



India: Supreme Court HPV vaccine controversy continues

By Norma Erickson

New Delhi: A petition currently before the Supreme Court alleges that the Drugs Controller of India issued licenses for Gardasil and Cervarix without adequate research on safety. The Parliamentary Standing Committee on Health and Family Welfare had asked for a premier investigating agency to enquire into it way back in 2010 and no action has been taken on it.

Petition number 558/2012, filed by Kalpana Mehta, Nalini Bhanot and V. Rukmini Rao, seeks to resolve this and several other issues by asking the Supreme Court of India to rescind the licenses for marketing and administration of HPV vaccines, make provisions to identify and treat any girls left with chronic health problems and/or autoimmune disorders after their participation in HPV vaccine trials, and strengthen the regulation of the Program for Appropriate Technology in Health (PATH), and other foreign NGOs so that they do not flout the laws of the country with such impunity.

12 August 2014, Supreme Court Judges Dipak Misra and V. Gopala Gowda allowed Gujarat, Andhra Pradesh and Telangana to be named as respondents in the case because some villages in these states were chosen for administering HPV vaccines as an experiment and reports estimate 1200 girls were left suffering from adverse reactions to Gardasil and Cervarix.

The judges directed government agencies to produce the file(s) relating to licensing of Gardasil and Cervarix, the report(s) of the Parliamentary Standing Committee on Health and Family Welfare which dealt with issues relating to HPV vaccines, and any files from the Indian Council of Medical Research dealing with HPV vaccines.

The judges want to examine whether proper protocol and procedures were followed prior to the introduction of HPV vaccines.

They also wish to see what action was taken after the parliamentary committee submitted its report and what the reasons were for choosing the specific locations in Gujarat, Andhra Pradesh and Telangana for introducing Gardasil and Cervarix on an experimental basis.

The Court seeks to know what actually caused the deaths of some participants in the demonstration projects/clinical trials and whether proper consent was obtained from the girls and/or their families prior to their participation in the experiment.

MSD Pharmaceuticals Pvt. Ltd. (subsidiary of Merck) and GlaxoSmithKline Ltd. were served notices.

Judges Misra and Gowda set the case for final hearing on October 28, 2014.

HPV Vaccine History in India:

- **2006:** As part of a four-nation initiative against cervical cancer, PATH decided to launch 'demonstration projects' for the HPV vaccination in Peru, Uganda, Vietnam and India, using a grant of \$27.8 million from the Bill and Melinda Gates Foundation. This decision was made by PATH with funding granted two years before HPV vaccines were approved for use in India.
- **2008:** Gardasil and Cervarix were approved for marketing in India, allegedly without following the standard government protocol for vaccine approval in the country.

- **July and August 2009:** The Andhra Pradesh and Gujarat governments, in association with the Indian Council of Medical Research (ICMR) and the Program for Appropriate Technology in Health (PATH), launched what they described as a 'demonstration project' for vaccination against cervical cancer.
- **During these demonstration projects:** Gardasil, manufactured by Merck Sharpe & Dohme (India) Pharmaceuticals Private Limited (MSD), was administered to 13,791 girls in Khammam district in Andhra Pradesh. Cervarix, manufactured by GlaxoSmithKline Biologicals (GSK) of Rixensart, Belgium, was administered to 9,637 girls in Vadodara district in Gujarat. An estimated 5% of those who participated were left with chronic health problems and/or autoimmune disorders.
- **Concurrently:** Women's groups, health networks, human rights groups and child rights groups in India voiced concerns about the safety, efficacy and public health value of both vaccines. Many joint memoranda enumerating these concerns were submitted to the Union Minister for Health and Family Welfare demanding an immediate halt to the demonstration projects.
- **2010:** The Ministry of Health and Family Welfare (MOHFW) conceded that the HPV vaccination project was in fact a "post-licensure operational research study." The Indian Council of Medical Research (ICMR) admitted that their ethical guidelines had been flouted in the course of this trial. The trial was temporarily suspended by the government, and a committee formed to conduct an inquiry.
- **The investigation revealed the so-called 'demonstration project' to be a calculated, multi-level violation of all existing protocol on clinical trials, as well as a glaring breach of children's rights.**
- **2012:** Ultimately, the suspension and subsequent investigations allowed advocates in India to take their case to the Supreme Court. The Writ of Petition (#558/2012) was filed asking that the licenses for sale and marketing of both HPV vaccines be revoked because Gardasil and Cervarix are unsafe and the permits were granted without adequate research.
- **2013:** The petition for the case was formally [admitted by the judges on January 7, 2013](#). By [September 2013](#), the court had issued notices to all participants involved while **the Indian Parliament issued a scathing comment condemning all organizations involved in the so-called 'demonstration projects' calling them a case of child abuse expressly carried out to create a market for the two companies – Merck and GlaxoSmithKline.**
- The Supreme Court issued notices to the Government of India and the Drugs Controller asking for their responses to the allegations in January 2013. By September, neither had bothered to file a reply.
- **2014:** As a result of continued investigations regarding clinical trials involving HPV vaccines in India, additional allegations of unethical conduct were lodged against Merck. The allegations pertain to Merck's recent trials of the new V503 HPV vaccine, a proposed nine valent HPV vaccine. The additional allegations of multiple ethics violations were added to the currently ongoing Supreme Court Case via an [affidavit added as an addendum](#) to the brief previously prepared regarding the 'demonstration projects'
- According to a [press release written by Kalpana Mehta, Nalini Bhanot and V. Rukmini Rao](#), there is documentary evidence that though PATH is a non-governmental organization (NGO), in this case it entered into a business agreement with Merck so Merck would have a ready market for HPV vaccines in resource poor countries. In fact PATH got funding for this purpose from the Bill & Melinda Gates Foundation in the same month that Gardasil was licensed in the USA, June 2006.
- **12 August 2014:** Supreme Court Judges Dipak Misra and V. Gopala Gowda sent notices to several respondents requesting further information as outlined above and set the petition for final hearing on October 28, 2014.

Will India be the first country in the world to revoke the marketing licenses for Gardasil and Cervarix?

Will the Supreme Court of India move to protect the health and welfare of their young citizens, or the interests of the HPV vaccine manufacturers?

Will PATH and similar agencies be banned from operating in India?

Will the victims of adverse reactions to HPV vaccines be located, treated and compensated for being forced to participate in a trial that violated their human rights?

Perhaps these questions will be answered on October 28th.

Sources:

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