

7th April, 2010
World Health Day

To,
Shri Ghulam Nabi Azad,
Union Minister for Health and Family Welfare,
Ministry of Health and Family Welfare,
Nirman Bhavan,
Maulana Azad Road,
New Delhi 110 011

Date: April 7th, 2010

Subject: Opposition against the unethical nature of the 'demonstration project' for the Human Papilloma Virus (HPV) vaccine being conducted in Andhra Pradesh and Gujarat.

Sir,

We the undersigned public health organizations, health networks, medical professionals, human rights groups and women's groups write to voice our intense opposition to the unethical nature of the ongoing HPV vaccination 'projects' being conducted in Andhra Pradesh and Gujarat by PATH International, in collaboration with ICMR and the State Governments. We also strongly stand in solidarity with the local efforts initiated by groups and Networks in Andhra Pradesh following the death of 4 young, tribal girls in Khammam district following the vaccination.

As was clearly detailed in a Memorandum, dated October 1st, 2009, signed by over 50 groups and individuals, the efficacy of the vaccines Gardasil and Cervarix is highly suspect and a number of very serious side effects, including deaths have been observed across the world, in vaccinated girls. As per the extensive documentation by a fact finding carried out by local groups in Khammam district in Andhra Pradesh (where 14000 girls in the age group of 10 – 14 years have been vaccinated with the three doses of HPV vaccine), the adverse reactions faced by over 120 girls include epileptic seizures, severe stomach ache head aches and mood swings. There have also been reports of early onset of menstruation following the vaccination, heavy bleeding and severe menstrual cramps. Moreover, the current, 'demonstration project' has no follow up mechanism in place for girls who suffer from adverse events following the vaccination. As a result many of the girls have had to seek treatment in the private sector and with local quacks.

The matter has further gained grave urgency with the deaths of four tribal girls in the area. The local authorities have refused to take cognizance of their probable association with the vaccine, two of the deaths have shockingly been written off as suicides, when the evidence clearly suggests otherwise! Along with sounding extremely suspicious this has also raised valid concerns of this being a massive cover up exercise.

Above all, the very nature of this project seems to be unethical and violates all norms of conducting trials on human subjects. In many Aashram Schools, a verbal consent to vaccinate girls living in the Aashram schools has been taken from the Hostel Warden/ teacher in-charge, while parents were not even informed about it. In cases of day scholars, where consent was obtained from the parents, the form given held the nomenclature of an **approval form "Angikaara Patram"** and only provided minimal

information with no provisions for addressing in detail the need for follow. In fact, when a lady warden of a hostel objected when she was told that the vaccine was being administered on girls in the hostel, she was informed that this vaccine is mandatory! This is a travesty of the entire concept of “informed consent.”

Consent and information, reserved for only a few, is a farce and was based on provision of wrong information. Many of the girls were told that the vaccine would prevent **uterine cancer** and would provide life-long protection. This information is factually incorrect and provides the recipient with a false sense of security against the “dreaded” disease. As per the claims by the pharmaceutical companies themselves, the vaccine only protects against infections caused by 2 types of HPV virus (of the 13 high risk strains of HPV) that are associated with a higher risk of cancer of the cervix. Moreover, once again as claimed by the companies themselves, the protection by the vaccines is understood to last for only 4.5 years with Gardasil and 7 years with Cervarix, while, the need for a booster has not yet been established. There are reports in developed countries that this number too is an over estimation and the protection in fact may not last for more than 3-5 years.

It is also shocking and worrying that these projects are being carried out under the NRHM banner, while the existing medical facilities in the region are extremely inadequate. While Pap smear facilities are not available in Government facilities in the area (a must for even those who have been vaccinated against HPV) the absence of a Gynaecologist in the entire tribal mandal of Bhadrachalam is absolutely appalling. It is highly irresponsible and negligent of the State and Central government that such large scale exploitation of poor and tribal populations is being carried out by subjecting them to a vaccine with a dubious track record, when even the basic public health facilities are not in place.

Although, the nomenclature suggests otherwise, the secrecy regarding the non-transparent selection criteria of the area, the girls and the aim of the project has raised undeniable fears that this is a Phase IV clinical trial being carried out under the guise of a ‘demonstration project’ Moreover, there is an inexcusable lack of clarity with regards to the role and accountability of international agencies such as PATH and Bill and Melinda Gates Foundation that appear to be funding this project. It is beyond doubt the worst case of human rights violation, where young healthy girls have to die for being part of a state-endorsed experiment, initiated by a profit making private company.

This constitutes shocking criminal negligence on the part of the authorities, who have provided permission and support to this programme within the public health system. We need immediate government intervention to prevent this. No NGO should be given such permission for clinical trials/ demonstration projects, regardless of which vaccine or drug is being administered. Financial support from the industry or from an international organization should not be the criteria to introduce any vaccine, whether in a pilot project or in the universal immunization programme.

Thus, standing in solidarity with groups, parents and the girls in Andhra Pradesh, we demand that:

1. the government should make sure that all these projects are immediately brought to a halt across the country, till concerns relating to safety, efficacy and cost effectiveness of the planned interventions are reevaluated.
2. the government should set up an inquiry:

- a. into the deaths of the tribal girls;
 - b. into the side effects of the vaccine on affected girls, so that responsibility can be fixed and action taken.
3. All agencies involved in the project need to be held accountable and culpable for any ethical, legal, medical violations that emerges in such an enquiry
4. the State Government should take immediate action, including providing compensation to the families who have lost their children and to the children suffering side-effects
5. all the sufferers should be provided proper medical treatment and follow up
6. the Government place in public domain::
 - All the documents pertaining to the agreement with vaccine manufacturers and all other bodies regarding the government's plan to introduce the HPV vaccine.
 - The list of projects planned, proposed, approved and completed, agencies involved, donors involved and proposed locations. and all the results of the pilot phase and clinical trials
7. the Government institute a national policy on this kind of medical 'experimentation', and a pro-people vaccine policy based on public health needs

Signed by

1. Jan Swasthya Abhiyan (JSA)
2. All India Democratic Women's Association (AIDWA)
3. All India Drug Action Network (AIDAN)
4. All India Peoples' Science Network (AIPSN)
5. Federation of Medical and Sales Representatives' Associations of India (FMRAI)
6. Sama- Resource Group for Women and Health, Delhi
7. Action India, Delhi
8. HAQ- Centre for Child Rights, Delhi
9. KRITI, Delhi
10. Jagori, Delhi
11. Breastfeeding Promotion Network of India, Delhi
12. Centre for Women's Development Studies (CWDS), Delhi
13. Centre for Legislative Research and Advocacy (CLRA), Delhi
14. Delhi Forum, Delhi
15. Diverse Women for Diversity, Delhi
16. RAHI Foundation, Delhi
17. SANGRAM, Maharashtra
18. Adivasi Aikya Vedika, Andhra Pradesh
19. Anthra, Hyderabad, Andhra Pradesh
20. Yakshi, Hyderabad, Andhra Pradesh
21. Asmita Collective, Secunderabad, Andhra Pradesh
22. Adarsha Women's Society, Khammam, Andhra Pradesh
23. Koyitur Kutuva, Khammam, Andhra Pradesh
24. Adivasi Seva Samiti, Khammam, Andhra Pradesh
25. ANKURAM, Hyderabad, Andhra Pradesh
26. Girijana Deepika, East Godavari, Andhra Pradesh
27. Tholakari Adivasi Mahila Vedika, East Godavari, Andhra Pradesh
28. Adiahsi Seva Sangham, West Godavari, Andhra Pradesh
29. Arunodaya Grameen Abhivridhi Sangham, Vijayanagarm, Andhra Pradesh
30. Adivasi Chaitanya Sangham, Adilabad, Andhra Pradesh

31. Chinnayya Adivasi Vikasa Sangham, Srikakulam, Andhra Pradesh
32. Manyam Girijana Seva Sangham, Vijayangaram, Andhra Pradesh
33. Adivasi Ahara Bhadrata Sangham, Visakhapatnam, Andhra Pradesh
34. Jeevam, Visakhapatnam, Andhra Pradesh
35. Savara mahila sangham, Srikakulam, Andhra Pradesh
36. Agricultural and Social Development society (ASDS), Khammam, Andhra Pradesh
37. Natwan Sangham (Tribal Women Federation), Khammam, Andhra Pradesh
38. Rukmini Rao, Gramya Resource Centre for Women, Hyderabad, Andhra Pradesh
39. Usha Seethalakshmi, Freelance Researcher & Consultant, Hyderabad, Andhra Pradesh
40. Kalpana.Kannabiran, Hyderabad, Andhra Pradesh
41. Vasanth Kannabiran, Hyderabad, Andhra Pradesh
42. Lalitha Kumari, Hyderabad, Andhra Pradesh
43. BHUMIKA Magazine, Andhra Pradesh
44. Anchita Ghatak, Parichiti- A Society for Empowerment of Women, West Bengal
45. Anu Gupta, Eklavya, Madhya Pradesh
46. Bimla Chandrasekar, EKTA, Tamil Nadu
47. Dr Veena Shatrugna, Hyderabad, Andhra Pradesh
48. Chinu Srinivasan, SAHAJ, Baroda, Gujarat
49. Dr Gopal Dabade, Drug Action Forum, Karnataka
50. Jaya Velankar, Women's Rights Activist, Delhi
51. Dr. Kaveri Rajaraman
52. K R Nayar, Jawaharlal Nehru University, Delhi
53. Manisha Gupte, MASUM, Pune, Maharashtra
54. Dr Mira Shiva, Initiative for Health Equity and Society (IHES), Delhi
55. Dr Mohan Rao, Jawaharlal Nehru University, Delhi
56. Neha Madhiwala, Centre for Studies in Ethics and Rights (CSER), Mumbai, Maharashtra
57. Prof Padmini Swaminathan, Madras Institute of Development Studies, Chennai, Tamil Nadu
58. Pallavi Sobti-Rajpal, Utthan, Gujarat
59. Rajashri Dasgupta, Kolkata, West Bengal
60. Renu Khanna, Sahaj, Baroda, Gujarat
61. Dr Vandana Prasad, Delhi
62. Ranjan De, Filmmaker, Delhi
63. Dr. Ajay Kumar Khare, Madhya Pradesh Vigyan Sabha/JSA, Bhopal, Madhya Pradesh
64. Bishakha Dutta, Filmmaker, Mumbai, Maharashtra
65. Dr. Y. Madhavi, Scientist, Council of Scientific and Industrial Research (CSIR), Delhi
66. Saheli, Delhi
67. Salai Selvam, Tamil Nadu
68. CREA, Delhi

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