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Give info on clinical trial deaths, says SC

PIL Says MNCs Using Indians As Guinea Pigs

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New Delhi: The Supreme Court on Monday asked the Centre and the states to furnish details of clinical trial deaths, compensation paid to families of victims and the legal regime in force in the country to regulate such trials on humans.

This direction came from a bench of Justices R M Lodha and A R Dave after an Indore-based NGO 'Swasthya Adhikar Manch' alleged that foreign multi-national companies were using Indians as guinea pigs for clinical trial of their newly patented drugs.

The NGO quoted a parliamentary committee report which said 2,374 persons died during such trials between 2007 and June 2012 and that families of only 37 victims had been paid meagre compensation in 2010-11.

Petitioner's counsel Sanjay Parikh said after the regulatory mechanism was relaxed through the 2005 amendment to the Drugs and Cosmetics Rules, 1945, there was a huge rush of foreign pharmaceutical companies to conduct clinical trials in India to exploit their patents and earn profits in shortest possible time.

The NGO said the foreign pharmaceutical companies holding patents of New Chemical Entities (NCEs) use developing countries as soft targets, given the low cost and absence of mechanism to fasten liability on them for mishaps, for finding out the efficacy and side-effects through clinical trials.

Asking the Centre to compile data received from the states and submit it to the court within eight weeks, the bench of Justices Lodha and Dave said, "All these malpractices in clinical trials should be stopped forthwith... Why the Drugs Controller General of India (DCGI) should not take immediate steps to stop such malpractices in government and private hospitals."

Additional solicitor general Siddharth Luthra's assurance that a legal regime was in place to prohibit unethical clinical trials and regulate the valid trials did not address the court's concern over problem areas.

The bench said, "We are concerned about the lives of human beings who become subject to clinical trials unknowingly, helplessly due to the malpractices of doctors and drug manufacturers."

Luthra said there were independent investigators in ethics committee, which was mandated to monitor such trials. The petitioners doubted the investigators' autonomy. The bench said, "Problem is of non-implementation and non-performance of rules. System is in place but there is no adherence to it. If you had adhered to rules in letter and sprit, such litigation will not come to us."