COMMENT

Cancer, access to investigational drugs, and patient rights in the USA and India

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The commentary (1) identifies important issues relating to the responsibilities of physicians, researchers and regulatory agencies.

The American case

Patients with advanced cancer at times feel that there is an unmet need. The need is to try out for themselves drugs deemed to be still in the experimental stage by research workers and by regulating agencies.

This unmet need is analogous to the need felt by patients suffering from advanced motor neurone disease to try out stem cell infusions.

In such cases the need does evoke sympathy. Running out of options for treatment, the desperate patient, knowing that death is around the corner, is willing to take risks not permitted by law, regulating agencies or research workers, in the hope of staving off the disease and postponing death. The patient and family can claim, with justification, that they have ascertained the state of knowledge on the drug and are willing to take whatever risks are involved in the use of the drug. Lack of informed consent is thus not an issue.

The stand adopted by the American regulating agencies and courts is rational, scientific and intended to benefit patients.

Lack of adequate knowledge of efficacy and safety cannot be ignored on the grounds of desperation. The sad fact remains that medicine is an evolving science and we have much to learn. The use of potentially harmful and dangerous treatment cannot be permitted until experiment has eliminated risks and shown that whilst the treatment is effective, it is also safe.

The Indian trial

There can be no justification for the use of a drug that has not yet been tested in human beings for efficacy and safety except under strictly controlled conditions and after obtaining the sanction of regulatory agencies.

The researchers in America and India knew that the respective national and local ethics committees had not sanctioned the study.

The researchers in India knew that they were bypassing a provision laid down under the Indian law to prevent Indian subjects from being used as guinea pigs.

They also knew that the trial they were conducting could not have been carried out in the USA by the American researcher who instigated the Indian experiments.

In this case an "unmet need" cannot be invoked, for the subjects knew little about the drug being used and were provided little if any opportunity for using their own judgement or exercising choice. In fact the principle of informed consent was also blatantly violated.