The Body Hunters

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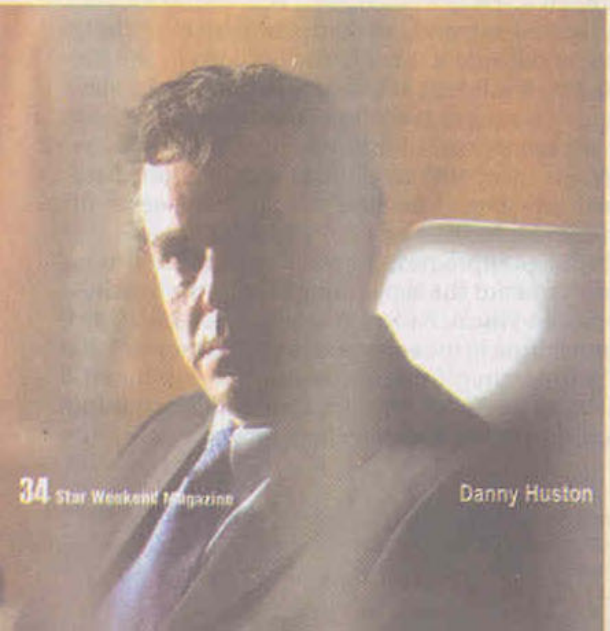
Ralph Fiennes

(Continued from last week)

THE rapid movement of drug studies to third-world countries began in 1980, when the US Food and Drug Administration (FDA), in considering applications to approve new drugs, first agreed to accept foreign trials as evidence of safety and effectiveness. Before a company can sell a drug in the US (or market an old drug for a new use), it must get approval from the FDA, which means it must demonstrate in clinical trials that the drug is reasonably safe and effective. Nearly every large drug company, wherever it is located, wants to get into the US market, because that is the major source of profit for pharmaceuticals.

Probably close to half of all clinical trials are now conducted in the third world, although there is no way to know for sure. The reasons are clear. It is cheaper and in many respects easier and faster to do them there. A huge new industry has arisen that conducts third-world research for drug companies (like le Carré's fictional research firm, ThreeBees). These companies, called contract research organisations, or CROs, hire local doctors to find people who will take part in clinical trials, and while the payments to the doctors per patient are lower than in first-world studies, by local standards they are munificent. Doctors can multiply their income tenfold or more. Patients, too, are readily enticed by small amounts of money and promises of free care. In fact, as in le Carré's story, enrolling in a trial may be the only way they can get any care at all.

This system makes a mockery of the notion of informed consent--the requirement that subjects be given full information about the nature of the research and have the right to refuse to participate, without penalty or consequences for their usual health care. That requirement is enforced in the



Danny Huston