US and other well-to-do countries, and partly for that reason, drug companies are having a hard time getting enough volunteers for the growing number of clinical trials. Not so in the third world, where authoritarian regimes and corrupt local government officials and health authorities are eager to be paid off by first-world organisations and to have good relations with them. They "encourage" entire villages or provinces to enroll in research programmes, while local doctors enrich themselves by providing human subjects.

Perhaps the most important reason for conducting human research in Africa and other poor regions outside the US is that it is a way of circumventing FDA regulations. In the US, drug companies are required to file "investigational new drug applications" (INDs) with the FDA before they begin human testing of a drug they hope to get approved. The applications give detailed descriptions of the proposed research, including plans for obtaining informed consent and for monitoring the progress of the study. Companies must also provide evidence that ethics committees (called institutional review boards, or IRBs) have been set up to review each clinical trial. These committees are supposed to ensure that risks to human subjects are, in the words of the applicable federal regulations, "reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result," and further, that all risks are "minimised." The FDA can deny approval of the IND or request changes in the proposed research. It may also conduct on-site inspections of the trials.

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The requirements for foreign research are much looser. In fact, the FDA may not even know about such trials until after they are completed, when the company applies for final approval of a new drug. Only then when there is no longer an opportunity to verify the information does the company have to describe the way in which the research was conducted, or say whether there was ethics committee approval and informed consent. Furthermore, the FDA rarely conducts on-site inspections abroad. While it conducts very few in the US, there is always the possibility that it will decide to do so. For research done in the third world, the agency simply takes the word of the sponsors of the research.

When research does not require FDA approval, there may be no oversight at all. Companies can conduct preliminary studies of drugs in poor countries before formal testing even begins. Quite literally, the participants in their studies are used as guinea pigs, subjects of research that really should be done on experimental animals. That was the case in le Carré's fictional account. Although some research in the US and other wealthy countries also escapes formal oversight, there are generally more restrictions on what researchers can get away with.

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