 in Gujarat, on days 18,20 and 23), while 4 were after this period (45,49,96,97 days after the vaccine).

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The ones within 30 days have been attributed to Fever of unknown origin - ? Viral, Malaria and Snake bite. Two of the 4 later deaths were attributed to Pesticide poisoning. In both cases post-mortem has been done and chemical report on record has confirmed presence of the poison in stomach.

In one case there was history of drowning in a pond. The fourth case has died after a brief illness of few hours, probably neurological ? Intracranial hemorrhage/ Intracranial space occupying lesion.

Dr. Dutta's observation was that – 1. There was no specific pattern of illness leading to death, 2. The illnesses can not be explained by expected adverse responses to vaccine, and 3. There was an alternate plausible diagnosis in most cases. Therefore, the deaths were unlikely to be related to the vaccine. However, post-mortem has been carried out only in 2 cases. And the alternate diagnosis is not confirmed in all the cases.

(v) Further a critical analysis of the reporting of other AE and SAE shows the inadequacies of the AEFI reporting system. Dr. Dutta was of the opinion whether it was an observational study or otherwise the vaccine was administered to the subjects and data collected for enerating knowledge. It should have followed all the rigors of the research.

4. The committee deliberated on the reports of the Experts and pertinent data received under various queries raised during previous meetings of the committee. Besides the factual information about the terms of reference the committee was greatly concerned with the aspect of commercial interests of manufacturers influencing the Government policy on this expensive vaccine. The committee observed that the study was initiated by PATH on its own having obtained funds from the Bill and Melinda Gates Foundation and supply of vaccine from the manufacturers – without any reference from the NTAGI, the official body of the GOI on vaccines. It is not clear whether the State expenses were funded by PATH or came from their own resources. The monetary contribution of ICMR is also not clear. The committee therefore felt that it would be in the fitness of the inquiry to document the sources and magnitude of funding of the study. It desired to obtain the following information from the PI, *i.e.* PATH in this case:

(i) Letter of Sanction of grant form Bill and Melinda Gates foundation for Indian study

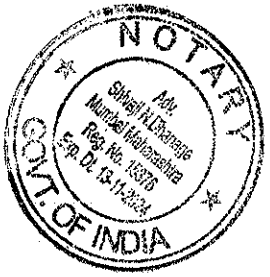
(ii) Letter of donation of vaccine by the manufacturers and the invoice indicating the cost of the vaccine for trial in India

(iii) Copies of the letters of PATH to ICMR and State Government, including the terms and conditions of collaboration

(iv) Financial contribution of the 3 parties to the study, *viz.*, the PA TH, ICMR and the State Governments from beginning till date

Action: Dr. Kishore Chaudhry

5. The committee noted the urgency to submit the report. Since most of the facts have been gathered and analyzed, including the critical input of the experts, it decided to expedite the finalization of the report. Since there was consensus on all issues among the members, the committee authorized the chairman to prepare the draft report which may be circulated to all the members and then finalized in a meeting called for the purpose. In the meantime the additional information as identified above may also be collected. The next meeting could be held in about 2 week time. (Action: Chairman)



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ANNEXURE-B

Government of India
Ministry of External Affairs

भारत सरकार
विदेश मंत्रालय, नई दिल्ली

New Delhi the_____200

No.AA/551/1/2011

Dt. 11th June, 2012.

OFFICE MEMORANDUM

Sub: Clinical Trial of HPV Vaccine – regarding

Reference O.M. No. RS.10/2(ii)/2011-Com. (H&FW) dated 4th June, 2012 from the Parliament of India, Rajya Sabha Secretariat, New Delhi, on the subject mentioned above.

2 As per the existing procedure, the clearance of the Ministry of External Affairs from Political angle is required before any foreign organisation/charity/foundation etc. sets up an office/branch in India. The concerned foreign entity may approach this Ministry with a detailed proposal, to be routed through the concerned nodal Ministry in India, for processing and issue of above Political clearance.

Sd/-
(R.K. Nagpal)
Deputy Secretary (Coord)

Parliament of India
Rajya Sabha Secretariat,
[Kind Attn: Ms. Arpana Mendiratta, Joint Director],
Parliament House/Annexe,
New Delhi. Telefax: 23035428
23012007

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ANNEXURE-C

No.II/20034/280/2012-IS-II
Government of India
Ministry of Home Affairs
IS-I Division, (IS-II Desk)

New Delhi, the 5th July, 2012

Office Memorandum

Subject:– Parliamentary Standing Committee on Health and Family Welfare – clinical trial of HPV Vaccine and related matters – furnishing of information to the Committee.

The undersigned is direacted to enclose a copy of Rajya Sabha Secretariat O.M No.RS.10/2(ii)/2011-Com.(H&FW) dated 21st June, 2012 along with a copy of earlier D.O. letter dated 4th June, 2012 regarding clinical trial of HPV Vaccine on the subject noted above and to state that Department of Economic Affairs is the concerned Administrative Ministry for "setting up of the Liaison Offices/Branch Offices/Project Offices in India by foreign entities". As such, laying down the procedure/rules/guidelines etc. for setting up of such offices falls within the ambit of DEA.

2. Department of Economic Affairs seeks MHA's comments from security angle on the applications received from various firms for setting up of the Liaison Offices/Branch Offices/Project Offices in India by foreign entities. As such, Ministry of Home Affairs assesses the suitability of the applicant company from security angle.

3. Further, a draft Circular proposed by RBI and forwarded by DEA containing additional reporting feature by foreign entities for implementing additional security safeguards is under consideration in this Ministry.

4. In view of foregoing, the above Rajya Sabha Secretariat O.M. dated 21st June, 2012 along with its enclosures is transferred to Department of Economic Affairs for giving a suitable reply to Rajya Sabha Secretariat, under intimation to this Ministry.

Sd/-
(Rakesh Mittal)
Director (IS-I)

Department of Economic Affairs,
(Shri R.K. Sinha, Under Secretary),
North Block, New Delhi.

Copy for information to: Rajya Sabha Secretatiat (Ms. Arpana Mendiratta, Joint Director), Parliament House Annexe, New Delhi-110001.

NOTARY
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"EXHIBIT "L4" "

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प्रति

१. पोलीस आयुक्त, पालघर जि. ठाणे.

२. मा. राज्यपाल, राजभवन, मुंबई.

३. मा. पोलीस महासंचालक, महाराष्ट्र

अर्जदार: श्रीमती किरण यादव

रा.विरार गार्डन, बिल्डिंग नं. ०१, रूम नं. १०७,

आगाशी रोड, विरार रोड (वेस्ट), मुंबई - ४०१३०३.

विषय: कोव्हीशील्ड लस ही प्राणघातक असून त्या लसीमुळे जीवघेणे दुष्परिणाम होवू शकतात याची स्पष्ट माहिती सर्वांना देणे हे राज्यातील टास्क फोर्स चे सदस्य व सर्व वरीष्ठ अधिकाऱ्यांना व डॉक्टरांना बंधनकारक असल्याचा स्पष्ट कायदा असताना गैरहेतू साध्य करण्याकरीता आरोपी डॉक्टर व अधिकाऱ्यांनी अपराधिक कट रचून सी वाय जाधून वुजून तपवून, तसेच लस पूर्णत: सुरक्षीत आहे अशा खोट्या जाहिराती करून आणि नंतर केंद्र शासनाच्या निर्देशांविरुद्ध जावून लोकल ट्रेन व कामाच्या ठिकाणी लस घेणे बंधनकारक असल्याचा नियम आणून माझ्या मुलास सक्तीलाजास्तव लस घेण्यास भाग पाडून सुनियोजित पद्धतीने त्याचा जीव घेतल्यामुळे आरोपीविरुद्ध भादंवि ३०२, ४२०,

NOTARY M.M. PABALE Mumbai Maharashtra Regd. No. 15220 Expiry Dt. 30-12-2024 GOVT. OF INDIA

लिपिक
पोलीस महासंचालक कार्यालय,
महाराष्ट्र राज्य, मुंबई - ०१

TRUE COPY

MANISH M. PABALE
B.Sc., LL.M.
ADVOCATE & NOTARY (GOVT. OF INDIA)
104, Natwar Chambers,
94 Nagindas Master Road,
Fort, Mumbai - 400 001

TRUE COPY
Mehra
ADVOCATE FOR Petitioner

27 OCT 2021

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४०९, १२०(बी), ३४ आदी कलमांतर्गत गुन्हा नोंद करून त्वरित कारवाई करण्याचे आदेश देणेबाबत.

महोदय,

१. मी वरील ठिकाणची रहिवाशी असून, मी मृतक श्री. हितेश कडवे याची आई आहे.

२. आरोपी लोकांच्या करास बळी पडून माझ्या मुलाने दिनांक २९.०९.२०२१ रोजी कोव्हीशील्ड ही लस घेतली व त्याने दोन तासानंतर माझ्या मुलाचा मृत्यू झाला.

३. सदर तक्रारीद्वारे मी माझ्या तरुण मुलाच्या हत्येस जबाबदार आरोपी डॉक्टर व अधिकाऱ्यांविरुद्ध सर्व पुराव्यांसहीत तक्रार देत असून आपण त्वरीत गुन्हा दाखल करून आरोपींना अटक करून त्यांच्याकडून होणारे पुढचे गुन्हे त्वरीत राखावेत व इतर लोकांचे जीव वाचवावेत ही विनंती करीत आहे.

४. माझ्या मुलाला दिलेली लस कोव्हीशील्ड ही पूर्णतः प्रमाणित नसून केवळ प्रायोगिक (Experimental) असल्याचे मला आता कळाले आहे. परंतु हि बाब कोणत्याही सरकारी अधिकाऱ्याने, डॉक्टरांनी व टास्क फोर्सच्या सदस्यांनी जनतेला सांगितलं नाही. तसेच लस घेताना सुद्धा माझ्या मुलास सांगितले नाही.

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५. नंतर मी माहिती घेतली असता मला असे कळाले की, कायद्यातील तरतुदीनुसार व विशेषकरून **Universal Declaration of Bioethics and Human Rights, 2005** आणि **International Covenant on Civil & Political Rights Art. ____** नुसार तसेच मा. सर्वोच्च न्यायालय यांचे **Montgomery v Lanarkshire Health Board [2015] UKSC 11** व इतर प्रकरणातील डॉक्टरांना व हॉस्पिटल्सना दिलेल्या कायदेशीर निर्देशानुसार कोणत्याही व्यक्तीला कोणतेही औषधे किंवा प्रायोगिक लस द्यावयाची असल्यास त्या लसीचे संपुर्ण दुष्परिणाम वैगरे समजावून सांगून त्याची लेखी संमती घेतल्याशिवाय लस देता येत नाही.

६. खुद्द कोव्हीशील्ड कंपनीनेच त्याच्या लसींसोबत दिलेल्या **Fact Sheet** मध्ये अँलर्जी व इतर विशिष्ट श्रेणीतील लोकांना लस देवू नये असे स्पष्ट नमूद केले आहे. परंतु लस देणारे आरोपी व त्या केंद्राचे प्रमुख डॉक्टर्स पासून ते महाराष्ट्राचे मुख्य सचिव श्री. सीताराम कुंटे पर्यंत तसेच दिल्लीच्या **AIIMS** चे डॉ. रणदीप गुलेरीया, **DGCI** चे डॉ. डी. जी. सोमाणी आदी अनेक आरोपींनी वेळोवेळी युट्यूब, दैनिक वर्तमानपत्र, न्यूज चैनल, फोनची कॉलर ट्यून आदी सर्व ठिकाणी जाहीराती देवून किंवा मुलाखतीमध्ये लस पूर्णतः सुरक्षित असल्याचा खोटा प्रचार केला.

७. **DGCI (Drugs Controller General of India)** चे डॉ. वी.जी. सोमानी यांनी तर त्यांच्या **'दि न्यू इंडियन एक्सप्रेस'** मध्ये दि. ०३

जानेवारी, २०२१ च्या संदेशात असे म्हटले की, लस ही ११०% सुरक्षित आहे.

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Link:-

https://www.newindianexpress.com/nation/2021/jan/03/covid-19-vaccines-110-per-cent-safe-impotency-rumours-complete-nonsense-dogi-2244820.html

८. वरील म्हणणे पूर्णतः खोटे असून लसीच्या दुष्परिणामाने हजारो लोकांचे जीव गेल्याचे पुरावे खालील लिंक वर उपलब्ध असल्याची माहिती मला आताच प्राप्त झाली आहे. आजपर्यंत कोरोनाच्या दुष्परिणामांमुळे मृत्यू झालेल्या लोकांची एकूण माहिती व संबंधीत प्रकाशीत बातम्या खालील लिंकवर उपलब्ध आहेत.

Link:
https://drive.google.com/file/d/1uikc1a6_KDzUx7HNLrTwal1NJRt0D_YP/view

९. जर वरील आरोपींनी सत्य परिस्थिती सांगितली असती तर माझ्या मुलाने लस घेतलीच नसती तर त्याचा जीव वाचला असता. अश्याप्रकारे वरील सर्व आरोपी व त्यांना या कटात सहकार्य करणारे सर्व लोक हे माझ्या मुलाच्या हत्येसाठी जबाबदार असून त्यांच्याविरुद्ध भादंवि ३०२, ४२०, १०९, १२०(ब)व ३४ अंतर्गत फौजदारी कारवाई त्वरीत करने आवश्यक आहे.

NOTARY M.M. PAWALE GOVT. OF INDIA

NOTARY Advocate & Notary Mumbai Maharashtra Reg. No. 15076 Exp. Dt. 13-11-2024 GOVT. OF INDIA

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१०. तसेच आरोपींनीं वरील गुन्हे करण्यामागे त्यांचा उद्देश लस निर्माता कंपनी कोव्हीशील्ड यांचे मालक अदार पुनावाला व त्यांचे भागीदार बिल गेट्स यांना गैरफायदा पोहचविण्याचा असल्याचे सिद्ध होते.

११. आरोपी डॉक्टर्स व अधिकाऱ्यांनी मुख्य लाभकर्ता लस कंपनीला फायदा पोहचविण्यासाठी त्यांच्या सरकारी नोकरीच्या पदाचा व शासकीय यंत्रणेचा दुरुपयोग केल्यामुळे आरोपींविरुद्ध भादंवि ४०९ कलमांतर्गत सुद्धा कारवाई आवश्यक आहे.

१२. माझ्या मुलाच्या हत्येनंतर सदर प्रकरणात मी सखोल चौकशी केल्यानंतर हे सिद्ध झाले की संपूर्ण कट हा एका मोठ्या आंतरराष्ट्रीय कटाचा भाग असून त्या कटाचा मुख्य सूत्रधार **'बिल गेट्स'** हा आहे व तो कोव्हीशील्ड या लस कंपनीचा भागीदार आहे. पुणे येथे सीरम इंस्टीट्यूट नावाची कंपनी असून त्या कंपनीमध्येच कोव्हीशील्ड चे उत्पादन होते.

१३. कटाचा मुख्य सूत्रधार **'बिल गेट्स अँड मिलिंडा गेट्स फाउंडेशन'** नावाच्या संस्थेमार्फत लस निर्माता कंपन्यांना फायदा होईल असे प्रकल्प राबविण्यासाठी देणगी देत असतो व लोकांना तो एक **Charitable** समाजपयोगी कार्य करीत असल्याचा खोटा आव आणतो. परंतु त्यांचा खरा उद्देश हा विविध लसीकरणाचा प्रचार करून ती लस शासकीय कार्यक्रमात **National Immunization Programme** मध्ये सामील करून घेण्याचा असतो. कारण तसे केल्यास त्यांचे भारतात दरवर्षी करोडो ग्राहक निश्चित होतात व

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त्यानंतर लस कंपन्या ह्या वर्षानुवर्षे लाखो कोटी रुपयांचा नफा काहीही न करता कमावत राहतात.

१४. आरोपी बिल गेट्स च्या अश्याच एका कटामुळे एचपीव्ही च्या लसींच्या अनाधिकृत वापरामुळे ८ मुलींची हत्या झाली होती व त्यामध्ये केंद्रीय संसदीय समिती (Parliamentary Committee) ने चौकशी करून आपल्या ७२व्या अहवालात (72nd report) **'बिल अँड मिलिंडा गेट्स फाऊंडेशन'** पुरस्कृत अनाधिकृत लसींच्या चाचण्या करणारी 'पाथ' नावाची संस्था व त्या त्या गुन्ह्यांमध्ये सामील **ICMR** आणि **DGHS** चे भ्रष्ट अधिकाऱ्यांविरुद्ध गुन्हा दाखल करून सी बी आय मार्फत चौकशी करण्याचे निर्देश दिले होते. तो अहवाल पुरावा म्हणून वापरता येईल असा स्पष्ट कायदा या सर्वोच्च न्यायालयाचे संविधान पीठाने **"कल्पना मेहता वि. युनियन ऑफ इंडिया 2018 (7) SCC 1**, प्रकरणात ठरवून दिला आहे.

१५. बिल गेट्स ने त्याच्या गुन्हेगारी व विकृत मानसिकतेपोटी या आधीसुद्धा अशास्त्रीय पद्धतीने पोलियो लसीचे डोज वाढवून भारत देशातील ४ लाख ५० हजार निष्पाप मुलांना जन्माचे पांगळे केले व हजारो मुलांचे जीव घेतले. शेवटी सरकारने बिल गेटचा तो जीवघेणा प्रकल्प गुंडाळून त्याला भारतातून जाण्यास सांगितले. त्याबाबत सविस्तर बातमी खालील लिंक वर उपलब्ध आहे.

Link:

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https://greatgameindia.com/bill-gates-path-tribal-girls-india/

१६. बिल गेट्सने त्याच्या विविध संस्थांच्या माध्यमातून **Public Health Foundation of India** ही संस्था भारतात उभारली असून त्या संस्थेच्या माध्यमातून तसेच त्याच्या ग्रुपमधील इतर काही प्रभावशाली डॉक्टर्स जसे डॉ. गगणदीप कांग, डॉ. बलराम भार्गव आदी लोकांच्या माध्यमातून ती लोक देशातील विविध राज्यांच्या आरोग्य मंत्रालयातील निर्णय प्रक्रीया प्रभावित करुन फक्त लस निर्माता कंपन्यांच्या फायद्याचेच नियम बनवीत असल्याची माहिती युवा शोध वैज्ञानिक श्री. योहान टेंगर यांनी त्यांच्या मुलाखतीमध्ये (interview) मध्ये दिली आहे.

Link:

https://awakenindiamovement.com/indias-covid-19-task-force-experts-exposed-conflicts-of-interest-in-our-public-health-system/

१७. तसेच 'बिल गेट्स व रॉकरफेलर फाऊंडेशन' अशा विविध संथांच्या माध्यमातून मुंबई महानगर पालिकेला निधी देवून त्यांच्याकडून लस कंपन्यांच्या\फायद्याचेच निर्णय घेतले जात असल्याची माहिती सुध्दा श्री. योहान टेंगर यांनी दिली आहे.

१८. आरोपींच्या कटात सामील दुसरे आरोपी म्हणजे गुगल चे मालक श्री. सुंदर पिचई व यु ट्युब चे संचालक हे आहेत.

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त्या लोकांनी जगातील अनेक नामवंत डॉक्टर्स, तज्ञ व वैज्ञानिकांचे लसीचे दुष्परीणाम सांगणारे अनेक व्हीडीओ व माहिती कडून टाकली असून फक्त 'लस ही पूर्णतः सुरक्षीत आहे' असा खोटा\संदेश देणारे व्हीडिओच फक्त ठेवले आहे व ते त्यांनी स्वतःहून यु ट्यूब वर अपलोड केले आहे. त्या व्हीडीओमध्ये मुख्य करुन सहआरोपी असलेले **AIIMS** चे डॉ. रणदीप गुलेरीया यांचा व्हीडीओ आहे.

१९. अशाप्रकारे आरोपी लोकांनी एका सुनियोजित कटाद्वारे थंड डोक्याने योजना आखून माझ्या मुलाची व इतर अनेक निष्पाप लोकांच्या हत्या केल्या आहेत. जर आरोपीविरुद्ध गुन्हा दाखल करून त्यांना ताबडतोब अटक केली नाही तर अनेक निष्पाप लोकांचे बळी जातील. तरी आपण यात त्वरित पावले उचलून दोषींविरुद्ध कठोर कारवाई करणे अत्यंत आवश्यक आहे.

२०. आरोपींनी त्यांच्या कटाद्वारे जनतेला फसवून स्वतःचा लाखो कोटींचा गैरफायदा करून घेतला असून ती सर्व चल-अचल संपत्ती जप्त करून पीडितांना नुकसान भरपाई देणे अत्यंत आव्यश्यक आहे.

२१. लस घेतलेली लोक कोरोना पासून सुरक्षित नसून त्यांचा मृत्यू कोरोनानेच झाल्याचे पुरावे उपलब्ध आहेत.

२२. इंडियन मेडिकल असोसिएशन चे पूर्व अध्यक्ष के.के. अग्रवाल व दिल्लीतील 60 डॉक्टर्स ज्यांनी कोरोना लसीचे दोन्ही डोस घेतले होते. परंतु त्यांचा मृत्यू कोरोनानेच झाला होता.

Link:

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i) https://www.ndtv.com/india-news/dr-kk-aggarwal-ex-chief-of-india-medical-association-ima-dies-of-covid-19-coronavirus-2443827

ii) https://theprint.in/health/at-least-60-delhi-doctors-have-died-in-2nd-covid-wave-families-are-left-to-pick-up-pieces/661353/

२३. ठाणे येथील 75 डॉक्टर्स चा मृत्यू कोरोनाने झाल्याची बातमी दि.01 जुलै, 2021 रोजी दै. लोकमत मध्ये प्रकाशित झाली होती.

Link:
https://drive.google.com/file/d/1eZGQoHzzl4pUShRYt7U0YZ82zvJ4UYEn/view

२४. लसींच्या दुष्परिणामांमुळे लोकांचे मृत्यू होत असल्यामुळे 11 युरोपियन देशांनी कोव्हीशिल्ड (Astrazenica) या लसीला बंदी घातली होती.

Link:

https://timesofindia.indiatimes.com/life-style/health-fitness/health-news/covishield-coronavirus-vaccine-with-covishield-astrazeneca-banned-in-some-countries-should-we-be-worried-about-its-safety/photostory/83398722.cms

२५. परंतु आरोपींनी नागरिकांना होणाऱ्या दुष्परिणामासंबंधी कोणतीही दखल घेतलेली नाही.

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केंद्र सरकारने व देशातील विविध न्यायालयांनी वेळोवेळी निर्णय देवून स्पष्ट कायदा ठरवून दिला आहे की कोरोना ची तस (वॅक्सीन) घेणाऱ्या व्यक्तीला सुद्धा पुन्हा कोरोनाची लागण होऊ शकते व तो सुद्धा कोरोनाचा संसर्ग पसरवू शकतो त्यामुळे लस घेतलेल्या व्यक्तीला सुद्धा वॅक्सीन न घेतलेल्या व्यक्तीप्रमाणेच सर्व निर्बंध लागू राहतील. तस घेतलेल्या व्यक्तीमध्ये आणी लस न घेतलेल्या व्यक्तीमध्ये कोणताही फरक नसतो त्यामुळे त्यांच्यामध्ये कोणताही भेदभाव करता येणार नाही जर लस न घेणाऱ्यासोबत भेदभावपूर्ण वागणूक करून त्यांना कोणत्याही लाभापासून वंचित ठेवल्यास ते नागरिकांच्या घटनादत्त मुलभूत अधिकारांचे उल्लंघन ठरते व असे गैरकृत्य करणारे अधिकारी, मंत्री इत्यादी हे भारतीय राज्यघटनेच्या कलम 14, 19, 21 चे उल्लंघन केल्याप्रकरणी भा.द.वि. चे कलम 166, 188 तसेच आपत्ती व्यवस्थापन कायदा. 2005 चे कलम 51, 55 नुसार कारवाईस पात्र ठरतात.

२६. तस (वॅक्सीन) घेणे किंवा न घेणे हे ऐच्छिक असून कोणतीही वैद्यकीय उपचार पद्धती स्वीकारणे व नाकारणे हा प्रत्येक व्यक्तिचा मूलभूत अधिकार आहे. त्याकरीता कोणालाही प्रत्यक्ष किंवा अप्रत्यक्ष दबाव आणता येणार नाही असा स्पष्ट कायदा सर्वोच्च न्यायालय, दिल्ली व इतर विविध उच्च न्यायालप यांनी ठरवून दिला आहे.

२७. तसेच गुवाहाटी उच्च न्यायालय, मणीपूर, त्रिपुरा, मेघालय आदि बन्याच उच्च न्यायालयाने कोरोना लसी संदर्भात असे भेदभाव करणारे राज्य शासनाचे आदेश स्थगीत व खारीज केले आहेत ते आदेश केंद्र

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NOTARY Adv. Shivaji M. Dhanawade Mumbai Maharashtra Reg. No. 15379 Exp. Dt. 13-11-2024 GOVT. OF INDIA

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सरकार (Union of India) उत्तरवादी असताना पारित केले असल्यामुळे देशातील सर्व राज्यांना लागू आहेत. **[Registrar Meghalaya Vs. State of Meghalaya 2021 SCC Online Megh 130. ,In Re: Dinthar Incident Aizawl Vs. State of Mizoram 2021 SCC OnLine Gau 1313.]**

केंद्र सरकारचे निर्देश खालील लिंक वर उपलब्ध आहेत.

Link:
https://drive.google.com/file/d/1DVWL0m4Do08uZJBZ7P5Y_URwyxza-r-t/view

२८. सदर प्रकरणात केंद्र शासनाचे निर्देशांचे व माननीय उच्च न्यायालयाच्या आदेशाचे उल्लंघन करून लसीकरण झालेल्या लोकांना विशेष सवलती देऊन लोकांना लस घेण्यास भाग पाडणाऱ्या योजना व निर्बंध राबविणारे व लोकल ट्रेनमध्ये प्रवासासाठी तशी शिफारस करणारे मुंबई महानगरपालिका आयुक्त इक्बाल चहल, यांना साथ देणारे सुरेश काकाणी व त्या बेकायदेशीर निर्बंधांना लागू करून लोकांच्या व माझ्या मुलाच्या हत्येस जबाबदार इतर नेते, मंत्री आदींना सुद्धा सहआरोपी बनविणे आवश्यक आहे.

२९. सदर प्रकरणात मी माझी तक्रार नोंदविण्याकरीता पो. स्टे. येथे या आधी न नुकतेच दि. **17.10.2021** रोजी गेले होते. परंतु तिथे उपस्थित पोलीस अधिकारी गुन्हा नोंदवून घेतला नाही.

३०. माझी तक्रार ही दखलपात्र व आज्ञामीनपात्र गुन्ह्यासंदर्भात असल्यामुळे संबंधित पोलीस अधिकाऱ्यांनी गुन्हा नोंद करणे बंधनकारक

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असल्याचा स्पष्ट कायदा मा. सर्वोच्चय न्यायालयाच्या संविधानपीठाने **Lalita Kumari Vs. Government of U.P. (2014) 2 SCC 1** प्रकरणात ठरवून दिला आहे. परंतु त्या आदेशाची अवमानना करून माझी तक्रार का नोंदविण्यात आली नाही याबाबत सखोल चौकशी व कारवाई आवश्यक आहे.

३१. सदर प्रकरणाची व्याप्ती फार मोठी असून यामध्ये मोठे अधिकारी व मंत्री यांचा सहभाग असल्यामुळे प्रकरणाचा तपास हा सी.बी.आय. (Central Bureau of Investigation) यांनी करावा असा कायदा सर्वोच्च न्यायालयाने ठरवून दिला असून त्याच कायधाच्या आधारे नुकतेच मा. मुंबई उच्च न्यायालयाने 5th April 2021 चे आदेशानुसार गृहमंत्री अनिल देशमुख यांच्याविरुद्धच्या गुन्हयाचा तपास सी. बी. आय. कडे दिला आहे व त्या प्रकरणात आरोपी मंत्री फरार सुद्धा झालेले आहेत.**[Parmbeer Singh Vs. State 2021 SCC OnLine Bom 516]**

३२. **विनंती**:- नम्र विनंती की,

i) कोव्हीशील्ड लस ही प्रायोगीक असून त्या लसीचे जीवघेणे दुष्परिणाम होवू शकतात याची स्पष्ट माहिती सर्वाना देणे हे राज्यातील टास्क फोर्स चे सदस्य व सर्व वरीष्ठ अधिकाऱ्यांना व डॉक्टरांना बंधनकारक असल्याचा स्पष्ट कायदा असताना गैरहेतू साध्य करण्याकरीता आरोपी डॉक्टर व अधिकाऱ्यांनी अपराधिक कट रचून ती बाब जाणून बुजून लपवून, तसेच लस पूर्णतः सुरक्षीत आहे अश्या खोट्या जाहिराती करून आणि

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नंतर केंद्र शासनाच्या निर्देशांविरुद्ध जावून लोकल ट्रेन व कामाच्या ठिकाणी लस घेणे बंधनकारक असल्याचा नियम आणून माझ्या मुलास नाईलाजास्तव लस घेण्यास भाग पाडून सुनियोजित पद्धतीने त्याचा जीव घेतल्यामुळे आरोपींविरुद्ध भादंवि **३०२, ४२०, ४०९, १२०(बी), ३४** आदी कलमांतर्गत गुन्हा नोंद करून त्वरित कारवाई करण्याचे आदेश देण्यात येवून प्रकरणाचा तपास सी.बी.आय. कडे देण्यात यावा.

ii) आरोपीमध्ये लस केंद्रावर लस देणारे डॉक्टर पासून या तक्रारीत नमूद सर्वांना आरोपी बनविण्यात यावे.

iii) सदरचा गुन्हा हा हत्येचा गुन्हा असून देशातील सर्वात मोठा व गंभीर स्वरूपाचा व अजामीनपत्र असल्यामुळे तसेच आरोपींचा कट व लोकांच्या हत्या याच सुरूच असल्यामुळे आरोपींना त्वरित अटक करून इतर लोकांचे जीव वाचवावेत.

iv) सर्व आरोपींची चल-अचल संपत्ती बँक अकाऊंट जप्त करण्या यावी.

सही/-

श्रीमती किरण यादव

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सत्यापन

मी. **श्रीमती किरण यादव,** रा. विरार गार्डन, बिल्डिंग नं. ०१, रूम नं. १०७, आगासी रोड, विरार रोड (वेस्ट), मुंबई – ४०१३०३, महाराष्ट्र, वय ४६ वर्षे, शपथेवर सत्यापित करते की, वर लिहलेला मजकूर हा माझ्या माहितीप्रमाणे खरा असून माझा त्यावर पूर्ण विश्वास आहे म्हणून मी आज रोजी सत्यापन अधिकारी / नोटरी समक्ष त्यावर स्वाक्षरी करीत आहे.

स्थान: मुंबई

दि. २५.१०.२०२१

सही/-

श्रीमती किरण यादव

सत्यपाक

BEFORE ME

MANISH M. PABALE
B.Sc. LL.M.
ADVOCATE & NOTARY (GOVT. OF INDIA)
104, Natwar Chambers,
94 Nagindas Master Road,
Fort, Mumbai - 400 001.

NOTED & REGISTERED
Page No. 113/24 Sr. No. 355
Date 25 OCT 2021

ID / Aadhar / PAN / DL: [illegible]
Seen Org. / POA / Board Resol.:

"EXHIBIT "M" "

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Public Interest Litigation No. 34 of 2021

Osbert Khaling v. State of Mánipur

2021 SCC OnLine Mani 234

In the High Court of Manipur at Imphal

(BEFORE SANJAY KUMAR, C.J. AND KH. NOBIN SINGH, J.)

Osbert Khaling ... Petitioner;

Versus

State of Manipur and Others ... Respondents.

Public Interest Litigation No. 34 of 2021

Decided on July 13, 2021

The Judgment of the Court was delivered by

SANJAY KUMAR, C.J.:— Heard Ms. Carolin Casar, learned counsel for the petitioner.

2. Notice before admission, returnable on 28.07.2021.

3. Mr. S. Rupachandra, learned Addl. Advocate General, Manipur, takes notice for the respondents and waives further notice. He seeks time to file a reply.

4. Needful shall be done by the next date of hearing with an advance copy to the counsel opposite.

5. Challenge is to the Notification dated 30th June, 2021, issued by the Home Department, Government of Manipur, and more particularly para 2 thereof, which states that the State Government proposes to relax curfew/containment zone orders in future in a calibrated manner by assessing the Covid infection scenario and while opening up, without compromising public health safety, the Government considered it prudent to prioritize opening of institutions, organizations, factories, shops, markets, private offices, etc., where employees and workers were Covid vaccinated. The Government further stated that this would also apply to NREGA job card holders and workers of Government/private projects.

6. *Prima facie*, the aforestated prescriptions seem to make vaccination mandatory as they favour those who are vaccinated, not only in terms of prioritizing the opening up of their institutions, organizations, etc., but also by linking vaccination as a condition precedent for employment of NREGA job card holders and workers in Government and private projects.

7. The Government of Manipur apparently issued the impugned notification, in keeping with the policy of the Central Government, seeking to promote Covid vaccinations. The objective of the Government is to ensure a degree of immunity in the people, at least to the extent of preventing dire consequences, if infected. However, the ground reality is that there is abounding ignorance amongst the people as to the side effects, if any, of the vaccination and in consequence, apprehensions of the risks that may ensue upon being vaccinated. It is for the State Government to dispel such fears by educating people as to the advantages of getting vaccinated and erase their apprehension of the adverse consequences of getting vaccinated.

8. Without addressing this issue, the State cannot seek to impose conditions upon the citizens so as to compel them to get vaccinated, be it by holding out a threat or by putting them at a disadvantage for failing to get vaccinated. Restraining people who are yet to get vaccinated from opening institutions, organizations, factories, shops, etc., or denying them their livelihood by linking their employment, be it NREGA job card holders or workers in Government or private projects, to their getting vaccinated

NOTARY GOVT. OF INDIA

TRUE COPY
Mehra
ADVOCATE FOR Petitioner

would be illegal on the part of the State, if not unconstitutional. Such a measure would also trample upon the freedom of the individual to get vaccinated or choose not to do so.

9. While so, Mr. S. Rupachandra, learned Additional Advocate General, Manipur, would seek to impress upon this Court that the impugned notification is merely an expression of intention by the Government as to what it proposes to do once relaxation of the curfew/containment zone orders is resorted to. He would therefore assert that the voiced intention of the Government will not be acted upon till such event comes to pass and pray that he may be given an opportunity to file a reply properly explaining the situation.

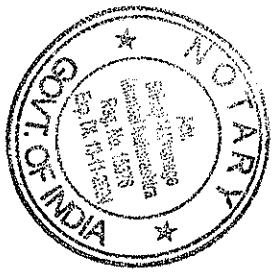
10. The aforestated stand of the Government is taken on record. However, by way of abundant caution, it is made clear that paragraph 2 of the impugned notification shall not be given effect to, even if the State resorts to any further relaxations, until the next date of hearing.

11. Reply shall be filed in the Registry on or before 27.07.2021, after service of an advance copy thereof to the counsel opposite so as to enable filing of a rejoinder, if necessary.

12. Post on 28.07.2021.

13. A copy of this order shall be communicated online/through WhatsApp to both the learned counsel.

———



"EXHIBIT "N-Colly"" (23)

Source:- MCTLaw

Date:- July 17th, 2018

Link:- https://www.mctlaw.com/101-million-dollar-vaccine-injury-mmr/

$101 MILLION AWARD FOR ENCEPHALOPATHY FROM MMR VACCINE

(July 17th, 2018. SARASOTA, FL) — **mctlaw** attorneys negotiated a $101 million settlement for an infant who suffered a severe reaction to the MMR vaccine.

O.R.* was a one-year-old healthy baby girl who was already walking and climbing. On February 13, 2013, she received vaccinations for Measles Mumps Rubella (MMR), Hepatitis A, Haemophilus Influenzae type B (Hip), Prevnar (pneumonia), and Varicella (chickenpox).

That evening, the mother noticed baby O.R. was irritable and feverish. After a call to the pediatrician, the doctor advised Mom to give her Tylenol and Benadryl. The fever continued for several days and on the evening before her scheduled pediatrician visit, O.R. began having severe seizures.

She was rushed to the emergency room. Baby O.R. went into cardiac and respiratory arrest and doctors placed her on a ventilator.

The seizures and cardiac arrest left O.R. with a severe brain injury, encephalopathy, cortical vision impairment, truncal hypotonia (low muscle tone), and kidney failure.

GOVT. OF INDIA NOTARY

TRUE COPY
ADVOCATE FOR Petitioner

After months of treatment at the hospital, baby O.R. finally went home, but her disabilities require specialized medical care and supervision around the clock for the rest of her life.

The $101 million-dollar settlement pays for the child's constant high-level medical care needed for the rest of her life. The family received a lump sum of $1 million dollars to cover the immediate costs of medical bills and expenses. The rest will be paid out through an annuity over the child's lifetime.

FILING THE VACCINE INJURY CLAIM IN FEDERAL COURT

Attorney Diana Stadelnikas represented the child and her parents in the National Vaccine Injury Compensation Program. Ms. Stadelnikas is an experienced Vaccine Injury Attorney and also a former Registered Nurse.
She filed a claim with the Vaccine Court on behalf of O.R. alleging the MMR immunization triggered the severe, but rare, reaction.

Stadelnikas filed the case in the U.S. Court of Claims against the Secretary of the Department of Health and Human Services (HHS). Upon reviewing the records and evidence, HHS conceded the case and agreed that O.R. was entitled to compensation for her vaccine-related injuries.

$101 MILLION VACCINE INJURY SETTLEMENT

The family received a lump sum of $1 million dollars to cover the immediate costs of medical bills and expenses from when the injury first happened.

The rest will be paid out through an annuity over the child's lifetime. Attorney's fees and costs are paid by the Vaccine Injury Compensation Program separately from the money awarded to the child.

You can read the actual decision on the Court of Federal Claims website: Case Number 16-119V: MMR Vaccine; Encephalopathy. Thankfully, this family reached out to our vaccine injury team and we were able to help them, says attorney Diana Stadelnikas. Vaccine injury cases are medically and legally complex; I cannot stress enough how important it is to work with an attorney who has experience representing injured families in the Vaccine Program to successfully navigate the complexities, urges Stadelnikas. The outcome here was a result of hard work, devotion, and the collaborative efforts of our experienced team.

The attorneys at Maglio Christopher & Toale, P.A. have extensive experience representing people in the National Vaccine Injury Compensation Program (NVICP).

For almost 20 years the lawyers at our firm have helped people in all 50 states file vaccine injury claims. We have offices located in Washington, DC, Sarasota, FL and Seattle, WA. Our DC office is located two blocks from the Vaccine Court.

Vaccine injuries are not personal injury cases, they are a unique part of the Federal Court system. There are a small number of attorneys across the US who regularly practice in this court. MCT Law represents our clients in vaccine injury cases at no cost to them.

The NVICP pays attorney's fees separately from the victim's claim. This way, the victim keeps 100% of their award and never shares any part of it with their attorney. You can review a list of over 500 of our case results here: https://www.mctlaw.com/vaccine-injury/cases/

In 1986 the federal government set up the National Vaccine Injury Compensation Program. This way, the government may compensate the small

percentage of people who experience rare and severe vaccine reactions. As of June 2018, the program trust contains over $3.75 billion dollars to compensate patients who experience adverse vaccine reactions.

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In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-119V
Filed: November 20, 2017
UNPUBLISHED

RAYMOND ROACH, on behalf of O.G.R., a minor child,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU); Damages Decision Based on Proffer; Measles Mumps Rubella (MMR) Vaccine; Encephalopathy

Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for petitioner.
Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

DECISION AWARDING DAMAGES[1]

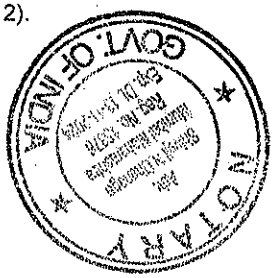
Dorsey, Chief Special Master:

On January 27, 2016, petitioner filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,[2] (the "Vaccine Act"). Petitioner alleges that O.G.R. was diagnosed with encephalopathy following receipt of Hepatitis A, Haemophilus influenza type B, measles, mumps and rubella (MMR), Prevnar, and varicella vaccinations on February 13, 2013. Petition at 2. The case was assigned to the Special Processing Unit of the Office of Special Masters.

On July 18, 2016, a ruling on entitlement was issued, finding petitioner entitled to compensation for O.G.R.'s encephalopathy injury. On November 17, 2017, respondent filed a proffer on award of compensation ("Proffer"). Respondent proffers that, based upon her review of the evidence of record, petitioner should be awarded:

[1] Because this unpublished decision contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).



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A. A lump sum in the amount of $1,191,475.29 paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of O.G.R.;

B. A lump sum in the amount of $1,043,951.66 paid to the court-appointed guardian(s)/conservator(s) of the estate of O.G.R for the benefit of O.G.R.;

C. A lump sum payment of $278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien; and

D. An amount sufficient to purchase the annuity contract described above in section II.D.

In the Proffer, respondent represented that petitioner agrees with the proffered award. Based on the record as a whole, the undersigned finds that petitioner is entitled to an award as stated in the Proffer.

Pursuant to the terms stated in the attached Proffer, **the undersigned awards petitioner:**

A. A lump sum in the amount of $1,191,475.29 paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of O.G.R.;

B. A lump sum in the amount of $1,043,951.66 paid to the court-appointed guardian(s)/conservator(s) of the estate of O.G.R for the benefit of O.G.R.;

C. A lump sum payment of $278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien payable jointly to petitioner and

Oklahoma Health Care Authority
P.O. Box 18497
Oklahoma City, Oklahoma 73154
Attn: Susan L. Eads
c/o Legal Unit
OHCA Case No: 502137

Petitioner agrees to endorse this payment to the State of Oklahoma.; and

D. An amount sufficient to purchase the annuity contract described in Proffer Section II.D.

This amount represents compensation for all damages that would be available under § 300aa-15(a).

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The clerk of the court is directed to enter judgment in accordance with this decision.[3]

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Chief Special Master

[3] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.

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IN THE UNITED STATES COURT OF FEDERAL CLAIMS
OFFICE OF SPECIAL MASTERS

RAYMOND ROACH, on behalf of O.G.R., a minor child, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	No. 16-119V Chief Special Master Dorsey

RESPONDENT'S PROFFER ON AWARD OF COMPENSATION

I. Items of Compensation

A. Life Care Items

The respondent engaged life care planner, M. Virginia NeSmith Walton, RN, MSN, FNP, CNCLP, and petitioner engaged Lynne Trautwein, MSN, RN, CCM, CMAC, CNLCP, to provide an estimation of O.G.R.'s future vaccine-injury related needs. For the purposes of this proffer, the term "vaccine related" is as described in the Chief Special Master's Ruling on Entitlement, filed July 18, 2016. All items of compensation identified in the life care plan are supported by the evidence, and are illustrated by the chart entitled Appendix A: Items of Compensation for O.G.R., attached hereto as Tab A.[1] Respondent proffers that O.G.R. should be

[1] The chart at Tab A illustrates the annual benefits provided by the life care plan. The annual benefit years run from the date of judgment up to the first anniversary of the date of judgment, and every year thereafter up to the anniversary of the date of judgment.

awarded all items of compensation set forth in the life care plan and illustrated by the chart attached at Tab A. Petitioner agrees.

B. Lost Future Earnings

The parties agree that based upon the evidence of record, O.G.R. will not be gainfully employed in the future. Therefore, respondent proffers that O.G.R. should be awarded lost future earnings as provided under the Vaccine Act, 42 U.S.C. § 300aa-15(a)(3)(B). Respondent proffers that the appropriate award for O.G.R.'s lost future earnings is $793,951.66. Petitioner agrees.

C. Pain and Suffering

Respondent proffers that O.G.R. should be awarded $250,000.00 in actual pain and suffering. See 42 U.S.C. § 300aa-15(a)(4). Petitioner agrees.

D. Past Unreimbursable Expenses

Petitioner represents that he has not incurred past unreimbursable expenses related to O.G.R.'s vaccine-related injury.

E. Medicaid Lien

Respondent proffers that O.G.R. should be awarded funds to satisfy a State of Oklahoma lien in the amount of $278,476.84, which represents full satisfaction of any right of subrogation, assignment, claim, lien, or cause of action the State of Oklahoma may have against any individual as a result of any Medicaid payments the State of Oklahoma has made to or on behalf of O.G.R. from the date of her eligibility for benefits through the date of judgment in this case as a result of her vaccine-related injury suffered on or about February 13, 2013, under Title XIX of the Social Security Act.

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II. Form of the Award

The parties recommend that the compensation provided to O.G.R. should be made through a combination of lump sum payments and future annuity payments as described below, and request that the Chief Special Master's decision and the Court's judgment award the following:[2]

A. A lump sum payment of $1,191,475.29, representing trust seed funds consisting of the present year cost of compensation for residential facility expenses in Compensation Year 2062 through Compensation Year 2066 ($949,000.00) and life care expenses in the first year after judgment ($242,475.29), in the form of a check payable to Regions Bank, as Trustee of the Grantor Reversionary Trust established for the benefit of O.G.R., as set forth in Appendix A: Items of Compensation for O.G.R.;

B. A lump sum payment of $1,043,951.66, representing compensation for lost future earnings ($793,951.66) and pain and suffering ($250,000.00), in the form of a check payable to petitioner as guardian(s)/conservator(s) of O.G.R., for the benefit of O.G.R. No payments shall be made until petitioner provides respondent with documentation establishing that he has been appointed as the guardian(s)/conservator(s) of O.G.R.'s estate. If petitioner is not authorized by a court of competent jurisdiction to serve as guardian of the estate of O.G.R., any such payment shall be made to the party or parties appointed by a court of competent jurisdiction to serve as

[2] Should O.G.R. die prior to entry of judgment, the parties reserve the right to move the Court for appropriate relief. In particular, respondent would oppose any award for future medical expenses, future lost earnings, and future pain and suffering.

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guardian(s)/conservator(s) of the estate of O.G.R. upon submission of written documentation of such appointment to the Secretary.

C. A lump sum payment of $278,476.84, representing compensation for satisfaction of the State of Oklahoma Medicaid lien, payable jointly to petitioner and

Oklahoma Health Care Authority
P.O. Box 18497
Oklahoma City, Oklahoma 73154
Attn: Susan L. Eads
c/o Legal Unit
OHCA Case No: 502137

Petitioner agrees to endorse this payment to the State of Oklahoma.

D. An amount sufficient to purchase the annuity contract,[3] subject to the conditions described below, that will provide payments for the life care items contained in the life care plan, as illustrated by the chart at Tab A attached hereto, paid to the life insurance company[4] from which the annuity will be purchased.[5] Compensation for Year Two (beginning on the first

[3] In respondent's discretion, respondent may purchase one or more annuity contracts from one or more life insurance companies.

[4] The Life Insurance Company must have a minimum of $250,000,000 capital and surplus, exclusive of any mandatory security valuation reserve. The Life Insurance Company must have one of the following ratings from two of the following rating organizations:

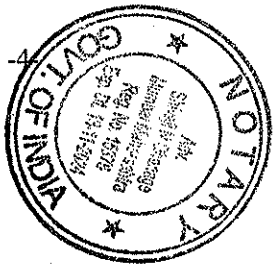
a. O.G.R. Best Company: A++, A+, A+g, A+p, A+r, or A+s;

b. Moody's Investor Service Claims Paying Rating: Aa3, Aa2, Aa1, or Aaa;

c. Standard and Poor's Corporation Insurer Claims-Paying Ability Rating: AA-, AA, AA+, or AAA;

d. Fitch Credit Rating Company, Insurance Company Claims Paying Ability Rating: AA-, AA, AA+, or AAA.

[5] Petitioner authorizes the disclosure of certain documents filed by the petitioner in this case consistent with the Privacy Act and the routine uses described in the National Vaccine Injury Compensation Program System of Records, No. 09-15-0056.



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anniversary of the date of judgment) and all subsequent years shall be provided through respondent's purchase of an annuity, which annuity shall make payments directly to the trustee only so long as O.G.R. is alive at the time a particular payment is due. At the Secretary's sole discretion, the periodic payments may be provided to the trustee in monthly, quarterly, annual or other installments. The "annual amounts" set forth in the chart at Tab A describe only the total yearly sum to be paid to the trustee and do not require that the payment be made in one annual installment.

1. Growth Rate

Respondent proffers that a four percent (4%) growth rate should be applied to all non-medical life care items, and a five percent (5%) growth rate should be applied to all medical life care items. Thus, the benefits illustrated in the chart at Tab A that are to be paid through annuity payments should grow as follows: four percent (4%) compounded annually from the date of judgment for non-medical items, and five percent (5%) compounded annually from the date of judgment for medical items. Petitioner agrees.

2. Life-Contingent Annuity

The trustee will continue to receive the annuity payments from the Life Insurance Company only so long as O.G.R. is alive at the time that a particular payment is due. Written notice shall be provided to the trustee and the Secretary of Health and Human Services and the Life Insurance Company within twenty (20) days of O.G.R.'s death.

3. Guardianship

No payments shall be made until petitioner provides respondent with documentation establishing that he has been appointed as the guardian of O.G.R.'s estate. If petitioner is not authorized by a

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court of competent jurisdiction to serve as guardian of the estate of O.G.R., any such payment shall be made to the party or parties appointed by a court of competent jurisdiction to serve as guardian(s)/conservator(s) of the estate of O.G.R. upon submission of written documentation of such appointment to the Secretary.

III. Summary of Recommended Payments Following Judgment

A.	Lump Sum paid to Regions Bank, as Trustee of the Grantor Reversionary Trust for the benefit of O.G.R.:	**$1,191,475.29**
B.	Lump Sum paid to the court-appointed guardian(s)/ conservator(s) of the estate of O.G.R for the benefit of O.G.R.:	**$1,043,951.66**
C.	Medicaid Lien:	**$ 278,476.84**
D.	An amount sufficient to purchase the annuity contract described above in section II. D.	

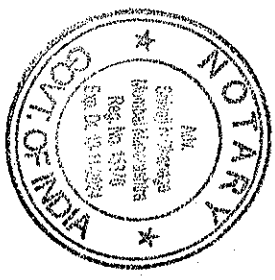
Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

C. SALVATORE D'ALESSIO
Acting Director
Torts Branch, Civil Division

CATHARINE E. REEVES
Deputy Director
Torts Branch, Civil Division

HEATHER L. PEARLMAN
Assistant Director
Torts Branch, Civil Division



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/s/Camille M. Collett
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P.O. Box 146, Benjamin Franklin Station
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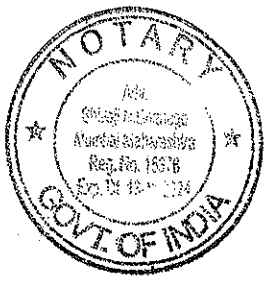
Direct dial: (202) 616-4098

Dated: November 17, 2017



ITEMS OF COMPENSATION	G.R.	*	Lump Sum Compensation Year 1	Compensation Year 2	Compensation Year 3	Compensation Year 4	Compensation Year 5	Compensation Year 6	Compensation Year 7	Compensation Year 8
			2017	2018	2019	2020	2021	2022	2023	2024
BCBS Premium	5%		4,341.36	4,341.36	4,341.36	4,341.36	4,341.36	4,341.36	4,341.36	4,341.36
BCBS MOP	5%		3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00
Medicare Part A Deductible	5%									
Medicare Part B Premium	5%									
Medicare Part B Deductible	5%									
Medigap	5%									
Medicare Part D	5%									
Primary Care Physician	5%	*								
Mileage: PCP	4%		1.36	1.36	1.36	1.36	1.36	1.36	1.36	1.36
Neurologist	5%	*								
Mileage: Neurologist	4%		10.54	10.54	10.54	10.54	10.54	10.54	10.54	10.54
Neuro Opthalmologist	5%	*								
Mileage: Neuro Opthalmologist	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Nephrology	5%	*								
Mileage: Nephrology	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Gastroenterologist	5%	*								
Mileage: Gastroenterologist	4%		7.82	7.82	7.82	7.82	7.82	7.82	7.82	7.82
General Surgery	5%	*								
Mileage: General Surgery	4%		9.18	9.18	9.18	9.18	9.18	9.18	9.18	9.18
Orthopedic Surgery	5%	*								
Mileage: Orthopedic Surgery	4%		37.40	37.40	37.40	37.40	37.40	37.40	37.40	37.40
PM&R	5%	*								
Mileage: PM&R	4%		74.80	74.80	37.40	37.40	37.40	37.40	37.40	37.40
Dentist	5%		414.00	414.00	414.00	414.00	414.00	414.00	414.00	414.00
Mileage: Dentist	4%		14.45	14.45	14.45	14.45	14.45	14.45	14.45	14.45
X-rays	5%	*								
Blood Work	5%	*								
Mileage: Blood Work	4%		19.04	19.04	19.04	19.04	19.04	19.04	19.04	19.04
Emergency Room	5%	*								
Care Management	4%		7,740.00	5,160.00	5,160.00	5,160.00	2,580.00	2,580.00	2,580.00	2,580.00
Lactulose	5%	*								
Ciprodex Otic	5%	*								
Keppra	5%	*								
Epaned Oral	5%	*								

ITEMS OF COMPENSATION	G.R.	*	Lump Sum Compensation Year 1	Compensation Year 2	Compensation Year 3	Compensation Year 4	Compensation Year 5	Compensation Year 6	Compensation Year 7	Compensation Year 8
			2017	2018	2019	2020	2021	2022	2023	2024
Nebulizer	5%	*								
Disposable Nebulizer Supplies	5%	*								
Omeprazol	4%		212.92	212.92	212.92	212.92	212.92	212.92	212.92	212.92
Kenalog	5%	*								
Pediasure Peptide	4%	*								
Pediasure	4%	*								
Real Food Blends	4%		4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25
Feeding Pump	4%	*								
Gastrostomy Tube Supplies	4%	*								
Diapers	4%		593.18	593.18	593.18	593.18	593.18	593.18	593.18	593.18
Gloves	4%		255.21	255.21	255.21	255.21	255.21	255.21	255.21	255.21
Wipes	4%		156.33	156.33	156.33	156.33	156.33	156.33	156.33	156.33
Disp Underpads	4%		127.71	127.71	127.71	127.71	127.71	127.71	127.71	127.71
Washable Underpads	4%		83.97	83.97	83.97	83.97	83.97	83.97	83.97	83.97
Amazon Prime	4%		99.00	99.00	99.00	99.00	99.00	99.00	99.00	99.00
Bibs	4%		36.98	36.98	36.98	36.98	36.98	36.98	36.98	36.98
Physical Therapy	4%	*	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00	2,070.00
Mileage: Physical Therapy	4%		204.00	204.00	204.00	204.00	204.00	204.00	204.00	204.00
Occupational Therapy	4%		4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00
Mileage: Occupational Therapy	4%		204.00	204.00	204.00	204.00	204.00	204.00	204.00	204.00
Speech Therapy	4%		4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00
Mileage: Speech Therapy	4%		204.00	204.00	204.00	204.00	204.00	204.00	204.00	204.00
Aug Comm Evaluation	4%	*	500.00	500.00	500.00	500.00	500.00	500.00	500.00	500.00
Mileage: Aug Comm Evaluation	4%		4.25	4.25	4.25	4.25	4.25	4.25	4.25	4.25
Aug Comm Devices	4%		100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
Special Needs Camp	4%					300.00	300.00	300.00	300.00	300.00
Overnight Camp	4%					325.00	325.00	325.00	325.00	325.00
Mileage: Camp	4%					68.17	68.17	68.17	68.17	68.17
Wheelchair	4%	*								
Sit & Stander	4%	*								
Shower Chair	4%							300.00	50.00	50.00
Kid Walk	4%					5,000.00				
Hoyer Lift	4%	*								
Lift Slings	4%							68.00	68.00	68.00

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NOTARY
Govt. of India
Adv. Shirish N. Deshpande
Mumbai Maharashtra
Reg. No. 15076
Exp. Dt. 19/11/2021

ITEMS OF COMPENSATION	G.R.	*	Lump Sum Compensation Year 1	Compensation Year 2	Compensation Year 3	Compensation Year 4	Compensation Year 5	Compensation Year 6	Compensation Year 7	Compensation Year 8
			2017	2018	2019	2020	2021	2022	2023	2024
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%		1,337.67					1,337.67		
Rehab Equipment	4%		800.00					800.00		
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%								23.99	
iPad	4%		799.00					799.00		
iPad Case	4%		19.95					19.95		
Attendant Care	4%		93,960.00	93,960.00	93,960.00	100,440.00	100,440.00	100,440.00	100,440.00	100,440.00
Respite Care	4%		7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00
McCarty Cntr	4%		1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
Attendant Care and Trust Seed	4%		949,000.00							
Ancillary Services-Housekeeping	4%									
Home Mods	4%		73,768.00							
Accessible Van	4%		28,500.00							
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings			793,951.66							
Pain and Suffering			250,000.00							
Medicaid Lien			278,476.84							
Annual Totals			2,513,903.79	134,670.67	134,633.27	146,806.44	139,226.44	142,551.06	139,368.43	139,344.44

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.
Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.
As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of O.G.R. for trust seed funds ($949,000.00) and Year 1 life care expenses ($242,475.29): $1,191,475.29.
As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of O.G.R. for lost future earnings ($793,951.66) and pain and suffering ($250,000.00): $1,043,951.66.
As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: $278,476.84.
Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.
Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.
Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

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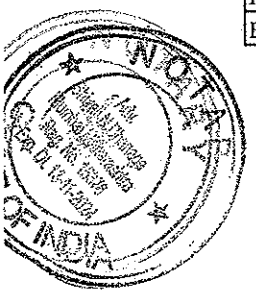
ITEMS OF COMPENSATION	G.R.	*	Compensation Year 9	Compensation Year 10	Compensation Year 11	Compensation Year 12	Compensation Year 13	Compensation Year 14	Compensation Year 15	Compensation Year 16
			2025	2026	2027	2028	2029	2030	2031	2032
BCBS Premium	5%		4,341.36	4,341.36	4,341.36	4,341.36	4,341.36	4,341.36	4,341.36	4,341.36
BCBS MOP	5%		3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00
Medicare Part A Deductible	5%		-							
Medicare Part B Premium	5%									
Medicare Part B Deductible	5%									
Medigap	5%									
Medicare Part D	5%									
Primary Care Physician	5%	*								
Mileage: PCP	4%		1.36	1.36	1.36	1.36	1.36	1.36	1.36	1.36
Neurologist	5%	*								
Mileage: Neurologist	4%		10.54	10.54	10.54	10.54	10.54	10.54	10.54	10.54
Neuro Opthalmologist	5%	*								
Mileage: Neuro Opthalmologist	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Nephrology	5%	*								
Mileage: Nephrology	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Gastroenterologist	5%	*								
Mileage: Gastroenterologist	4%		7.82	7.82	7.82	7.82	7.82	7.82	7.82	7.82
General Surgery	5%	*								
Mileage: General Surgery	4%		9.18	9.18	9.18	9.18	9.18	9.18	9.18	9.18
Orthopedic Surgery	5%	*								
Mileage: Orthopedic Surgery	4%		37.40	37.40	37.40	37.40	37.40	37.40		
PM&R	5%	*								
Mileage: PM&R	4%		37.40	37.40	37.40	37.40	37.40	37.40	37.40	37.40
Dentist	5%		414.00	414.00	414.00	414.00	414.00	414.00	414.00	414.00
Mileage: Dentist	4%		14.45	14.45	14.45	14.45	14.45	14.45	14.45	14.45
X-rays	5%	*								
Blood Work	5%	*								
Mileage: Blood Work	4%		19.04	19.04	19.04	19.04	4.08	4.08	4.08	4.08
Emergency Room	5%	*								
Care Management	4%		2,580.00	2,580.00	2,580.00	2,580.00	2,580.00	2,580.00	2,580.00	7,740.00
Lactulose	5%	*								
Ciprodex Otic	5%	*								
Keppra	5%	*								
Epaned Oral	5%	*								



ITEMS OF COMPENSATION	G.R.	*	Compensation Year 9	Compensation Year 10	Compensation Year 11	Compensation Year 12	Compensation Year 13	Compensation Year 14	Compensation Year 15	Compensation Year 16
			2025	2026	2027	2028	2029	2030	2031	2032
Nebulizer	5%	*								
Disposable Nebulizer Supplies	5%	*								
Omeprazol	4%		212.92	212.92	212.92	212.92	212.92	212.92	212.92	212.92
Kenalog	5%	*								
Pediasure Peptide	4%	*								
Pediasure	4%	*								
Real Food Blends	4%		4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25
Feeding Pump	4%	*								
Gastrostomy Tube Supplies	4%	*								
Diapers	4%		2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14
Gloves	4%		255.21	255.21	255.21	255.21	255.21	255.21	255.21	255.21
Wipes	4%		156.33	156.33	156.33	156.33	156.33	156.33	156.33	156.33
Disp Underpads	4%		127.71	127.71	127.71	127.71	127.71	127.71	127.71	127.71
Washable Underpads	4%		83.97	83.97	83.97	83.97	83.97	83.97	83.97	83.97
Amazon Prime	4%		99.00	99.00	99.00	99.00	99.00	99.00	99.00	99.00
Bibs	4%		36.98	36.98	36.98	36.98	36.98	36.98	36.98	36.98
Physical Therapy	4%	*								
Mileage: Physical Therapy	4%		102.00	102.00	102.00	102.00	102.00	102.00	25.50	25.50
Occupational Therapy	4%		4,390.00	4,390.00	4,390.00	4,390.00	4,390.00	4,390.00		
Mileage: Occupational Therapy	4%		204.00	204.00	204.00	204.00	204.00	204.00		
Speech Therapy	4%		2,230.00	2,230.00	2,230.00	2,230.00	2,230.00	2,230.00		
Mileage: Speech Therapy	4%		102.00	102.00	102.00	102.00	102.00	102.00		
Aug Comm Evaluation	4%	*	500.00	500.00	500.00	500.00	500.00	500.00		
Mileage: Aug Comm Evaluation	4%		4.25	4.25	4.25	4.25	4.25	4.25	4.25	4.25
Aug Comm Devices	4%		100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
Special Needs Camp	4%		300.00	300.00	300.00	300.00	300.00	300.00		
Overnight Camp	4%		325.00	325.00	325.00	325.00	325.00	325.00		
Mileage: Camp	4%		68.17	68.17	68.17	68.17	68.17	68.17		
Wheelchair	4%	*								
Sit & Stander	4%	*								
Shower Chair	4%		50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00
Kid Walk	4%			5,000.00						5,000.00
Hoyer Lift	4%	*								
Lift Slings	4%		68.00	68.00	68.00	68.00	68.00	68.00	68.00	68.00

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 9	Compensation Year 10	Compensation Year 11	Compensation Year 12	Compensation Year 13	Compensation Year 14	Compensation Year 15	Compensation Year 16
			2025	2026	2027	2028	2029	2030	2031	2032
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%				1,337.67					1,337.67
Rehab Equipment	4%				800.00					800.00
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%							34.90	3.49	3.49
iPad	4%				799.00					799.00
iPad Case	4%				19.95					19.95
Attendant Care	4%		155,520.00	155,520.00	155,520.00	155,520.00	155,520.00	155,520.00	157,140.00	157,140.00
Respite Care	4%		7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00	7,560.00
McCarty Cntr	4%		1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
Attendant Care and Trust Seed	4%									
Ancillary Services-Housekeeping	4%					1,638.00	1,638.00	1,638.00	1,638.00	1,638.00
Home Mods	4%									
Accessible Van	4%				28,500.00					
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings										
Pain and Suffering										
Medicaid Lien										
Annual Totals			192,159.40	197,159.40	223,616.02	193,797.40	193,782.44	193,817.34	187,172.86	200,289.48

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.
Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.
As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of O.G.R. for trust seed funds ($949,000.00) and Year 1 life care expenses ($242,475.29): $1,191,475.29.
As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of O.G.R. for lost future earnings ($793,951.66) and pain and suffering ($250,000.00): $1,043,951.66.
As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: $278,476.84.
Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.
Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.
Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 17	Compensation Year 18	Compensation Years 19-20	Compensation Year 21	Compensation Year 22	Compensation Year 23	Compensation Year 24	Compensation Year 25
			2033	2034	2035-2036	2037	2038	2039	2040	2041
BCBS Premium	5%		6,836.76	6,836.76	6,836.76	6,864.12	7,000.80	7,164.84	7,431.48	7,650.24
BCBS MOP	5%		3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00
Medicare Part A Deductible	5%									
Medicare Part B Premium	5%									
Medicare Part B Deductible	5%									
Medigap	5%									
Medicare Part D	5%									
Primary Care Physician	5%	*								
Mileage: PCP	4%		1.36	1.36	1.36	1.36	1.36	1.36	1.36	1.36
Neurologist	5%	*								
Mileage: Neurologist	4%		10.54	10.54	10.54	10.54	10.54	10.54	10.54	10.54
Neuro Opthalmologist	5%	*								
Mileage: Neuro Opthalmologist	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Nephrology	5%	*								
Mileage: Nephrology	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Gastroenterologist	5%	*								
Mileage: Gastroenterologist	4%		7.82	7.82	7.82	7.82	7.82	7.82	7.82	7.82
General Surgery	5%	*								
Mileage: General Surgery	4%		9.18	9.18	9.18	9.18	9.18	9.18	9.18	9.18
Orthopedic Surgery	5%	*								
Mileage: Orthopedic Surgery	4%									
PM&R	5%	*								
Mileage: PM&R	4%		37.40	37.40	37.40	37.40	37.40	37.40	37.40	37.40
Dentist	5%		414.00	414.00	414.00	414.00	414.00	414.00	414.00	414.00
Mileage: Dentist	4%		14.45	14.45	14.45	14.45	14.45	14.45	14.45	14.45
X-rays	5%	*								
Blood Work	5%	*								
Mileage: Blood Work	4%		4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08
Emergency Room	5%	*								
Care Management	4%		5,160.00	5,160.00	5,160.00	5,160.00	5,160.00	5,160.00	5,160.00	5,160.00
Lactulose	5%	*								
Ciprodex Otic	5%	*								
Keppra	5%	*								
Epaned Oral	5%	*								

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 17	Compensation Year 18	Compensation Years 19-20	Compensation Year 21	Compensation Year 22	Compensation Year 23	Compensation Year 24	Compensation Year 25
			2033	2034	2035-2036	2037	2038	2039	2040	2041
Nebulizer	5%	*								
Disposable Nebulizer Supplies	5%	*								
Omeprazol	4%		212.92	212.92	212.92	212.92	212.92	212.92	212.92	212.92
Kenalog	5%	*								
Pediasure Peptide	4%	*								
Pediasure	4%	*								
Real Food Blends	4%		4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25
Feeding Pump	4%	*								
Gastrostomy Tube Supplies	4%	*								
Diapers	4%		2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14
Gloves	4%		255.21	255.21	255.21	255.21	255.21	255.21	255.21	255.21
Wipes	4%		156.33	156.33	156.33	156.33	156.33	156.33	156.33	156.33
Disp Underpads	4%		127.71	127.71	127.71	127.71	127.71	127.71	127.71	127.71
Washable Underpads	4%		83.97	83.97	83.97	83.97	83.97	83.97	83.97	83.97
Amazon Prime	4%		99.00	99.00	99.00	99.00	99.00	99.00	99.00	99.00
Bibs	4%		36.98	36.98	36.98	36.98	36.98	36.98	36.98	36.98
Physical Therapy	4%	*								
Mileage: Physical Therapy	4%		25.50	25.50	25.50	25.50	25.50	25.50	25.50	25.50
Occupational Therapy	4%									
Mileage: Occupational Therapy	4%									
Speech Therapy	4%									
Mileage: Speech Therapy	4%									
Aug Comm Evaluation	4%	*								
Mileage: Aug Comm Evaluation	4%		4.25	4.25	4.25	4.25	4.25	4.25	4.25	4.25
Aug Comm Devices	4%		100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
Special Needs Camp	4%									
Overnight Camp	4%									
Mileage: Camp	4%									
Wheelchair	4%	*								
Sit & Stander	4%	*								
Shower Chair	4%		50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00
Kid Walk	4%						5,000.00	833.33	833.33	833.33
Hoyer Lift	4%	*								
Lift Slings	4%		68.00	68.00	68.00	68.00	68.00	68.00	68.00	68.00

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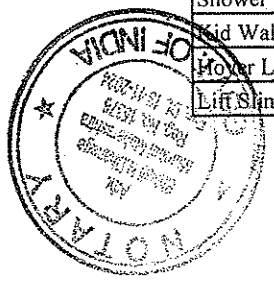

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 17	Compensation Year 18	Compensation Years 19-20	Compensation Year 21	Compensation Year 22	Compensation Year 23	Compensation Year 24	Compensation Year 25
			2033	2034	2035-2036	2037	2038	2039	2040	2041
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%					1,337.67	267.53	267.53	267.53	267.53
Rehab Equipment	4%					800.00	160.00	160.00	160.00	160.00
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%		3.49	3.49	3.49	3.49	3.49	3.49	3.49	3.49
iPad	4%					799.00	159.80	159.80	159.80	159.80
iPad Case	4%					19.95	3.99	3.99	3.99	3.99
Attendant Care	4%		157,140.00							
Respite Care	4%		7,560.00							
McCarty Cntr	4%		1,000.00							
Attendant Care and Trust Seed	4%			189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00
Ancillary Services-Housekeeping	4%		1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00
Home Mods	4%			73,768.00						
Accessible Van	4%					28,500.00	2,850.00	2,850.00	2,850.00	2,850.00
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings										
Pain and Suffering										
Medicaid Lien										
Annual Totals			192,248.26	290,116.26	216,348.26	247,832.24	224,953.62	220,950.99	221,217.63	221,436.39

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.
Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.
As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of O.G.R. for trust seed funds ($949,000.00) and Year 1 life care expenses ($242,475.29): $1,191,475.29.
As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of O.G.R. for lost future earnings ($793,951.66) and pain and suffering ($250,000.00): $1,043,951.66.
As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: $278,476.84.
Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.
Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.
Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

NOTARY GOVT. OF INDIA

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ITEMS OF COMPENSATION	G.R.	*	Compensation Year 26	Compensation Year 27	Compensation Year 28	Compensation Year 29	Compensation Year 30	Compensation Year 31	Compensation Year 32	Compensation Years 33-45
			2042	2043	2044	2045	2046	2047	2048	2049-2061
BCBS Premium	5%		7,759.68	7,923.72	8,087.88	8,190.36	8,299.80	8,354.52	8,409.12	
BCBS MOP	5%		3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	3,300.00	
Medicare Part A Deductible	5%									1,316.00
Medicare Part B Premium	5%									1,608.00
Medicare Part B Deductible	5%									183.00
Medigap	5%									3,147.00
Medicare Part D	5%									406.00
Primary Care Physician	5%	*								
Mileage: PCP	4%		1.36	1.36	1.36	1.36	1.36	1.36	1.36	1.36
Neurologist	5%	*								
Mileage: Neurologist	4%		10.54	10.54	10.54	10.54	10.54	10.54	10.54	10.54
Neuro Opthalmologist	5%	*								
Mileage: Neuro Opthalmologist	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Nephrology	5%	*								
Mileage: Nephrology	4%		74.80	74.80	74.80	74.80	74.80	74.80	74.80	74.80
Gastroenterologist	5%	*								
Mileage: Gastroenterologist	4%		7.82	7.82	7.82	7.82	7.82	7.82	7.82	7.82
General Surgery	5%	*								
Mileage: General Surgery	4%		9.18	9.18	9.18	9.18	9.18	9.18	9.18	9.18
Orthopedic Surgery	5%	*								
Mileage: Orthopedic Surgery	4%									
PM&R	5%	*								
Mileage: PM&R	4%		37.40	37.40	37.40	37.40	37.40	37.40	37.40	37.40
Dentist	5%		414.00	414.00	414.00	414.00	414.00	414.00	414.00	414.00
Mileage: Dentist	4%		14.45	14.45	14.45	14.45	14.45	14.45	14.45	14.45
X-rays	5%	*								
Blood Work	5%	*								
Mileage: Blood Work	4%		4.08	4.08	4.08	4.08	4.08	4.08	4.08	4.08
Emergency Room	5%	*								
Care Management	4%		5,160.00	5,160.00	5,160.00	5,160.00	5,160.00	5,160.00	5,160.00	5,160.00
Lactulose	5%	*								
Ciprodex Otic	5%	*								
Keppra	5%	*								
[illegible]paned Oral	5%	*								

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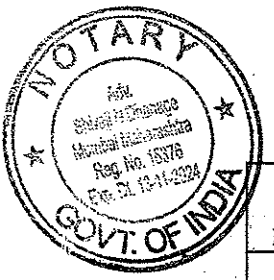

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 26	Compensation Year 27	Compensation Year 28	Compensation Year 29	Compensation Year 30	Compensation Year 31	Compensation Year 32	Compensation Years 33-45
			2042	2043	2044	2045	2046	2047	2048	2049-2061
Nebulizer	5%	*								
Disposable Nebulizer Supplies	5%	*								
Omeprazol	4%		212.92	212.92	212.92	212.92	212.92	212.92	212.92	212.92
Kenalog	5%	*								
Pediasure Peptide	4%	*								
Pediasure	4%	*								
Real Food Blends	4%		4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25	4,106.25
Feeding Pump	4%	*								
Gastrostomy Tube Supplies	4%	*								
Diapers	4%		2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14	2,762.14
Gloves	4%		255.21	255.21	255.21	255.21	255.21	255.21	255.21	255.21
Wipes	4%		156.33	156.33	156.33	156.33	156.33	156.33	156.33	156.33
Disp Underpads	4%		127.71	127.71	127.71	127.71	127.71	127.71	127.71	127.71
Washable Underpads	4%		83.97	83.97	83.97	83.97	83.97	83.97	83.97	83.97
Amazon Prime	4%		99.00	99.00	99.00	99.00	99.00	99.00	99.00	99.00
Bibs	4%		36.98	36.98	36.98	36.98	36.98	36.98	36.98	36.98
Physical Therapy	4%	*								
Mileage: Physical Therapy	4%		25.50	25.50	25.50	25.50	25.50	25.50	25.50	25.50
Occupational Therapy	4%									
Mileage: Occupational Therapy	4%									
Speech Therapy	4%									
Mileage: Speech Therapy	4%									
Aug Comm Evaluation	4%	*								
Mileage: Aug Comm Evaluation	4%		4.25	4.25	4.25	4.25	4.25	4.25	4.25	4.25
Aug Comm Devices	4%		100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
Special Needs Camp	4%									
Overnight Camp	4%									
Mileage: Camp	4%									
Wheelchair	4%	*								
Sit & Stander	4%	*								
Shower Chair	4%		50.00	50.00	50.00	50.00	50.00	50.00	50.00	50.00
Kid Walk	4%		833.33	833.33	833.33	833.33	833.33	833.33	833.33	833.33
Hoyer Lift	4%	*								
Lift Slings	4%		68.00	68.00	68.00	68.00	68.00	68.00	68.00	68.00

ITEMS OF COMPENSATION	G.R.	*	Compensation Year 26	Compensation Year 27	Compensation Year 28	Compensation Year 29	Compensation Year 30	Compensation Year 31	Compensation Year 32	Compensation Years 33-45
			2042	2043	2044	2045	2046	2047	2048	2049-2061
AFOs	4%	*								
Orthotic Shoes	4%		600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Tumblefoam Chair	4%		267.53	267.53	267.53	267.53	267.53	267.53	267.53	267.53
Rehab Equipment	4%		160.00	160.00	160.00	160.00	160.00	160.00	160.00	160.00
Hand Splints	4%		73.32	73.32	73.32	73.32	73.32	73.32	73.32	73.32
Blood Pressure Cuff	4%		3.49	3.49	3.49	3.49	3.49	3.49	3.49	3.49
iPad	4%		159.80	159.80	159.80	159.80	159.80	159.80	159.80	159.80
iPad Case	4%		3.99	3.99	3.99	3.99	3.99	3.99	3.99	3.99
Attendant Care	4%									
Respite Care	4%									
McCarty Cntr	4%									
Attendant Care and Trust Seed	4%		189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00	189,800.00
Ancillary Services-Housekeeping	4%		1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00	1,638.00
Home Mods	4%									
Accessible Van	4%		2,850.00	2,850.00	2,850.00	2,850.00	2,850.00	2,850.00	2,850.00	2,850.00
Van Mod Maint	4%		200.00	200.00	200.00	200.00	200.00	200.00	200.00	200.00
Lost Future Earnings										
Pain and Suffering										
Medicaid Lien										
Annual Totals			221,545.83	221,709.87	221,874.03	221,976.51	222,085.95	222,140.67	222,195.27	217,146.15

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Note: Compensation Year 1 consists of the 12 month period following the date of judgment.
Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.
As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of O.G.R. for trust seed funds ($949,000.00) and Year 1 life care expenses ($242,475.29): $1,191,475.29.
As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of O.G.R. for lost future earnings ($793,951.66) and pain and suffering ($250,000.00): $1,043,951.66.
As soon as practicable after entry of judgment, respondent shall make the following payment jointly to petitioners and the State of Oklahoma, as reimbursement of the state's Medicaid lien: $278,476.84.
Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.
Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.
Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

ITEMS OF COMPENSATION	G.R.	*	Compensation Years 46-50 2062-2066	Compensation Years 51-60 2067-2076	Compensation Years 61-Life 2077-Life
BCBS Premium	5%				
BCBS MOP	5%				
Medicare Part A Deductible	5%		1,316.00	1,316.00	
Medicare Part B Premium	5%		1,608.00	1,608.00	1,608.00
Medicare Part B Deductible	5%		183.00	183.00	183.00
Medigap	5%		3,147.00	3,147.00	1,707.48
Medicare Part D	5%		406.00	406.00	406.00
Primary Care Physician	5%	*			
Mileage: PCP	4%		1.36	1.36	1.36
Neurologist	5%	*			
Mileage: Neurologist	4%		10.54	10.54	10.54
Neuro Opthalmologist	5%	*			
Mileage: Neuro Opthalmologist	4%		74.80	74.80	74.80
Nephrology	5%	*			
Mileage: Nephrology	4%		74.80	74.80	74.80
Gastroenterologist	5%	*			
Mileage: Gastroenterologist	4%		7.82	7.82	7.82
General Surgery	5%	*			
Mileage: General Surgery	4%		9.18	9.18	9.18
Orthopedic Surgery	5%	*			
Mileage: Orthopedic Surgery	4%				
PM&R	5%	*			
Mileage: PM&R	4%		37.40	37.40	37.40
Dentist	5%		414.00	414.00	414.00
Mileage: Dentist	4%		14.45	14.45	14.45
X-rays	5%	*			
Blood Work	5%	*			
Mileage: Blood Work	4%		4.08	4.08	4.08
Emergency Room	5%	*			
Care Management	4%		5,160.00	5,160.00	5,160.00
Lactulose	5%	*			
Ciprodex Otic	5%	*			
Keppra	5%	*			
Epaned Oral	5%	*			

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ITEMS OF COMPENSATION	G.R.	*	Compensation Years 46-50	Compensation Years 51-60	Compensation Years 61-Life
			2062-2066	2067-2076	2077-Life
Nebulizer	5%	*			
Disposable Nebulizer Supplies	5%	*			
Omeprazol	4%		212.92	212.92	212.92
Kenalog	5%	*			
Pediasure Peptide	4%	*			
Pediasure	4%	*			
Real Food Blends	4%		4,106.25	4,106.25	4,106.25
Feeding Pump	4%	*			
Gastrostomy Tube Supplies	4%	*			
Diapers	4%		2,762.14	2,762.14	2,762.14
Gloves	4%		255.21	255.21	255.21
Wipes	4%		156.33	156.33	156.33
Disp Underpads	4%		127.71	127.71	127.71
Washable Underpads	4%		83.97	83.97	83.97
Amazon Prime	4%		99.00	99.00	99.00
Bibs	4%		36.98	36.98	36.98
Physical Therapy	4%	*			
Mileage: Physical Therapy	4%		25.50	25.50	25.50
Occupational Therapy	4%				
Mileage: Occupational Therapy	4%				
Speech Therapy	4%				
Mileage: Speech Therapy	4%				
Aug Comm Evaluation	4%	*			
Mileage: Aug Comm Evaluation	4%		4.25	4.25	4.25
Aug Comm Devices	4%		100.00	100.00	100.00
Special Needs Camp	4%				
Overnight Camp	4%				
Mileage: Camp	4%				
Wheelchair	4%	*			
Sit & Stander	4%	*			
Shower Chair	4%		50.00	50.00	50.00
Kid Walk	4%		833.33	833.33	833.33
Hoyer Lift	4%	*			
Lift Slings	4%		68.00	68.00	68.00

ITEMS OF COMPENSATION	G.R.	*	Compensation Years 46-50	Compensation Years 51-60	Compensation Years 61-Life
			2062-2066	2067-2076	2077-Life
AFOs	4%	*			
Orthotic Shoes	4%		600.00	600.00	600.00
Tumblefoam Chair	4%		267.53	267.53	267.53
Rehab Equipment	4%		160.00	160.00	160.00
Hand Splints	4%		73.32	73.32	73.32
Blood Pressure Cuff	4%		3.49	3.49	3.49
iPad	4%		159.80	159.80	159.80
iPad Case	4%		3.99	3.99	3.99
Attendant Care	4%				
Respite Care	4%				
McCarty Cntr	4%				
Attendant Care and Trust Seed	4%		-	189,800.00	189,800.00
Ancillary Services-Housekeeping	4%		1,638.00	1,638.00	1,638.00
Home Mods	4%				
Accessible Van	4%		2,850.00	2,850.00	2,850.00
Van Mod Maint	4%		200.00	200.00	200.00
Lost Future Earnings					
Pain and Suffering					
Medicaid Lien					
Annual Totals			27,346.15	217,146.15	214,390.63

Note: Compensation Year 1 consists of the 12 month period following the date of judgment.
Compensation Year 2 consists of the 12 month period commencing on the first anniversary of the date of judgment.
As soon as practicable after entry of judgment, respondent shall make the following payment to Regions Bank, Trustee of the Grantor Reversionary Trust established for the benefit of O.G.R. for trust seed funds ($949,000.00) and Year 1 life care expenses ($242,475.29): $1,191,475.29.
As soon as practicable after entry of judgment, respondent shall make the following payment to the court-appointed guardian(s)/ conservator(s) of O.G.R. for lost future earnings ($793,951.66) and pain and suffering ($250,000.00): $1,043,951.66.
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Annual amounts payable through an annuity for future Compensation Years follow the anniversary of the date of judgment.
Annual amounts shall increase at the rates indicated in column "G.R." above, compounded annually from the date of judgment.
Items denoted with an asterisk (*) covered by health insurance and/or Medicare.

NOTARY PUBLIC GOVT. OF GUAM

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"EXHIBIT – 'O'' "

THE UNITED STATES DEPARTMENT of JUSTICE
JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, July 2, 2012

GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data

Largest Health Care Fraud Settlement in U.S. History

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA). Under the terms of the plea agreement, GSK will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600. The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK's U.S. president and board of directors. GSK's guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states. The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

"Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud," said James M. Cole, Deputy Attorney General. "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law."

"Today's historic settlement is a major milestone in our efforts to stamp out health care fraud," said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). "For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing."

TRUE COPY
ADVOCATE FOR Petitioner

This resolution marks the culmination of an extensive investigation by special agents from HHS-OIG, FDA and FBI, along with law enforcement partners across the federal government. Moving forward, GSK will be subject to stringent requirements under its corporate integrity agreement with HHS-OIG; this agreement is designed to increase accountability and transparency and prevent future fraud and abuse. Effective law enforcement partnerships and fraud prevention are hallmarks of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaboration to fight fraud.

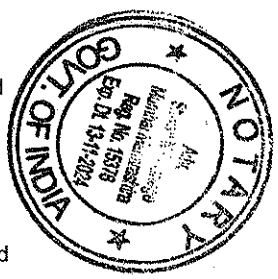
Criminal Plea Agreement

Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug. After the FDA approves the product as safe and effective for a specified use, a company's promotional activities must be limited to the intended uses that FDA approved. In fact, promotion by the manufacturer for other uses – known as "off-label uses" – renders the product "misbranded."

Paxil: In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a "black box warning" stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

Wellbutrin: The United States also alleges that, from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote Wlibutrin for these unapproved uses. GSK has agreed to plead guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses. For the Paxil and Wellbutrin misbranding offenses, GSK has agreed to pay a criminal fine and forfeiture of $757,387,200.

Avandia: The United States alleges that, between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack). GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.



"This case demonstrates our continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that decisions as to what drugs are prescribed

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to sick patients are based on best medical judgments, not false and misleading claims or improper financial inducements," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

"Patients rely on their physicians to prescribe the drugs they need," said John Walsh, U.S. Attorney for Colorado. "The pharmaceutical industries' drive for profits can distort the information provided to physicians concerning drugs. This case will help to ensure that your physician will make prescribing decisions based on good science and not on misinformation, money or favors provided by the pharmaceutical industry."

Civil Settlement Agreement

As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

Off-Label Promotion and Kickbacks: The civil settlement resolves claims set forth in a complaint filed by the United States alleging that, in addition to promoting the drugs Paxil and Wellbutrin for unapproved, non-covered uses, GSK also promoted its asthma drug, Advair, for first-line therapy for mild asthma patients even though it was not approvedor medically appropriate under these circumstances. GSK also promoted Advair for chronic obstructive pulmonary disease with misleading claims as to the relevant treatment guidelines. The civil settlement also resolves allegations that GSK promoted Lamictal, an anti-epileptic medication, for off-label, non-covered psychiatric uses, neuropathic pain and pain management. It further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women. It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million.

This off-label civil settlement resolves four lawsuits pending in federal court in the District of Massachusetts under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery.

Avandia: In its civil settlement agreement, the United States alleges that GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile, causing false claims to be submitted to federal health care programs. Specifically, the United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.

NOTARY ★ GOVT. OF INDIA ★ Adv. Shivaji M. Ghanage Mumbai Maharashtra Reg. No. 15376 Exp. Dt. 13-11-2024

Price Reporting: GSK is also resolving allegations that, between 1994 and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK's underpaying rebates owed under theMedicaid

Drug Rebate Program. By law, GSK was required to report the lowest, or "best" price that it charged its customers and to pay quarterly rebates to the states based on those reported prices. When drugs are sold to purchasers in contingent arrangements known as "bundles," the discounts offered for the bundled drugs must be reallocated across all products in the bundle proportionate to the dollar value of the units sold. The United States alleges that GSK had bundled sales arrangements that included steep discounts known as "nominal" pricing and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to the Department of Health and Human Services. Had it done so, the effective prices on certain drugs would have been different, and, in some instances, triggered a new, lower best price than what GSK reported. As a result, GSK underpaid rebates due to Medicaid and overcharged certain Public Health Service entities for its drugs, the United States contends. GSK has agreed to pay $300 million to resolve these allegations, including $160,972,069 to the federal government, $118,792,931 to thestates, and $20,235,000 to certain Public Health Service entities who paid inflated prices for the drugs at issue.

Except to the extent that GSK has agreed to plead guilty to the three-count criminal information, the claims settled by these agreements are allegations only, and there has been no determination of liability.

"This landmark settlement demonstrates the Department's commitment to protecting the American public against illegal conduct and fraud by pharmaceutical companies," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "Doctors need truthful, fair, balanced information when deciding whether the benefits of a drug outweigh its safety risks. By the same token, the FDA needs all necessary safety-related information to identify safety trends and to determine whether a drug is safe and effective. Unlawful promotion of drugs for unapproved uses and failing to report adverse drug experiences to the FDA can tip the balance of those important decisions, and the Justice Department will not tolerate attempts by those who seek to corrupt our health care system in this way."

Non-monetary Provisions and Corporate Integrity Agreement

In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.

"Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "For example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets."

"The FDA Office of Criminal Investigations will aggressively pursue pharmaceutical companies that choose to put profits before the public's health," said Deborah M. Autor, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration. "We will continue to work with the Justice Department and our law enforcement counterparts to target companies that disregard the protections of the drug approval

process by promoting drugs for uses when they have not been proven to be safe and effective for those uses, and that fail to report required drug safety information to the FDA."

"The record settlement obtained by the multi-agency investigative team shows not only the importance of working with our partners, but also the importance of the public providing their knowledge of suspect schemes to the government," said Kevin Perkins, Acting Executive Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system."

" Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

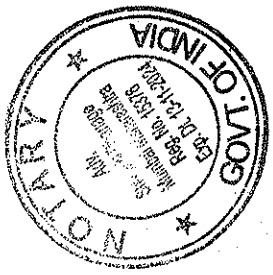
"Today's announcement illustrates the efforts of VA OIG and its law enforcement partners in ensuring the integrity of the medical care provided our nation's veterans by the Department of Veterans Affairs," said George J. Opfer, Inspector General of the Department of Veterans Affairs. "The monetary recoveries realized by VA in this settlement will directly benefit VA healthcare programs that provide for veterans' continued care."

"This settlement sends a clear message that taking advantage of federal health care programs has substantial consequences for those who try," said Rafael A. Medina, Special Agent in Charge of the Northeast Area Office of Inspector General for the U.S. Postal Service. "The U.S. Postal Service pays more than one billion dollars a year in workers' compensation benefits and our office is committed to pursuing those individuals or entities whose fraudulent acts continue to unfairly add to that cost."

A Multilateral Effort

The criminal case is being prosecuted by the U.S. Attorney's Office for the District of Massachusetts and the Civil Division's Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney's Office for the District of Massachusetts, the U.S. Attorney's Office for the District of Colorado and the Civil Division's Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division and FDA's Office of Chief Counsel as well as the National Association of Medicaid Fraud Control Units.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.



This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in

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settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

Court documents related to today's settlement can be viewed online at www.justice.gov/opa/gsk-docs.html .

Related Materials:

Remarks by the Deputy Attorney General James M. Cole at the GSK Press Conference
Remarks by Acting Assistant Attorney General for the Civil Division Stuart F. Delery at the GSK Press Conference

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Topic(s):
Consumer Protection

Component(s):
Civil Division

Press Release Number:
12-842

Updated May 22, 2015

NOTARY
Adv. Shivaji M. Dhanaga
Mumbai Maharashtra
Reg. No. 15376
Exp. Dt. 13-11-2024
GOVT. OF INDIA

IN THE HIGH COURT OF JUDICATURE AT BOMBAY
CRIMINAL APPELLATE JURISDICTION
WRIT PETITION NO. _____OF 2021
DIST. – THANE

Smt. Kiran Yadav)
[redacted])
)
) **...Petitioner**

Versus

1. The State of Maharashtra)
Through Chief Secretary)
The Government of Maharashtra)
Mantralaya, Mumbai - 400 023.)

2. Director General of Police)
Maharashtra State Police Headquarters,)
Old Council Hall, Shaeed Bhagat Singh)
Marg, Mumbai - 400 001.)

3. Commissioner of Police)
Shanti Gardens Rd, Panchmukhi Marg)
Sector 5, Srishti Complex, Mira Road)
Bldg No. 9, Ramnagar Development)
Corporation, near MBMC Office, Gaurav)
Galaxy, Mira Road, Mira Bhayandar,)
Maharashtra 401 107.)

4. Central Bureau of Investigation)
6th Floor, Lodhi Road, Plot No. 5-B,)

GOVT. OF INDIA NOTARY Adv. Shivaji N. Dhanawade Mumbai Maharashtra Reg. No. 15576 Exp. Dt. 13-11-2024

Jawaharlal Nehru Stadium Marg,)
CGO Complex, New Delhi, Delhi 110 003.)

5. Principal Secretary,)
Ministry of Health & Family Welfare)
Room No. 346; 'A' Wing, Nirman Bhavan,)
New Delhi - 110 011.) ...**Respondents**

VAKALATNAMA

To,

The Registrar,
Criminal Appellate Jurisdiction,
Bombay High Court.

I, **Smt. Kiran Yadav**, the Petitioner abovenamed, do hereby appoint Adv. Siddhi A. Dhamnaskar (I-30853) and Adv. Shivam Mehra (I-23521) Advocate Bombay High Court, to act, appear and plead for me in the above matter.

In the witness whereof, I have set my hand to this writing.

Dated of November, 2021)
Accepted)

Shivam Mehra & Siddhi Dhamnaskar
(I-23521)MAH/5888/2018&(I-30853)MAH/5734/2020
Address: 2 & 3, Kothari House,
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Fort, Mumbai 400 023.
Email: advsiddhidhamnaskar@gmail.com

(Smt. Kiran Yadav)
Petitioner

IN THE HIGH COURT OF JUDICATURE
AT BOMBAY
CRIMINAL APPELLATE JURISDICTION

WRIT PETITION NO. OF 2021

Smt. Kiran Yadav

...Petitioner

Versus

State of Maharashtra & Ors.

...Respondents

VAKALATNAMA

Dated this _____day of November, 2021

Shivam Mehra & Siddhi Dhamnaskar
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NOTARY
GOVT. OF INDIA
Adv. Shivaji Hiraman Mumbai Maharashtra
Reg. No. 15378
Exp. Dt. 13-11-2026

IN THE HIGH COURT OF JUDICATURE
AT BOMBAY
CRIMINAL APPELLATE JURISDICTION

WRIT PETITION NO. OF 2021

Smt. Kiran Yadav

...Petitioner

Versus

State of Maharashtra & Ors.

...Respondents

CRIMINAL WRIT PETITION

Dated this _____day of November, 2021

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[redacted]

NOTARY GOVT. OF INDIA