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Research Injury on Human Objects Focus on Piduguralla – (A.p)

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ABSTRACT *The weakest and poorest members of society are often the target of exploitation. The article explains which is the exploited by other humans.*

Clinical trials on humans that are used for drug development and approval purposes, trials conducted for marketing purposes alone, research that is conducted in the garb of clinical practice, and other unscientific and unethical research practices that may collect information to be used towards drug development.

The word 'Trial' is from the Anglo–French trier, meaning to try. Broadly, it refers to the action or process of putting something to a test or proof. The word 'Clinical' is from clinic, from the French cliniqu´e and from the Greek klinike, and refers to the practice of caring for the sick at the bedside. Clinical trial is the action or process of putting something to a test or proof at the bedside of the sick. However, broadly it refers to any testing done on human beings for the sake of determining the value of a treatment for the sick or for preventing disease or sickness.

The treatment can be anything considered to hold promise in caring for the sick, in the prevention of disease, or in the maintenance of health.

Compounds, no matter how promising or impassioned the pleas for use, have to go through a series of tests in animals before they can be tested in humans. Those considered to lack promise after animal testing do not come to testing in humans. Typically, the testing in humans is done in a time ordered sequence, as suggested by the phase label affixed to trials as defined below. However, in truth, adjoining phases overlap in purpose. Hence, the label, at best, serves only as a rough indicator of the stage of testing, especially when, as is often the case, drug sponsors, at any given point in time, may have several trials under way carrying different phase label, viz. Phase I: Usually the first stage of testing performed in anticipation of an Investigational New Drug Application (INDA); done to generate preliminary information on the chemical action and safety of the indicated drug and to find a safe dose; usually not randomized. Phase II: Usually the second stage of testing; generally carried out on persons having the disease or condition of interest; done to provide preliminary information on efficacy of the drug and additional information on safety; may be designed to include a control treatment and random assignment of patients to treatment. Phase I/II: A trial having some of the features of Phase I and II trials; designed to provide preliminary information on safety and efficacy. Phase III: Usually the third and final stage in testing, prior to submission of an INDA; concerned with assessment of dosage effects, efficacy, and safety; usually designed to include a control treatment and random assignment to treatment. When the test is completed (or nearly completed), the drug manufacturer or sponsor may request permission to market the drug for the indication covered in the testing by submission of an INDA.

Phase II/III: A trial having some of the features of Phase II and III trials; designed to provide information on safety and efficacy. Phase IV: A fourth stage of testing, sometimes carried out. Usually controlled and performed after approval of the INDA. Drugs, after marketing approval, remain under surveillance for serious adverse effects. The surveillance – broadly referred to as postmarketing surveillance – involves the collection of reports of adverse events via systematic reporting schemes and via sample surveys and observational studies. Sample size tends to increase with the phase of the trial. Phase I and II trials are likely to have sample sizes in the 10s or low 100s compared to 100s or 1000s for Phase III and IV trials.

The aim in the early phases of testing is to determine whether the drug is safe enough to justify further testing in human beings.

INTERNATIONAL TREATIES ON CLINICAL TRIALS:

There are many international treaties that govern clinical trials, such as: Nuremberg Code and Declaration of Helsinki (1964), Universal Declaration of Human Rights, International Health Regulations 2005, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ICH-GCP (Good Clinical Practice) Guidelines, World Health Organization (WHO) guidelines, and Universal Declaration on Bioethics and Human Rights, UNESCO 2005. A registry for clinical trials has been set up by the ICMR's National Institute of Medical Statistics (NIMS) and anybody who wishes to conduct a clinical trial in the country has to declare materials relevant to the trial, along with the Ethics Committee Approval Status, Regulatory Clearance by the DCGI, etc before the enrolment of the first patient. But it is not done by the pharmacy company.

AXIS CLINICALS:

Axis Clinicals, Hyderabad-based firm conducted research on human objects for a breast cancer drug. The Andhra Pradesh government has now directed the district health officials to probe the incident. "There is no illegality about clinical trials but there has to be proper monitoring," said Andhra Pradesh health minister DL Ravindra Reddy. The state government is also awaiting a compliance report from the Drug Controller General of India (DCGI) on this matter.

Axis Clinicals is engaged in bio-availability (BA) and non-equivalence (BE) studies and has a facility that includes a clinical pharmacology unit as well as a bio-analytical laboratory for drug analysis. When contacted, Business Development AGM Abhijit Chowdhary said the company was never involved in any trials for new drugs. "We were only conducting BE studies on healthy volunteers for a generic drug and not trials for any new drug. However, he refused to give any further details about the drug or the pharmaceutical company's name for which the BE trials were being conducted. The 25women at Pidiguralla town in the coastal district of Guntur,

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most of whom are poor quarry workers, were unaware that they were being used for trials.

FOCUS ON PIDUGURALLA:
The historic town of Piduguralla is popular as the gateway of erstwhile Palnadu region known for its fierce warriors and red hot chilies. But poverty in the arid region had driven even its women to become guinea pigs for clinical trials. The women in the age group of 25 to 45 years were not aware of what drugs were given to them and opted to give blood in exchange of cash and became volunteers for a clinical trial. They were paid amounts ranging from Rs 5,000 to Rs 1 0,000 depending on the number of doses of drug they were ready to consume.

Dhanalakshmi (30), who was a dancer, took up work in a stone crushing unit in Piduguralla after the society ostracized her. She says "My youngest son has congenital heart disease and I needed money for his treatment. I attended the selection round at the Miyapur-based firm and I received Rs 9,000. But the injections made me weak, and I am suffering from chest pain, body ache and nausea".

While Ademma (55) traveled to Hyderabad where she was made to take tablets "When I complained about giddiness, I was asked to go home and return only after gaining weight. Now I am not in a position to attend even to the routine household work," Ademma rues. Jakka Kumari managed to earn Rs 2,000 for the two visits she made to the clinic, but fell prey to many diseases.

The company brokers have spread a network to lure more women and they even accorded a warm reception to them at the railway station.

The Director of Medical and Health (DMHO) Dr Gopi Naik and Jayaramaulu, municipal commissioner of Piduguralla said: "It is illegal to test drugs directly on human beings.

We have started a probe into the incident." Meanwhile, the investigation had driven brokers like Kommu Karunamma, S Jameela and other agents of the companies go underground. When contacted an official of Axis labs confessed to have roped in one woman from Piduguralla for the trial.

"It is not a clinical trial of any new drug but only a routine bioequivalence study of a drug that is already in the market by another company," he claimed and refused to specify the name of the drug or the pharma company. The government action came after a complaint filed by the victims with the State Human Rights Commission, which took up the case *suo-moto* and directed the health authorities to file a report by July 18 on the status of clinical trials in the state.

Meanwhile, medical and paramedical personnel were sent to the colonies for a door-to-door survey so as to send the needy to the government general hospital in Guntur.

FILE A CASE:
A day after the stunning exposure of clinical trials on women by a pharma major in Hyderabad, police deliberately avoided naming the company in the FIR. Police booked a case under Sections 420 (cheating) and 336 (endangering public life) of IPC, but did not name the pharma company. Two brokers, who allegedly lured the women into the tests, were taken into custody.

Though strong protests and rallies were staged in Piduguralla demanding action against the company, police tried to shield the guilty the pharma company by slapping a case against the middlemen. Confirming that two brokers S Jameela and Karunamma were taken into custody, Sattenapalle DSP J Bhaskara Rao told that they would probe the case from all angles.

The Indian trend in the clinical trial litigations is unique till now. Media and NGOs appear as the flag holders rather than the participants in the trials. Few PILs and writs occupy the case domain, with very little judicial interpretation, but the spat of litigations abroad serve as a stern warning, making future litigations by the participants a certainty. Incidents such as diamond workers who have been rendered jobless becoming easy victims of clinical trials in and around Ahmedabad are worth taking notice.

The evolved response of the justice system to mass torts has been to shift from private-law Model litigation to something much more like public administration. Will the present trend of clinical trial cases in our country result in the same response or lead to the evolution of unique principles on liability, autonomy and jurisdiction, still remains to be seen.

REACTION BY NHRC:
The National Human Rights Commission (NHRC) will probe the Andhra Pradesh drug trial scandal. The women, all from Piduguralla, Guntur district, fell ill. The NHRC has now taken note of the poor illiterate women being lured by money to come for drug trials. The commission has also asked its director general, investigation to depute a team to inquire into the matter and submit its report. The SHRC observed that since trials of new drugs are usually done on guinea pigs or rats, the pharmacy company's action can be considered a basic violation of human rights.

CLARIFICATIONS:
Andhra Pradesh Drug Control Administration head RP Meena said the state had no power to regulate clinical trial research organizations (CROs). The CROs are supposed to form an ethical committee which should meet frequently to discuss the type of clinical trials being undertaken, the side-effects if any, and keep a record of who the subjects are and what precautions have been taken to do away with any side-effects.

But the so-called ethical committee remains only on paper, and a large number of innocent patients are becoming guinea pigs for all kinds of clinical trials. "The ethical committee is not functioning properly," said a top official from a pharmaceutical company. "The missing links in the trial registry have to be plugged through necessary rules and regulations and effective implementation," the official said.

There are several reasons why drug companies are drawn to India. These include a technically competent workforce, patient availability and a friendly drug-control system. However, the booming clinical trial industry is raising concerns because of a lack of regulation of private trials and proper ethics review, says a WHO report. More than 650 clinical trials are currently taking place in the country and all the leading global pharmaceutical companies have started moving their key trials to India. The country has a large number of patients in areas for clinical research, such as diabetes, cardiovascular disease, HIV and oncology.

The global clinical research market is pegged at around $20 billion with India's share being about $485 million. The latter is projected to cross the $1-billion mark by 2015, a Frost & Sullivan report says. Clinical trials are needed and new medicines are imperative, but more than the investment that would come in, the bigger task at hand is to ensure safety of volunteers and generate quality data, adds the report.

CONCLUSION:
As the energy and financing behind human clinical trials increase, litigation will assuredly increase alongside. Researchers have the greatest direct control over the implementation of the research protocol and the most extensive direct contact with subjects, and must bear corresponding responsibility for acts which fall below the standard of care. Provisions for post trial accessibility, no fault compensation in clinical trials, and a clear channel to seek remedy in case of injury are the need of the hour in our regulatory framework.