

FILM REVIEW

An ethical breakdown

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The Constant Gardener. DVD, 129 minutes. Director: Fernando Meirelles.

The catastrophic illness which affected six healthy volunteers in London on March 13, 2006, minutes after they were administered a new drug, underlined the risks inherent in testing new drugs in humans. In order to minimise the risks to human volunteers, the World Medical Association has laid down fairly stringent safeguards in the Helsinki Declaration. There are concerns that these safeguards are being violated, especially in the poorer nations of Africa and Asia.

This is the theme of *The Constant Gardener*, the film based on the book of the same name by John Le Carre. A big pharmaceutical company uses a contract research organisation to test its new drug for tuberculosis in Kenya. The drug works but it has fatal side effects in some people. The company is in a hurry to get the drug on the market so it tries to fudge the data.

The socially conscious wife (Rachel Weisz in an Oscar-winning performance) of a middle-level British embassy official (Ralph Fiennes, the "constant gardener") stumbles on the truth and is determined to stop the company from proceeding with the trial. She finds to her dismay that the company has paid off many important people and she is up against a wall of deceit, dissembling and denial. How the truth is finally exposed and the price that is paid forms the substance of the film.

Those who have read the book may find the film less subtle than Le Carre's prose. However, the film portrays many ethical concerns besides the obvious ethical breakdown of continuing to test a drug that can be fatal just to fulfil the requirements of licensing. For example, the only health care available in the shantytown where the drug is being tested comes from the contract research organisation. Although they have a research protocol and a form for informed consent, the method of obtaining "volunteers" is simple—only those who agree to test the new drug receive any medical care.

There is also the problem of corruption. The local director of research drives a huge limousine, bought from siphoning off some of the money donated to buy drugs for people with AIDS. There is also the obvious difference between the well-fed, well-dressed employees of the research organisation and the extremely poor patients. The imbalance between the company officials responsible for profits and the scientist is also highlighted. The scientist does not wish to continue with the trials once he becomes aware that some of the patients have fatal side effects, but company officials overrule him and he goes along.

The pharmaceutical business is one of the most lucrative in the world today. In *Fortune's* list of the most profitable companies in the US, Pfizer is at number 15, Merck is at number 30 and Wyeth at number 38. In order to maintain and increase profits, some companies resort to several unethical practices.

Writing in the Science and Development Network, Susan Bull notes: "Aspects of research that have proved particularly controversial in developing countries include the relevance of the research to participants, standards of care provided to participants, the design and conduct of processes used to obtain the consent of research participants, the appropriateness of international and national guidance on research ethics, and the care provided to both research participants and the wider community once research is over." (1)

The Indian Council for Medical Research has published guidelines for research on human subjects (2). However, in a poorly regulated scenario such as ours, there are real concerns that these guidelines are being violated. If the film draws the attention of researchers and the public to this growing ethical crisis, its purpose would be well served.

References

1. Bull Susan. Introduction to dossier on ethics of research. 2002 Nov <http://www.scidev.net/dossiers/index.cfm?fuseaction=dossierfulltext&Dossier=5>
2. ICMR. *Ethical Guidelines for Biomedical Research on Human Subjects*. New Delhi: Indian Council of Medical Research; 2000.