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Title: Need to strengthen laws to control incidents of people being used as guinea pigs in clinical trials.

SHRI P.K. BIJU (ALATHUR): The incidents of illegal drug trial practices on human being conducted by the private companies with or without the knowledge of the victims are increasing. For the First time since 2010 when six tribal girls from Gujarat and Andhra Pradesh involved in the clinical trials of anti-cervical cancer HPV vaccine died, the Government has admitted that 1,725 persons have lost their lives to drug trials in the last four years. The number of deaths has risen from 132 in 2007 and 288 in 2008 to 637 in 2009 and 668 last year, indicating the complete ineffectiveness of regulatory Controls over the \$400 million sector. Last year, the Government gave compensation in just 22 cases out of the 668 that resulted in deaths due to "serious adverse events" during drug trials. Currently, 1,868 clinical trials are going on as per the Clinical Trial Registry of India maintained by the office of the Drug Controller General of India (DCGI). Many of the drugs being tested are not even of specific relevance to the country and could have been tested anywhere. Equally shocking is the fact that the rules, under the Drugs and Cosmetics Act, entirely trust the trial investigator with the reason attributed for the death of a subject. This is resulting in gross under-reporting of actual deaths during clinical trials.

Illegal and unethical clinical trials were being done on poor persons including juveniles, tribals and dalits who were used like guinea pigs for testing of drugs and vaccines produced by multinational corporations. Most of the pharmaceutical companies that are involved in the spreading such activities are private and their policies are not always clearly revealed to the institutions that are supposed to regulate their behaviour. They use contract research organisations (CROs) to conduct the trials. Unfortunately there is no mechanism to control it.

I strongly urge the government to take stringent actions against the private companies for using people as guinea pigs. I also urge to enact new as well as strengthening of existing laws in order to ensure avoidance of such of above mentioned incidents in the future.