

Supreme Court issues notices on unethical drug trials

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1,727 persons have died during drug trials between 2007 and 2010, says public interest petition

The Supreme Court of India has issued notices to the Centre and the Madhya Pradesh government in connection with clinical drug trials being conducted across India. This follows a public interest petition filed by an Indore based non-profit, seeking the court's intervention to put a stop to unethical clinical trials. Reports of unethical trials conducted on children and mentally challenged patients in Madhya Pradesh surfaced recently in various media reports. The petition filed by Swasthya Adhikar Manch was admitted by the court on February 6.

The bench comprising R M Lodha and H L Gokhale issued notices to the Ministry of Health and Family Welfare, the Indian Council of Medical Research (ICMR), the Drugs Controller General of India (DCGI), the Medical Council of India (MCI) and the State of Madhya Pradesh. They have been asked to review and file replies on the existing rules governing drug trials and the desired amendments within six weeks.

Advocate for petitioner Sanjay Parekh argued in court that the country is increasingly witnessing many illegal and unethical drug trials. According to the petitioner, a total of 1,727 deaths occurred between 2007 and 2010. "We have accessed information through RTI. The replies given by the (Union) health minister Ghulam Nabi Azad in Rajya Sabha show that 3,138 trials were conducted between 2006 and 2009. Around 806 trials were conducted from January 2010 to December 2010 and 928 in the year 2011," says Amulya Nidhi, member of Swasthya Adhikar Manch.

"We have also asked the court to examine the present legal set up and guidelines concerning clinical trials on adults, children and even mentally ill patients and the compensation given to them in the country," he adds. The petitioner has also sought that regulations be imposed on the contract research organisations (CROs) that recruits volunteers for the drug trials and are operating in an unregulated and uncontrolled fashion.

The petition also highlights irregularities in drug trials like the principal investigator of a clinical trial also being a member of ethical committee in violation of the ethics guidelines, the inactive role played by ethics committees and no compensation being paid to patients for adverse effects. Down To Earth in its [cover article](#) [1] had extensively reported unethical drug trials taking place in India. The article has been used as a reference in the petition.

Source URL: <http://www.downtoearth.org.in/content/supreme-court-issues-notices-unethical-drug-trials>

NAPM Statement on the Notices issued by Supreme Court in case of Unethical and Illegal Drug Trials

February 9, 2012

New Delhi, 6th February : Supreme Court today admitted a PIL filed by Swasthya Adhikar Manch about illegal and unethical clinical trials conducted on adults, children and even mentally ill patients in the country. A notice was issued to respondents, Ministry of Health and Family Welfare, Indian Council of Medical Research (ICMR), The Drug Controller General of India (DCGI), Medical Council of India (MCI) and State of Madhya Pradesh by the bench of Justice R. M. Lodha and Justice H. L. Gokhale. The advocate for the petitioner is Pukhram Ramesh Kumar and the case was argued by Advocate Sanjay Parekh today.

Today Multi-National drug companies are very powerful and are making profits. After the Patent amendment came, pursuant to WTO, amendments were also made in the Drug and Cosmetic Rules in 1995 in our Country permitting multi-centric trials, including of Phase-I trial, which is the first trial of the new drug on human beings. For the purpose of clinical trials, these drug companies hire Contract Research Organizations (CRO), (more than 100 CROs exists in our country), who claim that they will be able to get the clinical trial done at a low cost and quickly. The trials are conducted in the countries which are vulnerable because of poverty and other reasons. In conducting these trials, the doctors, with the sole aim of making money grossly compromise with ethical medical practices which lead to trial subject to face either death or serious side effects. The PIL has also taken the reference of EOW (Economic Offence Wing) report where many irregularities has been found during investigation of drug trials conducted in the M.G.M. Medical College Indore. It has been highlighted in the PIL that the irregularities like, principal investigator being a member of ethical committee, violation of the ethical guidelines by principal investigator, inactive role played by ethical committees, compensation to patients for adverse effects not being paid etc. is a serious violation of laws and medical profession ethics and also a violation Article 32 of the constitution..

Swasthya Adhikar Manch hence through petition has requested the court for Direct Investigation into the cases of adverse effects of drug trials including deaths and submission of the report to the Honorable Court, examine the present legal set up and guidelines concerning the clinical trials, direct the Govt. of Madhya Pradesh to act on report of EOW, grant of compensation and other reliefs including medical treatment to trial patients adversely affected.

The petitioner seeks the regulations been imposed on the said Contract Research Organizations (C.R.O.) companies that are operating in unregulated and uncontrolled fashion. Specially so since it is not mandatory that these companies be registered. The petition asserts the CROs being operated in absence of any controlled even from Independent Ethics committee.

The petitioners asked for an extensive investigation into the matter of drug trials which has accounted for a total of 1727 deaths from year 2007 to 2010 as accepted in Rajya Sabha by Honorable Health Minister Gulam Nabi Azad. The petition calls the attention of the judiciary to innumerable drug trials conducted all over the nation which roughly amounts to about 4066 clinical drug trial experiments. 3138 of the trials were conducted in the year 2006-2009, 806 trials conducted from Jan 2010 to December 2010 and 928 drug trials are conducted in the year

Feb 2011 (The data has been taken from the statement made by Mr. Gulam Nabi Azad in Rajya Sabha and from RTI replies received by the petitioner). In Andhra Pradesh about 25,000 women have been subjected to such drug trials.

The Advocate for the petitioner Mr. Sanjay Parekh pleaded the matter of unethical drug trial to be of grave concern to entire nation with prevailing ambiguity of the rules and regulations governing such trials, consequently giving enough space for these companies to engage into their unethical and illegal intentions. The petitioners pleaded the Supreme Court to issue orders to the respective departments for reviewing the existing rules of governing such drug trials and bringing in the desired amendments. It was also pleaded that the systematic investigation be ordered in the all incidences of drug trial suffering from such irregularities. Taking cognizance of the matter, the apex court has issued notices to respective departments and organizations to submit their response.

Amulya Nidhi, Chinmay Mishra, Belu George