

# Illegal clinical trials creating “havoc”: Supreme Court



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The Supreme Court on Thursday said uncontrolled clinical trial of drugs on humans by multinational companies was creating “havoc” in the country and slammed the Centre for failing to stop the “rackets” which has caused deaths.

Observing that the Government has slipped into “deep slumber” in addressing this “menace”, the court ordered that all drug trials will be done under the supervision of the Union Health Secretary.

The apex court said the government has failed to put in place proper mechanisms to stop “rackets” of multinational companies, which are conducting illegal clinical trials, and asked it handle the problem on an urgent basis.

“You have to protect health of citizens of the country. It is your obligation. Deaths must be arrested and illegal trials must be stayed,” the bench comprising R.M. Lodha and A.R. Dave said.

“You have slipped into deep slumber. It pains us that children of the country are being used as guinea pigs by the companies. You do not have even respect of the Parliamentary Committee which has said that the companies are running racket and you are showing just draft rules,” the

bench said when the Additional Solicitor General Siddhath Luthra contended that Centre is considering to frame rules.

It pilloried the government after it was contended that various committees have been set up to look into the issue and that it will come back to the court after getting suggestions from them.

“You can get back to the court but what about those people who are losing their lives in such clinical trials. People who lost their lives can’t get their lives back,” the bench observed.

“It is very easy to form a committee or a commission. It is done just to divert people’s attention on the issue. It is the best way to divert attention on important issues,” the bench said.

“Give us performance of even one committee during the last 21 months. We gave you many opportunities,” it said adding, “Your officials are not working in a manner they should work. If there is foolproof mechanism then we would not have interfered in the matter”.

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## End illegal drug trials: Supreme court

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By [Rakesh Bhatnagar](#) | Place: New Delhi | Agency: DNA

The Supreme Court on Thursday castigated the Union government for being negligent in curbing illegal clinical trials despite the deaths of at least 2,374 persons who had undergone the dubious testing for unregistered drugs between 2007 and 2012.

During the resumed hearing of a PIL filed by an NGO Swasthya Adhikar Manch, the court sought an end to illegal clinical trials of untested drugs by multinational companies. The NGO has alleged that massive clinical drug trials, estimated at Rs8,000 crore annually by various pharmaceutical firms, use Indian citizens as guinea pigs.

“The drug trials are creating havoc in the country,” the court said, adding that all clinical trials will be done under the supervision of the Union health secretary. “You have to protect the health of the citizens of the country. It is your obligation. Deaths must be arrested and illegal trials must be stopped,” the bench said and directed the Centre to “handle the menace” in an effective manner.

The judges slammed the government for slipping into “deep slumber” on the issue and for being indifferent in evolving an effective mechanism to stop ‘rackets’ of some multinational drug companies which conduct illegal clinical trials.

In 2004, doctors at the Bhopal Memorial Hospital and Research Centre, an exclusive institute for the victims of the 1984 gas leak disaster, recruited unsuspecting survivors for clinical trials, without their knowledge or consent.

It is said that 14 participants died during the course of the trials. In an Indore-based hospital, 32 people died in clinical trials between 2005 and 2010.

A parliamentary panel says that the Central Drug Standard Control Organisation (CDSCO) is in collusion with drug companies and doctors, and approving at least one drug every month, without conducting clinical trials or seeking expert medical opinion.

A report quoting CDSCO says an estimated 150,000 people are enrolled for clinical trials in India. It has been reported that the number of 'subjects' in clinical trials between 2009 and 2012 were 352,475. The government says serious adverse events resulting in deaths "may occur during clinical trials due to various reasons. These deaths could be due to life-threatening diseases like cancer, cardio-vascular conditions like congestive heart failure/stroke and other serious diseases".

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## SC slams lax govt for illegal clinical trials

Dhananjay Mahapatra, TNN Jul 17, 2012, 02.36AM IST

NEW DELHI: Mounting deaths due to alleged unauthorized clinical trials of drugs on humans took centre stage in the Supreme Court which pulled up the Centre and the [Madhya Pradesh](#) government for showing lack of sensitivity and urgency in collecting data and responding to a public interest litigation.

Though it refused to order a roving inquiry into the alleged rampant illegal clinical trials of drugs, a bench of Justices R M Lodha and A R Dave expressed concern over the lethargic manner in which the Union government gathered data and the MP government took action against erring doctors.

"Every day, one death is allegedly taking place. If it is true, it is most unfortunate. People are dying and the state government is saying it is taking action when meagre penalties are being imposed on erring doctors. There cannot be laxity in this issue. Though we have issued notice (on the PIL) in February, the Centre has not responded. We do not know what information it is gathering. But the matter appears serious," the bench said while asking the Centre and the state governments to respond in six weeks.

Appearing for petitioner NGO 'Swasthya Adhikar Manch', advocate Sanjay Parikh said the Economic Offences Wing had identified doctors who carried out clinical trials of drugs on humans, mostly [women](#), children and mentally retarded, but the Madhya Pradesh government had let go the accused by imposing a fine of just Rs 500.

Advocate Vibha Makhija attempted to salvage some ground for the state by promising action and pleading that the state was not taking the petition as an adversarial litigation, but the bench was far from impressed. It asked, "Why the laxity and lethargy in such a matter when every human life is precious."

The court posed the same question to the Union government's counsel, senior advocate T S Doabia, who promised to collate data and file it within six weeks.

Parikh sought a detailed probe into clinical trials of drugs being done illegally across the country and quoted a parliamentary standing committee's March 2012 report to inform the court that 1,514 subjects had died between 2008 and 2010 in clinical trials, which made it more than a death per day.

"The committee also pointed out that 33 new drugs were approved for consumption by patients without conducting any clinical trial," the counsel said.

When the petitioner requested for guidelines laid down by the court that could be the precursor of a legislation, the bench said though the court was concerned by the magnitude of the problem, it was for Parliament to intervene with legislative action.

The court also accepted senior advocate U U Lalit's plea for making Indian Society for Clinical Research a party in the litigation even as the petitioner accepted that a total ban on clinical trials would not be in the interest of the country.

However, Parikh said, "The court must find out what is happening in the name of clinical trials. To stop unauthorized clinical trials, to withdraw drugs introduced illegally and take action against doctors, authorities and sponsors are hand-in-glove in such trials, an investigation by the CBI is necessary."

### **Times View**

Anywhere in the world, clinical trials are a carefully regulated area because of the obvious risks involved. In India, with its high levels of illiteracy, the risks become even greater since it is much more difficult for many of the potential 'volunteers' in trials to make an informed choice. Further, a public healthcare system that is woefully inadequate leaves most people who are not well-off desperately seeking any sort of treatment they can get. This again is a situation that heightens the possibility of unscrupulous exploitation of those in desperate needs. If anything, therefore, India needs to be even more cautious than most in regulating clinical trials. Our governments should be aware of this and act accordingly.

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# India's Supreme Court wants tighter clinical trial regulation

*Justice Lodha says illegal studies of investigational medicines causing “havoc to human life”*



**The Indian government needs to do more to stop illegal, unregulated clinical trials, according to Supreme Court judge Justice RM Lodha.**

Lodha made the comments during a hearing on a petition submitted by doctors and the non-profit organisation Swasthya Adhikar Manch, which claimed that citizens in the Madhya Pradesh region had been involved in drug trials without their permission.

As reported by the AFP, Lodha said: "Uncontrolled clinical trials are causing havoc to human life.

"There are so many legal and ethical issues involved with clinical trials and the government has not done anything so far."

The matter is increasingly prominent, with [India](#) emerging as one of the main players in hosting clinical trials due to its relative low cost and recent improvements in access to healthcare.

However, this growth has not come with improved regulation or penalties for those who abuse the system, and Lodha, along with fellow judge Justice AR Dave, demanded the government do more.

As an interim measure they called for India's Health Minister Ghulam Nabi Azad to monitor all new applications from pharmaceutical companies wishing to launch trials in India.

Lodha, who has been a Supreme Court judge since 2008, has previously voiced his concerns about clinical trial practices in India, and in February 2012 he requested public-interest litigation in order to create a proper regulatory framework for checking illegal and unethical trials.

The regulatory system for medicines in India has also come under fire from the government itself in the past year, with the Ministry of Health calling for a revamp of the [Central Drugs Standard Control Organization](#) – the agency responsible for regulating the pharmaceutical sector.

This followed an investigation from the Ministry of Health that implicated several companies, including Cipla, Sun Pharma, Novartis and Bayer, claiming that several studies had not met clinical trial requirements.

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## Supreme Court issues notices on unethical drug trials

Author(s): [Ankur Paliwal](#) (Down To Earth)

Date: Feb 7, 2012

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](#) had extensively reported unethical drug trials taking place in India. The article has been used as a reference in the petition.