

DIARY No. 37256/2026

DECLARATION

All defects have been duly cured. Whatever has been added/deleted/ modified in petition is the result of curing of defects and nothing else. Except curing the defects, nothing has been done. Paper books are complete in all respects.

Signature

AOR's

AOR co

Contact

REDACTED

Place: New Delhi

Date: 18/08/2026

ANNEXURE "D"**PROPOSED ADVOCATE'S CHECK LIST (TO BE CERTIFIED BY ADVOCATE-ON-RECORD)**

1.	SLP (C) has been filed in Form No. 28 with certificate.	Yes
2.	The Petition is as per the provisions of Order XV Rule 1.	Yes
3.	The papers of SLP have been arranged as per Order XXI, Rule (3)(1)(f).	Yes
4.	Brief list of dates/events has been filed.	Yes
5.	Paragraphs and pages of paper books have been numbered consecutively and correctly noted in Index.	Yes
6.	Proper and required number of paper books (1+1) have been filed.	Yes
7.	The particulars of the impugned judgment passed by the court(s) below are uniformly written in all the documents.	Yes
8.	In case of appeal by certificate the appeal is accompanied by judgment and decree appealed from and order granting certificate.	NA
9.	The Annexures referred to in the petition are true copies of the documents before the court(s) below and are filed in chronological order as per List of Dates.	Yes
10.	The annexures referred to in the petition are filed and indexed separately and not marked collectively.	Yes
11.	In SLP against the order passed in Second Appeal, copies of the orders passed by the Trial Court and First Appellate Court have been filed.	NA
12.	The complete listing proforma has been filled in, signed and included in the paper books.	Yes
13.	In a petition (PIL) filed under clause (d) of Rule 12(1) Order XXXVIII, the petitioner has disclosed:	NA

	(a) his full name, complete postal address, e-mail address, phone number, proof regarding personal identification, occupation and annual income, PAN number and National Unique Identity Card number, if any; (b) the facts constituting the cause of action; (c) the nature of injury caused or likely to be caused to the public; (d) the nature and extent of personal interest, if any, of the petitioner(s); (e) details regarding any civil, criminal or revenue litigation, involving the petitioner or any of the petitioners, which has or could have a legal nexus with the issue(s) involved in the Public Interest Litigation.	
14.	In case of appeals under Armed Forces Tribunal Act, 2007, the petitioner/appellant has moved before the Armed Forces Tribunal for granting certificate for leave to appeal to the Supreme Court.	NA
15.	All the paper books to be filed after curing the defects shall be in order.	Yes

I hereby declare that I have personally verified the petition and its contents and it is in conformity with the Supreme Court Rules, 2013. I certify that the above requirements of this Check List have been complied with. I further certify that all the documents necessary for the purpose of hearing of the matter have been filed.



UNIVERSAL HEALTH ORGANISATION PETITIONER

VERSUS

UNION OF INDIA RESPONDENT

I.A. No. 265838 OF 2026 APPLICATION SEEKING
CONDONATION OF DELAY 47
DAYS IN REFILEING OF THE
PRESENT PETITION

ADVOCATE FOR PETITION

REDACTED

RECORD OF PROCEEDINGS

Sl.No.	Date of Record of Proceedings	Remarks
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
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13.		
14.		
15.		

TOTAL PAGE NOS. A TO _____
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2.	Listing Proforma	A1- A2		
3.	Cover Page Paper Book		A3	
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IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)
WRIT PETITION (CIVIL) NO. OF 2026
(PUBLIC INTEREST LITIGATION)

IN THE MATTER OF:

**UNIVERSAL HEALTH
ORGANISATION**

....PETITIONER

VERSUS

UNION OF INDIA

....RESPONDENT

OFFICE REPORT ON LIMITATION

1. The petition is/are within time.
2. The petition is barred by time and there is ____ delay in filing the same against the impugned order dated and petition for the condonation of ____ days delay has been filed.
3. There is delay of 47 in refilling the petition and the petition for condonation of 47 days delay in filing has been filed.

NEW DELHI

DATED: 18.06.2026

BRANCH OFFICER

PROFORMA FOR FIRST LISTING**SECTION****The case pertains to** (Please tick/check the correct box):

☐	Central Act: (Title):	Constitution of India	
☐	Sections:	Article 32 14, 19(1)(a), and 21	
☐	Central Rule : (Title)	N.A.	
☐	Rule No(s):	N.A.	
☐	State Act: (Title)	N.A.	
☐	Section:	N.A.	
☐	State Rule: (Title)	N.A.	
☐	Rule No(s):	N.A.	
☐	Impugned Interim Order: (Date):	N.A.	
☐	Impugned final Order/Decree: (Date):	N.A.	
☐	High Court: (Name):	N.A.	
☐	Name of Judge(s):	N.A.	
☐	Tribunal/Authority: (Name)	N/A	
1.	Nature of matter:	☒ CIVIL	☐ Criminal
2. (a)	Petitioner:	UNIVERSAL HEALTH ORGANISATION	
(b)	e-mail ID:	N.A.	
(c)	Mobile Phone no.:	N.A.	
3. (a)	Respondent No. 1:	UNION OF INDIA	
(b)	e-mail ID:	N.A.	
(c)	Mobile Phone no.:	N.A.	
4. (a)	Main category classification:	PIL	
(b)	Sub classification:	PIL	
5.	Not to be listed before:	N.A.	
6. (a)	Similar disposed of matter with citation, if any, & case details:	No Similar Matter disposed off	
(b)	Similar pending matter with case details:	No Similar matter pending	
7.	Criminal Matters: N.A.		
(a)	Whether accused/convict has surrendered:	☐ Yes	☒ No
(b)	FIR No.:	NO	

(c)	Police Station:	NO
(d)	Sentence Awarded:	NO
(e)	Sentence Undergone:	NO
(f)	Whether any earlier case between the same parties is filed	No
(g)	Particulars of the FIR and Case	No
(h)	Whether any bail application was preferred earlier and decision thereupon:	No
8.	Land Acquisition Matters:	N/A
(a)	Date of Section 4 notification:	N.A.
(b)	Date of Section 6 notification:	N.A.
(c)	Date of Section 17 notification:	N.A.
9.	Tax Matters: State the tax effect:	N.A.
10.	Special Category (first petitioner/appellant only): N/A	
	☐ Senior citizen > 65 years ☐ SC/ST ☐ Woman ☐ Disabled ☐ Legal Aid Case ☐ In custody	
11.	Vehicle Number (in case of Motor Accident Claim matters):	N.A.
12.	Whether there was/is litigation on the same point of law, if yes, details thereupon:	No

Date: 18.06.2026

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REDACTED

(s)

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SYNOPSIS

That this Public Interest Litigation arises from the urgent need to safeguard the constitutional rights of minor children and their parents in the context of India's 2026 nationwide HPV vaccination programme. The petitioner, acting solely in the welfare of children and their natural guardians, approaches this Hon'ble Court to challenge the programme's design and implementation, which subjects over 1.15 crore adolescent girls annually to an irreversible medical intervention without adequate informed parental consent. The programme is justified by the Government on the claim that cervical cancer incidence is "rising" and that mass vaccination is the only effective response. Eminent oncologists, however, have publicly refuted this narrative, pointing to epidemiological data that shows cervical cancer incidence has declined over the past three decades, with a lifetime risk of only 2.5% and mortality risk of 1.4%. Consent obtained under the misrepresentation that the vaccine is a "cancer vaccine" rather than an anti-HPV vaccine is not valid consent in law, as parents are not informed that most HPV infections clear naturally, that the vaccine does not treat existing infections, and that low-cost screening alternatives are available and effective.

That the programme's deployment in schools transform what is notionally voluntary into structural coercion. In authority-laden environments where children are conditioned to comply, refusal requires visible dissent in front of peers and teachers, making meaningful refusal practically impossible. Parents informed only at the last moment face institutional pressure incompatible with the standard

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of voluntariness required under Article 21. This coercion is not speculative; the Gwalior incident of March 11, 2026, where girls were vaccinated without parental consent and subsequently fell ill, confirms it as ground reality. The Government's own Lok Sabha statement of March 14, 2026, acknowledging that the programme "requires mandatory parental approval," is a tacit admission that such approval was not being universally secured.

That the constitutional framework makes clear that bodily integrity and autonomy are fundamental rights under Article 21, as affirmed in *Justice K.S. Puttaswamy v. Union of India*. State action intruding upon these rights must satisfy legality, legitimate aim, and proportionality. The HPV programme fails each limb: no statute authorises mass vaccination without parental consent; the "rising cancer" narrative is factually disputed; and the availability of screening alternatives renders mass vaccination disproportionate. In *Jacob Puliyel v. Union of India*, this Court held that no individual can be compelled to be vaccinated and directed that Adverse Events Following Immunisation (AEFI) reports be made publicly accessible. Yet no India-specific AEFI dashboard exists for the HPV programme, leaving citizens in uncertainty. In *Aruna Shanbaug v. Union of India*, this Hon'ble Court affirmed the right to refuse medical treatment as an extension of autonomy under Article 21. The right to refuse vaccination flows naturally from this principle; to deny it fractures the integrity of Article 21 itself.

That the Statutory and regulatory safeguards have also been ignored. Under the Drugs and Cosmetics Act, 1940, Schedule Y and

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Good Clinical Practice Guidelines, clinical trial participants are entitled to comprehensive informed consent forms disclosing risks, alternatives, and withdrawal rights. By extension, recipients of new vaccine schedules deserve no less. Yet the HPV programme fails to provide standardised vernacular-language consent forms, restricting materials to Hindi and English. This exclusion silences tribal, rural, and linguistically marginalised communities where literacy in dominant languages is lowest, rendering consent functionally meaningless. True consent is not a ritual signature but comprehension, deliberation, and choice; without language access, there is no consent, only compliance. Such compliance corrodes dignity under Article 21 and violates equality under Article 14.

That Compounding these infirmities, India has failed to notify a Vaccine Injury Compensation Scheme. In the United States, the National Vaccine Injury Compensation Program is a statutory precondition for vaccine rollout, while in the United Kingdom, the Vaccine Damage Payments Scheme provides statutory redress. India offers no equivalent protection. Administering a vaccine with globally documented adverse events to millions of minors annually without a compensation framework violates the State's positive obligation under Article 21 to protect life and provide redress. To invite children into a nationwide programme without a safety net is to ask them to leap without a promise of care if they fall. Such omission corrodes trust, undermines dignity, and leaves the constitutional guarantee hollow.

That the grounds of challenge are therefore clear: the Government has fabricated an epidemiological emergency to justify

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mass vaccination; the programme's deployment in schools creates structural coercion incompatible with informed consent; no AEFI transparency mechanism exists despite judicial directions; no compensation scheme has been notified despite global practice; and consent materials restricted to Hindi and English exclude vulnerable communities, rendering consent meaningless. Each of these omissions collapses autonomy, equality, and dignity into silence, leaving the constitutional promise of life and liberty hollow in practice. The petitioner therefore seeks a declaration that the HPV vaccination programme, in its present form, violates Articles 14, 21, and 21A, and directions to the Union of India to notify a Vaccine Injury Compensation Scheme, establish a public AEFI dashboard, mandate written vernacular-language consent forms, and ensure that school-based vaccination is strictly voluntary with safeguards against coercion. This Hon'ble Court's intervention is necessary not to halt vaccination per se, but to ensure that it is conducted in a manner consistent with constitutional guarantees of autonomy, equality, dignity, and redress, so that public health is advanced without sacrificing the rights of the very citizens it seeks to protect.

That the Petitioner does not challenge the general scientific validity of HPV vaccines as a category, nor does this Petition seek to obstruct any bona fide public health measure. The challenge is specifically directed at the consent architecture, the data transparency framework, and the disproportionate, commercially-driven methodology of the present Programme, each of which independently violates Articles 14 and 21 of the Constitution of India as interpreted in a long line of decisions of this Court.

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LIST OF DATES AND EVENTS

2006	That the United States Food and Drug Administration (USFDA) grants approval for the HPV vaccine Gardasil, manufactured by Merck, intended to prevent infection from certain strains of Human Papillomavirus associated with cervical cancer.
2007	That the MoU was signed between PATH and ICMR, outlining cooperation for generating evidence regarding HPV vaccine introduction in India's public health system.
2008	That the Indian Government approved HPV vaccines for Indian school-aged girls.
2009	That the PATH International, funded by the Bill & Melinda Gates Foundation, conducts HPV vaccine demonstration project on approximately 26,000 tribal and hostel-resident girls aged 10–14 in Andhra Pradesh and Gujarat. Seven girls die during the project period. Consent forms are signed by hostel wardens — not parents — in thousands of cases. Vaccination dates precede consent dates in documented instances.
2010	That the Government of India suspends the PATH project following nationwide protests and reports by civil society organisations including Sama Resource Group for Women and Health.
30.08.2013	That the Parliamentary Standing Committee on Health and Family Welfare tables its 72nd Report on "Alleged Irregularities in the Conduct of Studies Using Human

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	Papilloma Virus (HPV) Vaccine by PATH in India". The Committee finds egregious consent violations, absence of adverse event monitoring, and characterises the project as an unethical clinical trial conducted under the guise of a "demonstration project" to avoid regulatory scrutiny.
2013	That the Study conducted and published in the American Journal of Reproductive Immunology, where the paper suggested that HPV vaccine triggered an autoimmune response and a diagnosis of Primary Ovarian Failure (POF) was determined.
2022	That the NTAGI recommends inclusion of HPV vaccine in Universal Immunisation Programme.
28.02.2026	That the Hon'ble Prime Minister of India launches nationwide HPV Vaccination Programme from Ajmer. Government sets target of 1.15 crore girls aged 14 per year. Vaccine: Gardasil (quadrivalent, Merck/MSD). Regimen: single dose.
11.03.2026	That the five girls fall ill in Barkari Jigniya village, Gwalior district, Madhya Pradesh, after being taken for vaccination by an anganwadi worker without parental consent.
05.05.2026	That the RTI reply from the Department of Public Health and Preventive Medicine, Tamil Nadu, providing

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	data on cervical cancer deaths recorded over the past ten years.
08.05.2026	That the RTI Reply from Department of Obestrics and Gynaecology, Goa Medical College & Hospital, Bambolim Goa, stating no. gynaecological death due to cervical cancer.
27.03.2026	That the Ministry of Health and Family Welfare, Union of India clarifies in the Lok Sabha that the Programme is "voluntary and requires mandatory parental approval." This clarification itself confirms that the existing implementation on the ground has failed to ensure such consent.
15.05.2026	That upon finding a systematic gap between the Government's stated consent policy and its ground-level implementation, compounded by data manipulation concerns raised by independent medical experts.

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(PUBLIC INTEREST LITIGATION)

IN THE MATTEER OF:

**UNIVERSAL
ORGANISATION**

HEALTH

REDACTED

....PETITIONER

VERSUS

UNION OF INDIA

Through the Secretary, Ministry of
Health and Family Welfare, Nirman
Bhawan, New Delhi - 110001

....RESPONDENT

**WRIT PETITION UNDER ARTICLE 32 OF THE CONSTITUTION
OF INDIA IN PUBLIC INTEREST, FOR ENFORCEMENT OF
FUNDAMENTAL RIGHTS GUARANTEED UNDER ARTICLES 14,
19(1)(a), AND 21 OF THE CONSTITUTION OF INDIA, SEEKING**

ISSUANCE OF A WRIT OF MANDAMUS, OR ANY OTHER APPROPRIATE WRIT, ORDER OR DIRECTION, DIRECTING THE UNION OF INDIA TO FORTHWITH SUSPEND THE SCHOOL-BASED COMPONENT OF THE HPV VACCINATION PROGRAMME PENDING THE FRAMING AND ESTABLISHMENT OF A LEGALLY COMPLIANT INFORMED-CONSENT PROTOCOL, AND FOR ALLIED AND FURTHER DIRECTIONS INCLUDING CONSTITUTION OF AN INDEPENDENT EXPERT COMMITTEE, ESTABLISHMENT OF A PUBLIC AEFI SURVEILLANCE DASHBOARD, NOTIFICATION OF A VACCINE INJURY COMPENSATION SCHEME, AND FRAMING OF A NATIONAL VACCINE CONSENT JURISPRUDENCE FRAMEWORK

TO

THE HON'BLE CHIEF JUSTICE OF INDIA & HIS COMPANION JUSTICES OF THE HON'BLE SUPREME COURT OF INDIA.

THE HUMBLE PETITION OF THE PETITIONER ABOVE NAMED

MOST RESPECTFULLY SOWETH:

1. The instant petition is being filed under Article 32 of the Constitution of India. The petitioner is seeking enforcement of fundamental rights guaranteed under articles 14, 19(1)(a), and 21 of the Constitution of India, seeking issuance of a writ of mandamus, or any other appropriate writ, order or direction, directing the Union of India to forthwith suspend the school-based component of the HPV vaccination programme pending the framing and establishment of a legally compliant informed-consent protocol, and

for allied and further directions including constitution of an independent expert committee, establishment of a public AEFI surveillance dashboard, notification of a vaccine injury compensation scheme, and framing of a national vaccine consent jurisprudence framework.

- 1A. The petitioner hasn't preferred any similar petition or petition seeking similar relief before any other Court.

2. The Petitioner has been informed that the Government of India, through its [REDACTED] under the aegis of the Universal Health Organisation (UHO), a forum dedicated to ensuring that impartial, truthful, unbiased, and relevant information reaches every citizen.

3. The Petitioner after going through the contents of the news reports published in various national publications, relating to the administration of the HPV vaccine to school going minor girls without adequate informed parental consent and the documented ground-level coercion as reported in Gwalior District on 11th March 2026, considered it solemn duty, for welfare of the minor children of this country and their natural guardians, to approach this Hon'ble Court to seek appropriate remedy for all those children who are being subjected to an irreversible medical intervention without the informed consent of their parents, in violation of their fundamental rights under Article 14 and 21 of the Constitution of India.
4. The petitioner submits that given the pan-India nature of the programme and the urgency of the matter, various States and the Union Territories are not impleaded as parties to the present petition.

In the humble submission of the petitioner, the Union of India is competent under its executive power under Article 73 of

the Constitution of India, read with the directions issuing authority under the National Health Policy and the Universal Immunisation Programme Framework, to give necessary directions to all states and Union Territories and to implement the order of this Hon'ble Court on the issues raised in the present petition.

5. The petitioner has no personal interest or any oblique motive in the filing of the instant petition. There is no civil, Criminal, revenue or any other litigation involving the petitioner which has or could have any legal nexus with the issues raised in the present petition made in the public interest. The instant writ petition is based entirely on information and documents which are in the public domain, including Parliamentary Committee Reports, published epidemiological studies, publicly broadcast expert interviews and official government press releases.

5A. That the cause of action for filing the present Writ Petition first arose when the Respondent commenced the nationwide implementation of the Human Papillomavirus (HPV) Vaccination Programme amongst minor school-going girls without instituting a constitutionally compliant framework for informed parental consent, transparent disclosure of material risks, public reporting of Adverse Events Following Immunisation (AEFI), or a Vaccine Injury Compensation Scheme. The cause of action is continuing in nature as the impugned programme is being implemented across the country and thousands of minor girls continue to be vaccinated under the existing framework, thereby giving rise to a recurring and subsisting violation of Articles 14 and 21 of the Constitution of India.

5B. That the present petition concerns the health, bodily autonomy and informed consent rights of millions of minor girls who are either presently covered or are likely to be covered under the nationwide HPV Vaccination Programme. The injury complained of is public in nature, inasmuch as the impugned programme exposes children throughout the country to vaccination without a uniform, legally enforceable informed-consent framework, without adequate disclosure of material information to parents or guardians in vernacular languages, without a transparent mechanism for reporting vaccine-related adverse events, and without any statutory vaccine injury compensation mechanism. The issues raised therefore transcend individual grievance and affect the constitutional rights, dignity and health of a large and indeterminate class of children and their families across India.

6. FACTUAL BACKGROUND AND EXPERT EVIDENCE:

A. That the cervical cancer is the second most common cancer affecting women in India, with nearly 128,000 new cases and 80,000 deaths yearly. While HPV vaccines have been approved for Indian school-aged girls since 2008, the government of India temporarily halted vaccine studies in 2010 after the deaths of seven young girls who received HPV vaccination through implementation projects in the states of Gujarat and Andhra Pradesh. A true copy of the report of Frontline Magazine dated 07.05.2010 regarding fata trials is annexed herewith and marked as

ANNEXURE P/1 [Pages 23-25]

- B.** That the Serum Institute of India, a prominent vaccine manufacturer in India, launched a new, indigenously-developed HPV vaccine in September 2022 at significantly cheaper cost per-dose than existing vaccines; the government subsequently announced a gradual roll-out for adolescent girls as part of India's National Immunization Program.
- C.** That as per World Health Organisation Human papillomavirus (HPV) refers to a group of around 200 related viruses that are sexually transmitted. Although most HPV infections subside on their own, typically without any symptoms, some persistent infections can result in cancer. Progression of an HPV infection into cancer can take up to 15–20 years, while symptoms may not appear during the initial phase when cancer cells begin to develop.
- D.** That India's present HPV vaccination programme is not its first encounter with such initiatives. The 2009 PATH trial left behind unresolved questions and public unease that continue to shape discourse around vaccine safety and consent. That the 72nd Parliamentary Standing Committee Report (2013) documented:

 - (i) hostel wardens not parents signed 2,763 consent forms in Andhra Pradesh;
 - (ii) 69 of 100 sampled consent forms had missing witness signatures;

- (iii) In documented instances, the date of vaccination preceded the date of consent, indicating retrospective fabrication;
- (iv) Girls and their parents were not informed that they were enrolled in a research project, believing it to be a routine government immunisation; and
- (v) Adverse events were neither systematically monitored nor reported. That the then Member of Parliament Shri Jagat Prakash Nadda who, as a member of the Parliamentary Standing Committee, signed a report condemning the 2009 HPV trial as unethical, now, as Union Health Minister, launched the 2026 mass HPV vaccination Programme without any publicly notified mechanism to prevent the recurrence of the same consent violations. Critically, the 2009 violations are not merely historical. A true copy of the 72nd Report on "Alleged Irregularities in the Conduct of Studies Using Human Papilloma Virus (HPV) Vaccine by PATH in India" presented in Parliament is annexed herewith and marked as

ANNEXURE P/2 [Pages 26-68]

- E. That in addition to the documented clusters of transient neuropsychiatric events in India, international peer-reviewed literature has raised grave concerns about the reproductive safety of HPV vaccines. A study published in the *American Journal of Reproductive Immunology* reported that adolescent girls developed **Primary Ovarian Failure (POF)**

following HPV vaccination, with clinical investigations suggesting an **autoimmune mechanism triggered by the vaccine antigens**. The diagnosis of POF is not a trivial adverse event—it represents irreversible infertility, menstrual cessation, and profound hormonal imbalance in otherwise healthy young women. The authors of the study underscored that the immunological insult was temporally associated with HPV vaccination, and that the autoimmune hypothesis warranted urgent regulatory scrutiny. A true copy of the study titled 'Human Papilloma Virus Vaccine and Primary Ovarian Failure' published by American Journal of Reproductive Immunology is annexed herewith and marked as **ANNEXURE P/3 [Pages 69-76]**

- F.** That on March 11, 2026 — thirteen days after the Programme's launch — five girls in Barkari Jigniya village, Gwalior, Madhya Pradesh, fell ill after being taken for vaccination by an anganwadi worker without the consent of their parents. A true copy of the Media reports regarding ill effects of vaccines is annexed herewith and marked as **ANNEXURE: P/4 [Pages 77-83]**
- G.** That the Respondent, rolled out national wide HPV Vaccination Programme for girls aged 14 years, aiming approximately 1.15 crore girls, every year across all states and union territories. The Government's central justification for the Programme rests on the claim that cervical cancer incidence is "rising" and that immediate mass vaccination is the only effective response. Whereas the RTI reply from two

states i.e. Goa and Tamil Nadu has been reportedly 4 and 1346 respectively and that too within a span of 10 years.

A true & typed copy of the RTI reply from the department of Public Health and Preventive Medicine, Tamil Nadu is annexed herewith and marked as **ANNEXURE P-5**
[Pages 84 - 84 A]

A true & typed copy of the RTI reply from the Department of Obstetrics and Gynaecology, Goa Medical College & Hospital, Bambolim Goa is annexed herewith and marked as **ANNEXURE P-6****[Pages 85 - 85 A]**

- H.** That the Government has marketed the Programme to parents and the public as a "cancer vaccine," thereby preventing free and informed consent. A parent consenting to a "cancer vaccine" is not the same as a parent consenting to an "anti-HPV vaccine", particularly when the parent has not been told that: (a) most HPV infections clear naturally without causing cancer; (b) the lifetime cervical cancer risk is 2.5%; (c) the vaccine does not treat existing HPV infection; and (d) regular screening (Pap smear / VIA) is an established, low-cost alternative with documented efficacy in the Indian context. Further the RTI Reply RTI reply from the Department of Public Health and Preventive Medicine, Tamil Nadu and RTI reply from Department of Obstetrics and Gynaecology, Goa Medical College & Hospital, Bambolim Goa; laying down no. deaths caused due to cervical cancer for the past 10 years reveals that mortality associated with the cervical cancer is extremely low.

- I. That the Programme's deployment in school settings transforms what the Government calls a "voluntary" programme into a structural coercion. The concept of "nudge" has been borrowed from behavioural economics which describes situations where the architecture of choice is designed to steer individuals toward a predetermined outcome without their active deliberation. When a school authority announces on a given day that students will receive a vaccination, with anganwadi workers, ASHA workers, and government nurses present, refusal requires an affirmative, visible act of dissent in a peer environment. Children and even parents who are informed only the day before face social and institutional pressure that is incompatible with the standard of voluntary, informed consent required by Article 21 of the Constitution.
- J. That this fear is not speculative, the Gwalior incident of March 11, 2026 confirms it as current ground reality. Further, the Government's own Lok Sabha statement of March 27, 2026, acknowledging that the Programme "requires mandatory parental approval," is a tacit admission that such approval was not being universally secured, necessitating a Parliamentary clarification. A true copy of the reply of the Ministry of Health in Lok Sabha is annexed herewith and marked as **ANNEXURE P-7 [Pages 86]**

7. CONSTITUTIONAL AND STATUTORY FRAMEWORK:

- A. That in *Justice K.S. Puttaswamy (Retd.) v. Union of India*, AIR 2018 SC (SUPP) 1841, a nine-judge Bench of this Hon'ble

court, unanimously held that the right to privacy including bodily integrity and the right to make personal choices about one's own body is a fundamental right under Article 21. Any state action intruding upon this right must satisfy a three-pronged test: (a) legality, the existence of a law; (b) legitimate state aim; and (c) proportionality, a rational and necessary connection between the means employed and the objective. The HPV Programme fails each limb: no statute authorises mass school-based vaccination of minors without individualised parental consent; the "rising cancer" narrative is factually disputed by epidemiological evidence; and the availability of screening alternatives renders the mass-vaccination approach disproportionate.

- B.** That this Hon'ble Court The Supreme Court in *Jacob Puliyel v. Union of India* (2022 INSC 503), underscored that bodily integrity is safeguarded under Article 21, affirming that no individual can be compelled to undergo vaccination. It cautioned that restrictions imposed on the unvaccinated must withstand constitutional scrutiny, and it directed that Adverse Events Following Immunization (AEFI) reports be made publicly accessible within a transparent pharmacovigilance framework. Yet, despite these clear principles, India's current HPV vaccination programme in 2026 proceeds without any India-specific public AEFI dashboard. The absence of such transparency leaves citizens navigating uncertainty, with questions about safety and accountability echoing unanswered in the public sphere.

- C.** That in *Aruna Ramachandra Shanbaug v. Union of India*, (2011) 4 SCC 454, this Hon'ble Court affirmed that the right to refuse medical treatment is an inseparable facet of personal autonomy under Article 21. That recognition of autonomy was not limited to end-of-life decisions; it was a broader affirmation that the human body is not a site for compelled intervention. The right to refuse vaccination flows naturally from this principle. To accept medical autonomy in one context but deny it in another would be to fracture the integrity of Article 21 itself. The freedom to say "no" to a medical procedure is as vital as the freedom to say "yes," and it is this balance that sustains dignity in a constitutional democracy.
- D.** That the selective omission of a written informed-consent requirement for HPV vaccination in schools strikes at the heart of constitutional guarantees. In India, surgical procedures, clinical trials, and invasive medical interventions uniformly demand documented consent, yet this vaccination programme alone is exempted—an arbitrary and discriminatory departure from established safeguards under Article 14. The school environment, moreover, is not a neutral space; it is authority-laden, where children are conditioned to comply with institutional directives. Administering vaccines in such settings without prior written parental consent transforms what is notionally voluntary into a de facto compulsory programme. This not only erodes the dignity and personal liberty of the child but also undermines the parents'

right to direct their child's healthcare, thereby intruding upon the constitutional promise of education under Article 21A. The omission is not a mere procedural lapse—it is a structural injustice that collapses autonomy, equality, and dignity into silence.

- E.** That Under the Drugs and Cosmetics Act, 1940, Schedule Y and the Good Clinical Practice Guidelines, every participant in a clinical trial is entitled to a comprehensive Informed Consent Form—one that discloses risks, alternatives, and the right to withdraw. By extension, recipients of newly introduced vaccine schedules deserve no less. Yet the 2026 HPV vaccination programme proceeds without publishing a standardised, vernacular-language consent form for parents before vaccination day. This omission is not a mere bureaucratic oversight; it is a denial of dignity. It strips families of the chance to weigh risks and choices in their own language, reducing consent to a hollow gesture. In a programme that touches the bodies of children, the absence of transparent, written consent is not only arbitrary- it is a profound breach of trust.

8. GROUND:

- A.** Because the Respondent has systematically overstated the incidence of and mortality from cervical cancer to construct a public health emergency that justifies mass vaccination without individualised consent assessment. Independent expert evidence establishes that cervical cancer mortality in India stands at approximately seven deaths per one lakh

women, that incidence has declined over the past three decades, and that the vaccine is an anti-HPV vaccine, not an anti-cancer vaccine, a distinction suppressed in all public communications. This misrepresentation vitiates the consent of any parent who has authorised vaccination in the belief that they are consenting to a "cancer vaccine." Consent obtained on the basis of material misrepresentation is not consent in law.

- B.** Because administering the HPV vaccine in school settings, without written advance consent and without a structured opt-out mechanism, converts the Programme into a coercive "nudge." The presence of government health workers, institutional authority, and peer pressure in a school environment makes meaningful refusal practically impossible for children and functionally difficult for parents informed only at the last moment. This violates the standard of voluntariness essential to lawful informed consent under Article 21 as interpreted in *Puttaswamy* and *Puliyel*.
- C.** Because no publicly accessible, real-time, India-specific pharmacovigilance dashboard has been established for the 2026 HPV Programme, in direct contravention of this Court's directions in *Jacob Puliyel v. Union of India*, (2022) 7 SCC 1. Post-marketing surveillance data from the United States VAERS database- for the identical vaccine Gardasil- has identified safety signals for Guillain-Barré syndrome, Complex Regional Pain Syndrome, Postural Orthostatic Tachycardia Syndrome, autoimmune thyroiditis, and death. These signals

have not been disclosed to parents through any consent material provided before vaccination. Vaccination in the absence of AEFI disclosure is vaccination without genuine informed consent.

- D.** Because no Vaccine Injury Compensation Scheme has been notified for the HPV Programme is a constitutional void of the gravest kind. In the United States, the National Vaccine Injury Compensation Program stands as a statutory pre-condition for vaccine rollout, ensuring that those who suffer rare but serious adverse events are not left abandoned. In the United Kingdom, the Vaccine Damage Payments Scheme provides statutory redress, acknowledging that when the State promotes mass immunisation, it must also shoulder responsibility for the few who bear its unintended burdens. India, however, offers no equivalent protection. The absence of a compensation mechanism in a programme that targets 1.15 crore minors annually- administered with a vaccine that has documented serious adverse events globally- renders families vulnerable and unprotected. It is not merely a policy gap; it is a violation of the State's positive obligation under Article 21 to protect life and to provide adequate redress when harm occurs. To invite children into a nationwide programme without a safety net is to ask them to leap without a promise of care if they fall. Such omission corrodes trust, undermines dignity, and leaves the constitutional guarantee of life and liberty hollow in practice.

- E.** Because the HPV Programme's informed consent materials are restricted to Hindi and English alone is a constitutional infirmity of deep consequence. India recognises 22 languages in its Constitution, each carrying the dignity of its speakers and the promise of equal citizenship. Yet the Programme excludes precisely those communities most vulnerable to cervical cancer- tribal, rural, and linguistically marginalised populations- where literacy in Hindi and English is lowest. Consent materials inaccessible to parents in their own language are not merely inadequate; they are discriminatory and functionally equivalent to no consent at all. This omission silences families who cannot comprehend the risks or choices presented, stripping them of the ability to make an informed decision about their child's health. It entrenches inequality by privileging dominant languages while marginalising those already on the periphery of healthcare access. In a programme that touches the bodies of over a crore minors annually, the failure to provide vernacular-language consent forms transforms the constitutional promise of autonomy into an illusion. True consent is not a ritual signature but comprehension, deliberation, and choice; without language access, there is no consent, only compliance, and such compliance corrodes dignity under Articles 14 and 21.
- F.** Because credible scientific evidence demonstrates that HPV vaccination may trigger autoimmune responses resulting in Primary Ovarian Failure (POF)- a condition causing irreversible infertility, menstrual cessation, and lifelong

hormonal imbalance- the programme violates Article 21 by exposing adolescent girls to grave reproductive risks without disclosure or informed consent; the absence of a vaccine injury compensation scheme and transparent AEFI reporting further compounds the arbitrariness, rendering the continuation of the programme unconstitutional, violative of reproductive autonomy, and contrary to both domestic fundamental rights and international bioethical norms.

PRAYER

In the premises stated above, it is most respectfully prayed that this Hon'ble Court be pleased to:

1. Issue a Writ of Mandamus directing the Respondent/Union of India to immediately suspend the school-based component of the HPV Vaccination Programme pending the establishment of a legally compliant informed-consent protocol, which protocol must, at minimum:
 - Be delivered in writing to the natural guardian(s) of every minor child, in the child's regional language, not less than fourteen days before the scheduled vaccination date;
 - Contain a plain-language description of: (i) the nature of HPV; (ii) the distinction between an anti-HPV vaccine and an anti-cancer vaccine; (iii) the actual lifetime cervical cancer risk for Indian women (2.5%); (iv) available alternatives including Pap smear screening, VIA, and HPV DNA testing; (v) all serious adverse events documented in post-marketing global pharmacovigilance data, including

Guillain-Barré syndrome, CRPS, POTS, anaphylaxis, autoimmune thyroiditis, and death; (vi) the experimental nature of the single-dose schedule and the absence of India-specific confirmatory data;

- Guarantee in writing that refusal shall not attract any adverse consequence to school attendance, grades, scholarship eligibility, or access to any government scheme or service;
 - Require a signed, dated, witnessed opt-in consent form before any minor is vaccinated;
2. Issue a Writ of Mandamus directing Respondent/Union of India to establish, within four weeks, a publicly accessible real-time online AEFI surveillance dashboard for HPV vaccine-related adverse events reported in India, consistent with this Hon'ble Court's directions in *Jacob Puliyel v. Union of India*, (2022) 7 SCC 1
 3. Issue directions constituting an independent Expert Committee comprising of oncologists, epidemiologists, bioethicists, and child rights specialists, with no institutional or financial conflict of interest with vaccine manufacturers or the GAVI-Gates ecosystem to: (i) independently verify the cervical cancer epidemiological data relied upon to justify the Programme; (ii) assess the comparative effectiveness and cost-efficiency of expanded screening infrastructure versus mass vaccination in the Indian context; (iii) review the safety and immunogenicity evidence for the single-dose schedule in Indian-specific populations; and (iv) report to this Court within twelve weeks;

4. Issue a Writ of Mandamus directing the Union of India to notify a Vaccine Injury Compensation Scheme specifically covering HPV vaccine-related injuries within twelve weeks, providing a no-fault compensation mechanism as a condition precedent to continuation of the Programme;
5. Issue directions for the drawing up of a binding Vaccine Consent Jurisprudence framework for India informed by but not slavishly adopting the United States NCVIA/VIS model and the European Union's written-consent practice across member states-establishing: (i) mandatory pre-vaccination disclosure standards; (ii) minor-assent protocols; (iii) guardian opt-out procedures; and (iv) a statutory vaccine injury compensation mechanism, applicable to all vaccines on the Universal Immunisation Programme schedule going forward;
6. Pass any other order or direction as this Hon'ble Court may deem just and proper in the facts and circumstances of the case, in the interest of the health, dignity, and constitutional rights of the minor children of India.

**AND FOR THIS ACT OF KINDNESS THE PETITIONER'S COUNSEL
BOUND SHALL EVER PRAY**

REDACTED

REDACTED

Drawn on: 15.05.2026

Filed on: 15.05.2026

Place: New Delhi

ADVOCATE FOR THE PETITIONER

ANNEXURE: P/1

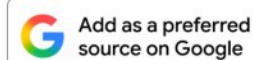
HOME / OTHER

Fatal trials

Published : May 07, 2010 00:00 IST

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Andhra Pradesh Minister for Cooperation R. Venkata Reddy inaugurating HPV vaccination at Tirumalayapalem in Khammam district in July 2009.-G.N. RAO

A CONCERTED campaign by womens organisations and health groups, together with media reports, has finally woken up the countrys health establishment to the dangers of a vaccination programme against cervical cancer currently under way in Andhra Pradesh and Gujarat.

The programme, under a private-public partnership arrangement involving the Indian Council of Medical Research (ICMR), an international non-governmental organisation

(NGO) called PATH, the Bill and Melinda Gates Foundation and the governments of the two States concerned, involved conducting operational research studies and vaccinating adolescent girls against the human papilloma virus (HPV), known to cause cervical cancer.

One of the vaccines, Gardasil, manufactured by the pharmaceutical major Merck, has allegedly resulted in the death of four teenaged tribal girls and caused debilitating problems such as epilepsy, headaches, stomach disorders and early menarche to 120 others in Andhra Pradesh's Khammam district. Since July 2009, a total of 42,000 girls have been administered three doses of Gardasil each.

The controversy began in September-October last year following an advertisement blitz launched by another HPV vaccine manufacturer (Frontline, February 12).

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The ICMR, though unconvinced that the deaths were caused by the vaccine, has ordered the suspension of the programme in the two States. Its Director-General, V.M. Katoch, and the Andhra Pradesh Health Minister, Danam Nagendar, remain convinced that the benefits of the vaccine far outweigh the risks. The Drug Controller General of India, Katoch stated, had approved the use of the vaccine. All the reported deaths, according to him, were not associated with the vaccination. Incidentally, two of the deaths were certified as suicides in the post mortem reports.

Unsurprisingly, the protesting groups view the ICMR's half-hearted intervention with cynicism. While welcoming the suspension of the trials, they said that the governments had to ensure the well-being of the children already covered under the programme. They pointed out that entire batches of the vaccine had been withdrawn in other countries where hospitalisation and deaths were reported following its use. They alleged that the other HPV vaccine, Cervarix (produced and marketed by GlaxoSmithKline in India), had been approved for use on children without any trials.

The ICMRs response followed a memorandum to Union Health Minister Ghulam Nabi Azad on April 7, World Health Day, by organisations such as the All India Democratic Womens Association (AIDWA), the Committee against Violence on Women, the Jan Swasthya Abhiyan, and the Saheli Womens Resource Centre demanding, among other things, the complete suspension of all studies and trials with Gardasil and Cervarix.

The organisations questioned the veracity of PATHs claim that the vaccine has no side effects other than irritation at the injection site and fever and that it has been safely administered to millions of girls in developed countries. They pointed out that the package insert said the vaccine did cause epilepsy-like seizures. A post-marketing surveillance, they said, had observed an increase in the occurrence of blood clotting, autoimmune diseases and disorders of the respiratory and nervous systems. In some cases, death was reported, they said. They said that data from the United States showed that the adverse effects of the HPV vaccine were far more numerous than those of all other vaccines administered to children.

The organisations wondered why and how various agreements were made with Merck and PATH, and why the Institute of Cytology and Preventive Oncology, the ICMRs own cancer research institute, was kept away from trials. The licensing of Gardasil and Cervarix, they alleged, was done on the basis of sketchy bridging studies. While Gardasil has been approved for the age group of 10-27 years, it has been tried only on a very small sample of girls in the 10-14 age group. Cervarix has been approved for the 10-45 age group, but has been tested only in women aged 18-35.

A report carried by local health organisations in Khammam district noted that 14,000 girls in the 10-14 age group in the district had been vaccinated with three doses of Gardasil. There were reports of these girls having early menarche, heavy bleeding and severe cramps following the vaccination. The demonstration project had no follow-up system in place to deal with the after-effects of the vaccination, the report said. It found that in many schools, only the verbal consent was taken from the hostel warden/ teacher-in-charge to vaccinate girls residing in the hostels and the parents had not been informed about it.

T.K. Rajalakshmi



**REPORT
NO.**

72

**PARLIAMENT OF INDIA
RAJYA SABHA**

**DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE ON
HEALTH AND FAMILY WELFARE**

SEVENTY-SECOND REPORT

On

**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 30th August, 2013)

(Laid on the Table of Lok Sabha on 30th August, 2013)



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



PARLIAMENT OF INDIA

RAJYA SABHA

DEPARTMENT-RELATED PARLIAMENTARY STANDING COMMITTEE

SEVENTY-SECOND REPORT

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(Laid on the Table of Lok Sabha on 30th August, 2013)

ON HEALTH AND FAMILY WELFARE



**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
Shri R. B. Gupta
Shrimati Arpana Mendiratta
Shri Dinesh Singh

Joint Secretary
Director
Joint Director
Committee Officer

**COMPOSITION OF THE COMMITTEE
(2010-2011)**

RAJYA SABHA

1. Shri Brajesh Pathak
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

- Chairman

LOK SABHA

11. Shri Ashok Argal
12. Shrimati Sarika Devendra Baghel Singh
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

* nominated to the Committee w.e.f 21/9/2010.
@ceased to be a member w.e.f 18th August, 2011.

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 Halder | |
| 17. | Dr. Monazir Hassan | |
| 18. | Dr. Sanjay Jaiswal | |
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| 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 | |
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| 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 | |

SECRETARIAT

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

* 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 and Member of Sub Committee II on CGHS W.E.F. 01st June, 2012.

&& ceased to be a member w.e.f 29th June, 2012

@ vacant vide resignation w.e.f. 30th April, 2012

COMPOSITION OF THE COMMITTEE ON HEALTH AND FAMILY WELFARE
(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 | | |

LOK SABHA

- | | |
|-------|---------------------------------------|
| @ 11. | Shri Ashok Argal |
| 12. | Shri Kirti Azad |
| 13. | Shri Mohd. Azharuddin |
| 14. | Shrimati Sarika Devendra Singh Baghel |
| 15. | Shri Kuvarjibhai M. Bavalia |
| 16. | Shrimati Priya Dutt |
| 17. | Dr. Sucharu Ranjan Halder |
| 18. | Mohd. Asrarul Haque |
| 19. | Dr. Monazir Hassan |
| 20. | Dr. Sanjay Jaiswal |
| 21. | Dr. Tarun Mandal |
| 22. | Shri Mahabal Mishra |
| 23. | Shri Zafar Ali Naqvi |
| 24. | Shrimati Jayshreeben Patel |
| 25. | Shri Harin Pathak |
| 26. | Shri Ramkishun |
| 27. | Dr. Anup Kumar Saha |
| 28. | Dr. Arvind Kumar Sharma |
| 29. | Dr. Raghuvansh Prasad Singh |
| 30. | Shri P.T. Thomas |
| #31. | Shri Chowdhury Mohan Jatua |

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

* ceased to be Member of the Committee w.e.f. 28th October, 2012.

@ 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.

& ceased to be Member of the Committee w.e.f. 24th July, 2013..

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.

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

Brajesh Pathak
Chairman,
Department-related Parliamentary
Standing Committee on Health and Family Welfare

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. CDSCO-Central Drugs Standard Control Organisation.
7. CTRI- Clinical Trials Registry- India.
8. COURT- Centre for operations Research and Training
9. DCGI- Drug Controller General of India.
10. DG, ICMR- Director General, Indian Council of Medical Research
11. FCRA-Foreign Currency Regulation Act
12. FERA- Foreign Exchange Regulation Act
13. FEMA- Foreign Exchange Management Act
14. GCP-Good Clinical Practice
15. GAVI- Global Alliance for Vaccines and Immunization
16. MEA-Ministry of External Affairs
17. MHA- Ministry of Home Affairs
18. HPV- Human Papilloma Virus.
19. HMSC- Health Ministry Screening Committee
20. ICMR- Indian Council of Medical Research.
21. MoU- Memorandum of Understanding.
22. MEA-Ministry of External Affairs
23. MHA- Ministry of Home Affairs
24. NGO- Non-Governmental Organization
25. NTAGI- National Technical Advisory Group on Immunization
26. O&G- Obstetrics and Gynaecology
27. PATH-Programme for Appropriate Technology in Health.
28. PBC-Public Benefit Corporation
29. ROC- Registrar of Companies
30. RBI- Reserve Bank of India
31. SAE- Serious Adverse Event.
32. UIP- Universal Immunization Programme.
33. USFDA-United States Food and Drug Administration

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 & 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 & 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 & 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 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 objectiveto 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 programmes 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 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 (Appendix 20.5):

"....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?), malarial, 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.

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 DRUGS CONTROLLER GENERAL, INDIA (DCGI)

4.1 The Committee noted that as per Rule 122-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 & percentage of vaccinated girls.
- Number & percentage of vaccinated girls experiencing Serious Adverse Events (SAEs)
- Number & 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 & 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.

(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 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.

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 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 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;
- (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 & 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 & 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 inquiry 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 (number 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 & 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 A**) and (b) permission from Ministry of Home Affairs (MHA) from "security angle" (**Annexure B**). In the latter case, application needs to be forwarded through proper channel such as Ministry of Health & 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 & 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 (number AAFCP2249G) is dated 19th April 1999. The Committee was intrigued because PAN card is issued just for income tax 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 & 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.

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.

Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/Inflammatory Syndrome Induced by Adjuvants

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Problem

Post-vaccination autoimmune phenomena are a major facet of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) and different vaccines, including HPV, have been identified as possible causes.

Method of study

The medical history of three young women who presented with secondary amenorrhea following HPV vaccination was collected. Data regarding type of vaccine, number of vaccination, personal, clinical and serological features, as well as response to treatments were analyzed.

Results

All three patients developed secondary amenorrhea following HPV vaccinations, which did not resolve upon treatment with hormone replacement therapies. In all three cases sexual development was normal and genetic screen revealed no pertinent abnormalities (i.e., Turner's syndrome, Fragile X test were all negative). Serological evaluations showed low levels of estradiol and increased FSH and LH and in two cases, specific auto-antibodies were detected (antiovarian and anti thyroid), suggesting that the HPV vaccine triggered an autoimmune response. Pelvic ultrasound did not reveal any abnormalities in any of the three cases. All three patients experienced a range of common non-specific post-vaccine symptoms including nausea, headache, sleep disturbances, arthralgia and a range of cognitive and psychiatric disturbances. According to these clinical features, a diagnosis of primary ovarian failure (POF) was determined which also fulfilled the required criteria for the ASIA syndrome.

Conclusion

We documented here the evidence of the potential of the HPV vaccine to trigger a life-disabling autoimmune condition. The increasing number of similar reports of post HPV vaccine-linked autoimmunity and the uncertainty of long-term clinical benefits of HPV vaccination are a matter of public health that warrants further rigorous inquiry.

Introduction

Vaccines against human papilloma virus (HPV) are thought to represent a useful approach in the fight against cervical cancer. Although vaccines have proven to be a successful and cost-effective asset for preventive medicine, local or systemic adverse events, following vaccination, have been described. Specifically, there are increasing reports that autoimmune disorders can develop after vaccination.^{1–4} At the same extent, the association between infectious agents exposure and the development of autoimmune diseases is well established.^{5,6} Recently, a new syndrome, namely the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) or Shoenfeld's syndrome,^{7–12} has been defined, alluding to the key role of adjuvants in inducing autoimmunity. The syndromes included in ASIA entail immune-mediated conditions that appear following a chronic stimulation of the immune system by agents with adjuvant characteristics.^{7,10} Post-vaccination autoimmune phenomena represent a major issue of ASIA and different vaccines, including the HPV vaccine, have been found as possible causes.^{3,9,13} Primary ovarian failure (POF) is a clinical condition with complex aetiology in which autoimmune mechanisms represent 20–30% of the cases.¹⁴ This assertion is supported by different evidences: the presence of lymphocytic oophoritis, the detection of ovarian autoantibodies and the frequent association with other autoimmune diseases.¹⁴ Herein, we describe three clinical cases, including two sisters, who developed POF following administration of the HPV vaccine. Genetic, metabolic and external environmental factors were excluded as POF causes, while the common denominator was the previous vaccination with HPV leading to the development of immune-mediated amenorrhoea.

Case 1

A young previously healthy girl received three administrations of the quadrivalent HPV vaccine (T0, T1 after 4 months, T2 after 9 months) when she was 14 years old. Six months before the first injection, the patient had menarche. Her psycho-physical and sexual development were normal except that at the time she received the first HPV vaccine dose, she was complaining of irregular periods (every 2 months). After the first vaccination, the patient

immediately started to complain of burning and heavy sensation in the injected arm, followed by skin rash and fever. Nausea and stomach aches lasted for 2 days after the injection, while in the subsequent 2 weeks, she further complained of cramping and headache. At the time of the second vaccine administration, she reported similar injection site related symptoms, accompanied by sleep disturbances, such as insomnia and night sweats. At the time of the third injection, the patient continued to experience the same symptoms: burning, pain and heavy sensation in the injected arm, headache and cramping. Insomnia associated with night sweats persisted and she started complaining of arthralgia, anxiety and depression. The patient reported that her last period occurred shortly after the last injection of the HPV vaccine. The hormonal screening showed the presence of increased follicle-stimulating hormone (FSH) and luteinizing hormone (LH) associated with very low levels of estradiol. Beta human chorionic gonadotropin (HCG) tested negative excluding pregnancy. The karyotype study was 46 XX, while molecular studies ruled out Fragile X syndrome and mutated follicle-stimulating hormone receptor (FSHR) gene. A pelvic ultrasound did not show any abnormality. According to these clinical and serological findings, POF diagnosis was determined. Even though the patient started therapy with medroxyprogesterone to stimulate bleeding, no improvement occurred and she continued to experience abnormal vaginal bleeding, night sweats, hot flashes and sleep disturbances.

Case 2

This patient (the younger sister of the above-mentioned case) received three administrations of the quadrivalent HPV vaccine at the age of 13 under the same protocol as her sister. At that time, she had normal growth and sexual development. The patient complained, 10 days after the first injection, of general symptoms such as depression and sleep disturbances. She also experienced episodes of lightheadedness and tremulousness, anxiety, panic attacks and difficulties in focusing/concentrating in her school work. She had menarche at the age of 15 years, followed by another period 1 month later and none thereafter. Laboratory analysis showed high serum levels of FSH and LH with undetectable estradiol. The genetic test for Turner's syndrome,

Fragile X syndrome and FSHR gene was performed and resulted negative. Interestingly, the patient tested positive for antiovarian antibodies. She underwent a pelvic ultrasound without an evidence of abnormalities. In the light of these findings, a diagnosis of POF was determined and the patient was treated with several different hormonal replacement therapies with a poor therapeutic response.

Case 3

The patient received the quadrivalent HPV vaccine in three administrations (T0, T1 after 2 months, T2 after 4 months) at the age of 21 years. Menarche occurred when she was 13 years old with normal monthly periods and a flow of 5–7 days, with mild cramps. A normal sexual development was reported. Few months after the last injection of HPV vaccine, she started complaining of irregular menses (off by 1–2 weeks) without an increase in bleeding or pain. The irregular periods worsened and the patient reported on menstruations every 3 months with bleeding only for 2 days. For this reason, she started drospirenone/ethinyl estradiol. Nonetheless, no improvement occurred and after discontinuation of therapy, at the age of 23 years, she complained of amenorrhoea. The laboratory tests showed the presence of very low levels of estradiol and increased FSH and LH. Testosterone, cortisol and prolactin serum level were found normal. Although the thyroid hormones were also in the normal range, the patients had positive antithyroid peroxidase (TPO) antibodies (134 IU/mL, n.v. 0–34). The karyotype evaluation and the search for Fragile X syndrome displayed no aberrations. A transvaginal and pelvic ultrasound did not reveal any abnormality. According to these findings and clinical features, a diagnosis of POF was determined. Thus, a therapy with medroxyprogesterone and estradiol was attempted, however, it did not improve her clinical condition.

Discussion

Herein, we have described three cases of POF following HPV vaccination. To the best of our knowledge, an additional case of POF in a 16-year-old young woman who was vaccinated with the quadrivalent HPV recombinant vaccine has already been reported by Little and Ward.¹⁵ In this case, as in our three cases, no other possible causes of POF were identified other than the HPV vaccine. Quoting the HPV

vaccine manufacturer, the authors emphasized the fact that the post-marketing reporting of vaccine adverse events is voluntary and consequently, it is not always possible to reliably estimate the frequency of such reactions, let alone to establish a causal relationship to the vaccine. Further according to the authors, there may potentially be a group for whom the HPV vaccine is contraindicated and because the occurrence of POF carries major health implications, a long-term follow-up of ovarian function in a cohort of HPV vaccinated woman should be undertaken.¹⁵

POF is a syndrome consisting of primary or secondary amenorrhoea, hypergonadotropinemia and hypoestrogenemia. POF affects 1% of women under 40 years of age, 0.1% under 30 and 0.01% of women under 20 years and it is an important cause of infertility and psychological stress.¹⁴ POF in young women can indeed have significant consequences for future health and prospects of motherhood. The aetiology includes specific genetic mutations (referred to oocyte, enzymes or hormones receptors), autoimmune or environmental causes (such as viral infections, chemotherapy, radiotherapy and pelvic surgery) or metabolic disturbances.¹⁴ The possible autoimmune origin for POF has been speculated for a long time,¹⁶ and one of the evidence which supports this origin is its frequent association with other autoimmune diseases (i.e. thyroiditis, Addison's disease, autoimmune polyglandular syndrome, systemic lupus erythematosus, Sjogren's syndrome, haemolytic anaemia and idiopathic thrombocytopenic purpura).¹⁷ The presence of autoantibodies reactive to different parts of the ovary has been detected in many POF cases and the most commonly recognized autoantigens are on the ooplasm, theca, granulosa, corpus luteum or zona pellucida.^{18–20} More specific antigenic targets of autoantibodies have been identified in steroid cell enzymes including 3 β -hydroxysteroid dehydrogenase (3 β -HSD), cytochrome P450 side-chain cleavage enzyme (P450SCC) and 17 α -hydroxylase/17,20 lyase enzyme (CYP17A1).¹⁴ Nonetheless, the detection of such antibodies has yielded conflicting results because of the different stages of disease in which the tests were conducted, methodological differences and the multiplicity of potential immune targets. In our cases, only one of the three patients had positive antiovarian antibodies. Given the difficulties in detecting these antibodies, an autoimmune origin of POF may be speculated for the other two cases. Indeed, the pres-

Table I The Suggested Criteria of Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA)⁷ in the Current Three Cases of Post-Human Papilloma Virus Vaccine Manifested Primary Ovarian Failure (POF). Note That for Positive Diagnosis of ASIA, Fulfilment of Either Two Major or One Major and Two Minor Criteria is Required

	Case 1	Case 2	Case 3
Major criteria			
1. Exposure to an external stimuli (infection, vaccine and/or immune adjuvants) prior to clinical manifestations	+	+	+
2. The appearance of 'typical' clinical manifestations;			
Myalgia, muscle weakness	—	—	Not reported
Arthralgia and/joint pain	+	—	—
Chronic fatigue, un-refreshing sleep or sleep disturbances	+	+	Not reported
Neurological manifestations	+	+	Not reported
Cognitive disturbances	—	+	Not reported
Pyrexia	—	—	—
3. Removal of inciting agent induces improvement	NA	NA	NA
4. Typical biopsy of involved organs	Not assessed	Not assessed	Not assessed
Minor criteria			
1. The appearance of autoantibodies (antiovarian, anti-TPO)	—	+	+
2. Other clinical manifestations (e.g. amenorrhoea)	+	+	+
3. Specific HLA (e.g. HLA DRB1, HLA DQB1)	Not assessed	Not assessed	Not assessed
4. Evolution of an autoimmune disease (POF)	+	+	+

ence of antiovarian antibodies in the second case, in addition to the finding of the anti-TPO antibodies in the third case, lends support to the idea that autoimmune responses underlying POF can develop following HPV vaccination. Moreover, as POF developed in two sisters, a genetic susceptibility predisposing to post-vaccination POF is probable. The very unusual early age of disease onset may reinforce this suggestion as it was already observed in other immune-mediated diseases.^{21,22} Furthermore, the patients experienced not only POF but also a constellation of other symptoms, including arthralgia, sleep disturbances and cognitive dysfunction, consistent with the diagnosis of the ASIA syndrome (Table I).^{7, 9}

POF as a Part of the ASIA Syndrome

The three cases of POF described herein clearly fulfilled the criteria for the ASIA syndrome (Table I). ASIA comprises a group of diseases including post-vaccination phenomena,^{9,11,13} silicone implant-induced autoimmunity,²³ Gulf War syndrome,²⁴ macrophagic myofasciitis with chronic fatigue syndrome^{25,26} and the sick-building syndrome²⁷ which share a common set of signs and symptoms. Shoenfeld and Agmon-Levin⁷ proposed four major and four minor criteria for ASIA (Table I), and to diagnose ASIA, fulfilment of either two major or

one major and two minor criteria is required. The criteria for ASIA enable the inclusion of patients with well-defined autoimmune diseases (i.e. multiple sclerosis, lupus) as well as those with ill-defined and non-specific yet clinically relevant conditions (i.e. myalgia, chronic fatigue and cognitive disturbances) under the spectrum of vaccine adjuvant-associated conditions.⁹ The inclusion of the latter category of manifestations under ASIA is of special importance as these non-specific manifestations are all too easily ignored or disregarded as irrelevant and non-vaccine related not only by patients and physicians, but also by scientists involved in design of vaccine trials.^{28,29} Nonetheless, many ill-defined medical conditions that fall under the ASIA spectrum are frequently disabling and thus of significant clinical relevance.^{9,25}

Apart from a shared set of clinical manifestations, the other main common feature in ASIA is the presence of an immune adjuvant. An adjuvant is defined as 'any substance that acts to accelerate, prolong or enhance antigen-specific immune response'.²⁴ The adjuvant is able to stimulate the immune system and to increase the response to a vaccine, without having any specific antigenic effect in itself.²⁴ Vaccines, which contain infectious antigens either attenuated or recombinant, may induce autoimmunity by means of similar 'infectious' mechanisms such as molecular

mimicry, epitope spreading, bystander activation and polyclonal activation.^{30,31} When this occurs, it can be subacute or sometimes a long time after the vaccination (i.e. months to years),^{32–37} which leads to difficulties in identifying a definite causality between vaccination and autoimmune phenomena. The latter will most commonly occur in genetically predisposed individuals. Indeed, personal or familial susceptibility to autoimmunity and adverse response to a prior dose of the vaccine both appear to be associated with a higher risk of post-vaccination autoimmunity.^{3,9}

HPV Vaccines and Autoimmunity

In the current literature, there are numerous cases substantiating the link between adverse immune reactions and HPV vaccines, including fatal reactions. For example, Lee³⁸ recently reported a case of a teenage girl who underwent sudden unexpected death approximately 6 months after her third Gardasil HPV vaccine booster. The patient experienced adverse manifestations shortly after the first dose of Gardasil injection (i.e. dizziness spells, paraesthesia and memory lapses) which were further exacerbated after the 2nd vaccine booster after which she also developed excessive tiredness (indicative of chronic fatigue), night sweats, loss of ability to use common objects, intermittent chest pain and sudden unexpected 'racing heart'. Although the autopsy examination failed to identify any toxicological, microbiological or anatomical cause of death, further investigations carried by Dr. Lee³⁹ showed that the post-mortem blood and splenic tissues tested positive for HPV-16 L1 gene DNA fragments corresponding to those previously found in 16 separate Gardasil vials from different vaccine lots (suspected to represent contaminants from the vaccine manufacturing process). These findings suggested that the quadrivalent HPV vaccine was indeed the most probable causal factor in this particular case. Specifically, the HPV DNA fragments detected in Gardasil vials appeared to be firmly bound to the aluminium adjuvant used in the vaccine formulation and thus likely protected against enzymatic degradation by endogenous nucleases.⁴⁰

Additionally, thus far HPV vaccination has been linked to several autoimmune diseases, including Guillain-Barré syndrome,⁴¹ other demyelinating neuropathies,^{42–44} systemic lupus erythematosus,³ pancreatitis,⁴⁵ vasculitis,⁴⁶ thrombocytopenic purpura⁴⁷ and autoimmune hepatitis.⁴⁸ Of note, the most prevalent adverse events associated with HPV

vaccines appear to be autoimmune neurological diseases.^{49,50} For instance, Sutton et al.⁴² reported five cases of female patients who developed a multifocal or atypical demyelinating syndrome within 21 days of immunization with the quadrivalent HPV vaccine. As hypothesized by the authors, the temporal association with demyelinating events in these cases may be explained by the potent immune-stimulatory properties of HPV virus-like particles which comprise the vaccine. Similarly, Chang et al.⁵¹ reported two cases who developed CNS demyelination closely following the administration of the HPV vaccine. Acute disseminated encephalomyelitis in young women (15 and 17 years old) within 3–8 weeks after HPV vaccination has also been described.^{52,53} Altogether, these observations led to the hypothesis that the HPV vaccine may have been released too quickly into the market, in the absence of rigorous safety evaluations.^{49,54,55} Indeed, Gardasil appears to have failed to meet a single one of the four criteria required by the FDA for Fast Track approval.⁵⁴

Adjuvants in HPV Vaccines and Assessment of HPV Vaccine Safety in Clinical Trials

One of the most commonly used adjuvant in vaccines is aluminium²⁴ which is also present in HPV vaccines. There are two different brands of the HPV vaccine: the quadrivalent Gardasil (MSD) and the bivalent Cervarix (GSK). Both are composed of HPV L1 proteins that self-assemble to form virus-like particles but differ in the use of adjuvants.⁵⁶ While the first contains only aluminium hydroxyphosphate sulphate, the second contains a combination of an oil-based adjuvant monophosphoryl lipid A (MPL) and aluminium hydroxide (a proprietary brand of the vaccine manufacturer otherwise known as ASO4), thus leading to diverse boosts in immune responses between the two vaccines.⁵⁷ Another difference is the medium in which the vaccines are produced, *Trichoplusia* cells for the Cervarix and *Saccharomyces cerevisiae* for the Gardasil. This distinction is even more intriguing because we know the potential of yeast to trigger autoimmune responses.⁵⁸ Nonetheless, a recent large observational study on the safety of the quadrivalent HPV vaccine allegedly identified no autoimmune safety concerns.⁵⁹ However, several important biases might have contributed to the negative findings of the study. Firstly, the study included all women who received at least one dose of the vaccine, thus making this particular population less sensitive for the detec-

tion of serious adverse reactions (given that such events occur with much lesser frequency when fewer doses of the vaccine are administered). Secondly, the research team failed to recruit appropriate expertise for diagnosis of autoimmune disorders. Namely, no immunologist/autoimmunologist, neurologist and ophthalmologist were present during the initial screening of the study participants which is particularly surprising in view of the fact that autoimmune conditions of interest that were examined included rheumatological, autoimmune disorders and neurological/ophthalmic conditions.^{29,59} Finally, the Safety Review Committee failed to take into account the fact that autoimmune manifestations may be non-specific and not fitting a well-defined autoimmune condition^{9,25,28} yet severely disabling.^{26,35,60} Of note, the study was entirely funded by the quadrivalent HPV vaccine manufacturer Merck and all authors received previous founding from Merck and/or were consultants for the HPV vaccine manufacturer.⁵⁹

Finally, a further major bias in evaluating HPV vaccine safety comes from the fact that in all clinical trials for both Gardasil and Cervarix, safety outcomes were compared between vaccine recipients and those who received an aluminium adjuvant containing 'placebo'.^{49,50} This practice is common in vaccine trials,⁶¹ despite much evidence showing that aluminium in vaccine relevant exposures can be toxic to humans,^{34,35,60} and therefore, its use as a 'placebo control' in vaccine trials can no longer be justified.⁶¹

Conclusions

We documented here the evidence indicating the potential of the HPV vaccine to trigger a life-disabling autoimmune-mediated condition such as POF. Given that persistently infected women with HPV seem not to develop cancer if they are regularly screened and that the long-term clinical benefits of HPV vaccination are still a matter of speculation, a more rigorous assessment of vaccine risks and benefits is recommended.^{49,50,62} Thus, physicians should remain within the rigorous rules of evidence-based medicine, to adequately assess the risks versus the benefits of HPV vaccination.^{63,64}

Disclosure

An informed consent has been received from the patients present their cases. Y Shoenfeld has served

as an expert witness in cases involving adverse vaccine reaction in the no-fault U.S. National Vaccine Injury Compensation Program. LT, SC and CP declare no conflict of interests. The authors thank the Dwoskin Family Foundation for support.

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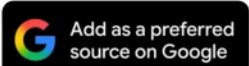
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MP News: Five Teenage Girls Hospitalised After HPV Vaccination In Gwalior

Five girls in Gwalior fell ill after receiving the HPV vaccine in Barkari Jigniya village. They reported vomiting, dizziness and fever and were admitted to Dabra Civil Hospital. Doctors said they are now stable. Families alleged they were not informed before vaccination. Health officials have ordered an inquiry into the incident during the state's cervical cancer vaccination drive.

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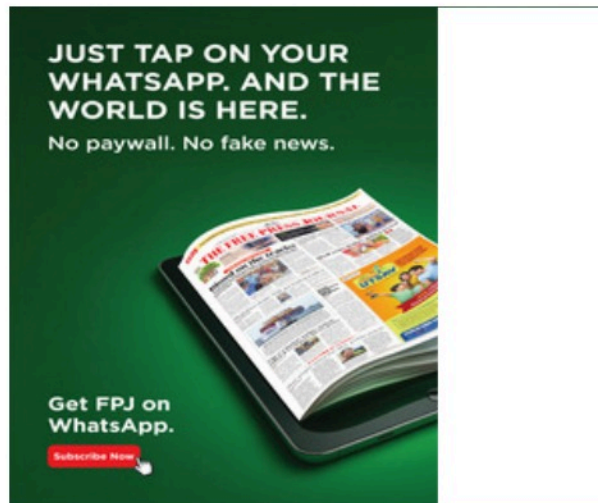
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MP News: Five Teenage Girls Hospitalised After HPV Vaccination In Gwalior | FP Photo

Gwalior (Madhya Pradesh): Five teenage girls fell ill after receiving the HPV vaccine in a village in Madhya Pradesh's Gwalior district, as reported on Wednesday. The incident was reported from Barkari Jigni village in the Pichhor area of Dabra.



According to family members, the girls were taken for vaccination by an *anganwadi* worker without clearly informing their parents.

The families alleged that the girls were told they would receive ₹50k and assistance for their marriage and were asked to sign a form before the vaccination.



After returning home, the girls informed their families about the vaccine. Soon after, they complained of vomiting, dizziness and fever, which worried their parents.

The families then took them to the Civil Hospital in Dabra, where they were admitted for treatment.



Girls in stable condition

The girls - identified as Anjali, Poonam, Rajni, Bharti and Rekha from Barkari Jigniye village - were given primary medical care at the hospital. Doctors later said that all five girls are now stable and out of danger.

Family members alleged that they were not informed in advance about the vaccination and that their consent was not taken.

They claimed that health workers may have administered the vaccine to meet their vaccination targets.

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Responding to the incident, Chief Medical and Health Officer (CMHO) Dr Sachin Srivastava said the girls had complained of vomiting, fever and dizziness, but their condition is now normal.

He said a team has been formed to investigate the matter and the report is expected by the evening.

Officials also clarified that the HPV vaccine has been administered earlier as well. Previously it was available only through private purchase, but the government is now providing it free of cost.

The vaccination drive is part of the state government's campaign to protect teenage girls aged 14 - 15 years from cervical cancer.

The government aims to vaccinate around 8 lakh girls across the state through government hospitals and *anganwadi* centres.

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📞 शेयर

सिटी रिपोर्टर | बखरी

बखरी प्रखंड के राटन पंचायत स्थित उत्कर्मित मध्य विद्यालय राटन में गुरुवार को एचपीवी टीकाकरण के दौरान तीन छात्राएं बेहोश हो गईं, जिससे स्कूल परिसर में अफरातफरी मच गई। बेहोश होने वाली छात्राओं में श्वेता कुमारी (12), साक्षी भारती (11) और राखी कुमारी (12) शामिल हैं। घटना से नाराज परिजनों ने आरोप लगाया कि छात्राओं के बेहोश होने के बावजूद टीकाकरण नहीं रोका गया और उन्हें समय पर सूचना भी नहीं दी गई। आक्रोशित लोगों ने कुछ देर के लिए बखरी-खगड़िया मुख्य मार्ग को जाम कर दिया। जानकारी के अनुसार स्वास्थ्य विभाग की टीम स्कूल में सर्वाइकल कैंसर से बचाव

उन्हें समय पर सूचना भी नहीं दी गई। आक्रोशित लोगों ने कुछ देर के लिए बखरी-खगड़िया मुख्य मार्ग को जाम कर दिया। जानकारी के अनुसार स्वास्थ्य विभाग की टीम स्कूल में सर्वाइकल कैंसर से बचाव के लिए छात्राओं को एचपीवी टीके का दूसरा डोज दे रही थी। इसी दौरान एक-एक कर तीन छात्राएं बेहोश हो गईं। घटना के बाद परिजन और शिक्षक तत्काल उन्हें प्राथमिक स्वास्थ्य केंद्र ले गए। सूचना पर पहुंचे इंस्पेक्टर सह थानाध्यक्ष शैलेन्द्र कुमार ने मौके पर पहुंचकर स्थिति को नियंत्रित किया। वहीं पीएचसी के डॉ. नवीन कुमार ने बताया कि यह गंभीर मामला नहीं था, सभी छात्राएं सुरक्षित हैं और होश में आने के बाद उन्हें एम्बुलेंस से घर भेज दिया गया।

क्या कहते हैं सीएस : सिविल सर्जन डॉ अशोक कुमार ने कहा कि टीका को लेकर बच्चियों में भ्रांति थी। टीका लेना नहीं चाह रहे थे। स्वास्थ्य विभाग की टीम ने जब कुछ बच्चियों को टीका दिया तो उसमें से कुछ बच्चियों ने सर चकराने की शिकायत की तो उन्हें पीएचसी बखरी लाया गया।

BY RPAD With Ack:**DEPARTMENT OF PUBLIC HEALTH AND PREVENTIVE MEDICINE**

From

Tmt.E.Jayanthi,
Public Information Officer and
Administrative Officer (VC),
Department of Public Health and
Preventive Medicine,
359, Annasalai, Chennai -600 006.

R.No.13803742/SBHI-II/S2/2026, Date: 05.05.2026

Sir,

Sub: Public Health – RTI Act'05 – Certain information
requested regarding Cervical Cancer deaths by

Ref:

With reference to your petition, pertaining to the details of Cervical Cancer related Deaths for the 2018 to 2024 registered under Civil Registration System is as below.

S. No	Questions	Reply																
1	Year-wise data on the number of deaths due to Cervical Cancer in the State for the last 10 years.	Year wise Cervical Cancer Deaths in Tamil Nadu <table><thead><tr><th>Year</th><th>No. of Deaths</th></tr></thead><tbody><tr><td>2018</td><td>155</td></tr><tr><td>2019</td><td>147</td></tr><tr><td>2020</td><td>133</td></tr><tr><td>2021</td><td>268</td></tr><tr><td>2022</td><td>206</td></tr><tr><td>2023</td><td>207</td></tr><tr><td>2024</td><td>230</td></tr></tbody></table> Source: Civil Registration System Note: Annual Report for 2025 is under process District wise data available only from 2018 onwards	Year	No. of Deaths	2018	155	2019	147	2020	133	2021	268	2022	206	2023	207	2024	230
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2	Year-wise data on the number of HPV cases in the State for the last 10 years.	The number of HPV cases not available																
3	District-wise breakdown of Cervical Cancer deaths for the last 10 years, if available.	District wise Cervical Cancer deaths from 2018 to 2024 is enclosed herewith.																
4	Copies of any reports, studies, or datasets	Copy of report is given for question no.3 studies, or datasets are not available.																

	maintained by the Department related to Cervical cancer mortality.	
5	Details of the sources and methodology used for compiling the above data.	Civil Registration System. Cause wise data which reported under Medical Certification of Cause of Death is consolidated for annual report.

BY RPAD With Act:

DEPARTMENT OF PUBLIC HEALTH AND PREVENTIVE MEDICINE

From

Tmt.E.Jayanthi,
Public Information Officer and Administrative Officer (VC),
Department of Public Health and Preventive Medicine,
359, Annasalai, Chennai -600 006.

R.No.13803742/SBHI-II/S2/2026, Date: 05.05.2026

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Government of Goa
Department of Obstetrics & Gynaecology
Goa Medical College & Hospital, Bambolim-Goa 403 202
Phone No.: - +91 (832) 2495269

No. GMC/OBG/2026/ 755

Date: - 08/05/2026

Sub:- Application under Right to Information Act, 2005.
Ref:-No. GMC/MS/RTI/2026-27/32 dated 29/04/2026.

Sir,

With reference to above information pertaining to point no. 1 and 3 in the Department of Obstetrics & Gynaecology, Goa Medical College is as follows:

Sr. No.	Year	Number of Gynaecology deaths due to cervical cancer	District
1.	2016	Nil	-
2.	2017	Nil	-
3.	2018	01	Sindhudurg (Maharashtra)
4.	2019	01	North Goa
5.	2020	04	North Goa (All)
6.	2021	Nil	-
7.	2022	01	North Goa
8.	2023	02	North Goa (1) South Goa (1)
9.	2024	Nil	-
10.	2025	01	South Goa

Information to point No. 4 is Yes, we have a Cancer Registry in Goa Medical College to document all cancers taking treatment here.

This is for your kind information.

Thanking You.

Associate Professor
 Dept. of Obst. & Gynae
 Goa Medical College
 Bambolim-Goa

K. S. G. G. G.
 Public Information Officer
 Department of Obstetrics & Gynaecology
 Goa Medical College,
 Bambolim-Goa.
DR. AJIT. A. NAGARSENKAR
 ASSOCIATE PROFESSOR.

Copy to :

1. The Medical Superintendent, Goa Medical College & Hospital, Bambolim Goa.
2. The Dy. Director (HIB)/Public Information Officer, Health Intelligence Bureau (HIB), Directorate of Health Services, Campal, Panaji, Goa.

**Government of Goa
Department of Obstetrics & Gynaecology
Goa Medical College & Hospital, Bambolim-Goa 403 202
Phone No.: +91 (832) 2495269**

No. GMC/OBG/2026/755

Date: 08/05/2026

Sub.: Application under Right to Information Act, 2005.Ref.: No. GMC/MS/RTI/2026-27/32 dated 29/04/2026.

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4.	2019	01	North Goa
5.	2020	04	North Goa (All)
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7.	2022	01	North Goa
8.	2023	02	North Goa (1); South Goa (1)
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10.	2025	01	South Goa

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This is for your kind information.

Thanking You.

Sd/-(illegible)
Public Information Officer
Department of Obstetrics & Gynaecology
Goa Medical College,
Bambolim-Goa.

Copy to:

1. The Medical Superintendent, Goa Medical College & Hospital, Bambolim Goa.
2. The Dy. Director (HIIB)/Public Information Officer, Health Intelligence Bureau (HIIB), Directorate of Health Services, Campal, Panaji, Goa.

**GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA
UNSTARRED QUESTION NO. 5605
TO BE ANSWERED ON 27th MARCH 2026**

VACCINE MANUFACTURERS AND USE OF DOMESTIC HPV VACCINES

5605. DR. BACHHAV SHOBHA DINESH:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) the details of the Human Papillomavirus (HPV) vaccines programme approved and the age cohorts targeted under the programme;
- (b) the names of vaccine manufacturers whose products are being procured or used, including details of any domestically produced HPV vaccines such as those developed with participation of Indian companies;
- (c) whether any international organisations, partners or foundations such as the Bill and Melinda Gates Foundation, Gavi or WHO have provided technical support, funding or collaboration in the planning, introduction or implementation of the HPV vaccination programmes, if so, the details thereof;
- (d) whether the Government is aware of any judicial inquiries, regulatory investigations, parliamentary probes or civil litigation conducted anywhere in the world concerning HPV vaccines or their manufacturers and if so, the details and the outcomes thereof; and
- (e) the current coverage achieved, programme targets and timelines for achieving nationwide vaccination goals against cervical cancer?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)**

(a) to (e) The Nationwide free HPV vaccination campaign was launched on 28th February 2026 for approximately 1.2 crore eligible beneficiary girls aged 14 years across all 36 States and Union Territories. The vaccine is administered free of cost at government health facilities, including Ayushman Arogya Mandirs-Primary Health Centres (PHCs), Community Health Centers (CHCs), Sub-District Hospitals (SDH)/District Hospitals (DHs) & Government Medical Colleges (GMCs) in presence of medical officer. Training of medical and paramedical staff across all 36 States/UTs in the country has been completed. HPV vaccination is voluntary and parental consent is mandatory before administration of vaccine. The Vaccine manufactured by Merck Sharp Dhome (MSD) has been secured as kind support from GAVI, the Vaccine Alliance. The 72nd Parliamentary Standing Committee covers various issues concerning HPV vaccine related matters. As on 24th March 2026, a total of 5,03,008 girls have been administered the HPV vaccine.

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
(UNDER ARTICLE 32 OF THE CONSTITUTION OF INDIA)
WRIT PETITION (CIVIL) NO. _____ OF 2026
(PUBLIC INTEREST LITIGATION)

IN THE MATTER OF:

UNIVERSAL HEALTH ORGANISATION VERSUS UNION OF INDIA	...PETITIONER ...RESPONDENT
--	--

APPLICATION SEEKING CONDONATION OF DELAY 47 DAYS IN
REFILING OF THE PRESENT PETITION

TO,

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

THE HUMBLE PETITION ON BEHALF
OF THE PETITIONER ABOVE NAMED

MOST RESPECTFULLY SHOWETH:

- 1.** That instant petition is being filed under Article 32 of the Constitution of India. The petitioner is seeking enforcement of fundamental rights guaranteed under articles 14, 19(1)(a), and 21 of the Constitution of India, seeking issuance of a writ of mandamus, or any other appropriate writ, order or direction, directing the Union of India to forthwith suspend the school-based component of the HPV vaccination programme pending the framing and establishment of a legally compliant informed-consent protocol, and for allied and further directions including constitution of an independent expert committee, establishment of a public AEFI surveillance dashboard,

notification of a vaccine injury compensation scheme, and framing of a national vaccine consent jurisprudence framework.

- 2.** That the Writ Petition was initially filed within time. However, upon scrutiny by the Registry of this Hon'ble Court, certain office objections/defects were notified, inter alia, requiring clarification regarding the cause of action, the nature of injury to the public and certain other procedural compliances.
- 3.** That the defects pointed out by the Registry were not merely formal in nature and required detailed examination of the pleadings, verification of the record, incorporation of additional pleadings and consequential modifications in various parts of the petition so as to ensure that the pleadings adequately addressed the objections raised by the Registry.
- 4.** That considerable time was consumed in obtaining the necessary instructions, examining the defects pointed out by the Registry, carrying out the requisite amendments and finalising the corrected pleadings in consultation with the Petitioner.
- 5.** That the delay in re-filing has thus occurred solely on account of the bona fide time taken in curing the defects pointed out by the Registry and is neither deliberate, intentional nor attributable to any negligence or lack of diligence on the part of the Petitioner.
- 6.** That no prejudice whatsoever shall be caused to the Respondents if the delay in re-filing is condoned, whereas grave prejudice would be caused to the Petitioner and the larger public interest involved if the accompanying Writ Petition

is rejected on a mere technical ground without being considered on merits.

- 7.** That the Petitioner has a strong prima facie case involving substantial questions relating to enforcement of fundamental rights under Articles 14 and 21 of the Constitution of India, affecting a large section of the public, and the balance of convenience lies in favour of condoning the delay in re-filing.
- 8.** That the present application is made bona fide and in the interest of justice.

PRAYER

It is therefore, most respectfully prayed, that this Hon'ble Court may graciously be pleased to:

- A.** Condone the delay of 47 days in refiling of the present Writ petition; and/or
- B.** Pass any other order/orders that this Hon'ble Court may deem fit and proper in the facts and circumstances of this case and in the interest of justice.

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

Drawn on: 18.08.2026

Filed on: 18.08.2026

Place: New Delhi

REDACTED

**IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
I.A. NO. _____ OF 2026**

**IN
WRIT PETITION (CIVIL) DY. NO. 37256 OF 2026
PUBLIC INTEREST LITIGATION**

IN THE MATTER OF:

UNIVERSAL HEALTH ORGANISATION.

... PETITIONERS

VERSUS

UNION OF INDIA.

..... RESPONDENTS

A F F I D A V I T

I, Shivam Raghuwanshi s/o Mukesh Singh Raghuwanshi aged about 29 years R/o First Floor, L-89, L Block, Lajpat Nagar 2, New Delhi- 110024, do hereby solemnly affirm and say as under: -

1. That, I am Drafting Advocate in the above noted case and as such I am fully conversant with the facts.
2. That, I have read and understood the contents of I.A. and I say that the facts stated herein are true and correct to my knowledge and belief.
3. That the Annexures filed to the accompanying application are true and correct copies of the originals.
4. That, the contents of this affidavit are true and correct to my knowledge and belief. No part of it is false and nothing material has been concealed there from.



IDENTIFIED

VERIFICATION

Shivam
DEPONENT

I, Shivam Raghuwanshi s/o Mukesh Singh Raghuwanshi aged about 29 years R/o First Floor, L-89, L Block, Lajpat Nagar 2, New Delhi- 110024. presently at New Delhi, do hereby state on oath that, the contents of para nos. 1 to 4 are true and correct to the best of my personal knowledge and belief.

Hence verified at New Delhi on

Shivam
DEPONENT

18 AUG 2026

ATTESTED
NOTARY PUBLIC DELHI
Govt. of India