Illegal clinical trials creating “havoc”: Supreme Court

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The Hindu A view of the Supreme Court of India. File photo

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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 uses 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".

Comments:

Clinical Research is always a soft target. In India the lack of regulations in the early stage of clinical trials should not lead to terming each trial as "dubious". World has to see innovations in research, but with it comes an obvious window of risk (and there is no denying it).
Rightly,people who misuse the opportunity during the process of bringing a new medicine in a market should be damned, but simultaneously let us not discourage the honest and ethical efforts. Let us not forget doctors and people from pharmaceutical companies are experts in their field. Somebody said that we should get only clinically tested drugs!! how does one clinically test it without these trials??!! Would you like to take a drug which have only gone through pre-clinical testing (one which is actually done on rodents)?!
Nevertheless as my teacher says "whatever goes through fire and survives, is only getting stronger"- gives me all the hope to see the best days of clinical research in India.

from: Rimi
Posted on: Jan 4, 2013 at 12:13 IST

The medical (hospital+pharma) industry has clear control over the licensing and supervisory authorities and the details are in the frontline report. (here is a sample - letters recommending approval for Cipla's pirfenidone were received by the DGCI from four different sources in Delhi, Mumbai and Chandigarh and Secunderabad on the same day and recorded under consecutive reference numbers).

Even the courts are not very keen to bring the executive to task other than issuing warnings. While the parliamentary committe report has been idling for seven months for followup, the court has given it one more - the matter is posted for hearing four weeks later. Finally the court will note the assurances of some secretary or AG and close the petition.

from: shyam
Posted on: Jan 4, 2013 at 11:01 IST

In this country there is no limits of fraud sources of incomes even in medical fields. There are many doctors who are even found to be done Homeopathy course but running Allopathy medical clinics. Nobody to scan and nobody to stop their license. Then on that basis even the prescription also will be the same level of treatments then. This is one of the incorrect way of medication that is widely followed in this country in many places but our Great Government and IMA is yet silent show watcher. Their hands are tied up to stop all these by many their own reasons. We just have to sit and tolerate these until we ourselves blow off all the corruptions just like Aparichit movie.

from: Biswas
Posted on: Jan 3, 2013 at 17:22 IST

This is an important article. First there in formal Institutional review board.Second, most of the drug companies write their own protocol and have well known physicians do their"trials". The MNCs by looking at the sheer numbers of patients embark on a project to improve their bottom line.
A similar situations is in the USA where most Clinical Psychiatrist have been promoted to drug salespeople. The FDA in India can be compared to a toothless tiger.
Unless this is done ethically it will be hard to justify and drug that is released in India.Mere rubber stamping is not enough to protect patient's interests.

from: ramanan
Posted on: Jan 3, 2013 at 17:12 IST

The doctors who prescribe these medicines to be checked thoroughly and they should be shamed for their acts if they are found to be prescribing these medicines. Also the Govt should make use of social websites to issue the banned medicines list and to create awareness among the public.

Govt is really missing great opportunities in connecting with public through social websites and other media where people are glued always.

from: Haripriya
Posted on: Jan 3, 2013 at 14:57 IST

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