



Update: HPV vaccines and India's Supreme Court

By Norma Erickson

January 2013, the government of India was ordered by their Supreme Court to file an answer to allegations put forth in a petition filed on behalf of Gramya Resource Centre for Women from Andhra Pradesh. This petition challenged the licensing of Gardasil and Cervarix for use in the private sector as well as attempts to introduce HPV vaccines for use in the public sector. The petition implicated the Drugs Controller for having licensed the vaccines without adequate research on safety and efficacy; the Health Ministry for not carrying out an enquiry into licensing of these vaccines as ordered by the Parliamentary Standing Committee on Health and Family Welfare in April 2010 and not taking any action on the report of the internal enquiry committee despite all alleged irregularities associated with the PATH project being confirmed.

October 2014, India's Supreme Court Justices issued instructions for all petitioners and respondents in the ongoing case against to either serve the opposition with copies of affidavits filed and/or file any affidavits and rejoinder affidavits pertinent to the case within the next four weeks. The matter was then set for what was supposed to be a final hearing on January 13, 2015.

When the 'final' hearing date arrived, several respondents had still not complied with these instructions. At least one of them went so far as to hold their two-and-a-half-foot tall affidavit for presentation to the Court on January 13th. The Honorable Supreme Court Justices did not seem to be amused.

After hearing the evidence presented on January 13th, Justices Dipak Misra and Prafulla C. Pant issued an order reminding all participants of concerns raised in a prior hearing on 12 August 2014. Those concerns are as follows:

- Did the Drugs Controller of India and the ICMR (Indian Council on Medical Research) follow proper protocol for the introduction of HPV vaccines prior to the use of said vaccines in the demonstration projects in India?
- What actions were taken after the submission of the Parliamentary Committee's 72nd report on August 30, 2014?
- What were the reasons for choosing certain places in Gujarat and Andhra Pradesh for the HPV vaccine demonstration projects?
- What actually caused the deaths and other ailments experienced after HPV vaccine administration in said demonstration projects?
- What steps were taken to monitor the safety of HPV vaccines by the Union of India and the State Governments who have an equal role in guarding the health of the nation?
- Was proper consent given by the parents/guardians of all girls who were administered HPV vaccines, as the Justices have been apprised?
- What protocol is required to be observed/followed when this type of vaccination program is conducted?

The Honorable Supreme Court Justices deemed it appropriate to grant permission for the State of Gujarat, State of Andhra Pradesh, and State of Telangana to be added as parties to the current case.

The Justices also agreed to M/S Glaxosmithkline Asia Pvt. Ltd. and MSD Pharmaceuticals Pvt. Ltd., the companies responsible for manufacturing HPV vaccines, being served as respondents in the proceedings.

Justices Misra and Pant granted permission for the attorneys representing the petitioners to serve papers on the concerned Ethics Committees of all three States involved in the HPV demonstration projects.

In view of the fact that the above mentioned concerns had still not been adequately addressed, some respondents had failed to appear for prior hearings, and others had ignored requests for information or failed to submit affidavits in a timely manner the Justices included the following statements in the current order:

- This Court hopes and trust(s) that on the next date of hearing, the Standing Counsel of all the States shall remain present and argue the matter.
- The Union of India shall direct its competent authority to produce the file by which the Drugs Controller General of India approved HPV vaccines for use along with any other relevant documents to the Court and the Counsellors for the Petitioners in this case.
- Learned Counsel for the Union of India shall apprise this Court what steps have been taken to comply with the recommendations put forth in the Parliamentary Committee's Report on HPV vaccine demonstration projects in India.
- Counsel for the State shall file their counter-affidavits within a period of four weeks.
- The Union of India shall file their counter-affidavit (case #921/2013) within four weeks. Rejoinder affidavit, if any, within two weeks therefrom.
- By the same time, rejoinder affidavit to the counter-affidavit filed by PATH International to be filed.
- The Advocate for ICMR shall produce the file dealing with HPV vaccines by the next date.
- Regarding the 'concept of consent' and the resultant deaths: it has been submitted that though innovative explanations have been given stating that some girls in the States of Gujarat and Telangana expired due to snake bite and fever, in actuality, it is due to the administration of vaccinations.
- It was noted that though HPV vaccines were administered for the purpose of experimentation, there is no data with regard to the adverse effects faced by the young girls.
- Counsel for the Union of India, the State of Gujarat, and the State of Telangana shall state by way of affidavit what the procedure and protocols are to be followed while obtaining informed consent. The stand taken by the Union of India and the States shall be clear and in consonance with law, for the affidavit is not expected to be filed in contravention of that has been envisaged in law.
- The present public interest litigation has to be perceived from the point of view of rectification and caution for the future.
- The 'caution' would convey what steps have to be taken in the future so that this kind of grievances do not arise.

In conclusion, the Supreme Court order states:

Learned counsel appearing for the Union of India and the States of Gujarat and Telangana shall file their respective affidavits keeping in view the directions given herein-above. To elucidate, the affidavit filed by the Union of India shall contain explicitly (i) what steps they intend to take on the basis of the report given by the Parliamentary Standing Committee, (ii) what is the procedure to be followed for the purposes of consent and what steps are required to be taken to find out the sufferings, if any, by the persons who were vaccinated, and (iii) the liability of compensation, if any, to be paid and whose liability it would be.

Justices set the next hearing date for April 21, 2015.

References:

[India: HPV vaccines Gardasil and Cervarix make it to the Supreme Court](#)

[India: Supreme Court HPV Vaccine Controversy Continues](#)

Original Supreme Court Documentation, go to this link -

http://courtnic.nic.in/supremecourt/casestatus_new/caseno_new_alt.asp then select "Writ Petition (civil)" as the case type; 558 as the case number; and 2012 as the year. Then click submit. Follow links from there to access original documents.