

# EUROPEAN CENTER FOR CONSTITUTIONAL AND HUMAN RIGHTS



## NEWS RELEASE

### ECCHR pushes for accountability in clinical trials in India

—  
EUROPEAN CENTER FOR  
CONSTITUTIONAL AND  
HUMAN RIGHTS e.V.  
—

ZOSSENER STR. 55-58  
AUFGANG D  
10961 BERLIN, GERMANY  
—

PHONE +49.(030).40 04 85 90  
FAX +49.(030).40 04 85 92  
MAIL INFO@ECCHR.EU  
WEB WWW.ECCHR.EU

*Berlin, 11 February 2014:* Today, ECCHR submitted an Affidavit to the Indian Supreme Court concerning a petition on human rights violations in a clinical trial. 24,000 girls in Gujarat and Andhra Pradesh were vaccinated against the human papilloma virus (HPV), which causes most cervical cancer cases. After news reports about irregularities, a parliamentary inquiry committee concluded that the trial was conducted without proper informed consent or monitoring. It especially questioned the fact that school head masters signed consent forms on behalf of the children. Women's health activists now seek accountability and brought a public interest petition to the Court.

According to ECCHR, *“a proper investigation should include the organizations conducting the trial as well as the pharmaceutical companies that benefit from the scientific results.”* The project was designed and executed by the US-based NGO PATH (Program for Appropriate Technology in Health) and funding was received from the Bill & Melinda Gates Foundation. The tested vaccines were provided by GlaxoSmithKline (United Kingdom) and Merck (United States).

This case gives the Indian Supreme Court the opportunity to address the obligations of trial sponsors and manufacturers. Therefore, ECCHR's brief offers a review of relevant standards for trial sponsors and manufactures that have been developed in international treaties, legislation, and jurisprudence. This comparative analysis can inform the standard of care that can be expected from “reasonable corporations.” The Affidavit is supported by legal experts from the Business and Human Rights Project at Essex University.

The New Delhi-based Human Rights Law Network (HRLN) represents the petitioners. *Kerry McBroom*, the Director of HRLN's Reproductive Rights Initiative notes that *“the Affidavit from ECCHR is very valuable as it highlights the double standards these organizations apply to their work in India.”*

#### **Special care for vulnerable trial subjects**

In this case, special care was required by three separate human rights conventions. The trial subjects were young girls between 10-14 years old, and several of them were from tribal backgrounds. They were thus particularly vulnerable and entitled to special protection under the Convention on the Rights of the Child, the Convention on the Elimination of All Forms of Racial Discrimination and the Convention to Eliminate All Forms of Discrimination Against Women.



**More information on our website:**

<http://www.ecchr.de/index.php/clinical-trials.html>

**For questions and requests for the Affidavit, contact:**

ECCHR, Carolijn Terwindt, info@ecchr.eu, +49 (0)30 4004 8590

**Other sources:**

[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 (upper house of the parliament in India) on 30<sup>th</sup> of August, 2013