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Fatal errors in clinical trials

Sacrificing people, mostly the poor, for advancements in medical science is inhuman. Pharma companies exploit loopholes in law to get away with murder

Beyond the immediate facts on shocking negligence in a cervical cancer clinical trial, lies the familiar story of big bucks and exploitation. In the course of the 10-year US-funded experiment, 254 poor women, part of an unscreened group of 138,624 women, have died, making it amply clear why pharma companies prefer India to developed countries. Aside from the costs involved, human lives here are considered cheap, and laws governing such trials can be bent at will. Forget exemplary action against the guilty, the families of clinical trial victims are rarely compensated. While there were 1,725 clinical trial deaths between 2007 and 2010, only 22 people received compensation. What had made it easy for corporates to get away with murder was a conducive system that mandated only the ethics community, which had given the go-ahead for the trial, would decide on the quantum of compensation. It has been alleged that members of these committees are motivated more by commercial concerns than humanitarian considerations. It's a win-win situation for all, barring the human subjects, in the clinical trial industry currently pegged at $500 million in India and most likely to grow to $1 billion by 2016.

At the heart of clinical trials is the critical issue of consent of those willing to offer themselves for a trial-and-error course. In most cases, this thumb rule is violated because the candidates chosen to be 'guinea pigs' are impoverished and uninformed. Taking full advantage of their vulnerability, sponsors keep them in the dark, rarely spelling out the risks involved. When the high fatality rate of the cervical cancer trial came to light, the sponsors argued that the practice of having unscreened groups is ethically permissible in India since no-screening is considered "standard care". However, it has been proved beyond doubt that the treatment available for cervical cancer would have saved these 254 women. The worst part is these victims weren't even told how screening would have helped them escape death. In this case, it is reasonable to say that precious lives were sacrificed to highlight the importance of cervical cancer screening — a gross violation of the international guidelines on medical research.

It is not that the legal framework had left little scope for medical watchdogs to prevent malpractices. Apart from the central agencies — Drug Controller General of India (DCGI) and the Central Drugs Standard Control Organisation (CDSCO) — the Indian Council of Medical Research (ICMR) serves as the apex regulatory body for clinical trials. Even then high death rates forced the Supreme Court to intervene and stop more than 100 trials last year as it felt that guidelines were being violated.

> Continental Clinical (@Conti_Clinical), Research clinic
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> **In otherwise avoidable trial deaths, hard to argue ethical behaviour**

An apex court order brought about a raft of new draft guidelines to ensure greater transparency in conducting trials. It includes audio-visual recordings of trial patients being apprised of the details of the medical procedure they have enlisted for. What's unfortunate is in spite of the DGCI and the CDSCO becoming more vigilant and the Centre setting up committees for supervision in the last few months, deaths from clinical trials continue to make news. Sensing the emotive nature of the issue, the government has come up with an amended Drugs and Cosmetic Bill, 2013, subject to scrutiny and approval of a Parliamentary panel.

The least the government and the medical fraternity can do is put an end to the inhuman practice of making people scapegoats under the pretext of noble pursuits.

Clinical Research